

# Medtronic

## Medtronic

Medtronic Xomed, Inc.  
6743 Southpoint Drive North  
Jacksonville, Florida 32216  
USA  
www.medtronic.ru

tel 800 874 5797

Tel: 817-788-6400  
www.medtronic.com  
Jacksonville FL 32216-4980 USA  
Medtronic Xomed, Inc.  
6743 South point Drive North

Custodian:

*Alexandra Oliver*

Alexandra Oliver  
Assoc. Regulatory Affairs Specialist

Medtronic Xomed Inc.

08/11/2017

Date

Instructions for use of Integrated Power Console (IPC) System and Instrument Tray

StraightShot M5 Microdebrider with accessories

### ATTESTATION

STATE OF FLORIDA  
DUVAL COUNTY

On this 10<sup>th</sup> day of August I attest that the preceding or attached documents are true, exact, complete, and unaltered photocopies made by me of the following, Instructions for use of Integrated Power Console (IPC) System and Instrument Tray, issued by Medtronic Xomed, Inc., presented to me by the document's custodian, Alexandra Oliver, and, to the best of my knowledge, that the photocopied document is neither a public record nor a publicly recordable document, certified copies of which are available from an official source other than a notary public.

Notary:

*Michelle G. Hughes*

Official Notary Signature

Subscribed and sworn to before me

This 10<sup>th</sup> day of August, 2017.





# Integrated Power Console (IPC®) System

MODEL: 1898001



## User's Guide

RxOnly

CUSTOMER SERVICE

For further information regarding the use of this product or to report any problems, please contact Medtronic using the appropriate information provided on the blue and white contact information card packaged with each device; or contact your local distributor.

Medtronic Xomed, Inc.  
6743 Southpoint Drive North  
Jacksonville, Florida 32216 USA  
[www.medtronic.com](http://www.medtronic.com)

US Help Line  
800 874 5797  
  
International Service  
International Customers should contact their local Medtronic Xomed office.

The following are trademarks or registered trademarks of Medtronic, Inc. in the United States and other countries: CD HORIZON®, Endo-Scrub®, Hydrodebrider®, Indigo™, Intelliflow®, IPC®, Legend®, Legend EHS®, Legend EHS Stylus , Magnum®, Midas Rex®, Mednext®, NIM®, NIM-ECLIPSE®, POWEREASE®, Skeeter®, SOLERA®, StraightShot®, Stylus Touch®, Triton®, TSRH® 3Dx™, Visao® and XPS®. All other trademarks, service marks, registered trademarks, or registered service marks are the property of their respective owners in the United States and other countries.

# Contents

|                                                                                     |      |
|-------------------------------------------------------------------------------------|------|
| GLOSSARY.....                                                                       | 1-1  |
| INDICATIONS FOR USE .....                                                           | 1-1  |
| DEVICE DESCRIPTION .....                                                            | 1-1  |
| CONTRAINDICATIONS .....                                                             | 1-1  |
| WARNINGS.....                                                                       | 1-1  |
| System Warnings.....                                                                | 1-1  |
| Component Warnings.....                                                             | 1-2  |
| Disposable Warnings .....                                                           | 1-2  |
| PRECAUTIONS .....                                                                   | 1-3  |
| SYSTEM REQUIREMENTS AND SPECIFICATIONS.....                                         | 1-4  |
| Console Specifications .....                                                        | 1-4  |
| Power Cord Product Numbers .....                                                    | 1-4  |
| SYSTEM SOUNDS AND FIGURES .....                                                     | 1-5  |
| PRE-OPERATING INSTRUCTIONS .....                                                    | 1-8  |
| When the System Arrives .....                                                       | 1-8  |
| Set up the IPC .....                                                                | 1-8  |
| Install the Pump Cartridges or Irrigation Tubing .....                              | 1-8  |
| Prepare IPC for Use .....                                                           | 1-8  |
| Calibrate Touchscreen.....                                                          | 1-8  |
| Change System Settings .....                                                        | 1-9  |
| Set up and Prime Pumps .....                                                        | 1-10 |
| Confirm System Operation .....                                                      | 1-10 |
| IPC COMPONENTS .....                                                                | 1-11 |
| Auxillary Power to Console.....                                                     | 1-11 |
| Multifunction Foot Pedal.....                                                       | 1-11 |
| Y-Splitter .....                                                                    | 1-11 |
| IntelliFlow Irrigation Remote Control .....                                         | 1-11 |
| GUIDANCE AND MANUFACTURER’S DECLARATION – ELECTROMAGNETIC IMMUNITY .....            | 1-12 |
| LIMITED WARRANTY.....                                                               | 1-14 |
| FOR ITEMS CONTAMINATED WITH TSE AGENTS .....                                        | 1-14 |
| TRITON ELECTRIC HIGH-TORQUE HANDPIECE.....                                          | 2-1  |
| SUCTION IRRIGATOR .....                                                             | 3-1  |
| ENDO-SCRUB 2.....                                                                   | 4-1  |
| SPINE SHAVER (SC1) HANDPIECE .....                                                  | 5-1  |
| STRAIGHTSHOT M5, STRAIGHTSHOT M4, STRAIGHTSHOT MAGNUM II, AND STRAIGHTSHOT III..... | 6-1  |
| LEGEND EHS AND LEGEND EHS STYLUS .....                                              | 7-1  |
| STYLUS TOUCH.....                                                                   | 8-1  |
| LEGEND EHS, LEGEND EHS STYLUS AND STYLUS TOUCH ATTACHMENTS .....                    | 9-1  |
| SKEETER ULTRA-LITE OTO-TOOL .....                                                   | 10-1 |
| VISAO HIGH-SPEED DRILL .....                                                        | 11-1 |
| INDIGO HIGH-SPEED OTOLOGIC DRILL.....                                               | 12-1 |
| MIDAS REX MICROSAWS .....                                                           | 13-1 |
| POWEREASE DRIVER .....                                                              | 14-1 |



**TROUBLESHOOTING AND ERROR CODES..... A-1**

**CLEANING AND STERILIZATION .....B-1**

Post-Operative Instructions .....B-1

Triton Electric High-Torque Handpiece .....M000030A322

Endo-Scrub 2 Finger Switch.....68E4005

StraightShot M5, StraightShot M4, StraightShot Magnum II, StraightShot III, or Midas Rex Spine Shaver 68E3282

Legend EHS and Legend EHS Stylus .....M000030A234

Stylus Touch.....68E4132

Legend Attachments/Tubes .....M000030A235

Skeeter Oto-Flex Burs .....68E3968

Skeeter Handpiece .....68E3969

Visao .....68E3281

Indigo High-Speed Otologic Drill .....68E4187

Indigo High-Speed Otologic Drill Attachments .....68E4188

Microsaws.....M000030A231

POWEREASE Driver .....68E4189

**SYMBOLS ..... C**

GLOSSARY

The following words and acronyms may be used in this guide.

|             |                                                                                                                                                |
|-------------|------------------------------------------------------------------------------------------------------------------------------------------------|
| FCU         | Foot Control Unit                                                                                                                              |
| FWD         | Forward - Rotation is clockwise                                                                                                                |
| I.V.        | Intravenous                                                                                                                                    |
| IPC         | Integrated Power Console                                                                                                                       |
| NIM         | Nerve Integrity Monitor - One or all of the Nerve Integrity Monitor units: NIM-Response 2.0, NIM-Neuro 2.0, NIM-Response 3.0 and NIM-Neuro 3.0 |
| NIM-ECLIPSE | Nerve Integrity Monitor for spinal surgeries                                                                                                   |
| OSC         | Oscillate                                                                                                                                      |
| REV         | Reverse - Rotation is counter-clockwise                                                                                                        |
| XPS         | Xomed Power System                                                                                                                             |

INDICATIONS FOR USE

The IPC is indicated for the incision/cutting, removal, drilling and sawing of soft and hard tissue and bone in Head & Neck/ENT (Otologic, Neurologic, Neurotologic, Sinus, Rhinologic, Nasopharyngeal/Laryngeal), Oral/Maxillofacial and Plastic/Reconstructive/Aesthetic surgical procedures.

DEVICE DESCRIPTION

The IPC System is a powered microdebrider, drill and saw system that will remove soft tissue, hard tissue and bone during surgical procedures. The system consists of a power control console, foot pedal, connection cables and assorted handpieces to drive various burs, blades, drills, rasps, cannulae and saws. It includes integrated irrigation pumps for irrigation of blades, burs and for motor coolant.

In addition to the handpieces and pumps there is a connection for continuous stimulation of the Visao straight burs that enables nerve integrity monitoring during surgical procedures. The Nerve Integrity Monitor (NIM) is a separate device that stimulates and monitors the nerve. This system has connections that allow the NIM to be connected with the Visao handpiece and Stimulating Bur Guard, enabling the NIM to stimulate and monitor the nerve at the surgical site.

This device is intended for use by physicians trained in the procedures described.

The system can be used to clear the end of a rigid rod endoscope in order to maintain good visualization of endoscopic procedures without having to remove the scope from the surgical site.

CONTRAINDICATIONS

None.

WARNINGS

System Warnings

- W1 It is important that the IPC system operator be familiar with the system User’s Guide, its precautions, procedures and safety issues.
- W2 Do not use the IPC POWEREASE system in the presence of flammable anesthetics. Avoid potential ignition or explosion of gases.
- W3 When not operating handpiece, eliminate accidental foot control activation. Control energy to and through the handpiece to prevent unintended tissue, bone, or nerve resection.
- W4 Disconnect power to the IPC system before cleaning the unit to avoid electrical macro shock.
- W5 Do not attach unapproved components to the IPC system to avoid electrical macro shock.
- W6 To avoid the risk of electrical shock, achieve electrical grounding reliability with proper connections. Connect the IPC system to hospital grade receptacles only.
- W7 This medical device complies with EN60601-1-2 safety standard for electromagnetic compatibility, requirements and test. However, if this equipment is operated in the presence of high levels of electromagnetic interference (EMI) or highly sensitive equipment, interference may be encountered and the user should take whatever steps are necessary to eliminate or reduce the source of the interference. Diminished performance may lengthen operating time for the anesthetized patient.
- W8 Medical Electrical Equipment needs special Precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this Guide.
- W9 Portable and mobile RF communications equipment can affect Medical Electrical Equipment.
- W10 Do not operate the IPC POWEREASE system in the presence of Magnetic Resonance Imaging devices.
- W11 Use of accessories and cables other than those specified and sold by Medtronic may result in increased emissions and decreased immunity of this unit.
- W12 The IPC system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the IPC system should be observed to verify normal operation in the configuration in which it will be used.
- W13 Do not attempt to run the IPC POWEREASE system handpiece immediately after autoclaving. Allow an adequate “cool down” period (Typically 1 hour).
- W14 Consult the Legend Bone Mill product insert before use with the IPC system.
- W15 For metal transection, observe the following safety precautions:
  - W15a Eye wear protection is essential.
  - W15b Irrigate well to cool the cutting surfaces.
  - W15c Protect the wound site from metal debris.
  - W15d Use a clamp or grasping device to control loose fragments during transection of any metal component.
- W16 Do not operate the IPC POWEREASE system without eye protection.
- W17 All service must be performed by Medtronic qualified personnel only.
- W18 Repair and/or modification to the IPC system by anyone other than qualified service personnel may significantly compromise the unit’s ability to perform effectively and/or void the equipment warranty.

INTEGRATED POWER CONSOLE (IPC)

Component Warnings

- W19 Do not use any parts other than Medtronic system components as damage or substandard performance could result.
- W20 Always inspect the components before and after use for any damage. If damage is observed, do not use damaged part until it is repaired or replaced. Damaged parts may deposit metal shavings on surgical site.
- W21 When precise location of blade tip is required, engage the rotation lock on the handpiece, then calibrate and verify the blade tip on Image Guided Surgery (IGS) system. Always lock M4 handpiece when driving non-rotatable blades to maintain their IGS calibration.
- W22 Employ visualization, including use of imaging techniques (for example: fluoroscopy, image guided surgery) when using rotating powered accessories. Discontinue powered application in the event of lack of visualization of surgical site.
- W23 Midas Rex Variable Exposure attachments: Surgeons should familiarize themselves with the performance of dissecting tools before use, and should explore the effect of various levels of tool exposure on dissection stability. If the tool exhibits excessive chatter, vibration, or movement, decrease the tool exposure.
- W24 Motors and attachments may fail due to extended use and allow a component to detach and fall from the motor or attachment, causing patient injury.
- W25 Electrical contacts must be dry prior to use.
- W26 Heavy side loads and/or long operating periods may cause the device to overheat.
- W27 Do not use an overheated device, as it may cause thermal injury to the patient or operator.
- W28 Use adequate irrigation. The use of a tool without irrigation may cause an inordinate amount of heat buildup resulting in a thermal injury to tissue. Depending on the amount of irrigation used, the drill bits and saw blades can achieve temperatures in excess of 50 °C.
- W29 Do not attempt to change a dissecting tool, saw blade, or attachment while the motor is running, or when the motor or attachment is in an overheated state.
- W30 Do not immerse the system components, except as noted.
- W31 Do not place motor, attachment and tool on the patient or in an unsecured location during surgery.
- W32 A system that is not functioning properly should not be used until all necessary repairs have been made and the unit is tested to ensure that it is functioning in accordance with Medtronic specifications.
- W33 Match the nomenclature and color code on the tool packaging to the same nomenclature and color code on the attachment.
- W34 Make sure that the attachment is still in the locked position after each adjustment of the tool exposure, as attempting to increase the tool exposure too far, may result in the attachment accidentally being unlocked.
- W35 Midas Rex Legend EHS Motor and Midas Rex Legend EHS Stylus Motor should only be operated when the attachment is in the locked position. Attempting to operate the Midas Rex Legend EHS Stylus Motor when the attachment is in the unlocked position may result in the motor stalling.
- W36 Smoke and/or excessive heat may be generated if attachment is not in the fully locked position. This may result in thermal injury to the surgeon or staff.
- W37 The Indigo and Legend EHS motors will not run properly unless the attachment is in the locked position.
- W38 DO NOT change accessory with handpiece running to prevent laceration of user and cross-contamination through compromised glove.
- W39 Remove Legend Footed Attachments cautiously and slowly as per instructions to avoid injury to the operator.
- W40 DO NOT modify accessories used with the handpiece. Performance could be diminished with modified accessories.
- W41 The safe use of the Endo-Scrub 2 System in procedures where surgical lasers are also employed has not been clinically demonstrated.
- W42 In order to ensure compliance with requirements of IEC 60601-1, use a Medtronic approved power cable.
- W43 To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.
- W44 Keep NIM Muting Probe cable away from IPC system cables.
- W45 Verify reusable device was sterilized prior to use. If not sterilized, do not use.

Disposable Warnings

- W46 Tools are available for resection of soft tissue and bone for surgical procedures. Use of tools depends on the intended application and patient needs. Sharp-cutting powered tools induce bleeding and removal of significant tissue and bone.
- W47 Use methods at the operative site to control bleeding that do not compromise patient safety during at-risk surgery.
- W48 Always keep the cutting area of the tool/saw blade away from fingers and loose clothing. Prevent laceration of user and cross-contamination through compromised glove.
- W49 Operate the tool only after the appropriate anatomical landmarks and the intended surgical site have been confirmed.
- W50 Use care in application of the moving cutting end to only appropriate anatomical landmarks and the intended surgical site when using powered accessories.
- W51 Insertion of metal objects in accessory tip may cause the accessory to break leaving fragments in the wound. The fragments may be difficult to remove, causing irritation, inflammation and foreign-body response at surgical site.
- W52 Bending or prying may break the accessory, causing harm to patient or staff.
- W53 Do not use excessive force to pry or push bone with the attachment, tool or blade during dissection.
- W54 A tool's size and geometry may create excessive vibration at certain speeds. Increase or decrease speed on console. Change to a new tool to prevent unintended tissue removal from patient.
- W55 Test for wobble at desired speed prior to use. Discontinue use of accessory if tip begins to wobble and replace accessory to prevent unintended tissue removal from patient.
- W56 Eccentricity of the tool can cause tool vibration and may result in excess tissue and bone destruction and hearing damage.
- W57 Excessive noise from the tool when drilling close to the cochlea or ossicular chain may cause hearing damage.
- W58 CONSULT the cranial perforator device labeling for the recommended speed specifications.
- W59 Tools with "L" identification are longer tools intended for light bone dissection. The increased tool head/stem configuration may affect dissection stability.
- W60 Tool flutes and blade teeth are sharp and may perforate surgical gloves. Tools/blades may be grasped with a hemostat to aid in installation and removal.
- W61 DO NOT attempt to sharpen used tools. Worn tools should be replaced with new ones frequently to ensure effective cutting and control.
- W62 Carefully inspect tool both prior to and following each use for signs of excessive wear, fragmentation, eccentricities or other defects. Replace any suspicious tools with a new one prior to use.
- W63 Excessive pressure applied to bur may cause bur fracture. Should a tool fracture in use, extreme care must be exercised to ensure that all fragments of the tool are retrieved and removed from the patient. Unremoved tool fragments may cause tissue damage to the patient.
- W64 Do not use metal-cutting tools on bone.
- W65 Use only rotary tools specifically designed for use with this drill system.
- W66 When using non-rotatable tools, ensure rotation lock is engaged to prevent inadvertent rotation.
- W67 The use of powered reciprocating instruments may result in vibration / related injury.
- W68 Powered blades should be operated in the Oscillate mode only. Operating in the Forward mode may cause damage to the blade.
- W69 Do not attempt to sterilize disposable devices. The disposables are packed sterile and are not intended for repeat use. To prevent contamination, use only once.
- W70 Any tubing or other tip protectors used during shipping must be removed prior to cleaning and sterilization.
- W71 Do not use accessory if package is opened or damaged. Broken seal offers no protection against cross-contamination.

- W72 Properly dispose of single-use devices removed from sterile packages. Devices lose sterility upon removal from packaging.
- W73 Do not use dull, damaged or bent tools. Use of dull tools can reduce handpiece effectiveness and cause the handpiece temperature to increase.
- W74 T&A Blades: Gently remove the inner tube from the outer tube. The inner tube may elongate upon removal from the outer tube. If this occurs, the inner tube may not lock properly into the handpiece or the blade may not work properly.
- W75 T&A Blades: Rotate the inner tube when removing and inserting it in the outer tubes to prevent damage to the internal seal. If the seal is damaged, the blade will leak at the handpiece.
- W76 Always ensure that the drill is securely engaged into the handpiece prior to operating the system.
- W77 Always examine operation of each tool in a handpiece before use.
- W78 Powered burs and drills should be operated in the Forward mode only.
- W79 This system requires insulated connectors for the StraightShot M4 Microdebrider, StraightShot Magnum II Microdebrider, StraightShot III Microdebrider, Midas Rex SC1, Visao, or Skeeter handpieces and the Multi Function Foot Control Unit.
- W80 Sterilize and dry reusable device before storing the system. Decrease likelihood of cross-contamination with timely sterilization.
- W81 After each procedure, properly clean all reusable system components.
- W82 Auxiliary Power Outlet with protective cover is for use with the Hydrodebrider or Bone Mill consoles only.
- W83 Place Stylus Touch in safe mode while not in use.
- W84 Do not place Stylus Touch handpiece in the proximity of magnetic field, such as magnetic drape and MRI equipment, to avoid inadvertent handpiece activation.
- W85 Do not apply excessive side loading. Excessive side loading could cause angled attachments to unlock accidentally from motor.

## PRECAUTIONS

- P1 PRIME/FLUSH Priming is a feature designed to purge air out of the tubing set(s) during setup. The first time a Prime or Flush button is pressed it will turn on pump 1 and/or 2 long enough to purge air out of the tubing set(s). Turning power Off and On resets the PRIME feature. Once pressed all Prime buttons will change to Flush buttons.
- P2 To prevent damage to curved tools, disconnect suction tube prior to changing tool during procedure.
- P3 When using an angled attachment, hold the handpiece assembly by the attachment so that the attachment does not inadvertently loosen from the handpiece.
- P4 For Legend tools only:  
If a tool package is opened, but the tool is not used or contaminated, the tool can be re-sterilized. Remove tool from original packaging and place into an approved autoclave package. Steam sterilize as follows:  
High-Vacuum Steam 132 °C for 5 minutes  
Gravity Displacement 132 °C for 15 minutes  
The re-sterilized tool must be used promptly following re-sterilization. If rust or corrosion is encountered after re-sterilization, do not use the re-sterilized tool.
- P5 DO NOT run the 16 MF attachment with operating speed above 62,000 rpm. This may cause over heating and damage to internal gears of attachment.
- P6 DO NOT use twist drill or Contra-Angle tool at an operating speed over 62,000 rpm.
- P7 Do not attempt to disconnect the cable from the Midas Rex Legend EHS Stylus Motor.
- P8 Do not kink cables. Inspect cables and pins for cracks, tears or corrosion.
- P9 Do not use anti fog on scope or sheath, as weeping or leaking may result.
- P10 Disconnect cable from Midas Rex Legend EHS motor prior to sterilization.
- P11 The use of a washer-disinfector for cleaning may cause a premature degradation in performance.
- P12 Remove devices from instrument case before placing into washer disinfector and allow devices to drain.
- P13 Orient devices in the washer-disinfector by following manufacturer recommendations.
- P14 DO NOT use low temperature hydrogen peroxide gas plasma sterilization due to the lumen internal diameter and length restrictions.
- P15 DO NOT use low-temperature liquid peracetic acid sterilization due to immersion procedure.
- P16 DO NOT steam or EO sterilize the Legend Attachment Cleaning Nozzle.
- P17 Remove and discard accessories following local regulations for proper disposal of contaminated materials.
- P18 Disposable devices are for single-use only.
- P19 Clean the motor and cable while still connected together. This will help to reduce ingress of debris.
- P20 Use ONLY recommended cleaning agents.
- P21 Do not use excessive force to insert the endoscope into the Endo-Scrub 2 sheath. This will damage the endoscope as well as the Endo-Scrub 2 sheath.
- P22 If the endoscope tip can be seen extending beyond the tip of the Endo-Scrub 2 sheath, then the sheath has been damaged. Damaged product must be immediately discarded.
- P23 When using a Y-Splitter, only one Multifunction Foot Pedal shall be active at a time.
- P24 Only one Y-Splitter shall be used at a time.
- P25 Ensure the blade or bur is fully engaged in the microdebrider. For blades, verify the tip is fully engaged with the outer cannula prior to use.

SYSTEM REQUIREMENTS AND SPECIFICATIONS

Console Specifications

Functional Standards for Electrical Systems

|                           |                              |                                                                                                                       |                   |
|---------------------------|------------------------------|-----------------------------------------------------------------------------------------------------------------------|-------------------|
| ANSI/AAMI ES60601-1       | Medical electrical equipment | Part 1: General requirements for basic safety and essential performance                                               | 2005              |
| IEC 60601-1               | Medical electrical equipment | Part 1: General requirements for basic safety and essential performance                                               | 2005              |
| EN 60601-1                | Medical electrical equipment | Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)                            | 2006              |
| IEC 60601-1-4             | Medical electrical equipment | Part 1: General Requirements for Safety, Part 4: Programmable Electrical Medical Systems                              | 2000              |
| EN 60601-1-2              | Medical electrical equipment | Part 1-2: General Requirements for Safety Collateral Standard: Electromagnetic Compatibility - Requirements and Tests | 2001/<br>A1: 2006 |
| CAN/CSA C22.2 No. 60601-1 | Medical Electrical Equipment | Part 1: General Requirements for basic safety and essential performance                                               | 2005              |

Physical Dimensions

Size 277 mm Width x 353 mm Height x 267 mm Depth

Weight 7.3 kg

Operational Environment

Temperature +10 °C to +33 °C

Humidity 30 % to 75 % RH

Barometric Pressure 700 - 1060 hPa

Transport and Storage Environment

Temperature -40 °C to +70 °C

Humidity 10 % to 95 % RH

Barometric Pressure 500 to 1060 hPa

Display / Touchscreen

Type High contrast, digital, graphic color, visible in complete darkness

Resolution Display 21 cm diagonal, resolution 480 X 640 pixels

Audio Output

Baseline Audio Sound Level 60 dBA minimum SPL (1 m)

Electrical

Input Voltage 100 V-240 V ± 10%

Frequency 50/60 Hz

Power Consumption 500 VA

Auxiliary AC output 200 VA Max.

Internal Fuse 5 x 20 mm T. L. 5 A, 250 V

Medtronic Xomed P/N 11270066

Duty Cycle for Applied Part Maximum On Time 120 Seconds

Minimum Off Time 180 Seconds

Power Cord Product Numbers

|                                                                                                                                                           |                                                                                    |                                                                                                                                                                          |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| North America:<br>USA, Barbados, Belize, Bolivia, Canada,<br>Colombia, Ecuador, Venezuela<br>Standard P/N EA600 or 1895820<br>6 meter P/N EA650 or 189721 | United Kingdom,<br>Ireland, Hong Kong, Malaysia, Singapore<br>P/N EA606 or 1895821 | Continental Europe:<br>Austria, Belgium, Finland, France, Germany,<br>Greece, Korea, Luxembourg, Netherlands,<br>Norway, Portugal, Spain, Sweden<br>P/N EA602 or 1895822 |
| China<br>P/N EA604                                                                                                                                        | India, South Africa<br>P/N EA607                                                   | Switzerland<br>P/N EA601                                                                                                                                                 |
| Argentina<br>P/N EA608                                                                                                                                    | Israel<br>P/N EA609                                                                | Denmark<br>P/N EA610                                                                                                                                                     |
| Australia, New Zealand<br>P/N EA605                                                                                                                       | Japan<br>P/N EA603 or 1895823                                                      | Italy, Chile<br>P/N EA611                                                                                                                                                |



SYSTEM SOUNDS AND FIGURES

Audible Alarms and Tones

The following alarms and tones can sound while using the IPC Console.

Audible Alarm

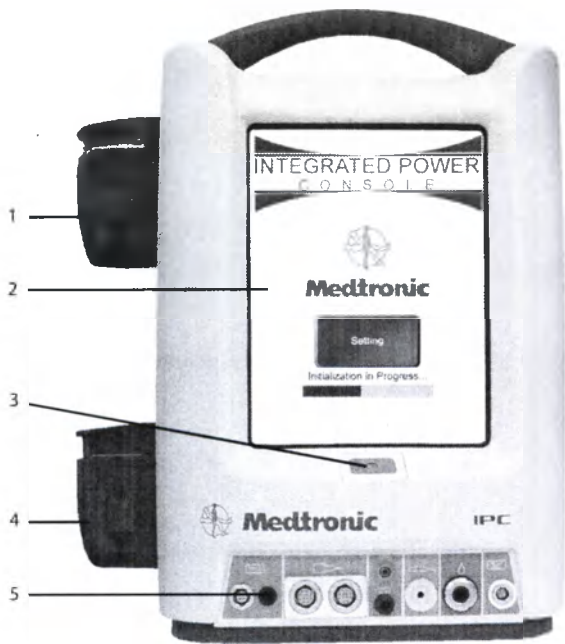
When the system detects an error, a message appears on the touchscreen and the system emits a sequence of three tones.

Audible Tones

| IPC Tone  | Cause(s)                                                                                                                                                                                                                                        |
|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 Tone    | <ul style="list-style-type: none"><li>• Confirmation of change button pressed.</li><li>• Change from Forward to Oscillate.</li><li>• Change of active handpiece.</li></ul>                                                                      |
| 2 Tones   | Change from Oscillate to Forward.                                                                                                                                                                                                               |
| 3 Tones   | <ul style="list-style-type: none"><li>• Audible Alarm. Error detected. See screen for error message.</li><li>• Active handpiece is in Reverse and foot pedal pressed.</li><li>• First time accessory changes from Forward to Reverse.</li></ul> |
| Long Tone | Change from handpiece to drill.                                                                                                                                                                                                                 |

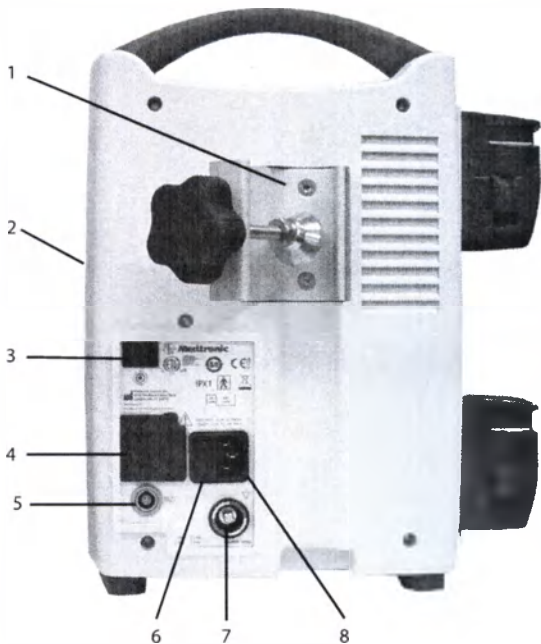
System Figures

Figure 1-1. IPC Console Front



- 1 Pump 1: Coolant, lens cleaning or irrigation
- 2 Touchscreen
- 3 Power on/off
- 4 Pump 2: Irrigation or lens cleaning
- 5 Console connector panel for peripheral devices

Figure 1-2. IPC Console Back



- 1 Pole clamp
- 2 Compact flash card port (Medtronic Use)
- 3 Manual start/stop
- 4 Auxiliary power outlet
- 5 Endo-Scrub 2 connector
- 6 Fuse access
- 7 Equipotential Ground Connector. Apply potential equalization conductor.
- 8 Hospital grade power cord connector



Figure 1-3. IPC Console Connector Panel

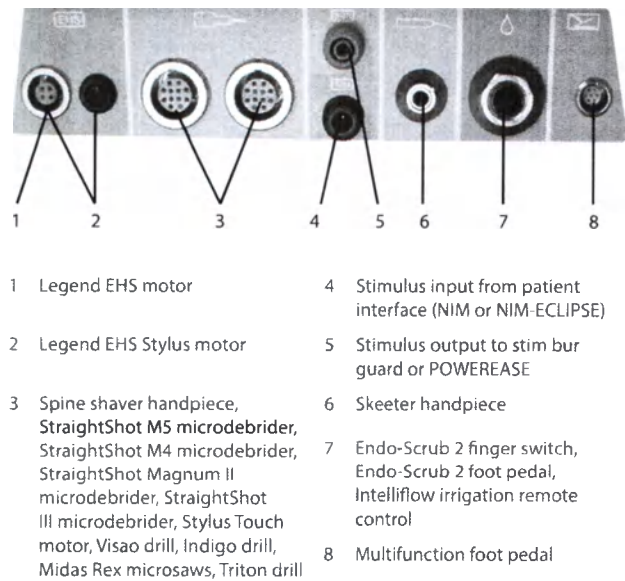


Figure 1-4. Multifunction Foot Pedal & Y-Splitter

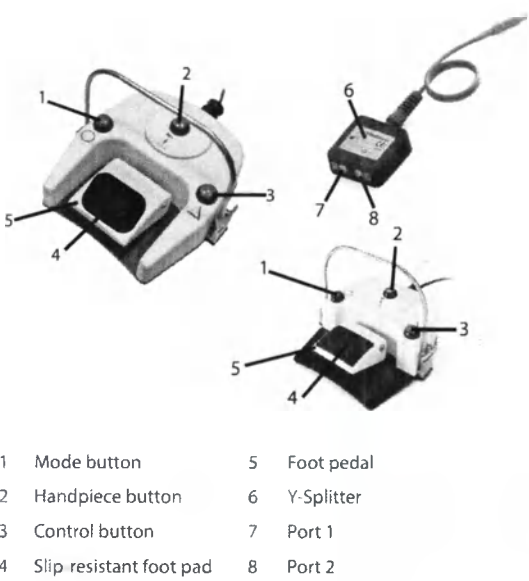


Figure 1-5. IPC Touchscreen

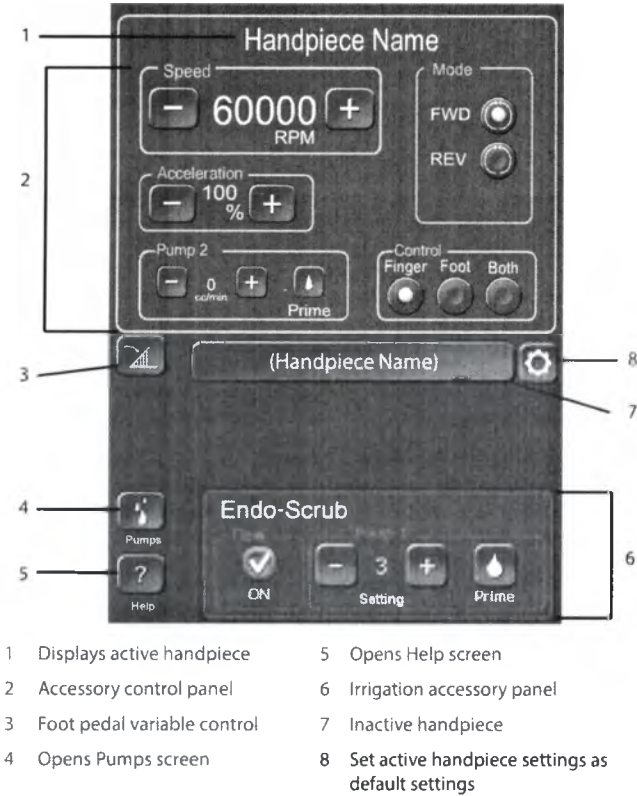


Figure 1-6. IPC Pumps Screen

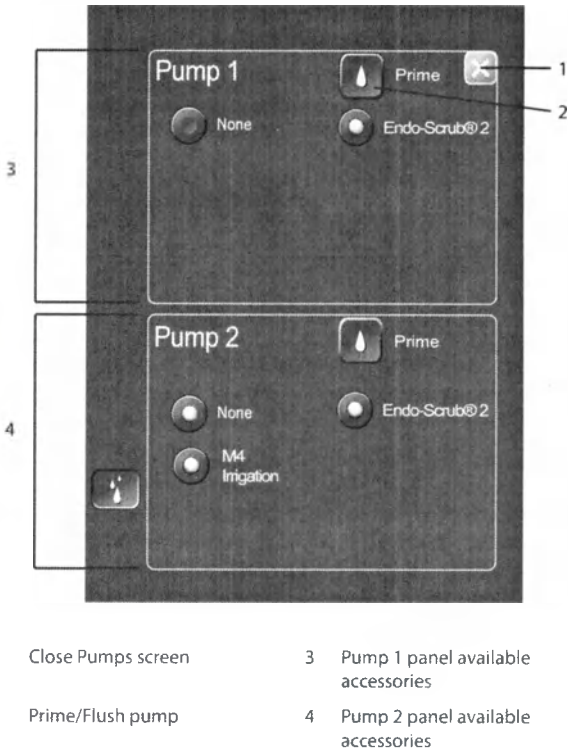
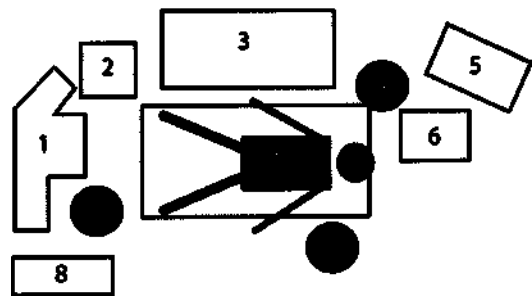
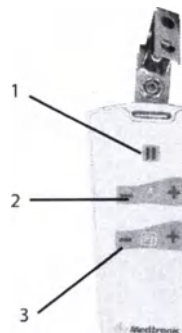


Figure 1-7. Operating Room Setup



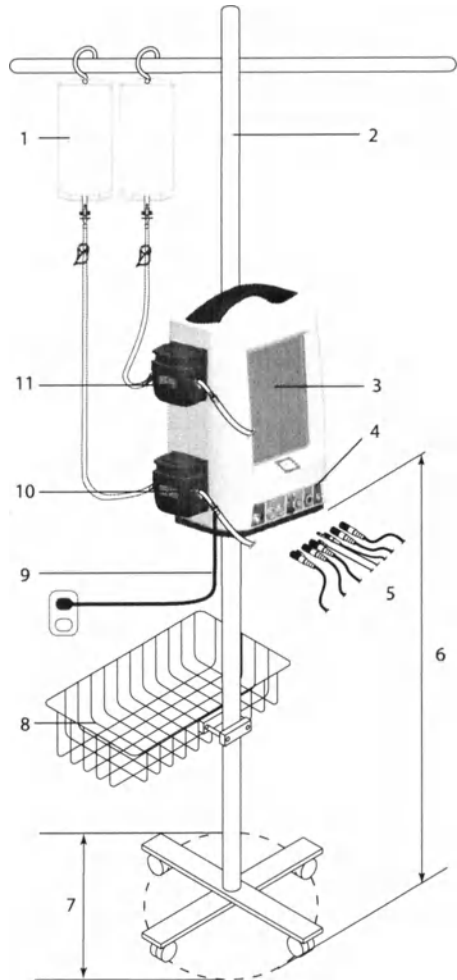
- |   |                                       |    |                       |
|---|---------------------------------------|----|-----------------------|
| 1 | Mode anesthesia equipment             | 6  | Microscope            |
| 2 | IPC system                            | 7  | Surgeon               |
| 3 | Nursing supplies/Surgical instruments | 8  | Electro-Surgical unit |
| 4 | Scrub nurse                           | 9  | Anesthesiologist      |
| 5 | NIM Monitor                           | 10 | Patient               |

Figure 1-9. IntelliFlow Remote Control



- |   |                                                                                                                      |
|---|----------------------------------------------------------------------------------------------------------------------|
| 1 | Pause/On-Off                                                                                                         |
| 2 | Increase/Decrease Fine Adjustment                                                                                    |
| 3 | Increase/Decrease Coarse Adjustment OR<br>Select stainless steel tubing size (French size) for<br>suction irrigator. |

Figure 1-8. IPC System Configuration



- |   |                             |    |                               |
|---|-----------------------------|----|-------------------------------|
| 1 | Irrigation and coolant bags | 7  | Irrigation pole base diameter |
| 2 | Irrigation pole             | 8  | Irrigation pole basket        |
| 3 | IPC console                 | 9  | Power cord                    |
| 4 | Console connector panel     | 10 | Pump 2                        |
| 5 | Accessory cables            | 11 | Pump 1                        |
| 6 | Console height              |    |                               |

PRE-OPERATING INSTRUCTIONS

The following are general IPC pre-operating instructions. Refer to other sections of this IFU for operating instructions specific to individual handpieces or accessories.

When the System Arrives

- Verify the contents of the box match the packing slip. If incomplete or damaged, notify Medtronic Customer Service.
- If container is damaged, or cushioning material shows stress, notify carrier and Medtronic Customer Service. Keep shipping materials for carrier inspection.
- Save the cartons and packing material. If the instrument is to be shipped the shipping package will provide proper protection.

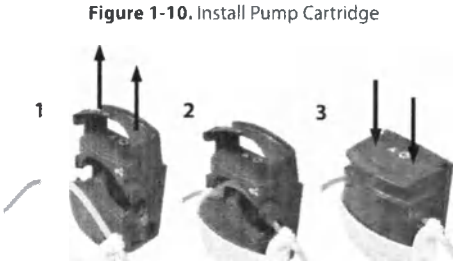
Set up the IPC

Refer the related topics for detailed instruction.

1. Install pump cartridges or irrigation tubing.
2. Prepare IPC for use.
3. Calibrate touchscreen, if necessary.
4. Change system settings, if necessary.
5. Set up and prime pumps.
6. Confirm system operation.
7. Press the manual start/stop button on the back of the console (Figure 1-2) and verify you can start/stop the handpiece, irrigation and/or coolant flow.

Install the Pump Cartridges or Irrigation Tubing

1. Locate the correct pump and lift up the lock (Figure 1-10).  
Pump 1: Coolant, lens cleaning or irrigation  
Pump 2: Irrigation  
**Important:** The number on the pump must match the number on the cartridge (either 1/1 or 2/2). If the cartridge does not have a pump designator number, use the Pump Setup Screen to install the pump cartridge.
2. Insert the pump cartridge.
3. Snap the pump lock shut.  
**Warning:** Ensure the pump cartridge does not crimp the tubing.



Prepare IPC for Use

1. Verify Operation Room set up (Figure 1-7). The surgeon may have preferences to the location and visibility.
2. Verify the wheels are locked on the IPC cart.
3. Inspect all components for damage and determine if the system is ready for use.
4. Mount the IPC and irrigation/coolant bags on the I.V. pole (Figure 1-8).  
**Important:**
  - Mount irrigant and coolant bags above the IPC to ensure adequate flow.
  - It is recommended to use an irrigation pole with minimum base diameter of 53 cm and to mount all items as low as possible to increase stability during use.
  - For transport or uneven floor conditions greater than 10 degrees, maximum height to mount the console is 38 cm if irrigation and coolant bags are at fully extended pole height.
5. Plug the IPC into the power source. Position the IPC so that it does not obstruct the power source for the purpose of disconnecting the Main voltage by the power cord.
6. Locate the correct foot pedal or accessory connection port on the connector panel (Figure 1-3), align the mark on the connector to the mark on the console, and then insert the connector.
7. Connect suction, cooling and/or irrigation tubing.
8. Turn on the IPC and verify the system passes the self-test.  
**Note:** If the IPC does not detect a handpiece or foot pedal the Connect Handpiece/Connect Foot Switch screen appears. Do the following:
  - Verify the cable is connected to the correct connection port.
  - Press [OK] in the Connect Handpiece/Connect Foot Switch message window to continue use of the IPC without the handpiece or foot pedal.

Calibrate Touchscreen

**Note:** This step is optional.

1. Turn on the IPC console.
2. When the system starts, on the Splash screen, press [Settings].
3. On the Settings screen, press **Touch Screen Calibration** and follow the screen prompts.

Change System Settings

**Note:** During surgery, system settings can be overwritten.

- 1. Turn on the IPC console.
- 2. While the system starts, on the Splash screen, press **[Settings]**.
- 3. To change the language, press the appropriate language.
- 4. To change the default settings, press **[Default]**.
  - On the Default screen, press the Forward or Backward arrow to change the accessory.
  - Make changes to the default settings.
  - To confirm system settings and return to the Splash screen, press **[OK]**.
- 5. For accessories with audible tones, press the REV Audible Tones button to control the following:
  - The system delivers one set of reverse beeps when the Reverse mode is activated.
  - The system delivers one set of reverse beeps the first time the drill is used in Reverse mode after the Reverse mode has been activated.
- 6. To confirm system settings and continue to the IPC touchscreen, press **[OK]**.
- 7. To restore settings to factory default, press **[Restore]**.

Handpiece Default Settings

The system configuration is dependent on the handpiece(s) connected to the console. The following table defines the default configurations, default settings (X) and default options (O).

**Note:** During use, update the default settings for the active handpiece by pressing the **set active handpiece settings as default settings** button (Figure 1-5).

| Table 1. IPC Touchscreen Default Configurations |       |      |     |                            |           |         |              |              |      |      |            |         |
|-------------------------------------------------|-------|------|-----|----------------------------|-----------|---------|--------------|--------------|------|------|------------|---------|
| Handpiece                                       | Speed |      |     | Mode or Mode Select Switch |           |         |              |              |      |      |            |         |
|                                                 | rpm   | cpm  | %   | Forward                    | Oscillate | Reverse | Acceleration | Deceleration | Size | Flow | Irrigation | Control |
| Visao                                           | 80000 |      |     | X                          |           | O       |              |              |      |      | 30         |         |
| Indigo                                          | 52000 |      |     | X                          |           | O       |              |              |      |      | 30         |         |
| Midas Rex SC1                                   |       | 3400 |     | O                          | X         |         |              |              |      |      | 60         |         |
| StraightShot M5                                 | 5000  |      |     | O                          | X         |         |              |              |      |      | 05         |         |
| StraightShot M4                                 | 5000  |      |     | O                          | X         |         |              |              |      |      | 05         |         |
| StraightShot III, Magnum II                     | 5000  |      |     | O                          | X         |         |              |              |      |      | 30         |         |
| Legend EHS Stylus                               | 60000 |      |     | X                          |           | O       | 45 %         | 45 %         |      |      | 0          |         |
| Legend EHS                                      | 70000 |      |     | X                          |           | O       |              |              |      |      | 0          |         |
| Stylus Touch                                    | 60000 |      |     | X                          |           | O       | 80 %         | 100 %        |      |      | 0          | Finger  |
| Skeeter                                         | 16000 |      |     | X                          |           | O       | v            |              |      |      | 0          |         |
| Endo-Scrub 2                                    |       |      |     |                            |           |         |              |              |      | 3    |            |         |
| Suction Irrigator                               |       |      |     |                            |           |         |              |              | 8    | 50 % |            |         |
| Triton                                          |       |      | 100 | X                          |           |         |              |              |      |      |            |         |
|                                                 |       |      | 100 |                            |           | X       |              |              |      |      |            |         |
| Midas Rex Microsaws                             |       |      | 100 |                            |           |         |              |              |      |      | 0          |         |
| POWEREASE                                       | 120   |      |     | X                          |           |         |              |              |      |      |            |         |
|                                                 | 120   |      |     |                            | X         |         |              |              |      |      |            |         |
|                                                 | 250   |      |     |                            |           | X       |              |              |      |      |            |         |

Set up and Prime Pumps

- The IPC turns on pump 1 and/or 2 long enough to purge air out of the tubing set(s) the first time the prime button is pressed.
  - The IPC resets the prime feature when you turn IPC power Off and On.
  - After you prime the pump, the prime button and functionality become flush functionality.
1. Connect tubing from an IPC cartridge to irrigation or coolant tubing on an accessory.
  2. On the irrigation tubing, turn the clamp to OPEN.
  3. If an accessory uses the clear drip chamber (Visao), fill the clear drip chamber with coolant. To fill, squeeze and release the chamber until full.
  4. On the IPC touchscreen (Figure 1-5), press the pumps button.
- Note:** The IPC pumps screen is also available from the Connect Handpiece/Connect Foot Switch screen which the system displays during IPC preparation for use if a handpiece or foot switch is not detected by the system.
5. On the IPC pumps screen (Figure 1-6), select the accessory for each pump.
  6. For each pump, press the prime button and verify the following:
    - Pump(s) run until air is completely purged from tubing.
    - Small amount of lubricant flows at the tip of the irrigation device.
    - Pump(s) turns off.
  7. Press the close button.

Pump Default Configurations

The pump configuration is dependent on the handpiece(s) connected to the console. The following table defines the pump default settings (X) and default options (O).

| Table 2. IPC Pumps Screen Default Configurations |         |            |            |              |        |                   |        |
|--------------------------------------------------|---------|------------|------------|--------------|--------|-------------------|--------|
| Handpiece                                        | Pump 1  |            | Pump 2     | Endo-Scrub 2 |        | Suction Irrigator |        |
|                                                  | Cooling | Irrigation | Irrigation | Pump 1       | Pump 2 | Pump 1            | Pump 2 |
| Visao                                            | X       |            | X          |              | O      |                   | O      |
| Indigo                                           |         | O          | X          | O            | O      | O                 | O      |
| Midas Rex SC1                                    |         | O          | X          | O            | O      |                   |        |
| StraightShot M5                                  |         | O          | X*         | X            | O      |                   |        |
| StraightShot M4                                  |         | O          | X*         | X            | O      |                   |        |
| StraightShot III, Magum II                       |         | O          | X*         | X            | O      |                   |        |
| Legend EHS Stylus                                |         | X          | O*         | O            | O      | O                 | O      |
| Legend EHS                                       |         | X          | O          | O            | O      | O                 | O      |
| Stylus Touch                                     |         | X          | O          | O            | O      | O                 | O      |
| Skeeter                                          |         |            |            | O            | O      | O                 | O      |
| Endo-Scrub 2                                     |         | X          | O          | X            | O      |                   |        |
| Suction Irrigator                                |         | O          | O          |              |        | O                 | O      |
| Midas Rex Microsaws                              |         | O          | X          | O            | O      | O                 | O      |
| POWEREASE                                        |         |            |            | O            | O      | O                 | O      |

\* When the IPC detects both the StraightShot M4 or StraightShot M5 and the Legend EHS Stylus Touch handpiece, by default, the system sets pump 2 as a "shared" irrigation pump. You must manually connect the irrigation tubing to the active handpiece.

Confirm System Operation

1. Confirm the irrigation pedal starts handpiece and irrigation flow. Verify the speed changes from white to yellow in the Speed box on the touchscreen.
2. Confirm the foot pedal buttons operate. Refer to "Multifunction Foot Pedal" for details.
3. On the touchscreen, verify you can do all of the following:
  - Adjust Speed: In the Speed box, press the plus and minus buttons.
  - Change Modes: In a Mode box, press any mode button.
  - Adjust Flow Rate: In the Irrigation box, press the plus and minus buttons.



## IPC COMPONENTS

### Auxiliary Power to Console

**Warning:** The auxiliary power outlet is available for use with the Hydrodebrider and Bone Mill IPC consoles only (see W82). The auxiliary power outlet is for use at grid voltage  $\leq 120$  VAC only.

### Multifunction Foot Pedal

You can use the multifunction foot pedal (Figure 1-4) to start/stop the handpiece, control handpiece speed, handpiece selection and mode of operation. Refer to the Multifunction Foot Pedal Controls topic for each handpiece for specific use and control.

### Y-Splitter

Y-Splitter (Figure 1-4) allows using a maximum of two multifunction foot pedals connected to a single IPC (see P23 & P24). In this configuration, the Y-Splitter shall be connected to the IPC, and the Multifunction Foot Pedal(s) shall be connected to the Y-Splitter. When connecting a single foot pedal to the Y-Splitter, you may connect to either Port 1 or 2.

### IntelliFlow Irrigation Remote Control

Use the IntelliFlow irrigation remote control (Figure 1-9) to start/stop and change irrigation flow while in the sterile field.

If you are using handpiece irrigation:

- To pause irrigation flow, press the Pause/On-Off button.
- To adjust flow rate, press the Fine Adjustment or Coarse Adjustment Increase/Decrease button.

If you are using the Suction Irrigator:

- To pause or turn on/off the Suction Irrigator, press the Pause/On-Off button.
- To adjust flow rate, press the Fine Adjustment Increase/Decrease button.
- To select the stainless steel tubing size (French size), press the Stainless Steel Tubing Size button.

GUIDANCE AND MANUFACTURER’S DECLARATION – ELECTROMAGNETIC IMMUNITY  
Part I

| The IPC is intended for use in the electromagnetic environment specified below. The customer or the user of the IPC should assure that it is used in such an environment. |                                                                                                                                                                   |                                                                                                                                                                   |                                                                                                                                                                                                                                                                         |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Immunity test                                                                                                                                                             | IEC/EN60601-1-2 test level                                                                                                                                        | Compliance level                                                                                                                                                  | Electromagnetic environment - guidance                                                                                                                                                                                                                                  |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2                                                                                                                            | ±6 kV contact<br>±8 kV air                                                                                                                                        | ±6 kV contact<br>±8 kV air                                                                                                                                        | Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.                                                                                                                         |
| Electrical fast transient/burst<br>IEC 61000-4-4                                                                                                                          | ±2 kV for power supply lines<br>±1 kV for input/output lines                                                                                                      | ±2 kV for power supply lines<br>±1 kV for input/output lines                                                                                                      | Mains power quality should be that of a typical commercial or hospital environment.                                                                                                                                                                                     |
| Surge<br>IEC 61000-4-5                                                                                                                                                    | ±1 kV differential mode<br>±2 kV common mode                                                                                                                      | ±1 kV differential mode<br>±2 kV common mode                                                                                                                      | Mains power quality should be that of a typical commercial or hospital environment.                                                                                                                                                                                     |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11                                                                    | <5 % UT (>95 % dip in UT) for 0.5 cycle<br>40 % UT (60 % dip in UT) for 5 cycles<br>70 % UT (30 % dip in UT) for 25 cycles<br><5 % UT (>95 % dip in UT) for 5 sec | <5 % UT (>95 % dip in UT) for 0.5 cycle<br>40 % UT (60 % dip in UT) for 5 cycles<br>70 % UT (30 % dip in UT) for 25 cycles<br><5 % UT (>95 % dip in UT) for 5 sec | Mains power quality should be that of a typical commercial or hospital environment. If the user of the IPC requires continuous operation during power mains interruptions, it is recommended that the IPC be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field<br>IEC 61000-4-8                                                                                                                | 3 A/m                                                                                                                                                             | 3 A/m                                                                                                                                                             | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.                                                                                                                               |

Note: UT is the a.c. mains voltage prior to application of the test level.

| Guidance and manufacturer’s declaration – electromagnetic emissions                                                                                                       |            |                                                                                                                                                                                                                                                                                                                                                                                      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The IPC is intended for use in the electromagnetic environment specified below. The customer or the user of the IPC should assure that it is used in such an environment. |            |                                                                                                                                                                                                                                                                                                                                                                                      |
| Emissions test                                                                                                                                                            | Compliance | Electromagnetic environment - guidance                                                                                                                                                                                                                                                                                                                                               |
| RF emissions<br>CISPR 11                                                                                                                                                  | Group 1    | The IPC uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.<br><br>The IPC is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings for domestic purpose. |
| RF emissions<br>CISPR 11                                                                                                                                                  | Class A    |                                                                                                                                                                                                                                                                                                                                                                                      |
| Harmonic emissions<br>IEC 61000-3-2                                                                                                                                       | Class A    |                                                                                                                                                                                                                                                                                                                                                                                      |
| Voltage fluctuations<br>IEC 61000-3-3                                                                                                                                     | Complies   |                                                                                                                                                                                                                                                                                                                                                                                      |

| Recommended separation distances between portable and mobile RF communications equipment and the IPC                                                                                                                                                                                                                                                                                                                 |                                                                  |                                |                                 |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|--------------------------------|---------------------------------|
| The IPC is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the IPC can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the IPC as recommended below, according to the maximum output power of the communications equipment. |                                                                  |                                |                                 |
| Rated maximum power of transmitter<br>W                                                                                                                                                                                                                                                                                                                                                                              | Separation distance according to frequency of transmitter meters |                                |                                 |
|                                                                                                                                                                                                                                                                                                                                                                                                                      | 150 kHz to 80 MHz<br>d = 1.2√P                                   | 80 MHz to 800 MHz<br>d = 1.2√P | 800 MHz to 2.5 GHz<br>d = 2.3√P |
| 0.01                                                                                                                                                                                                                                                                                                                                                                                                                 | 0.12                                                             | 0.12                           | 0.23                            |
| 0.10                                                                                                                                                                                                                                                                                                                                                                                                                 | 0.38                                                             | 0.38                           | 0.73                            |
| 1.00                                                                                                                                                                                                                                                                                                                                                                                                                 | 1.20                                                             | 1.20                           | 2.30                            |
| 10.00                                                                                                                                                                                                                                                                                                                                                                                                                | 3.80                                                             | 3.80                           | 7.30                            |
| 100.00                                                                                                                                                                                                                                                                                                                                                                                                               | 12.00                                                            | 12.00                          | 23.0                            |
| For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.                                                                                     |                                                                  |                                |                                 |
| NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.                                                                                                                                                                                                                                                                                                                        |                                                                  |                                |                                 |
| NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.                                                                                                                                                                                                                                                   |                                                                  |                                |                                 |

Part II

| The IPC is intended for use in the electromagnetic environment specified below.<br>The customer or the user of the IPC should assure that it is used in such an environment.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                            |                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Immunity test                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | IEC/EN60601-1-2 test level | Compliance level | Electromagnetic environment - guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                            |                  | Portable and mobile RF communications equipment should be used no closer to any part of the IPC , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance                                                                                                                                                                                                                                                                               |
| Conducted RF                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 3 Vrms                     | 3 Vrms           | $d = 1.2 \sqrt{P}$                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| IEC 61000-4-6                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 150 kHz to 80 MHz          |                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Radiated RF                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 3 V / m                    | 3 V / m          | $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| IEC 61000-4-3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 80 MHz to 2.5 GHz          |                  | $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                            |                  | Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).<br><br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey , should be less than the compliance level in each frequency range <sup>a</sup> .<br><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br> |
| NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.<br>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.<br>NOTE 3 When operating the IPC with Stylus Touch, the compliance level is 3 V/m except from 88 MHz to 91 MHz where it is 1 V/m. The formula for separation distance for the IPC with Stylus Touch will be $d = 3.5 \sqrt{P}$ in that frequency range.                                                                                                                                                                                                                                                                                                          |                            |                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the IPC is used exceeds the applicable RF compliance level above, the IPC should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the IPC .<br><br><sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. |                            |                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

LIMITED WARRANTY

- A. This Limited Warranty provides the following assurance for the customer who purchases a Medtronic IPC System. This Limited Warranty is extended only to the buyer purchasing the IPC System directly from Medtronic or from its affiliate or its authorized distributor or representative. The IPC System includes the console, motor or handpiece, foot control, motor cables, instrumentation cases and trays (hereafter referred to as System Components), straight and angled motor attachments (hereinafter referred to as "Attachments"), bur guards and telescoping tubes (hereinafter referred to as Semi-reusable Components) and dissecting tools, irrigation and coolant tubing, and Intelliflow remote control (hereinafter referred to as Single Use Components) and jointly referred to as the IPC System, unless specifically noted.
- i. Should a System Component fail to function to Medtronic's published specifications during the term of this Limited Warranty (one [1] year from the date of sale of a new System Component or ninety [90] days from the date of sale of a refurbished or used System Component), Medtronic will either repair or replace the Motor Component or any portion thereof.
  - ii. Should an Attachment fail to function to Medtronic's published specifications during the term of this Limited Warranty (ninety [90] days from the date of sale of a new Attachment), Medtronic will either repair or replace the Attachment or any portion thereof.
  - iii. Should a Semi-reusable Component fail to function to Medtronic's published specifications during the term of this Limited Warranty (thirty [30] days from the date of sale of a new Semi-reusable Component), Medtronic will replace the Semi-reusable Component or any portion thereof.
  - iv. Should a Single Use Component fail to function to Medtronic's published specifications prior to its "use by" date Medtronic will replace the Single Use Component.
- B. To qualify for this Limited Warranty, the following conditions must be met:
- i. The Product must be used on or before its "Use By" or "Use Before" date, if applicable.
  - ii. The Product must be used in accordance with its labeling and may not be altered or subjected to misuse, abuse, accident or improper handling.
  - iii. Medtronic must be notified in writing within thirty (30) days following discovery of a defect.
  - iv. The Product must be returned to Medtronic within thirty (30) days of Medtronic receiving notice as provided for in (3) above.
  - v. Upon examination of the Product by Medtronic, Medtronic shall have determined that: (i) the Product was not repaired or altered by anyone other than Medtronic or its authorized representative, (ii) the Product was not operated under conditions other than normal use, and (iii) the prescribed periodic maintenance and services, if applicable, have been performed on the Product.
- C. This Limited Warranty is limited to its express terms. THIS LIMITED WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED WHETHER STATUTORY OR OTHERWISE, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. In no event shall Medtronic be liable for any consequential, incidental, prospective or other similar damage resulting from a defect, failure, or malfunction of the IPC System, whether a claim for such damage is based upon the warranty, contract, negligence or otherwise.
- D. The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. Users may benefit from statutory warranty rights under legislation governing the sale of consumer goods. If any part or term of this Limited Warranty is held by any court of competent jurisdiction to be illegal, unenforceable, or in conflict with applicable law, the validity of the remaining portion of the Limited Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Limited Warranty did not contain the particular part or term held to be invalid.

FOR ITEMS CONTAMINATED WITH TSE AGENTS

Medtronic ENT/NT Transmissible Spongiform Encephalopathy (TSE) Return Policy

Medtronic will not authorize or accept the return of products that directly contact patients or is contaminated with a patient's body fluids suspected or confirmed with a Transmissible Spongiform Encephalopathy / Creutzfeldt-Jakob Disease (TSE/CJD) diagnosis.

The following are recommended guidelines and may vary according to specific policy and procedures among hospitals. Hospital personnel should contact their infection control personnel for current procedures and policy for reusable equipment processing when suspected of contamination with Creutzfeldt-Jakob Disease (CJD) or other Transmissible Spongiform Encephalopathy (TSE) agent.

Medtronic dissecting tools, burs, or blades used on a patient suspected of a TSE/CJD diagnosis should be incinerated. Reusable equipment that has been used on patients with suspected Creutzfeldt-Jakob Disease (CJD) or other Transmissible Spongiform Encephalopathy (TSE) should be quarantined and not reused until diagnosis is confirmed or excluded. Reusable equipment should be quarantined after having been cleaned, decontaminated, sterilized and packed in a rigid sealed container until final diagnosis. If TSE/CJD is excluded as a diagnosis, the quarantined reusable equipment may be returned for use after appropriate cleaning, decontamination and sterilization.

Medtronic recommends that all Medtronic products used directly on a patient confirmed with a TSE diagnosis be incinerated. Contact your Sales Representative to purchase replacement products or secure loaner equipment.

For additional information contact your Customer Service Representative.

# TRITON ELECTRIC HIGH-TORQUE HANDPIECE

## DEVICE DESCRIPTION

The Triton Electric High-Torque Handpiece is capable of removing hard and soft tissue, drilling pilot holes, and driving screws, wires, and pins during spinal, cranial, and small-bone surgical procedures performed in an operating-room environment by surgeons trained in its use.

The following instructions for the Triton Electric High-Torque Handpiece are in addition to "Set up the IPC" general assembly instructions. Complete IPC setup, then continue to the instructions below.

## BEFORE USE

Clean and sterilize the device, prior to first use. Refer to the Reprocessing Instructions contained in this manual for additional information.

## TRITON SAGITTAL SAW ASSEMBLY

**Warning:** Triton saw attachments should only be used with Medtronic Triton saw blades. Refer to the Triton Quick Reference Saw Blade Guide (LIT200017) for additional information on Triton saw blades.

1. Insert the Sagittal Saw Attachment into the handpiece in a position to allow easy insertion of the Sagittal Saw Key (Figure 2-1).
- Note:** You can install the attachment in 12 different positions to facilitate proper surgical access.
2. Insert the Sagittal Saw Key into the attachment and turn counterclockwise until there is slight resistance.
3. Insert the blade into the space between the two jaws, ensuring that the blade is fully seated.
4. Turn the Sagittal Saw Key clockwise to lock the blade. Run briefly, then retighten blade.

**Caution:** Do not over-tighten.

Figure 2-1. Sagittal Saw Assembly



## TRITON SAGITTAL SAW DISASSEMBLY

To remove the Triton saw blade, insert the Sagittal Saw Key into the Attachment and turn counterclockwise.

## TRITON RECIPROCATING SAW ASSEMBLY

**Warning:** Triton saw attachments should only be used with Medtronic Triton saw blades. Refer to the Triton Quick Reference Saw Blade Guide (LIT200017) for additional information on Triton saw blades.

1. Loosen the collet nut then insert the blade until it is fully seated (Figure 2-2).
- Note:** You can install the attachment in different positions to facilitate proper surgical access.
2. Finger-tighten the collet nut. Run briefly, then retighten collet nut.

Figure 2-2. Reciprocating Saw Assembly



## TRITON RECIPROCATING SAW DISASSEMBLY

To remove the Triton Reciprocating Saw blade, unscrew the collet nut.

## TRITON AO/SYNTHES CHUCK AND TRINKLE CHUCK ASSEMBLY

1. To install a drill bit, pull back on the attachment collar (Figure 2-3).
2. Insert the drill bit and release the attachment collar.

Figure 2-3. AO/Synthes Chuck and Trinkle Chuck Assembly



## TRITON AO/SYNTHES CHUCK AND TRINKLE CHUCK DISASSEMBLY

1. To remove a drill bit, pull back on the attachment collar.
2. Remove the drill bit and release the attachment collar.



TRITON ELECTRIC HIGH-TORQUE HANDPIECE

TRITON JACOBS CHUCK ASSEMBLY

- 1. To install a drill bit, turn the key to open the chuck or spin the collar if using a keyless chuck attachment (Figure 2-4).
- 2. Insert the drill bit.

TRITON JACOBS CHUCK DISASSEMBLY

- 1. To remove a drill bit, turn the key to open the chuck or spin the collar if using a keyless chuck attachment.
- 2. Remove the drill bit.

Figure 2-4. Jacobs Chuck Assembly



TRITON HUDSON AND ZIMMER CHUCK ASSEMBLY

To install an instrument, pull back on the attachment collar, then insert the male end of the instrument into the chuck (Figure 2-5).

Figure 2-5. Hudson and Zimmer Chuck Assembly



TRITON HUDSON AND ZIMMER CHUCK DISASSEMBLY

To remove an instrument, pull back on the attachment collar, then remove the instrument from the chuck.

TRITON WIRE AND PIN COLLET ASSEMBLY

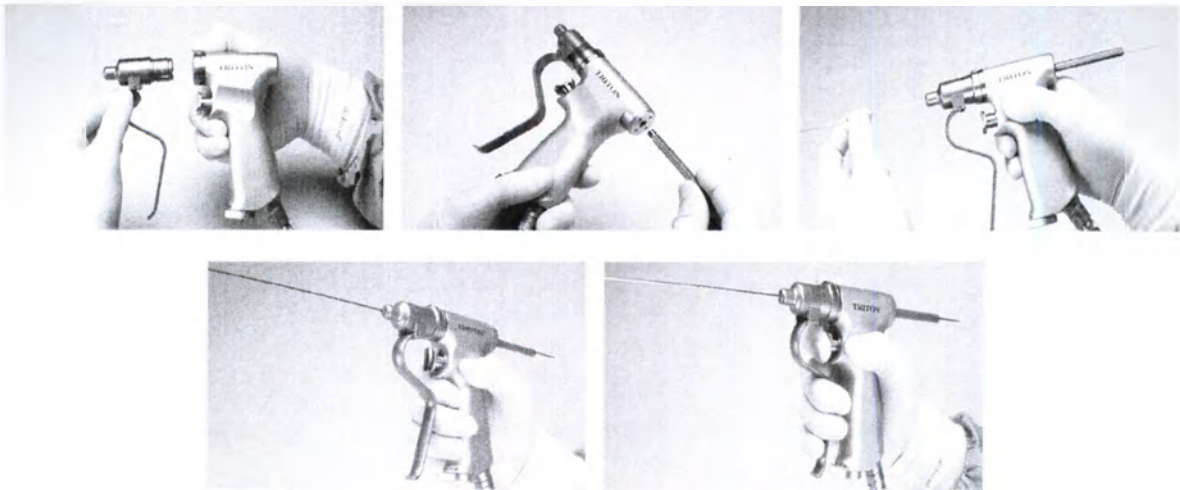
The Wire Collet accepts wires up to 1.6 mm (.062 inches) in diameter. The Pin Collet accepts pins up to 3.2 mm (.125 inches) in diameter.

- 1. Insert the Wire or Pin Collet (Figure 2-6) while the handpiece is in the SAFE position (Figure 2-7).
- 2. Screw the Cannulated Extension in the back of the handpiece to protect the operator from the point of the wire or pin, as necessary.
- 3. Insert the wire or pin into the front or back of the handpiece.
- 4. Put the instrument in the RUN position by positioning the trigger control vertically.
- 5. Turn the Mode select switch at the base of the handle to the FORWARD position.
- 6. Squeeze the Wire/Pin Advance lever and hold it down.
- 7. Press the trigger control to drive the wire/pin. The pressure-sensitive trigger allows variable speed operation.
- 8. To obtain additional wire/pin length, release the wire/pin.
- 9. Advance the lever and trigger control.
- 10. Pull back on the instrument.
- 11. Squeeze the Wire/Pin Advance lever and trigger control to drive the wire.

TRITON WIRE AND PIN COLLET DISASSEMBLY

To remove threaded wire/pin, put the Mode select switch in REVERSE, squeeze the Wire/Pin Advance lever and press the trigger control.

Figure 2-6. Wire and Pin Collet Assembly



TRITON ELECTRIC HIGH-TORQUE HANDPIECE OPERATION

You can preload attachments before insertion into the handpiece.

**Caution:** Insert all attachments into the handpiece with the handpiece in the SAFE position (Figure 2-7).

**Note:** The handpiece has an Extension Handle that screws into the back of the handpiece. The handle extension provides balance and two-handed control for various drilling and cutting applications.

- 1. With the handpiece in the SAFE position (Figure 2-7), insert a preloaded attachment by pressing the quick-release button on top of the handpiece. Snap the attachment into the handpiece with a slight twisting motion until it is seated.
- 2. Place the handpiece in the RUN position, with the trigger control vertical. The Mode select switch at the base of the handle should be in the FORWARD position.
- 3. After use, return the trigger control to the SAFE position prior to removing the attachment.
- 4. Remove the attachment by pressing the quick-release button on top of the handpiece.

Safe Position

The handpiece will not operate in the SAFE position. To operate the handpiece, activate and press the trigger control.

Figure 2-7. Triton Handpiece Safe and Run positions



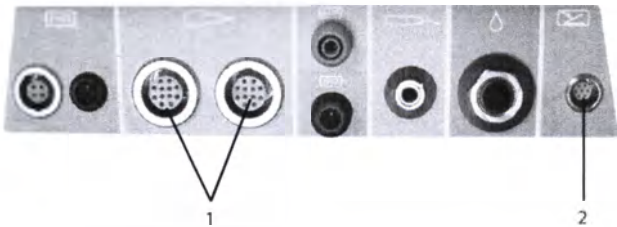
SAFE: Turn trigger control to either side to lock handpiece in SAFE mode.      RUN: Trigger control in the vertical position will allow activation of the handpiece.

CONNECT TRITON ELECTRIC HIGH-TORQUE HANDPIECE TO IPC

Locate the Triton Electric High-Torque Handpiece connection port on the connector panel (Figure 2-8) and insert the connector.

**Note:** To insert multi-pin connectors (indicated by a silver or red mark on the connector), align the mark on the connector to the mark on the console, then insert the connector.

Figure 2-8. Triton IPC Connection Ports

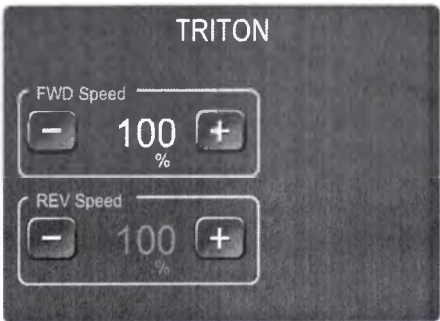


- 1    Triton handpiece connection port
- 2    Multifunction foot pedal connection port

TRITON ELECTRIC HIGH-TORQUE HANDPIECE TOUCHSCREEN CONTROLS

To adjust Triton Electric High-Torque Handpiece variable speed, on the IPC touchscreen, in the FWD Speed or REV Speed control box (Figure 2-9), press the plus button to increase variable speed or the minus button to decrease variable speed.

Figure 2-9. Triton Touchscreen



TRITON ELECTRIC HIGH-TORQUE HANDPIECE MODE SELECT SWITCH

Use the mode select switch to change the handpiece from Forward to Reverse when the handpiece is the active handpiece. When the handpiece is the inactive handpiece, use the mode select switch to activate the handpiece.

TRITON ELECTRIC HIGH-TORQUE HANDPIECE MULTIFUNCTION FOOT PEDAL CONTROLS

**Important:** By default, press each button on the foot pedal for at least 100 mS for the selection to become active. Use the IPC touchscreen Settings screen to change the default value.

To use the multifunction foot pedal (Figure 2-10) to control the handpiece to do the following:

- To toggle between the start/stop mode and variable speed mode, press the control button. 
- To change the handpiece, press the handpiece button. 

Triton Electric High-Torque Handpiece Reverse Foot Pedal Control

When you connect the optional foot pedal to the IPC console, the pedal can be used as an alternative method of activating Reverse mode (without manipulating the Mode select switch at the bottom of the handpiece). When the pedal is connected, the Reverse Pedal control box appears on the screen (Figure 2-11).

**Note:** By default, pedal functionality is turned OFF.

1. To use the pedal, press ON in the Reverse Pedal control box on the IPC touch screen.
2. With the pedal turned on, step on the foot pedal to put the handpiece into Reverse mode (regardless of what position the Mode select switch is in).  
**NOTE:** The trigger control must be pressed to activate the handpiece, even when you are stepping on the foot pedal.
3. Remove your foot from the pedal to return the handpiece to the mode currently defined by the Mode select switch on the handpiece.

Figure 2-10. Multifunction Foot Pedal & Y-Splitter

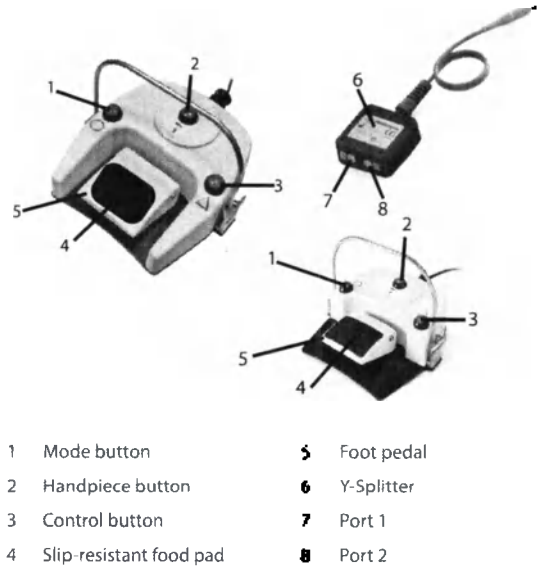


Figure 2-11. Reverse Pedal Control Box



TRITON ELECTRIC HIGH-TORQUE HANDPIECE CLEANING AND STERILIZATION INSTRUCTIONS

Refer to document M000030A322 in the Cleaning and Sterilization section.

TRITON ELECTRIC HIGH-TORQUE HANDPIECE TECHNICAL SPECIFICATIONS

Triton Electric High-Torque Handpiece ED500

|                             |                                                                                                                                                                                                                |
|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Size                        | 3.5 inches Length x 5.4 inches Height x 1.1 inches Width                                                                                                                                                       |
| Weight                      | 2.1 lbs                                                                                                                                                                                                        |
| Speed                       | 180-1800 rpm (actual speed depends on attachment used)                                                                                                                                                         |
| Duty Cycle for Applied Part | Cycle Time: 20 seconds on maximum / 20 seconds off minimum<br>Maximum number of cycles before resting handpiece: 6<br>Maximum number of cycles before resting attachment: 3<br>Minimum rest period: 25 minutes |

# SUCTION IRRIGATOR

The following instructions for the Suction Irrigator are in addition to “Set up the IPC” general assembly instructions. Complete IPC setup, then continue to the instructions below.

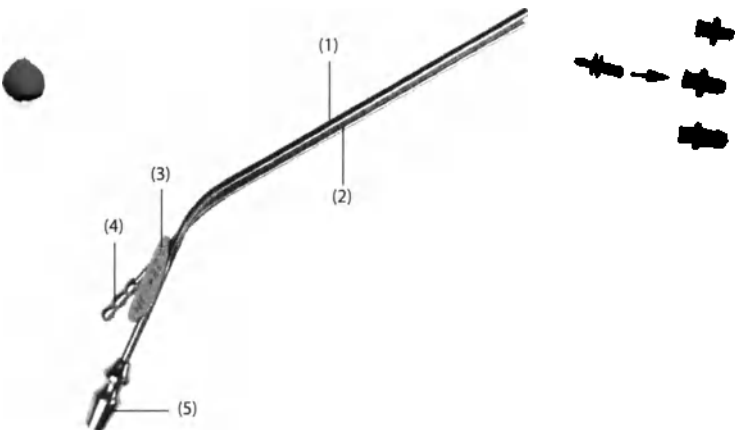
## SUCTION IRRIGATOR ASSEMBLY

- 1. Connect the suction tubing from a suction source to the suction fitting on the Suction Irrigator (Figure 3-1).
- 2. On the IPC touchscreen (Figure 1-5), press the pumps button: [Pumps Button]
- 3. On the IPC pumps screen (Figure 1-6), select a pump for the Suction Irrigator.  
**Note:** When using a handpiece that connects to a pump, the IPC automatically incorporates the Suction Irrigator at the pump not in use by the handpiece.
- 4. Connect the irrigation tubing from the IPC cartridge (Figure 1-8) to the irrigation fitting on the Suction Irrigator (Figure 3-1).
- 5. On the irrigation tubing, turn the clamp to OPEN.

## SUCTION IRRIGATOR ADAPTER KIT

- 1. Connect an adapter to the high-speed irrigation tubing (blue adapter) or the IPC tubing (white adapter).
- 2. Connect an adapter to the irrigation connector tube (Figure 3-2).
- 3. Connect an irrigation connector tube to the irrigation fitting on the Suction Irrigator.

Figure 3-1. Suction Irrigator



- |   |                 |   |                    |
|---|-----------------|---|--------------------|
| 1 | Suction tube    | 4 | Irrigation fitting |
| 2 | Irrigation tube | 5 | Suction fitting    |
| 3 | Tube size       |   |                    |

Figure 3-2. Suction Irrigator Adapter Kit



SUCTION IRRIGATOR IN STANDALONE MODE

The Suction Irrigator tool can operate as a standalone device by changing the IPC system defaults.

- 1. On the Defaults menu (Figure 3-3), in the Stand Alone section, select **Suction Irrigator** and then press **[OK]**.
- 2. On the Handpiece Connection screen (Figure 3-4), in the Suction Irrigator box, press **[OK]**.

Figure 3-3. IPC General System Default Menu

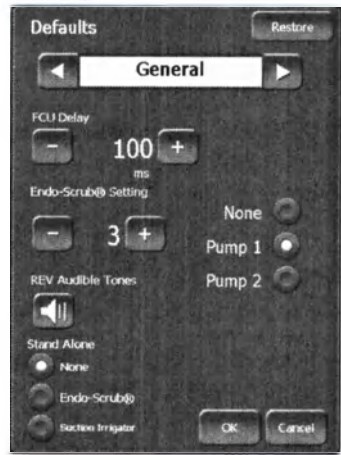


Figure 3-4. Handpiece Connection Screen



SUCTION IRRIGATOR TOUCHSCREEN CONTROLS

To set or adjust Suction Irrigator controls, on the IPC touchscreen, in the Suction Irrigator control box (Figure 3-5), do the following:

- To set the tubing size, in the Size control box, press the plus and minus buttons.
- Note:** The system defaults to size 8.
- To enable or disable the irrigation flow, in the Flow control box, select the On/Off box.
- To adjust the flow rate, in the Flow control box, press the plus and minus buttons.

Figure 3-5. Suction Irrigator Touchscreen





# ENDO-SCRUB 2

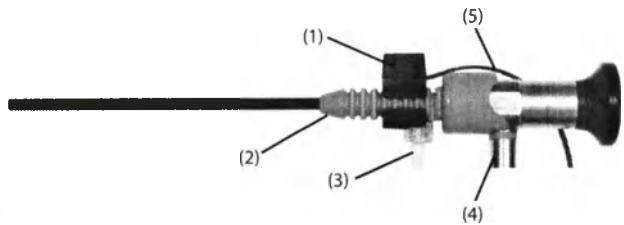
The following instructions for the Endo-Scrub 2 are in addition to “Set up the IPC” general assembly instructions. Complete IPC setup, then continue to the instructions below. Refer to the Endo-Scrub 2 System Instructions for Use, Endo-Scrub Sheaths Instructions for Use and Endo-Scrub 2 Finger Switch Instructions for Use for additional information.

The IPC System incorporates Endo-Scrub 2 functionality by using irrigation pump number one (1) and controlling operation with the touch screen and an external foot pedal or finger switch.

DO NOT use the Endo-Scrub 2 for infusion, for disinfection or sterilization of an endoscope, or for suction removal of blood and debris.

Use the Endo-Scrub 2 sheath only with an endoscope listed on the sheath product label, as malfunction or poor performance could result.

Figure 4-1. Endo-Scrub 2 Finger Switch



- |   |                       |   |                     |
|---|-----------------------|---|---------------------|
| 1 | Finger switch         | 4 | Light connection    |
| 2 | Endo-Scrub 2 sheath   | 5 | Finger Switch cable |
| 3 | Irrigation connection |   |                     |

Figure 4-2. Endo-Scrub 2 Foot Pedal



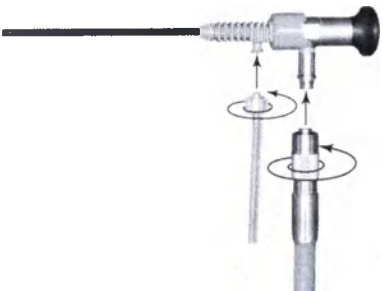
## ENDO-SCRUB 2 ASSEMBLY

1. Wet the endoscope.
2. Slowly, slide the approved endoscope into the Endo-Scrub 2 sheath (Figure 4-3).
3. Connect the irrigation tubing and a light source (Figure 4-4).

Figure 4-3. Endo-Scrub 2 Assembly



Figure 4-4. Endo-Scrub 2 Assembly



## ENDO-SCRUB 2 FINGER SWITCH ASSEMBLY

If using the Endo-Scrub 2 finger switch, complete the following:

1. Slide the finger switch onto the Endo-Scrub 2 sheath (Figure 4-1). Align the cutout section of the ring with the luer connector of the tubing set. The finger switch is properly installed when the cutout section of the ring is firmly seated against the luer connector.
2. Activate the pump by pressing the actuator button located on the finger switch.

## ENDO-SCRUB 2 ACTIVATION

Note: The procedure below also applies if using the multifunction foot pedal.

1. To activate the Endo-Scrub wash cycle, press and release the finger switch.
2. To initiate a continuous flow of irrigant, press and hold the finger switch.

## CONNECT ENDO-SCRUB 2 TO IPC CONSOLE

1. Locate the Endo-Scrub 2 connector cover on the back of the IPC console (Figure 1-2).
2. Insert a small screwdriver in the notch on the cable connector cover and pull.
3. Connect the control switch cable to the cable connector.
4. Connect the Endo-Scrub 2 finger switch (Figure 4-1) or the foot pedal (Figure 4-2) to the console (Figure 4-5).

Figure 4-5. IPC Endo-Scrub 2 Connection Port



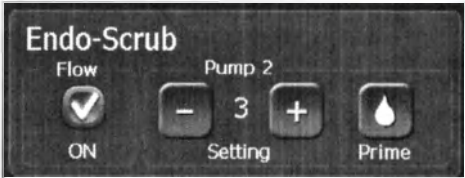
- 1 Finger switch or foot pedal connection port

ENDO-SCRUB 2 TOUCHSCREEN CONTROLS

To set or adjust Endo-Scrub 2 controls, on the IPC touchscreen, in the Flow section of the Endo-Scrub control box (Figure 4-6), do the following:

- To enable the Endo-Scrub 2 , press the On/Off check-box.
- To adjust the flow rate, press the plus button to increase flow rate or the minus button to decrease flow rate.  
- To prime the pump, press the prime button. 

Figure 4-6. Endo-Scrub 2 Touchscreen



ENDO-SCRUB 2 IN STANDALONE MODE

The Endo-Scrub 2 can operate as a standalone device by changing the IPC system defaults.

1. On the Defaults menu (Figure 4-7), in the Stand Alone section, select **Endo-Scrub** and then press **[OK]**.
2. On the Handpiece Connection screen (Figure 4-8), in the Endo-Scrub box, press **[OK]**.

Figure 4-7. IPC General System Default Menu



Figure 4-8. Handpiece Connection Screen



ENDO-SCRUB 2 CLEANING AND STERILIZATION INSTRUCTIONS

Refer to document 68E4005 in the Cleaning and Sterilization section.

Endo-Scrub 2 Foot Pedal Cleaning

**Important:** If debris is found under the foot pedal boot, return for warranty service.

DO NOT immerse or sterilize the foot pedal unit.

DO NOT use alcohol, other solvents or abrasive cleaners.

1. Wipe down the Endo-Scrub 2 foot pedal with a cloth dampened with a neutral enzymatic detergent, pH 6.0-8.0 or phenol based disinfectant.
2. Dry the unit with a clean, non-abrasive cloth.

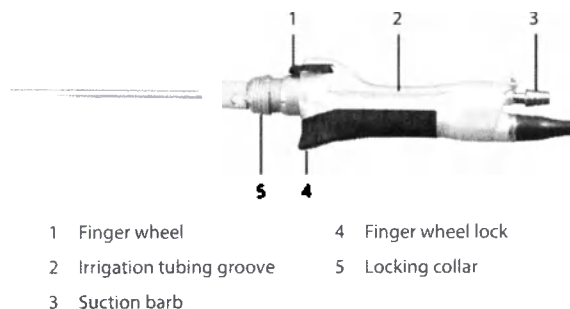
# SPINE SHAVER (SC1) HANDPIECE

## DEVICE DESCRIPTION

The following instructions for the Spine Shaver (SC1) Handpiece are in addition to "Set up the IPC" general assembly instructions. Complete IPC setup, then continue to the instructions below. Refer to the Midas Rex User's Guide for additional information.

The IPC incorporates the Midas Rex Spine Shaver (SC1) at pump 2. Control operation of the Midas Rex Spine Shaver (SC1) with the IPC touchscreen and the multifunction foot pedal.

Figure 5-1. Spine Shaver (SC1) Handpiece



## SPINE SHAVER (SC1) BLADE OR BUR ASSEMBLY

1. Insert the tool aligning the tabs with the notches (Figure 5-2). Orientate the irrigation barb to the left or right side.  
**Note:** The StraightShot M4 uses a four-tab alignment system.
  - For rotating straight blades, orient the irrigation barb at the 3 o'clock position for right-handed surgeons and 9 o'clock for left-handed surgeons.
  - For rotating curved blades, orient the irrigation barb at 3 o'clock.
2. Press the locking collar (Figure 5-3).
3. Release the locking collar.  
**Note:** If collar does not return to full out position adjust the finger wheel with small back-and-forth motions until collar pops out.
4. Pull on the blade or bur to ensure engagement and visually check to make sure the distal tip of the inner blade is in contact with the distal tip of the outer cannula (Figure 5-4).

Figure 5-2. Spine Shaver (SC1) Assembly



Figure 5-3. Spine Shaver (SC1) Assembly

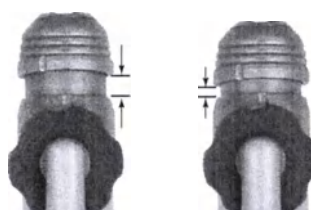
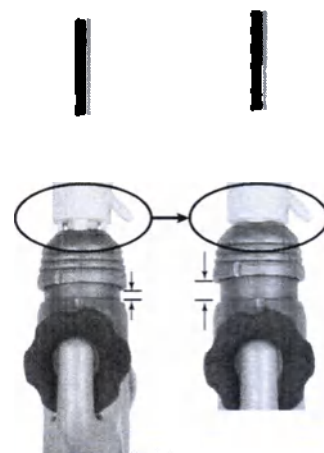


Figure 5-4. Spine Shaver (SC1) Assembly



SPINE SHAVER (SC1) HANDPIECE

SPINE SHAVER (SC1) SUCTION AND IRRIGATION TUBE ASSEMBLY

- 1. Attach a suction tube to the suction source (Figure 5-5) and an irrigation tube on the irrigation barb (Figure 5-5).
- 2. Secure suction and irrigation in the irrigation groove on the handpiece (Figure 5-6).

Figure 5-5. Spine Shaver (SC1) Suction Irrigation Assembly

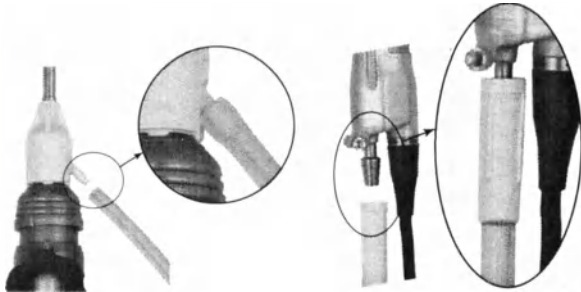


Figure 5-6. Spine Shaver (SC1) Suction Irrigation Assembly

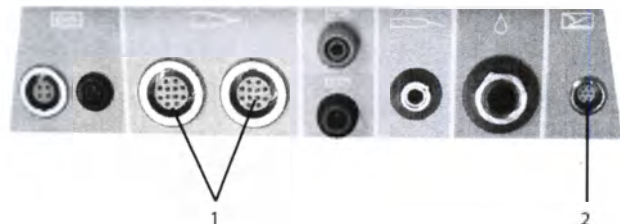


CONNECT SPINE SHAVER (SC1) TO IPC CONSOLE

Locate the Spine Shaver (SC1) connection port on the connector panel (Figure 5-7) and insert the connector.

**Note:** To insert multi-pin connectors (indicated by a silver or red mark on the connector), align the mark on the connector to the mark on the console, then insert the connector.

Figure 5-7. Spine Shaver (SC1) IPC Connection Ports



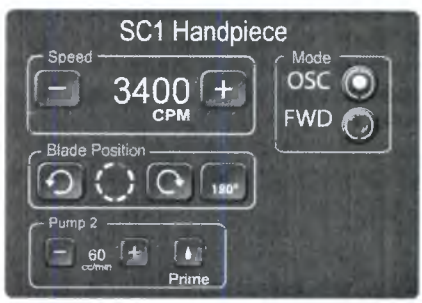
- 1 Spine Shaver (SC1) handpiece connection port
- 2 Multifunction foot pedal connection port

SPINE SHAVER (SC1) TOUCHSCREEN CONTROLS

To set or adjust Spine Shaver (SC1) controls, on the IPC touchscreen, in the control box (Figure 5-8), do the following:

- To change rotation mode, in the Mode control box select OSC (oscillating) or FWD (forward).
- To adjust speed, in the Speed control box, press the plus button to increase speed and the minus button to decrease speed. 
- Forward Mode: Default, 12000 rpm; variable adjustment from 50 to 12000 rpm.  
Oscillate Mode: Default, 3400 cpm; variable adjustment from 50 to 5000 rpm.
- To adjust the irrigation flow rate, in the Pump control box, press the plus button to increase flow rate or the minus button to decrease flow rate. If intermittent flow is available, pressing the plus or minus button progresses the system through intermittent and continuous flow. The system displays **Intermittent** when in intermittent flow mode.  
Forward Mode: Default, 30 cc per minute.  
Oscillate Mode: Default, 60 cc per minute.  
**Note:** To adjust flow rate, you can use the touchscreen or the IntelliFlow Irrigation remote control.
- In oscillating mode only, you can use the Blade Position control box to do any of the following:
  - To rotate the inner blade 180° press the delta button. 
  - To rotate the inner blade in small increments, press the clockwise or counter-clockwise buttons. 
  - Note:** The motion indicator indicates rotation direction of the blade. 
- To rotate the outer blade, use the finger wheel (Figure 5-1).

Figure 5-8. Spine Shaver (SC1) Touchscreen

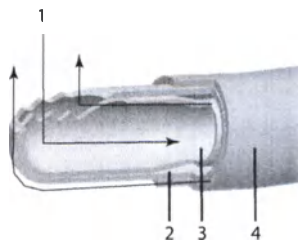


SPINE SHAVER (SC1) BLADE CONTROL

**Note:** Periodically submerge blade tip in sterile water, with suction on, to keep blades clear during the procedure.

- To rotate the outer blade (Figure 5-9), use the finger wheel (Figure 5-1).
- To rotate the inner blade, use the Blade Position control box on the IPC touchscreen.

Figure 5-9. Blade Dissection



- 1 Suction flow in through inner blade  
Irrigation flow between inner and outer blades
- 2 Outer blade
- 3 Inner blade
- 4 Outer sleeve

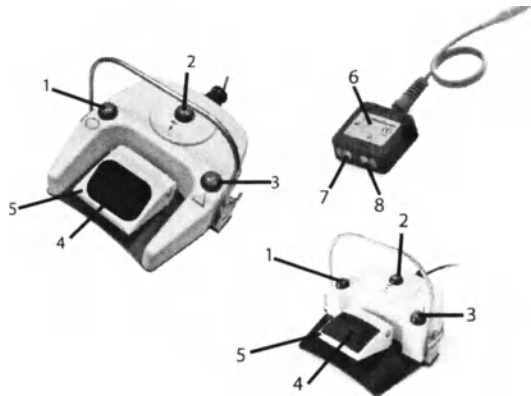
SPINE SHAVER (SC1) MULTIFUNCTION FOOT PEDAL CONTROLS

**Important:** By default, press each button on the foot pedal for at least 100 mS for the selection to become active. Use the IPC touch screen Settings screen to change the default value.

Use the multifunction foot pedal (Figure 5-10) to control the following:

- To select forward or oscillating mode, press the mode button.
- To start or adjust the speed of a handpiece in variable mode, press the foot pedal.
- To rotate the inner blade (180°) press the control button.
- To change the handpiece, press the handpiece button.

Figure 5-10. Multifunction Foot Pedal & Y-Splitter



- 1 Mode button
- 2 Handpiece button
- 3 Control button
- 4 Slip-resistant foot pad
- 5 Foot pedal
- 6 Y-Splitter
- 7 Port 1
- 8 Port 2

SPINE SHAVER (SC1) CLEANING AND STERILIZATION INSTRUCTIONS

Refer to document 68E3282 in the Cleaning and Sterilization section.

SPINE SHAVER (SC1) TECHNICAL SPECIFICATIONS

Spine Shaver (SC1) ED100

|                             |                                                              |
|-----------------------------|--------------------------------------------------------------|
| Size                        | 14.3 cm Length x 1.8 cm Width (ED100)                        |
| Weight                      | 228 g ED100                                                  |
| Speed                       | 50-5000 rpm oscillate<br>50-12000 rpm forward                |
| Duty Cycle for Applied Part | Maximum on time = 60 seconds. Minimum off time = 30 seconds. |



# STRAIGHTSHOT M5, STRAIGHTSHOT M4, STRAIGHTSHOT MAGNUM II, AND STRAIGHTSHOT III

## DEVICE DESCRIPTION

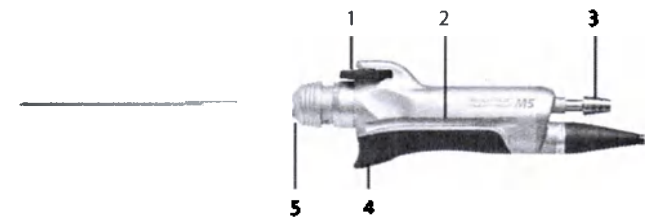
**Note:** The StraightShot III is not for sale in the United States.

The following instructions for the StraightShot M5, StraightShot M4, StraightShot Magnum II, and the StraightShot III are in addition to “Set up the IPC” general assembly instructions. Complete IPC setup, then continue to the instructions below.

The IPC incorporates the microdebrider at pump 2. Control operation of the microdebrider with the IPC touchscreen and the multifunction foot pedal.

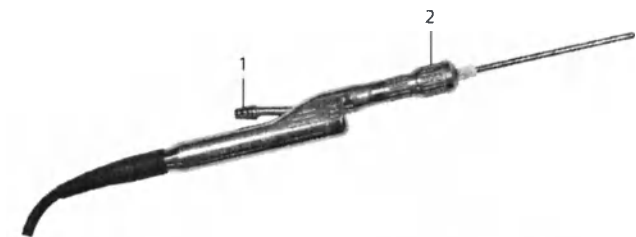
When the IPC detects both the StraightShot M4 or StraightShot M5 and the Legend EHS Stylus handpieces, the system defaults Pump 2 to the **Shared** configuration. You must manually move the irrigation tubing from the inactive to the active handpiece. Use the pumps screen to override the **Shared** default by selecting the StraightShot M4 or the Legend EHS Stylus for Pump 1. Refer to “Set up and Prime Pumps” for more information.

Figure 6-1. StraightShot M5 Handpiece



- |                            |                     |
|----------------------------|---------------------|
| 1 Finger wheel             | 4 Finger wheel lock |
| 2 Irrigation tubing groove | 5 Locking collar    |
| 3 Suction barb             |                     |

Figure 6-2. StraightShot Magnum II and III Handpiece



- |                |                  |
|----------------|------------------|
| 1 Suction barb | 2 Locking collar |
|----------------|------------------|

## STRAIGHTSHOT M4 AND STRAIGHTSHOT M5 BLADE OR BUR ASSEMBLY

1. Insert the tool aligning the tabs with the notches (Figure 6-3). Orientate the irrigation barb to the left or right side.

**Note:** The StraightShot M4 and the StraightShot M5 use a four-tab alignment system.

- For rotating straight blades, orient the irrigation barb at the 3 o'clock position for right-handed surgeons and 9 o'clock for left-handed surgeons.
- For rotating curved blades, orient the irrigation barb at 3 o'clock.
- For rotatable blades, adjust the finger wheel with small back-and-forth motions until the blade is engaged.

2. Press the locking collar (Figure 6-4).

3. Release the locking collar.

**Note:** If the collar does not return to full out position adjust the finger wheel with small back-and-forth motions until collar pops out.

4. Pull on the blade or the bur to ensure engagement and visually check to make sure the distal tip of the inner blade is in contact with the distal tip of the outer cannula (Figure 6-5).

Figure 6-3. Blade or Bur Assembly

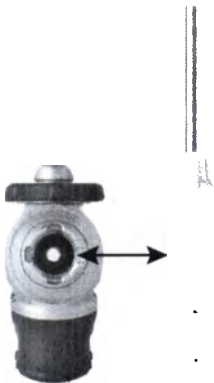


Figure 6-4. Blade or Bur Assembly

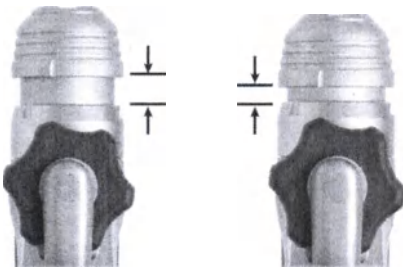
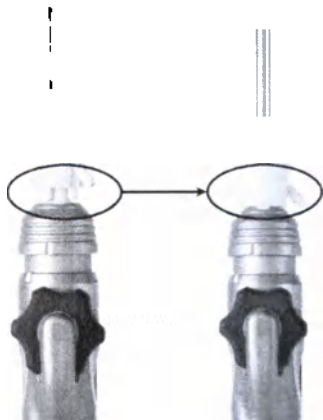


Figure 6-5. Blade or Bur Assembly



STRAIGHTSHOT M5, STRAIGHTSHOT M4, STRAIGHTSHOT MAGNUM II, and STRAIGHTSHOT III

**STRAIGHTSHOT M4 AND STRAIGHTSHOT M5 SUCTION AND IRRIGATION TUBE ASSEMBLY**

- 1. Attach a suction tube to the suction source and an irrigation tube on the irrigation barb (Figure 6-6).
- 2. Secure suction and irrigation in the irrigation groove on the handpiece (Figure 6-7).

Figure 6-6. Suction and Irrigation Assembly

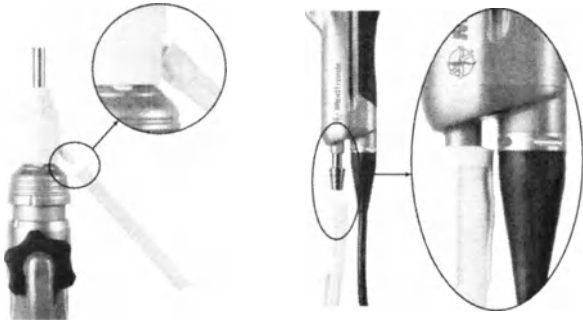


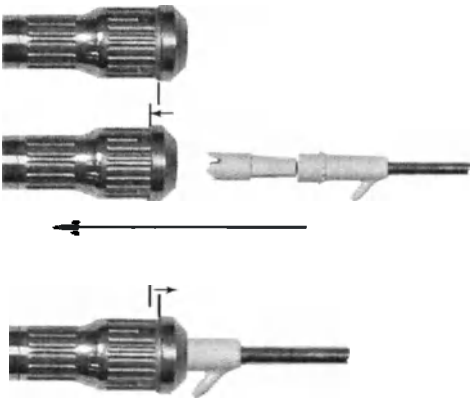
Figure 6-7. Suction and Irrigation Assembly



**STRAIGHTSHOT MAGNUM II AND STRAIGHTSHOT III BLADE AND BUR ASSEMBLY**

- 1. Press the collet and insert blade in collet (Figure 6-8).
- 2. Release the collet (Figure 6-8).
- 3. Pull on the tool to ensure engagement and check distal tip of inner blade is in contact with the distal tip of the outer cannula.

Figure 6-8. StraightShot II and III Blade and Bur Assembly



**STRAIGHTSHOT MAGNUM II AND STRAIGHTSHOT III SUCTION AND IRRIGATION ASSEMBLY**

- 1. Attach a suction tube to the suction source and an irrigation tube on the irrigation barb (Figure 6-9).
- 2. Secure suction and irrigation tubing with tubing clips.

Figure 6-9. StraightShot II and III Suction and Irrigation Assembly

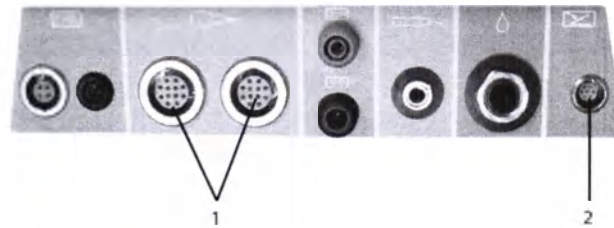


## CONNECT STRAIGHTSHOT TO IPC CONSOLE

Locate the StraightShot connection port on the connector panel (Figure 6-10) and insert the connector.

**Note:** To insert multi-pin connectors (indicated by a silver or red mark on the connector), align the mark on the connector to the mark on the console, then insert the connector.

Figure 6-10. IPC Connection Ports



- 1 Handpiece connection port
- 2 Multifunction foot pedal connection port

## STRAIGHTSHOT M4, STRAIGHTSHOT MAGNUM II AND STRAIGHTSHOT III TOUCHSCREEN CONTROLS

**Note:** The StraightShot M4, StraightShot Magnum II and StraightShot III handpiece screens feature the same controls as those shown on the StraightShot M4 Control Box.

**Note:** When you stop the blade, one of the following occurs:

- If the IPC button is visible on the touchscreen, the inner blade returns to the same position it began.
- If the XPS button is visible on the touchscreen, the inner blade stops the current position.

To set or adjust StraightShot controls, on the IPC touchscreen, in the StraightShot Handpiece control box (Figure 6-11), do the following:

- To change rotation mode, select OSC (oscillating) or FWD (forward).

**Note:** The system displays the default Oscillating or Forward mode speed.

- To adjust speed, in the Speed control box, press the plus to increase speed or the minus button to decrease speed.    
Forward Mode: Default, 12000 rpm; variable adjustment from 50 to 12000 rpm.  
Oscillate Mode: Default, 5000 rpm; variable adjustment from 50 to 5000 rpm.
- To adjust the irrigation flow rate, in the Pump control box, press the plus button to increase flow rate or the minus button to decrease flow rate. If intermittent flow is available, pressing the plus or minus button progresses the system through intermittent and continuous flow. The system displays **Intermittent** when in intermittent flow mode.  
Forward Mode: Default, 30 cc per minute.  
Oscillate Mode: Default, 5 cc per minute.

**Note:** To adjust flow rate, you can use the touchscreen or the IntelliFlow Irrigation remote control.

- To rotate outer blade, use the finger wheel (Figure 6-1).
- In oscillating mode only, you can use the Blade Position control box to do any of the following:

**Note:** The motion indicator indicates rotation direction of the blade. 

To enable the multifunction foot pedal to change rotation displacement, press the delta button.  

To rotate inner blade in small increments, press the counter-clockwise buttons. 

Figure 6-11. StraightShot M4 Touchscreen



STRAIGHTSHOT M5 TOUCHSCREEN CONTROLS

**Note:** When you stop the blade, one of the following occurs:

- If the IPC button is visible on the touchscreen, the inner blade returns to the same position it began.
- If the XPS button is visible on the touchscreen, the inner blade stops the current position.

To set or adjust StraightShot controls, on the IPC touchscreen, in the StraightShot Handpiece control box (Figure 6-11), do the following:

- To change rotation mode, select OSC (oscillating) or FWD (forward).  
**Note:** The system displays the default oscillating or forward mode speed.
- To adjust speed, in the Speed control box, press the plus to increase speed or the minus button to decrease speed.  
Forward Mode: Default, 12000 rpm; variable adjustment from 50 to 30000 rpm.  
Oscillate Mode: Default, 5000 rpm; variable adjustment from 50 to 7500 rpm.
- To adjust the irrigation flow rate, in the Pump control box, press the plus button to increase flow rate or the minus button to decrease flow rate. If intermittent flow is available, pressing the plus or minus button progresses the system through intermittent and continuous flow. The system displays **Intermittent** when in intermittent flow mode.  
Forward Mode: Default, 30 cc per minute.  
Oscillate Mode: Default, 5 cc per minute.  
**Note:** To adjust flow rate, you can use the touchscreen or the IntelliFlow Irrigation remote control.
- To rotate outer blade, use the finger wheel (Figure 6-1).

**In oscillating mode only**, you can use the Blade Position control box to do any of the following:

**Note:** The motion indicator indicates rotation direction of the blade.

To enable the multifunction foot pedal to change rotation displacement, press the delta button.

To rotate inner blade in small increments, press the counter-clockwise buttons.

Figure 6-12. StraightShot M5 Touchscreen

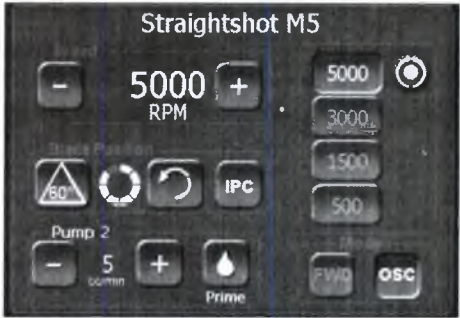
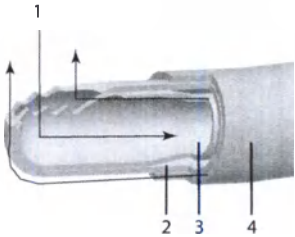


Figure 6-13. Blade Dissection



- 1 Suction flow in through inner blade irrigation flow between inner and outer blades
- 2 Outer blade
- 3 Inner blade
- 4 Outer sleeve

MICRODEBRIDER BLADE CONTROL

**Important:** If airway blade becomes clogged during use, 1-5 cc of irrigant could be aspirated by the patient before you detect the clog.

**Note:** Periodically submerge blade tip in sterile water, with suction on, to keep blades clear during the procedure.

- To rotate the outer blade (Figure 6-13), use the finger wheel (Figure 6-1).
- To rotate the inner blade, use the Blade Position control box on the IPC touchscreen. Refer to the related accessory Controls topic for further information.

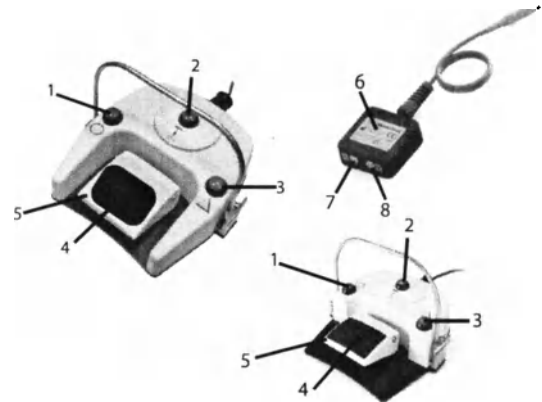
MULTIFUNCTION FOOT PEDAL CONTROLS

**Important:** By default, press each button on the foot pedal for at least 100 mS for the selection to become active. Use the IPC touch screen Settings screen to change the default value.

To use the multifunction foot pedal (Figure 6-14) to control the handpiece do the following:

- To select forward or oscillate mode, press the mode button.
- To start or adjust the speed of a handpiece in variable mode, press the foot pedal.
- To rotate the inner blade (60° or 180°), press the control button.
- To change the handpiece, press the handpiece button.

Figure 6-14. Multifunction Foot Pedal & Y-Splitter



- |   |                         |   |            |
|---|-------------------------|---|------------|
| 1 | Mode button             | 5 | Foot pedal |
| 2 | Handpiece button        | 6 | Y-Splitter |
| 3 | Control button          | 7 | Port 1     |
| 4 | Slip-resistant foot pad | 8 | Port 2     |

CLEANING AND STERILIZATION INSTRUCTIONS

Refer to document 68E3282 in the Cleaning and Sterilization section.

STRAIGHTSHOT M4 TECHNICAL SPECIFICATIONS

StraightShot M4 1898200T

|                             |                                                                                                                                                                     |
|-----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Size                        | 14.3 cm Length x 1.8 cm Width (1898200T)                                                                                                                            |
| Weight                      | 228 g 1898200T                                                                                                                                                      |
| Speed                       | 50-5000 rpm oscillate<br>50-12000 rpm forward                                                                                                                       |
| Duty Cycle for Applied Part | The StraightShot M4 handpiece under full load is rated for intermittent operation per the following:<br>Maximum On Time: 60 seconds<br>Minimum Off Time: 30 seconds |

STRAIGHTSHOT M5 TECHNICAL SPECIFICATIONS

StraightShot M5 1899200

|                             |                                                                                                                                                                     |
|-----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Size                        | 12.5 cm Length x 2.0 cm Width (1899200)                                                                                                                             |
| Weight                      | 203 g 1899200                                                                                                                                                       |
| Speed                       | 50-7500 rpm oscillate<br>50-30000 rpm forward                                                                                                                       |
| Duty Cycle for Applied Part | The StraightShot M5 handpiece under full load is rated for intermittent operation per the following:<br>Maximum On Time: 60 seconds<br>Minimum Off Time: 30 seconds |



STRAIGHTSHOT MAGNUM II AND STRAIGHTSHOT III TECHNICAL SPECIFICATIONS

StraightShot Magnum II 1897200

StraightShot III 1897201

|                             |                                                                                                                                       |
|-----------------------------|---------------------------------------------------------------------------------------------------------------------------------------|
| Size                        | 17 cm Length x 1.6 cm Width (1897200/1897201)                                                                                         |
| Weight                      | 240 g 1897200, 1897201<br>254 g 1897200T                                                                                              |
| Speed                       | 50-5000 rpm oscillate<br>50-12000 rpm forward                                                                                         |
| Duty Cycle for Applied Part | Under full load is rated for intermittent operation per the following:<br>Maximum On Time: 60 seconds<br>Minimum Off Time: 30 seconds |

# LEGEND EHS AND LEGEND EHS STYLUS

The Legend EHS motor (Figure 7-1) is a high speed, high torque, reversible electric motor used to dissect bone and biomaterial at selectable speeds from 200 to 75000 rpm.

The Legend EHS Stylus motor (Figure 7-2) is a smaller, compact, high speed, high torque, reversible electric motor used to dissect bone and biomaterials at selectable speeds from 200 to 75000 rpm.

The following instructions for the Legend EHS and Legend EHS Stylus are in addition to “Set up the IPC” general assembly instructions. Complete IPC setup, then continue to the instructions below.

Figure 7-1. Legend EHS Motor

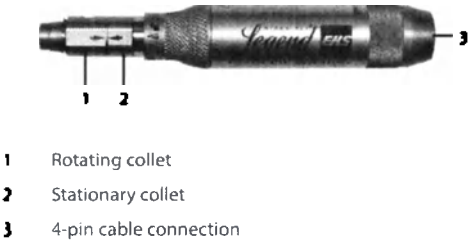
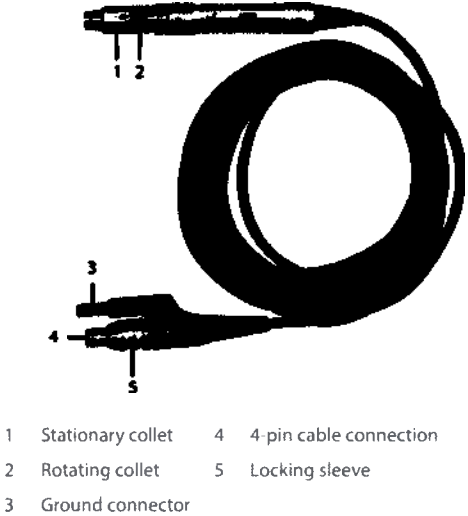


Figure 7-2. Legend EHS Stylus Motor



## LEGEND EHS AND LEGEND EHS STYLUS ATTACHMENT ASSEMBLY

Refer to “Legend EHS, Legend EHS Stylus and Stylus Touch Attachments” for attachment assembly instructions.

### CONNECT LEGEND EHS CABLE TO MOTOR

**Note:** The Legend EHS Stylus motor cable is integrated in the handpiece and cannot be removed from the motor.

To connect the Legend EHS cable to the Legend EHS motor, align the mark on the cable to the red mark on the motor (Figure 7-3) and connect the two pieces.

### REMOVE LEGEND EHS CABLE FROM MOTOR

**Note:** The Legend EHS Stylus motor cable is integrated in the handpiece and cannot be removed from the motor.

To remove the Legend EHS cable from the Legend EHS motor, (1) push the cable towards the motor, then (2) pull out the cable by the locking ring ONLY (Figure 7-4).

Figure 7-3. Legend EHS Motor Cable Connection

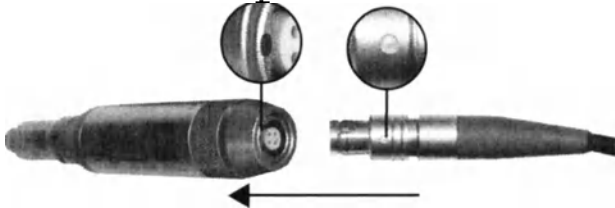
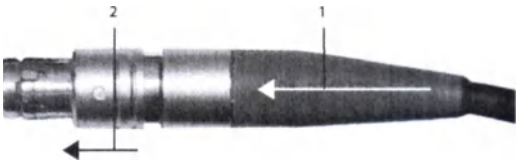


Figure 7-4. Disconnect Legend EHS Cable from Motor



CONNECT LEGEND EHS OR LEGEND EHS STYLUS TO IPC

Locate the Legend EHS or Legend EHS Stylus connection port on the connector panel (Figure 7-5) and insert the connector.

**Note:** To insert multi-pin connectors (indicated by a silver or red mark on the connector), align the mark on the connector to the mark on the console, then insert the connector. The IPC incorporates the Legend EHS or Legend EHS Stylus irrigation at pump 1. When the system detects the Legend EHS or Legend EHS Stylus, pump 2 defaults to **None**.

When the IPC detects both the Legend EHS Stylus handpieces and the StraightShot M4, the system defaults Pump 2 to the **Shared** configuration. You must manually move the irrigation tubing from the inactive to the active handpiece. Use the pumps screen to override the **Shared** default by selecting the StraightShot M4 or the Legend EHS Stylus for Pump 1. Refer to “Set up and Prime Pumps” for more information.

Control operation of the Legend EHS or Legend EHS Stylus with the IPC touchscreen and the multifunction foot pedal.

LEGEND EHS AND LEGEND EHS STYLUS TOUCHSCREEN CONTROLS

To set or adjust Legend EHS or Legend EHS Stylus controls, on the IPC touchscreen, in the control box (Figure 7-6), do the following:

- To change rotation mode, in the Mode control box, select FWD (forward) or REV (reverse).  
**Important:** System configuration may be different from the default. If the REV (reverse) button appears raised (Figure 7-7) and does not have a selectable radio button, you cannot select the Reverse mode. If the REV button appears concave (Figure 7-7) and has a selectable radio button, you can select the Reverse mode via the touchscreen or the multifunction foot pedal.
- To adjust speed in Forward (FWD) or Reverse (REV) mode, in the Speed control box, press the plus button to increase speed or the minus button to decrease speed.  Default, 70000 rpm; variable adjustment from 200 to 75000 rpm.
- To adjust the irrigation flow rate, in the Pump control box, press the plus button to increase flow rate or the minus button to decrease flow rate. If intermittent flow is available, pressing the plus or minus button progresses the system through intermittent and continuous flow. The system displays **Intermittent** when in intermittent flow mode.  
Default, 0cc per minute in Forward or Reverse mode.  
**Note:** To adjust flow rate, you can use the touchscreen or the IntelliFlow Irrigation remote control.
- To adjust acceleration and deceleration, on the Defaults menu (Figure 7-8), press the corresponding plus or minus button. Acceleration is the rate at which the motor speeds up to reach the target speed. Deceleration is the rate at which the motor slows down to reach the target speed or stop.  
**Note:** While in the default menu, the motor will not be active to demonstrate the selected acceleration and deceleration. In order to determine the desired values, adjust the acceleration and deceleration during motor operation and note the preferred values.
- To enable adjustment of acceleration or deceleration during handpiece operation and to display the acceleration and deceleration adjustment options on the motor operational screen; On the Defaults menu, select **Show On Screen** and then press **[OK]**. To hide the acceleration and deceleration during handpiece operation, on the Defaults menu, deselect **Show On Screen**.

Figure 7-5. Legend EHS and Legend EHS Stylus Connection Ports

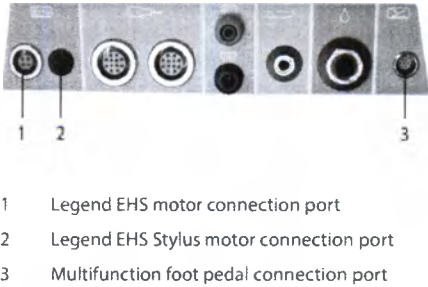


Figure 7-6. Legend EHS Stylus Touchscreen



Figure 7-7. Legend EHS or Legend EHS Stylus Mode

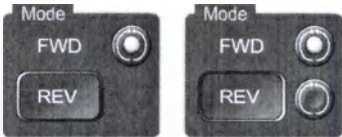


Figure 7-8. Stylus Default Setting Menu

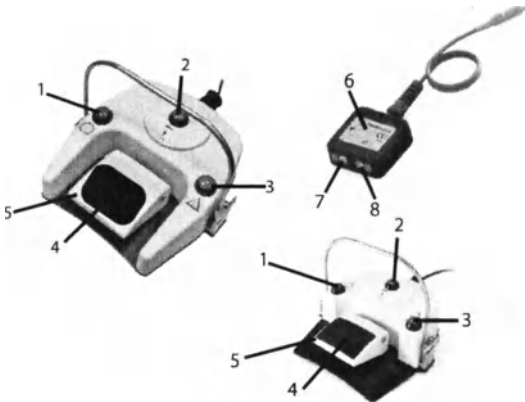


LEGEND EHS AND LEGEND EHS STYLUS MULTIFUNCTION FOOT PEDAL CONTROLS

**Important:** By default, press each button on the foot pedal for at least 100 mS for the selection to become active. Use the IPC touch screen Settings screen to change the default value.  
To use the multifunction foot pedal (Figure 7-9) to control the handpiece do the following:

- To select Forward or Reverse mode, press the mode button.
  - To start or adjust the speed of a handpiece in variable mode, press the foot pedal.
  - To toggle between the start/stop mode and variable speed mode, press the control button.
- Note:** Functionality of the control button may be changed in the handpiece Defaults menu to pause irrigation. Refer to Change System Settings in the Pre-Operating Instructions section.
- To change the handpiece, press the handpiece button.

Figure 7-9. Multifunction Foot Pedal & Y-Splitter



- |   |                         |   |            |
|---|-------------------------|---|------------|
| 1 | Mode button             | 5 | Foot pedal |
| 2 | Handpiece button        | 6 | Y-Splitter |
| 3 | Control button          | 7 | Port 1     |
| 4 | Slip-resistant foot pad | 8 | Port 2     |

LEGEND EHS AND LEGEND EHS STYLUS CLEANING AND STERILIZATION INSTRUCTIONS

Refer to documents M000030A234 and M000030A235 in the Cleaning and Sterilization section.

LEGEND EHS TECHNICAL SPECIFICATIONS

Legend EHS EM100-A

|                             |                                                                                                                                                            |
|-----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Size                        | 9.02 cm Length x 2.03 cm Diameter                                                                                                                          |
| Weight                      | 180 g                                                                                                                                                      |
| Speed                       | 75000 rpm forward/reverse                                                                                                                                  |
| Duty Cycle for Applied Part | For use in operating room temperatures up to 40°C (104°F), the Legend EHS Motor is rated for a cutting time of 3 minutes at 70000 rpm.                     |
|                             | For normal operating room temperatures (typically 20°C/68°F), the Legend EHS Motor is rated for cutting time of 10 minutes followed by 25 minutes or rest. |
|                             | The Legend EHS Motor is rated for intermittent use of 20 seconds ON / 20 seconds OFF, indefinitely at 70000 rpm.                                           |

LEGEND EHS STYLUS TECHNICAL SPECIFICATIONS

Legend EHS Stylus EM200

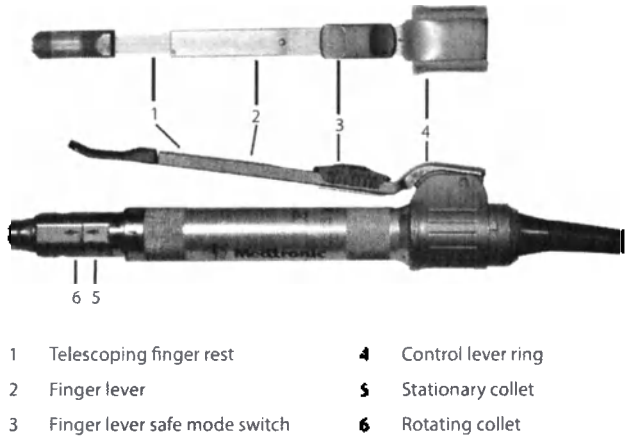
|                             |                                                                                                                                                            |
|-----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Size                        | 7.77 cm Length x 1.65 cm Diameter                                                                                                                          |
| Weight                      | 90 g                                                                                                                                                       |
| Speed                       | 75000 rpm forward/reverse                                                                                                                                  |
| Duty Cycle for Applied Part | For use in operating room temperatures up to 40°C (104°F), the Legend EHS Stylus Motor is rated for 3 minutes at 60000 rpm followed by 25 minutes or rest. |
|                             | For normal operating room temperatures (typically 20°C/68°F), the Legend EHS Stylus Motor is rated for cutting indefinitely at 60000 rpm.                  |

# STYLUS TOUCH

The Stylus Touch (Figure 8-1) is a small, compact, high-speed, high-torque, reversible electric motor used to dissect bone and biomaterials at variable speeds from 200 to 75000 rpm. The Stylus Touch motor includes a rotating finger lever that emulates the functions of the multifunction foot pedal.

The following instructions for the Stylus Touch are in addition to “Set up the IPC” general assembly instructions. Complete IPC setup, then continue to the instructions below.

Figure 8-1. Stylus Touch Motor



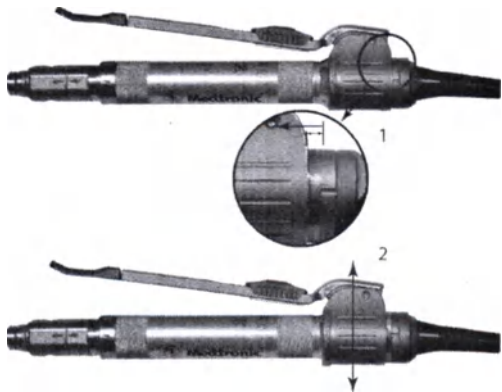
## STYLUS TOUCH ATTACHMENT ASSEMBLY

Refer to “Legend EHS, Legend EHS Stylus and Stylus Touch Attachments” for attachment assembly instructions.

### ROTATE STYLUS TOUCH FINGER LEVER

- 1. Press the control lever ring forward (Figure 8-2).
- 2. Rotate the lever clockwise or counter clockwise until the lever locks in a new position.

Figure 8-2. Stylus Touch Finger Lever Rotation



## CONNECT STYLUS TOUCH TO IPC CONSOLE

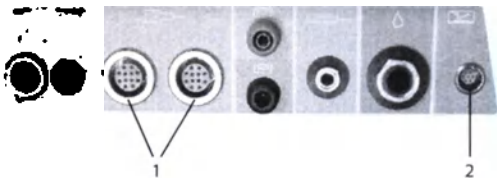
Locate the Stylus Touch connection port on the connector panel (Figure 8-3) and insert the connector.

**Note:** To insert multi-pin connectors (indicated by a silver or red mark on the connector), align the mark on the connector to the mark on the console, then insert the connector.

The IPC incorporates the Stylus Touch at pump 1. If you do not use irrigation for the Stylus Touch, manually change the Pump 1 to **None**. Refer to “Set up and Prime Pumps” for more information.

Control operation of the Stylus Touch with the IPC touchscreen and the multifunction foot pedal.

Figure 8-3. Stylus Touch Connection Ports



- 1 Stylus Touch connection port
- 2 Multifunction foot pedal connection port



STYLUS TOUCH TOUCHSCREEN CONTROLS

To set or adjust Stylus Touch controls, on the IPC touchscreen, in the control box (Figure 8-4), do the following:

- To change rotation mode, in the Mode control box, select FWD (forward) or REV (reverse).  
**Important:** System configuration may be different from the default. If the REV (reverse) button appears raised (Figure 8-7) and does not have a selectable radio button, you cannot select the Reverse mode. If the REV button appears concave (Figure 8-7) and has a selectable radio button, you can select the Reverse mode via the touchscreen or the multifunction foot pedal.
- To adjust speed, in the Speed control box, press the plus button to increase speed or the minus button to decrease speed.   
Default, 60000 rpm; variable adjustment from 200 to 75000 rpm.  
**Note:** When the handpiece is in safe mode, the Speed control box displays SAFE (Figure 8-6). Refer to the Stylus Touch Safe Mode topic for additional information.
- To adjust the irrigation flow rate, in the Pump control box, press the plus button to increase flow rate or the minus button to decrease flow rate. If intermittent flow is available, pressing the plus or minus button progresses the system through intermittent and continuous flow. The system displays Intermittent when in intermittent mode.  
Default, 0cc per minute.  
**Note:** To adjust flow rate, you can use the touchscreen or the IntelliFlow Irrigation remote control.
- To adjust acceleration and deceleration, on the Defaults menu (Figure 8-5), press the corresponding plus or minus button. Acceleration is the rate at which the motor speeds up to reach the target speed. Deceleration is the rate at which the motor slows down to reach the target speed or stop.  
**Note:** While in the default menu, the motor will not be active to demonstrate the selected acceleration and deceleration. In order to determine the desired values, adjust the acceleration and deceleration during motor operation and note the preferred values.
- To enable the adjustment of acceleration or deceleration during handpiece operation and to display the acceleration and deceleration adjustment options on the motor operational screen; On the Defaults menu, select **Show On Screen** and then press **[OK]**. To hide the acceleration and deceleration during handpiece operation, on the Defaults menu, deselect **Show On Screen**.

STYLUS TOUCH SAFE MODE

When the handpiece is in safe mode, it is inoperable until the safety is turned off. The Speed control box on the Stylus Touch touchscreen displays SAFE when the handpiece is the active handpiece and in safe mode (Figure 8-6).

Switch the device to safe mode any time it is attached to the console, but not currently being used. To set the Stylus Touch to Safe Mode, on the Stylus Touch handpiece, switch the Safe Mode finger lever (Figure 8-1) to on.

When more than one handpiece is attached to the console, use the safety switch of an inactive handpiece to activate that handpiece and make it ready for use.

Figure 8-4. Stylus Touch Touchscreen



Figure 8-5. Stylus Touch Default Setting Menu



Figure 8-6. Stylus Touch Safe Mode



Figure 8-7. Stylus Touch Rotation Mode



STYLUS TOUCH MULTIFUNCTION FOOT PEDAL CONTROLS

**Important:** By default, press each button on the foot pedal for at least 100 mS for the selection to become active. Use the IPC touch screen Settings screen to change the default value.

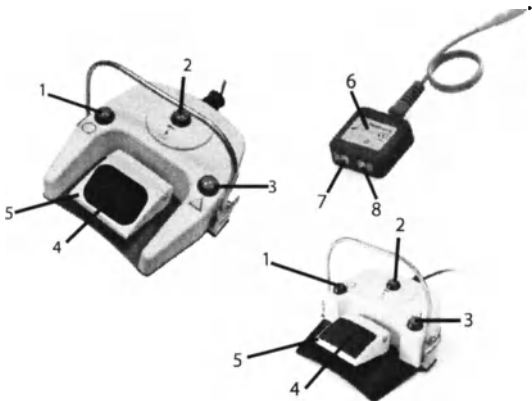
To use the multifunction foot pedal (Figure 8-8) to control the handpiece do the following:

- To select Forward or Reverse mode, press the mode button.
- To start or adjust the speed of a handpiece in variable mode, press the foot pedal.
- To toggle between the start/stop mode and variable speed mode, press the control button.

**Note:** Functionality of the control button may be changed in the handpiece Defaults menu to pause irrigation. Refer to Change System Settings in the Pre-Operating Instructions section.

- To change the handpiece, press the handpiece button.

Figure 8-8. Multifunction Foot Pedal & Y-Splitter



- |                           |              |
|---------------------------|--------------|
| 1 Mode button             | 5 Foot pedal |
| 2 Handpiece button        | 6 Y-Splitter |
| 3 Control button          | 7 Port 1     |
| 4 Slip-resistant foot pad | 8 Port 2     |

STYLUS TOUCH CLEANING AND STERILIZATION INSTRUCTIONS

Refer to documents 68E4132 and M000030A235 in the Cleaning and Sterilization section.

STYLUS TOUCH TECHNICAL SPECIFICATIONS

Stylus Touch EM210

|                             |                                                                                                                                                          |
|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| Size                        | 15.26 cm Length x 1.65 cm Diameter                                                                                                                       |
| Weight                      | 130 g                                                                                                                                                    |
| Speed                       | 75000 rpm forward/reverse                                                                                                                                |
| Duty Cycle for Applied Part | For use in operating room temperatures up to 40°C, the Legend EHS Stylus Touch Motor is rated for 3 minutes at 60000 rpm followed by 25 minutes of rest. |
|                             | For normal operating room temperatures (typically 20°C), the Legend EHS Stylus Touch Motor is rated for cutting indefinitely at 60000 rpm.               |

# LEGEND EHS, LEGEND EHS STYLUS AND STYLUS TOUCH ATTACHMENTS

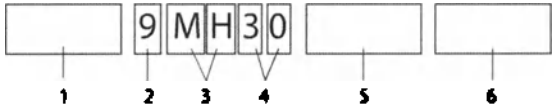
The following instructions for the Legend EHS, Legend EHS Stylus and Stylus Touch attachments are in addition to “Set up the IPC” and motor-specific general instructions. Complete IPC setup, motor specific instructions and then continue to the instructions below.

## DISSECTING TOOLS NOMENCLATURE

**Note:** Match the nomenclature and color code on the dissecting tool packaging to the same nomenclature and color code on the attachment.

Part numbers for dissecting tools follow a standard naming convention (Figure 9-1). A basic part number consists of five characters, representing the associated attachment length, the tool-head shape, and the tool-head diameter. Part numbers can also include a variety of prefixes to identify specific attachment types, as well as a variety of suffixes to provide additional information about the dissecting tool. Tools that use a design taken from the Mednext line are designated by an additional “-MN” suffix.

Figure 9-1. Dissecting tool nomenclature naming convention



- |   |                   |   |                                      |
|---|-------------------|---|--------------------------------------|
| 1 | Optional prefix   | 4 | Tool head diameter (x.x millimeters) |
| 2 | Attachment length | 5 | Optional suffix                      |
| 3 | Tool head shape   | 6 | Optional “-MN” suffix                |

## Tool Number Prefixes

- F For use with footed attachments.
- MC For use with metal-cutting attachments.
- T For use with telescoping attachments.

## Tool Head Shapes

- |    |            |    |               |
|----|------------|----|---------------|
| AC | Acorn      | MH | Match Head    |
| BA | Ball       | OV | Oval          |
| CY | Cylinder   | RT | Reverse Taper |
| HM | Hole Maker | TA | Tapered       |
| HS | Hole Saw   | TD | Twist Drill   |

## Tool Number Suffixes

**Note:** More than one suffix can be combined in a single part number.

- |   |         |    |                      |
|---|---------|----|----------------------|
| L | Long    | S  | Spiral               |
| D | Diamond | SH | Short                |
| X | Extra   |    |                      |
| F | Fine    | DC | Diamond Coarse       |
| C | Carbide | DX | Diamond Extra Coarse |

## ALIGN MOTOR COLLET

**Note:** An attachment will not seat on the Legend EHS, Legend EHS Stylus or Stylus Touch motor if the arrows on the collet flats are not aligned.

1. Verify alignment of arrows on motor collet flats. Prior to installation of an attachment and dissecting tool on the Legend EHS, Legend EHS Stylus or Stylus Touch motor, ensure that arrows on the motor collet flats are in proper alignment. (Figure 9-2).
2. If the arrows are not aligned (Figure 9-3), use the motor wrench (Figure 9-4) to turn the rotational collet until its arrow is aligned with the arrow on the stationary collet.

**Note:** DO NOT use any other components except for the motor wrench to align arrows on motor collet.

Figure 9-2. Correct alignment



Figure 9-3. Incorrect alignment



Figure 9-4. Motor wrench



STRAIGHT ATTACHMENT ASSEMBLY

**Warnings:** Refer to warnings W36 and W54.

**Caution:** Match the nomenclature and color code on the tool packaging to the same nomenclature and color code on the attachment.

**Notes:**

- An attachment will not seat on the motor if the arrows on the collet flats are not in alignment.
  - The Legend EHS motors will not run properly unless the attachment is in the locked position.
  - Smoke and/or excessive heat may be generated if attachment is not in the fully locked position. This may result in thermal injury to the surgeon or staff.
1. Slide a straight attachment over the motor collet aligning triangular arrows on the attachment and the motor case (Figure 9-5). An audible click, heard and perceptible by touch, confirms that the tool is fully seated.

Figure 9-5. Straight Attachment Assembly



2. Insert the tool into the attachment with a slight rotational motion (Figure 9-6). An audible click, heard and perceptible by touch, confirms that the tool is fully seated.

Figure 9-6. Straight Attachment Assembly



3. Rotate the attachment in the direction indicated by arrow until the attachment alignment mark is directly in line with the locked symbol (Figure 9-7). You will hear two clicks as the attachment is rotated.

Figure 9-7. Straight Attachment Assembly



4. Gently pull on the tool to ensure that it is locked into the handpiece.  
**Note:** Tool should rotate freely. If not, unlock the attachment, re-seat the tool, and re-lock the attachment.

STRAIGHT ATTACHMENT DISASSEMBLY

1. Hold the motor in palm of hand. Rotate the attachment to the unlocked position.
2. Remove the dissecting tool from the attachment and discard the tool.
3. Use thumb and index finger to lift the attachment off of the motor.

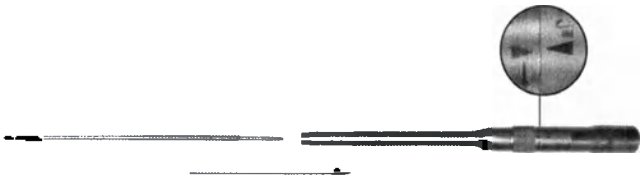
ANGLED ATTACHMENT ASSEMBLY

**Caution:** When using an angled attachment, hold the handpiece assembly by the attachment so that the attachment does not inadvertently loosen from the handpiece.

**Notes:**

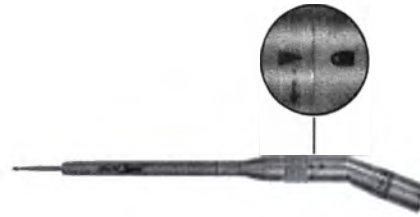
- A dissecting tool may be installed and locked in the attachment before the angled attachment is installed onto the motor.
  - Angled and straight attachments with the same length, marking and color band share the same dissecting tools.
  - The Legend EHS Motors will not run properly unless the attachment is in the locked position.
  - Smoke and/or excessive heat may be generated if attachment is not in the fully locked position. This may result in thermal injury to the surgeon or staff.
1. With the tool lock in the unlocked position, insert a tool into the angled attachment with a slight rotational motion (Figure 9-8). An audible click, heard and perceptible by touch, confirms that the tool is fully seated.

Figure 9-8. Angled Attachment Assembly



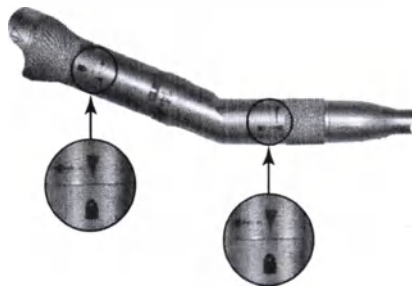
2. Rotate the tool lock in the direction indicated by arrow until the tool lock alignment mark is directly in line with the locked symbol (Figure 9-9).

Figure 9-9. Angled Attachment Assembly



3. Gently pull on the tool to ensure that it is locked into the handpiece.  
**Note:** Tool should rotate freely. If not, unlock the attachment, re-seat the tool, and re-lock the attachment.
4. Slide the angled attachment over the motor collet aligning triangular arrows on the attachment and the motor case. An audible click, heard and perceptible by touch, confirms that the tool is fully seated.
5. Rotate the attachment in the direction indicated by the arrow until attachment alignment mark is directly in line with the locked symbol. You will hear two clicks as the attachment is rotated.
6. Verify that both the attachment to motor alignment mark and the tool lock alignment mark are directly in line with the locked symbol (Figure 9-10).

Figure 9-10. Angled Attachment Assembly



## ANGLED ATTACHMENT DISASSEMBLY

1. Rotate the Tool Lock to the unlocked position to remove the tool from the attachment.
2. Rotate the attachment to the unlocked position and lift attachment off of the motor.

## FIXED FOOTED ATTACHMENT ASSEMBLY

**Warning:** Refer to Warning W37.

1. Insert a dissecting tool into the motor collet with a slight rotational motion (Figure 9-11). An audible click, heard and perceptible by touch, confirms that the tool is fully seated.

Figure 9-11. Footed Attachment Assembly



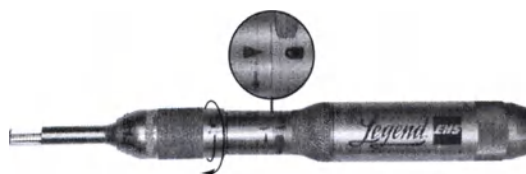
2. Slide the footed attachment over the dissecting tool onto the motor aligning triangular arrows on the attachment and the motor case (Figure 9-12).

Figure 9-12. Footed Attachment Assembly



3. Pull the footed attachment towards the motor and rotate the attachment to the locked position on the motor case (Figure 9-13).

Figure 9-13. Footed Attachment Assembly

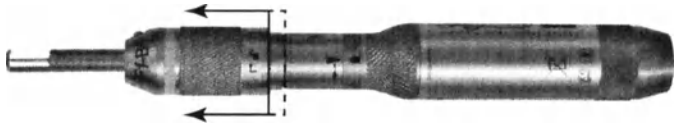




**FIXED FOOTED ATTACHMENT DISASSEMBLY**

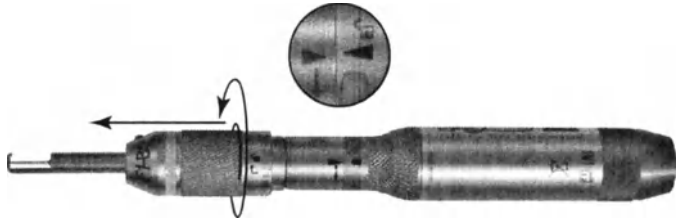
1. To remove the footed attachment, hold the motor in the palm of your hand. Push the sleeve on the footed attachment distally while rotating the attachment to the unlocked position on the motor case. Release the sleeve (Figure 9-14).

Figure 9-14. Footed Attachment Disassembly



2. To avoid injury from the dissecting tool, use thumb and index finger to cautiously and slowly lift the attachment off of the motor and away from the dissecting tool (Figure 9-15).

Figure 9-15. Footed Attachment Disassembly



3. Pull the dissecting tool out of the motor collet and discard the tool (Figure 9-16).

Figure 9-16. Footed Attachment Disassembly



**ROTATING FOOTED ATTACHMENT ASSEMBLY**

**Warnings:** Refer to Warnings, W20 and W52.

**Notes:**

- Rotating and fixed footed attachments with the same length, marking and color band share the same dissecting tools.
- The footed end of the attachment has 360 ° of unrestricted rotation.

Attach the Rotating Footed attachment using the Fixed Footed Attachment Assembly Instructions.

**ROTATING FOOTED ATTACHMENT DISASSEMBLY**

Remove the Rotating Footed attachment using the Fixed Footed Attachment Disassembly Instructions.

**CONTRA-ANGLE ATTACHMENT AC-16 ASSEMBLY**

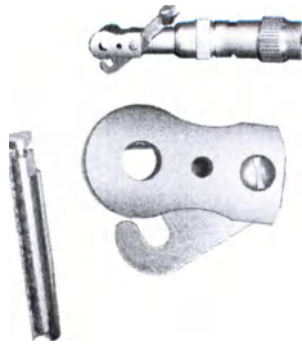
1. On the IPC Touchscreen, adjust the speed setting to 62,000 rpm using the speed control buttons.
2. Slide the Contra-Angle Attachment over the motor collet aligning triangular arrows on the attachment and the motor case. An audible click, heard and perceptible by touch, confirms that the tool is fully seated.
3. Rotate the attachment to the locked position on the motor case (Figure 9-17).

Figure 9-17. Contra-Angle Attachment Assembly



4. Rotate the attachment head's lever laterally to the open position and insert a dissecting tool (Figure 9-18).
5. Close lever (Figure 9-19).

**Figure 9-18.** Contra-Angle Attachment Assembly



**Figure 9-19.** Contra-Angle Attachment Assembly



6. Gently pull on the dissecting tool shaft to ensure proper installation.

### CONTRA-ANGLE ATTACHMENT AC-16 DISASSEMBLY

1. Rotate the lever on the attachment head laterally to remove the dissecting tool.
2. Discard the dissecting tool.
3. Rotate the 16-MF attachment to the unlocked position and lift the attachment off of the motor.

### METAL CUTTING ATTACHMENT ASSEMBLY

**Warning:** Refer to Warning W15.

**Important:** The Metal Cutting attachment uses the tungsten carbide or diamond wheel dissecting tools. All metal cutting dissecting tools have an "MC" attachment prefix in their nomenclature (for example, MC254 and MC30). Metal cutting dissecting tools cannot be installed into any other Attachment.

1. Slide the Metal Cutting attachment over the motor collet aligning triangular markers on the attachment and the motor case. An audible click, heard and perceptible by touch, confirms that the tool is fully seated.
2. Rotate the attachment to the locked position on the motor case.
3. With the tool lock unscrewed several turns and holding the attachment UPRIGHT, insert a dissecting tool into attachment (Figure 9-20).
4. Rotate the dissecting tool until it drops into position and is fully seated. You will feel a tactile click indicating that the tool is fully seated (Figure 9-20).

**Figure 9-20.** Metal Cutting Attachment Assembly



### METAL CUTTING ATTACHMENT DISASSEMBLY

1. Unscrew the tool lock with several turns, then withdraw the dissecting tool.
2. Rotate the attachment to the locked position on the motor case and lift attachment off of the motor.

### VARIABLE EXPOSURE ATTACHMENT ASSEMBLY

**Warnings:** Refer to Warnings W23, W34, W53 and W57.

The Variable Exposure attachments can be distinguished from standard attachments by the dual color bands on the attachment. Match the color band on the attachment to the color code on the dissecting tool packaging.

1. Assemble the attachment using the Straight Attachment Assembly Instructions.
2. After assembly, use the TUBE adjustment ring to adjust the exposure of the dissecting tool (Figure 9-21).

With the tool pointing away from you, turn the ring to the right to increase the length of the tube, thereby decreasing the exposure of the tool. Turn the ring to the left to decrease the length of the tube, thereby increasing the exposure of the tool.

**Figure 9-21.** Variable Exposure Attachment Assembly



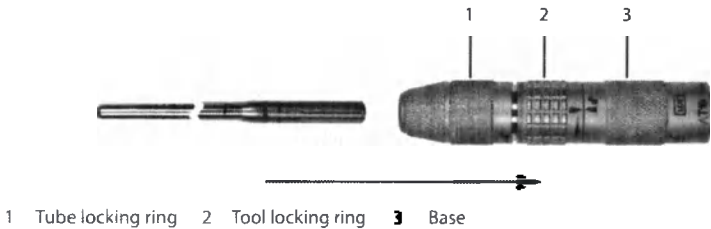
### VARIABLE EXPOSURE ATTACHMENT DISASSEMBLY

Remove the Variable Exposure Attachment using the Straight Attachment Disassembly Instructions.

TELESCOPING STRAIGHT ATTACHMENT AT10 ASSEMBLY

- 1. Assemble the attachment using the Straight Attachment Assembly Instructions.
  - 2. Insert the base end of the selected telescoping tube into the attachment.
  - 3. To lock tube in place, turn the TUBE Locking Ring clockwise until finger tight (Figure 9-22).
- Note:** DO NOT over tighten.

Figure 9-22. Telescoping Straight Attachment Assembly



- 4. Be sure that the TOOL Locking Ring is in the unlocked position. Insert the dissecting tool into the telescoping tube (Figure 9-23). Tactile feedback is felt when the dissecting tool is fully seated.

Figure 9-23. Telescoping Straight Attachment Assembly



- 5. Turn the TOOL Locking Ring to the locked position (Figure 9-24).

Figure 9-24. Telescoping Straight Attachment Assembly



- 6. Verify that the tool is in place by gently pulling on the tool.
- 7. If the tube position needs to be changed, rotate the TUBE Locking Ring toward the unlocked position, re-position the tube, then rotate the TUBE Locking Ring toward locked.
- 8. Gently pull on the dissecting tool, then the tube, to ensure proper installation.

TELESCOPING CURVED ATTACHMENT AT10 ASSEMBLY

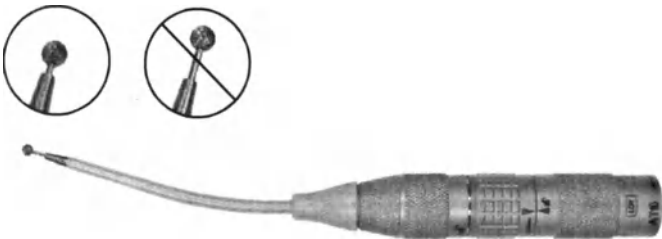
- 1. Assemble the attachment using the Straight Attachment Assembly Instructions.
  - 2. Insert the base end of the curved bur into the attachment until the hub is fully seated. To lock in place, turn the TUBE Locking Ring until finger tight (Figure 9-25).
- Note:** DO NOT over tighten.

Figure 9-25. Telescoping Curved Attachment Assembly



- 3. Verify that the hub is in place by gently pulling on the tool.
- 4. Seat the tool in the tool Locking Ring by applying a slight amount of inward pressure on the bur (Figure 9-26). An audible click, heard and perceptible by touch, confirms that the tool is fully seated.

Figure 9-26. Telescoping Curved Attachment Assembly



- 5. Rotate the Tool Locking Ring until the tool lock alignment mark is directly in line with the locked symbol (Figure 9-27).
- 6. Verify that the bur is in place by gently pulling on the bur.
- 7. Prior to initial use, soak the cooling sleeve by dipping it into a cup of saline or DI water (Figure 9-28).
- 8. During use, maintain copious irrigation of the cooling sleeve and bur by dribbling saline or DI water along the entire length of the cooling sleeve.

Figure 9-27. Telescoping Curved Attachment Assembly



Figure 9-28. Curved Bur Cooling



TELESCOPING TUBE ATTACHMENT ASSEMBLY

- 1. Assemble the attachment to the motor using the Straight Attachment Assembly Instructions.
- 2. Insert the base end of the tool into the attachment until the hub is fully seated. To lock in place, turn the TUBE Locking Ring until finger tight (Figure 9-27).
- Note:** DO NOT over tighten.
- 3. Verify that the hub is in place by gently pulling on the tool.
- 4. Seat the tool in the tool Locking Ring by applying a slight amount of inward pressure on the bur (Figure 9-27). An audible click, heard and perceptible by touch, confirms that the tool is fully seated.

TELESCOPING ATTACHMENT AT10 DISASSEMBLY

- 1. Rotate the TUBE Locking Ring towards the unlocked position.
- 2. Rotate the TOOL Locking Ring to the unlocked position.
- 3. Pull the telescoping tube out of the attachment.
- 4. Rotate the attachment to the unlocked position on the motor case and lift the attachment off the motor.

PERFORATOR ATTACHMENT AD01 & AD03 ASSEMBLY

**Warning:** Refer to Warning W56.

**Note:** A cranial perforator device may be installed in the attachment before the perforator attachment is installed on the motor.

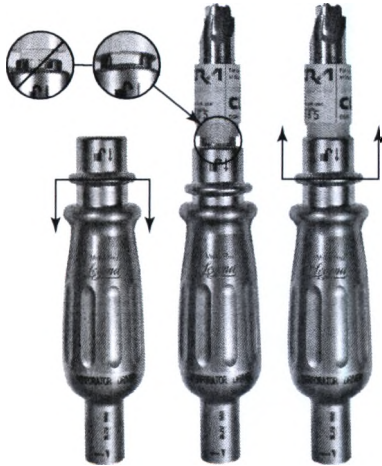
| Console Setting | Maximum Speed           |                         |
|-----------------|-------------------------|-------------------------|
|                 | AD01 Output Speed (MAX) | AD03 Output Speed (MAX) |
| 60000 rpm       | 645 rpm                 | 830 rpm                 |
| 70000 rpm       | 745 rpm                 | 965 rpm                 |
| 72000 rpm       | 770 rpm                 | 995 rpm                 |
| 74000 rpm       | 790 rpm                 | 1020 rpm                |
| 75000 rpm       | 805 rpm                 | 1035 rpm                |

- 1. Assemble the attachment using the Straight Attachment Assembly Instructions.
- 2. To install a cranial perforator device with a Hudson shank, pull back proximally on the collar of the Perforator Attachment. Insert a device and release the collar to its original position (Figure 9-29).

PERFORATOR ATTACHMENT AD01 & AD03 DISASSEMBLY

Pull back proximally on the collar of the Perforator Attachment to remove the cranial perforator device. Rotate the Perforator Attachment to the unlocked position and lift the attachment off of the motor.

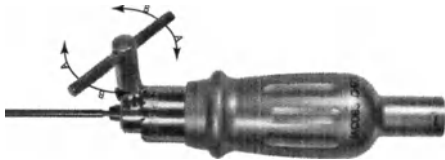
Figure 9-29. Perforator Attachment Hudson Shank Assembly



JACOBS CHUCK ATTACHMENT ASSEMBLY

- 1. Assemble the attachment using the Straight Attachment Assembly Instructions.
- 2. To install a drill bit, turn Jacobs key to open ridged collar. Insert drill bit and tighten collar with key (Figure 9-30).

Figure 9-30. Jacobs Chuck Tool Assembly



JACOBS CHUCK ATTACHMENT DISASSEMBLY

Use the Jacobs key to open the collar. Remove and discard the drill bit in an appropriate container. Rotate the Jacobs Chuck Attachment to the unlocked position and lift the attachment off of the motor.

ANGLED DOUBLE LOCK ATTACHMENT ASSEMBLY

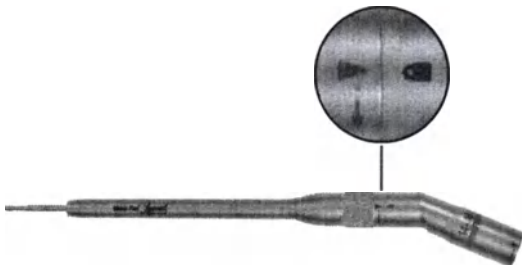
Notes:

- Angled attachments with the same length, marking, and color band share the same dissecting tools.
  - You can insert and lock a tool in the attachment before the angled attachment is installed on the motor.
1. Assemble the attachment using the Straight Attachment Assembly Instructions.
  2. Insert the tool into the attachment with a slight rotational motion. An audible click, perceptible by touch, confirms that the tool is fully seated (Figure 9-31).
  3. Rotate the tool lock in direction indicated by arrow until the tool lock alignment mark is directly in line with the locked symbol (Figure 9-32).
  4. Pull on the tool to ensure that it is locked into the handpiece.
  5. The tool should rotate freely. If not, unlock the attachment, re-seat the tool, and re-lock the attachment.
  6. Verify that both the attachment to motor and the tool-lock alignment mark is directly in line with the locked symbol.

Figure 9-31. Angled Double Lock Attachment Assembly



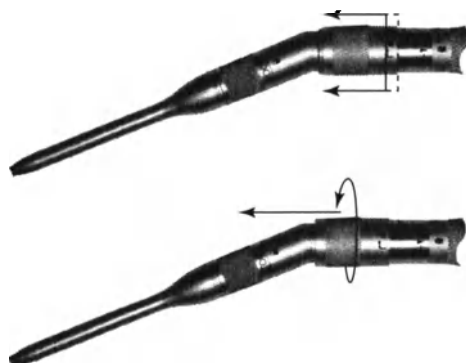
Figure 9-32. Angled Double Lock Attachment Assembly





**ANGLED DOUBLE LOCK ATTACHMENT DISASSEMBLY**

1. To remove the attachment, hold the motor in the palm of your hand, and push the sleeve on the attachment distally while turning the attachment to the unlocked position (Figure 9-33).
2. Release the sleeve and remove the attachment.

**Figure 9-33.** Angled Double Lock Attachment Disassembly**TRANS-NASAL SKULL BASE BUR ATTACHMENT ASSEMBLY**

1. Slide the attachment over the motor collet aligning triangular arrows on the attachment and the motor case. An audible click, heard and perceptible by touch, confirms that the tool is fully seated.
2. Rotate the attachment to the locked position on the motor case (Figure 9-34).
3. Attach irrigation tubing (Figure 9-35).

**Figure 9-34.** Trans-Nasal Skull Base Bur Assembly**Figure 9-35.** Trans-Nasal Skull Base Bur Assembly

1 Irrigation tubing connection

**TRANS-NASAL SKULL BASE BUR ATTACHMENT DISASSEMBLY**

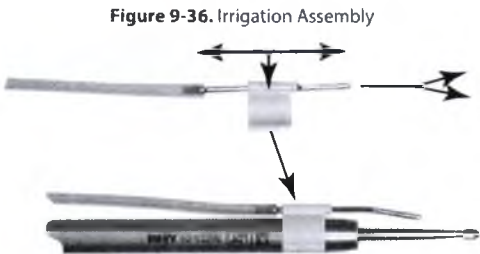
1. Remove irrigation tubing.
2. Rotate the attachment to the unlocked position on the motor case.
3. Remove the attachment from the motor.

LEGEND EHS, LEGEND EHS STYLUS, and STYLUS TOUCH ATTACHMENTS

IRRIGATION ASSEMBLY

**NOTE:** Clip may not fasten to small bore attachment after having been used on large bore attachment.

- 1. Adjust the plastic clip on the stainless-steel irrigation tube (Figure 9-36).
- 2. Bend the irrigation tube to the desired angle.
- 3. Snap the clip onto the handpiece near the tool.



LEGEND EHS, LEGEND EHS STYLUS AND STYLUS TOUCH CLEANING AND STERILIZATION INSTRUCTIONS

Refer to documents M000030A234, 68E4132 and M000030A235 in the Cleaning and Sterilization section.

Variable Exposure Attachment Cleaning

When cleaning, clean the attachment completely. First without adjusting the tube length, then with the tube fully extended, and finally with the tube fully retracted.

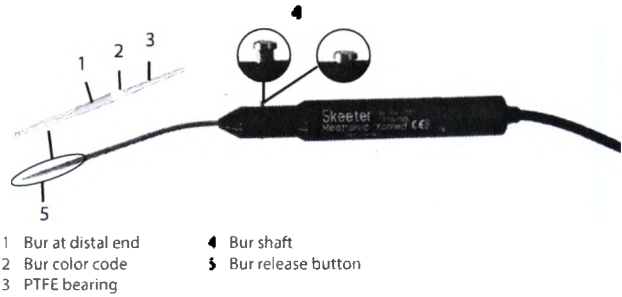
# SKEETER ULTRA-LITE OTO-TOOL

The following instructions for the Skeeter Ultra-Lite Oto-Tool are in addition to “Set up the IPC” general assembly instructions. Complete the IPC setup, then continue to the instructions below. Refer to the Skeeter Ultra-Lite Oto-Tool System Instructions for Use for additional information.

## SKEETER ASSEMBLY

1. Press the bur release button (Figure 10-1).
2. Load the desired bur for the procedure into the handpiece by inserting the bur shaft through the distal end of the handpiece with a slight twisting motion while simultaneously pressing the bur release button.
3. The bur is locked into place when a “click” is noted. Locking of the bur should be checked prior to use by firmly pulling on the bur after the “click” is noted.
4. Tug the bur to ensure it fits securely in the handpiece.
5. To remove the bur from the handpiece, press the bur release button on the handpiece and pull the bur out.

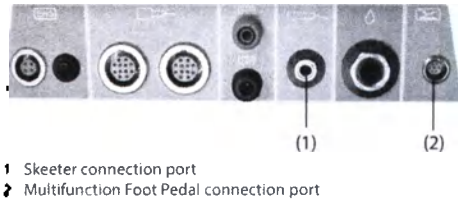
Figure 10-1. Skeeter Handpiece Assembly



## CONNECT SKEETER HANDPIECE TO IPC CONSOLE

On the IPC Console, locate the Skeeter accessory connection port on the connector panel (Figure 10-2), align the mark on the connector to the mark on the console, then insert the connector.

Figure 10-2. IPC Skeeter Connection Port



The Skeeter does not use irrigation. By default, the system sets both pumps to **None**.

Control the operation of the Skeeter with the IPC touchscreen and the multifunction foot pedal.

## SKEETER TOUCHSCREEN CONTROLS

To set or adjust Skeeter controls, on the IPC touchscreen, in the Skeeter control box (Figure 10-3), do the following:

- To change rotation mode, in the Mode control box, select FWD (forward) or REV (reverse).
  - To adjust speed, in the Speed control box, press the plus button to increase speed or the minus button to decrease speed.
- Default, 16000 rpm; variable adjustment from 1000 to 16000 rpm.

Figure 10-3. Skeeter Touchscreen



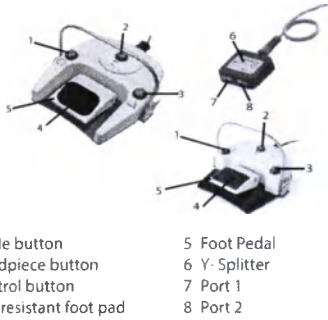
## SKEETER MULTIFUNCTION FOOT PEDAL CONTROLS

**Important:** By default, press each button on the foot pedal for at least 100 mS for the selection to become active. Use the IPC touch screen Settings screen to change the default value.

To use the multifunction foot pedal (Figure 10-4) to control the handpiece do the following:

- To select Forward or Reverse mode, press the mode button.
- To start or adjust the speed of a handpiece in variable mode, press the foot pedal.
- To toggle between the start/stop mode and variable speed mode, press the control button.
- To change the handpiece, press the handpiece button.

Figure 10-4. Multifunction Foot Pedal & Y-Splitter



SKEETER

**SKEETER CLEANING AND STERILIZATION INSTRUCTIONS**  
Refer to documents 68E3968 and 68E3969 in the Cleaning and Sterilization section.

**SKEETER TECHNICAL SPECIFICATIONS**  
Skeeter 3055601

|                             |                                |
|-----------------------------|--------------------------------|
| Size                        | 17 cm Length x 1.6 cm Diameter |
| Weight                      | 57 g                           |
| Speed                       | 1000-16000 rpm forward/reverse |
| Duty Cycle for Applied Part | Continuous run                 |
| Storage Temperature         | -40 °C to +70 °C               |
| Humidity                    | 10 % to 100 % RH               |
| Barometric Pressure         | 500 to 1060 hPa                |

# VISAO HIGH-SPEED DRILL

## DEVICE DESCRIPTION

The IPC incorporates the Visao coolant at pump 1 and irrigation at pump 2. The Visao coolant pump cartridge uses both a pump tube and a drip chamber return tube. If you will not use irrigation, select None for pump 2. Refer to "Set up and Prime Pumps". Control operation of the Visao with the IPC touchscreen and the multifunction foot pedal.

**Important:** During use, maintain free flow irrigation to the cooling sleeve and bur by dribbling saline or DI water along the entire length of the cooling sleeve.

The following instructions are specific for the use of the Visao with the IPC. They are in addition to "Set up the IPC" general accessory instructions.

## SET UP VISAO PUMP

Fill the clear-drip chamber with coolant before you prime the coolant system. Refer to "Set up and Prime Pumps" for instruction.

## VISAO BUR GUARD ASSEMBLY

**Important:** On the Visao, a bur guard (Figure 11-2) is required for use with all burs.

Slide bur guard over the front end of the Visao until fully seated (Figure 11-1).

Figure 11-1: Bur Guard Assembly

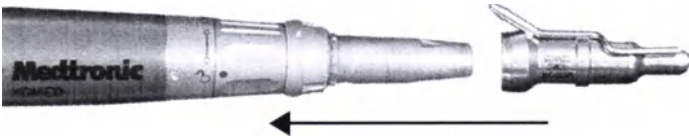
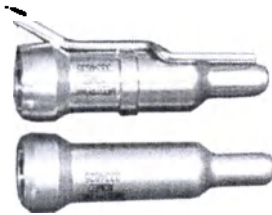


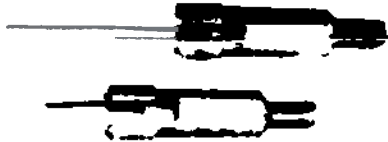
Figure 11-2: Visao Bur Guards



Visao Reusable Bur Guards with and without irrigation.



Visao Single Use Bur Guard with irrigation.



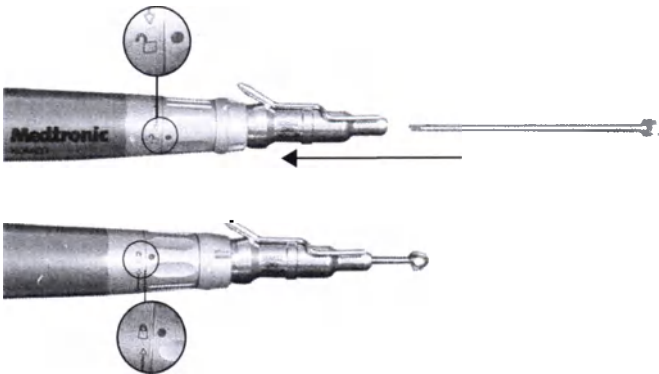
Visao Single Use STIM Bur Guard with and without irrigation. The STIM Bur Guard also provides nerve stimulation to standard burs in static and dynamic modes when used with both the Medtronic Nerve Integrity Monitor (NIM) and the IPC System.

## VISAO STRAIGHT BUR ASSEMBLY

**Important:** On the Visao, a bur guard (Figure 11-2) is required for use with all burs.

1. Align the alignment point on the Visao locking collar with the unlock symbol (Figure 11-3).
2. Insert the tool until fully seated.
3. Move the locking collar so that the alignment point aligns with the lock symbol.
4. To ensure a secure fit, gently pull the tool.

Figure 11-3: Visao Straight Tool Assembly



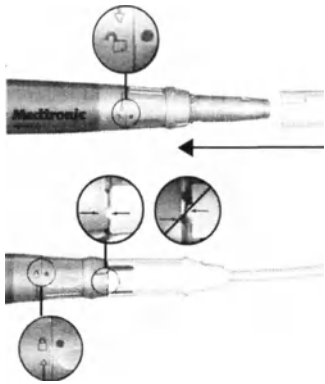


VISAO CURVED BUR ASSEMBLY

**Important:** On the Visao, a bur guard (Figure 11-2) is required for use with all burs.

- 1. Align the alignment point on the Visao locking collar with the unlock symbol (Figure 11-4).
- 2. Align the notch on the tool with the notch on the Visao collar.
- 3. Gently press on the tool until full seated.
- 4. Align the alignment point on the Visao locking collar with the lock symbol.
- 5. To ensure a secure fit, gently pull the tool.

Figure 11-4. Visao Curved Bur Assembly

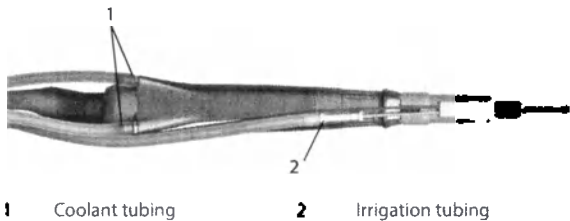


VISAO IRRIGANT AND COOLING TUBE ASSEMBLY

**Caution:** Do not confuse the coolant tube with irrigation tube.

- 1. Connect one coolant tube to each coolant port (Figure 11-5). The coolant can flow in the left or right port if you connect the return tubing to the opposite port.
  - 2. Connect the free end of the irrigation tube to the irrigation barb.
  - 3. Confirm the coolant pedal starts the handpiece and coolant flow.
- Note:** The coolant pump runs for 1 minute after you release the pedal
- 4. Prior to initial use, soak the cooling sleeve in a cup of saline or DI water.
  - 5. During use, maintain copious irrigation of the cooling sleeve and bur by dribbling saline or DI water along the entire length of the cooling sleeve.

Figure 11-5. Visao Irrigant and Cooling Assembly



CONNECT VISAO TO IPC CONSOLE

Locate the Visao connection port on the connector panel (Figure 11-6) and insert the connector.

**Note:** To insert multi-pin connectors (indicated by a silver or red mark on the connector), align the mark on the connector to the mark on the console, then insert the connector.

VISAO TOUCHSCREEN CONTROLS

To set or adjust Visao controls, on the IPC touchscreen, in the Visao control box (Figure 11-7), do the following:

- To change rotation mode, in the Mode control box, select FWD (forward) or REV (reverse).
  - To adjust speed, in the Speed control box, press the plus button to increase speed or the minus button to decrease speed.    
Default, 80000 rpm; variable adjustment from 200 to 80000 rpm.
  - To adjust the irrigation flow rate, in the Pump control box, press the plus button to increase flow rate or the minus button to decrease flow rate. If intermittent flow is available, pressing the plus or minus button progresses the system through intermittent and continuous flow. The system displays Intermittent when in intermittent mode.  
Forward Mode: Default, 30 cc per minute.
- Note:** To adjust flow rate, you can use the touchscreen or the IntelliFlow Irrigation remote control.

Figure 11-6. IPC Visao Connection Port

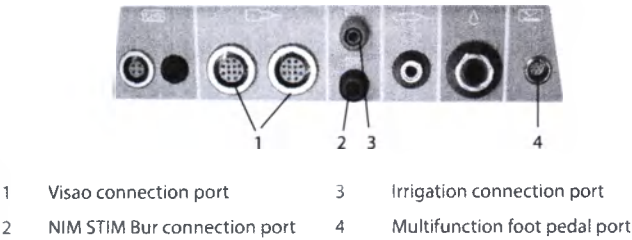


Figure 11-7. Visao Touchscreen

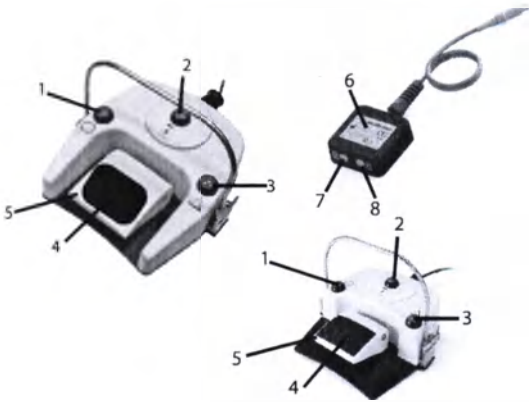


VISAO MULTIFUNCTION FOOT PEDAL CONTROLS

**Important:** By default, press each button on the foot pedal for at least 100 mS for the selection to become active. Use the IPC touch screen Settings screen to change the default value.  
To use the multifunction foot pedal (Figure 11-8) to control the handpiece do the following:

- To select Forward or Reverse mode, press the mode button.
  - To start or adjust the speed of a handpiece in variable mode, press the foot pedal.
  - To toggle between the start/stop mode and variable speed mode, press the control button.
- Note:** Functionality of the control button may be changed in the handpiece Defaults menu to pause irrigation. Refer to Change System Settings in the Pre-Operating Instructions section.
- To change the handpiece, press the handpiece button.

Figure 11-8. Multifunction Foot Pedal & Y-Splitter



- 1 Mode button                      5 Foot pedal  
2 Handpiece button                6 Y-Splitter  
3 Control button                   7 Port 1  
4 Slip-resistant foot pad        8 Port 2

VISAO CLEANING AND STERILIZATION INSTRUCTIONS

Refer to document 68E3281 in the Cleaning and Sterilization section.

VISAO TECHNICAL SPECIFICATIONS

Visao 3334800

|                             |                                                                                                   |
|-----------------------------|---------------------------------------------------------------------------------------------------|
| Size                        | 16.0 cm Length x 2.0 cm Diameter                                                                  |
| Weight                      | 148 g                                                                                             |
| Speed                       | 200-80000 rpm forward/reverse. Visao High-Speed Drill, water cooled                               |
| Duty Cycle for Applied Part | The Visao High-Speed Drill under full load is rated for intermittent operation per the following: |
|                             | Maximum On Time: 60 seconds                                                                       |
|                             | Maximum Off Time: 30 seconds                                                                      |

VISAO USE WITH IPC AND NIM

To use the NIM with the IPC use the Stim Bur Guard (Figure 11-2). The Stim Bur Guard connects the IPC to the NIM via the Stim bur stimulus output port (Figure 11-6). The Stim Bur Guard carries stimulating current to the tool's tip and provides nerve stimulation to standard burs in static and dynamic modes. Refer to the NIM User's Manual and Stim Bur Guard Product Information and Instructions for further information.

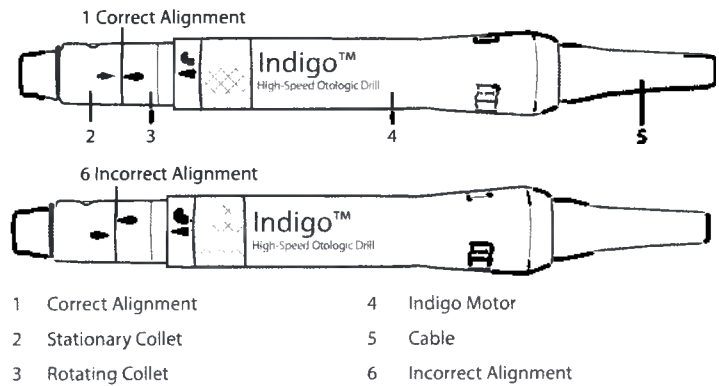
# INDIGO HIGH-SPEED OTOLOGIC DRILL

## DEVICE DESCRIPTION

The Indigo drill is a small, compact high-speed, high-torque, reversible electric drill that can be used to dissect bone and biomaterial at variable speeds from 200 to 60000 rpm. The cable cannot be removed from the drill. The following instructions for the Indigo drill are in addition to "Set up the IPC" general assembly instructions. Complete IPC setup, then continue to the instructions below.

## INDIGO DRILL STRAIGHT ATTACHMENT ASSEMBLY

Figure 12-1. Indigo Alignment



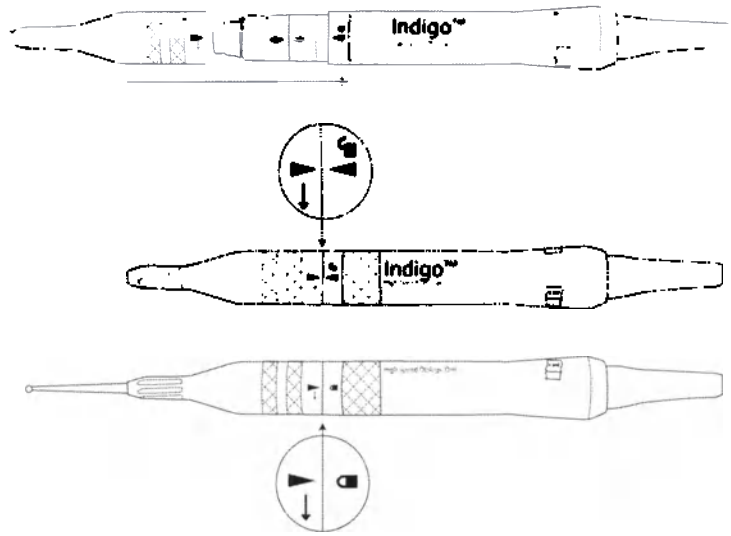
**Important:** The Indigo High-speed Otologic drill is designed to work only with Medtronic Xomed burs and Indigo attachments. The use of other burs and attachments may result in sub-standard performance and will void the manufacturer's warranty. Do not use with Midas Rex attachments or burs.

1. Verify the alignment marks on the motor collet are in alignment (Figure 12-1).  
**Note:** If the marks are misaligned, turn the collet until the marks are aligned.
2. Slide the attachment over the motor collet (Figure 12-2) so that the alignment mark on the attachment aligns with the alignment mark (unlocked symbol) on the motor collet.
3. Insert the bur with a slight twisting motion until you feel it seat into position.
4. Turn the attachment so the alignment mark aligns with the locked symbol on the motor collet. You will hear two clicks while rotating the attachment.
5. To ensure a secure fit, gently pull the tool.

**Important:** The Indigo motor will not run correctly unless the attachment is in the locked position.

**Warning:** Smoke may be generated if attachment is not in the locked position (W36).

Figure 12-2. Indigo Straight Attachment Assembly



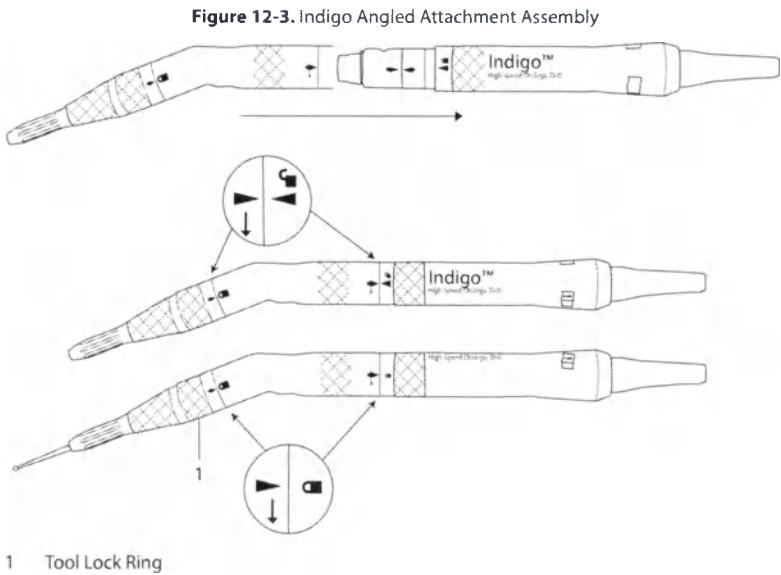
INDIGO DRILL ANGLED ATTACHMENT ASSEMBLY

**Important:** The Indigo High-speed Otologic drill is designed to work only with Medtronic Xomed burs and Indigo attachments. The use of other burs and attachments may result in sub-standard performance and will void the manufacturer's warranty. Do not use with Midas Rex attachments or burs.

- 1. Verify the alignment marks on the motor collet are in alignment (Figure 12-1).
- Note:** If the marks are misaligned, turn the collet until the marks are aligned.
- 2. Slide the attachment over the motor collet (Figure 12-3) so that the alignment mark on the attachment aligns with the alignment mark (unlocked symbol) on the motor collet.
- 3. Turn the attachment so the alignment mark aligns with the locked symbol on the motor collet. You will hear two clicks while rotating the attachment.
- 4. Verify the alignment marks on the tool lock ring align with the unlocked symbol on the attachment.
- 5. Insert the bur with a slight twisting motion until you feel it seat into position.
- 6. Turn the lock ring so the alignment mark aligns with the locked symbol on the attachment. You will hear two clicks while rotating the attachment.
- 7. To ensure a secure fit, gently pull the tool.

**Important:** The Indigo motor will not run correctly unless the attachment and lock ring is in the locked position.

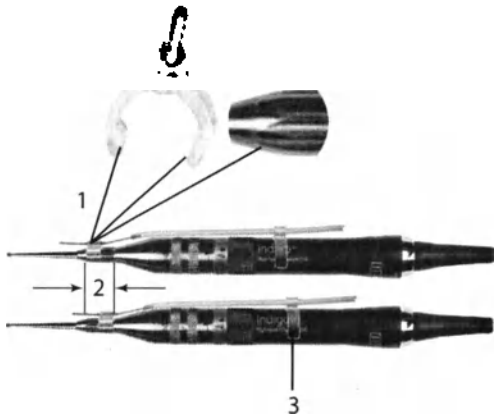
**Warning:** Smoke may be generated if attachment is not in the locked position (W36).



INDIGO DRILL IRRIGATION AND TUBING CLIP ASSEMBLY

- 1. Snap or slide the irrigation clip on to the attachment (Figure 12-4).
- Note:** The irrigation clip is designed with two nodules that fit in the grooves on the attachment.
- 2. Bend the irrigation tube to a desirable angle and adjust the clip closer to or farther from the bur, as necessary.
- 3. Snap the tubing clip on the handpiece or angled attachment.

Figure 12-4. Irrigation and Tubing Clip Assembly



## CONNECT INDIGO DRILL TO IPC

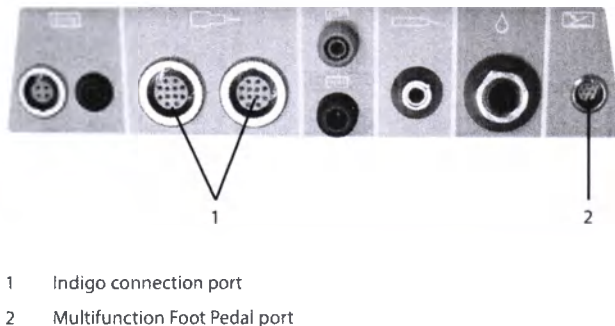
Locate the Indigo drill connection port on the connector panel (Figure 12-5) and insert the connector.

**Note:** To insert multi-pin connectors (indicated by a silver or red mark on the connector), align the mark on the connector to the mark on the console, then insert the connector.

The IPC incorporates Indigo on-drill irrigation at pump 2. If you do not use drill irrigation, select **None** for pump 2. If you will use a suction irrigator, you must manually select it for pump 1 or pump 2.

Control operation of the Indigo drill with the IPC touchscreen and the multifunction foot pedal.

Figure 12-5. IPC Indigo Connection Ports



- 1 Indigo connection port
- 2 Multifunction Foot Pedal port

## INDIGO DRILL TOUCHSCREEN CONTROLS

To set or adjust Indigo drill controls, on the IPC touchscreen, in the control box (Figure 12-6), do the following:

- To change rotation mode, in the Mode control box, select FWD (forward) or REV (reverse). **Important:** System configuration may be different from the default. If the REV (reverse) button appears raised and does not have a selectable radio button (Figure 12-7), you cannot select the Reverse mode. If the REV button appears concave (Figure 12-7) and has a selectable radio button, you can select the Reverse mode via the touchscreen or the multifunction foot pedal.

- To adjust speed, in the Speed control box, press the plus button to increase speed or the minus button to decrease speed.  

Default, 52000 rpm; variable adjustment from 200 to 60000 rpm in increments of 200, 500 and then 1000 until 60000.

**Note:** The speed you set remains constant when you switch between modes.

**Warning:** A tool's size and geometry may create excessive vibration at certain speeds. Increase or decrease speed on console. Change to a new tool to prevent unintended tissue removal from patient (W54).

- To adjust the irrigation flow rate, in the Pump control box, press the plus button to increase flow rate or the minus button to decrease flow rate. If intermittent flow is available, pressing the plus or minus button progresses the system through intermittent and continuous flow of irrigation at 5, 10, 15 and 20 cc per minute. The system displays **Intermittent** when in intermittent mode. Default, 30cc per minute.

**Note:** To adjust flow rate, you can use the touchscreen or the IntelliFlow Irrigation remote control.

Figure 12-6. Indigo Touchscreen



Figure 12-7. Indigo Mode





INDIGO DRILL MULTIFUNCTION FOOT PEDAL CONTROLS

**Important:** By default, press each button on the foot pedal for at least 100 mS for the selection to become active. Use the IPC touchscreen Settings screen to change the default value.

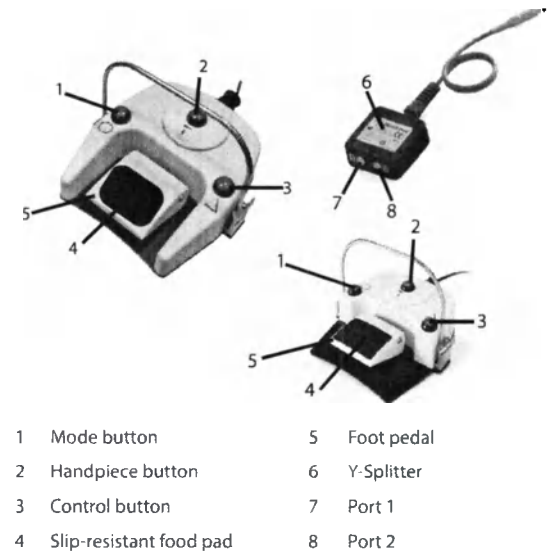
To use the multifunction foot pedal (Figure 12-8) to control the handpiece do the following:

- To select Forward or Reverse mode, press the mode button.
- To start or adjust the speed of a handpiece in variable mode, press the foot pedal.
- To toggle between the start/stop mode and variable speed mode, press the control button.

**Note:** Functionality of the control button may be changed in the handpiece Defaults menu to pause irrigation. Refer to Change System Settings in the Pre-Operating Instructions section.

- To change the handpiece, press the handpiece button.

Figure 12-8. Multifunction Foot Pedal & Y-Splitter



INDIGO DRILL CLEANING AND STERILIZATION INSTRUCTIONS

Refer to documents 68E4187 and 68E4188 in the Cleaning and Sterilization section.

INDIGO DRILL TECHNICAL SPECIFICATIONS

Indigo Drill 1845000

|                             |                                                                                                                                                     |
|-----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|
| Size                        | 11.9 cm Length x 1.53 cm Diameter                                                                                                                   |
| Weight                      | 102 g                                                                                                                                               |
| Speed                       | 60000 rpm forward/reverse                                                                                                                           |
| Duty Cycle for Applied Part | For continuous use in operating room temperatures up to 40°C, the Indigo motor is rated for 3 minutes at 60000 rpm, followed by 25 minutes of rest. |
|                             | For normal operating room temperatures (typically 20°C), the Indigo motor is rated for continuous cutting indefinitely at 60000 rpm.                |

# MIDAS REX MICROSAWS

## DEVICE DESCRIPTION

Use Midas Rex Microsaws to remove hard tissue and bone during surgical procedures. Both the foot and finger-controlled saws are powered by the IPC. Operate the foot-controlled saws via the multifunction foot pedal. Operate the finger-controlled saws by pressing the finger lever.

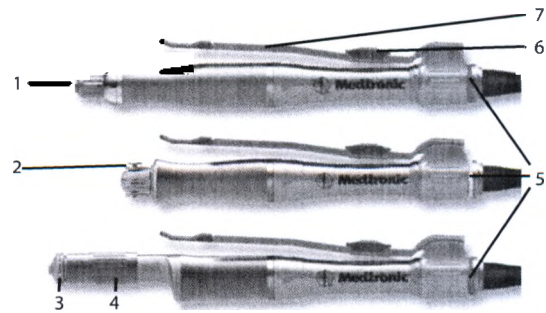
The IPC incorporates microsaws irrigation at pump 2. If you do not use irrigation, select **None** for pump 2. Control operation of the microsaws with the IPC touchscreen and the multifunction foot pedal.

Figure 13-1. Foot-Controlled Microsaw Handpieces



- 1 Reciprocating saw collet
- 2 Sagittal saw blade release button
- 3 Oscillating saw head
- 4 Oscillating saw collet
- 5 Color band

Figure 13-2. Finger-Controlled Microsaw (Microsaw Touch) Handpieces



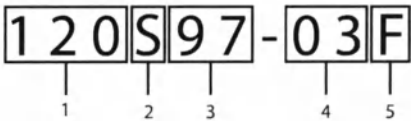
- 1 Reciprocating saw collet
- 2 Sagittal saw blade release button
- 3 Oscillating saw head
- 4 Oscillating saw collet
- 5 Color band
- 6 Finger lever safe mode switch
- 7 Finger lever

## BLADE AND RASP NOMENCLATURE

**Important:** You can only use reciprocating blades and rasps with the reciprocating saw. You can use sagittal and oscillating blades interchangeably.

Saw blade part numbers follow a standard naming convention.

|   |                    |                                                                                                             |
|---|--------------------|-------------------------------------------------------------------------------------------------------------|
| 1 | Cut Depth Limit    | XX.X mm*                                                                                                    |
| 2 | Saw Type           | S Sagittal / Oscillating<br>R Reciprocating                                                                 |
| 3 | Cut Width / Length | X.X mm                                                                                                      |
| 4 | Blade Thickness    | X.X mm                                                                                                      |
| 5 | Other Identifiers  | F Fine Teeth PT Pointed Blade<br>ARC Rounded Blade ST Straight Rasp<br>BAY Bayoneted Blade CC Crosscut Rasp |



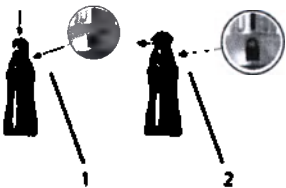
\* Blade depth markings are approximate and should be used for reference only.

## RECIPROCATING MICROSAW ASSEMBLY

**Important:** Verify that the color code on the blade package matches the color band on the handpiece (Figures 13-1 and 13-2).

1. On the reciprocating handpiece (red band), verify that the collet is in the unlocked position (Figure 13-3).
2. Insert the reciprocating blade into the collet.
3. Rotate the collet knob 90 ° to the locked position.
4. To ensure a secure fit, gently pull the blade.

Figure 13-3. Reciprocating Saw Assembly



SAGITTAL MICROSAW ASSEMBLY

**Important:** Verify that the color code on the blade package matches the color band on the handpiece (Figures 13-1 and 13-2).

- 1. On the sagittal handpiece (yellow band), press the blade release button (Figure 13-4).
- 2. Insert the blade at the desired angle (Figure 13-5).
- 3. Release the blade release button.
- 4. To ensure a secure fit, gently move the blade from side to side.

Figure 13-4. Sagittal Saw Assembly

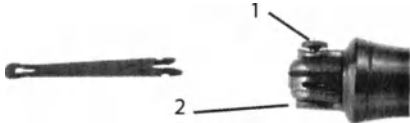


Figure 13-5. Blade Installation Angles



OSCILLATING MICROSAW ASSEMBLY

**Important:** Verify that the color code on the blade package matches the color band on the handpiece (Figures 13-1 and 13-2).

- 1. On the oscillating handpiece (blue band), verify that the collet is in the unlocked position (Figure 13-6).
- 2. Insert the blade into the collet. The blade "clicks" into place.  
**Note:** You can insert the blade every 45 ° in a 360 ° circle in up to 8 locations (Figure 13-7).
- 3. Rotate the collet to the locked position (Figure 13-6).
- 4. To ensure a secure fit, gently move the blade from side to side.

Figure 13-6. Oscillating Saw Assembly

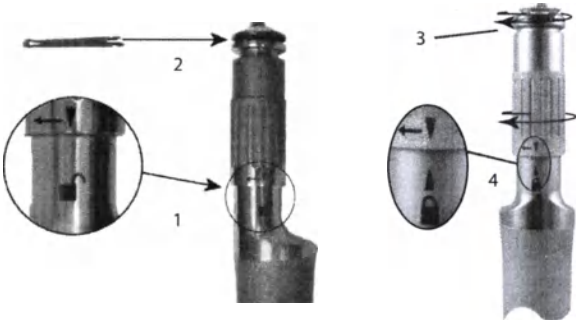
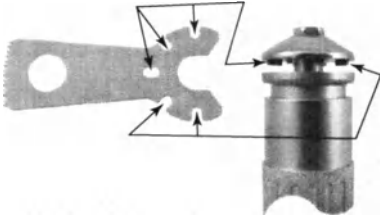


Figure 13-7. Oscillating Pin Alignment



MICROSAW IRRIGATION AND TUBING CLIPS ASSEMBLY

**Note:** Saw irrigation is optional.

- 1. Snap the irrigation clip on to the handpiece (Figures 13-8 and 13-9).  
**Note:** On finger-controlled handpieces, attach the rear portion of the irrigation clip to the rotatable finger lever base (Figure 13-9).
- 2. Disengage the front of the irrigation clip to adjust the irrigation length, if necessary.
- 3. Snap the tubing clip on to the handpiece.

Figure 13-8. Foot-Controlled Microsaw Irrigation and Tubing Clip Assembly

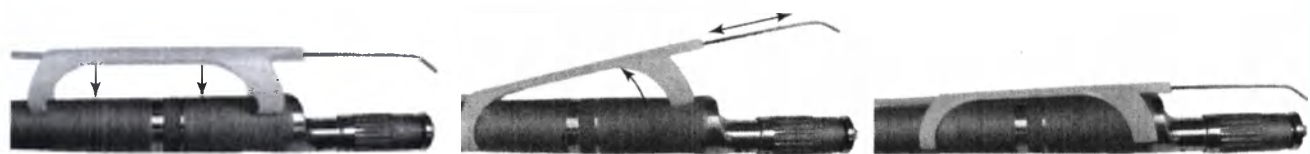
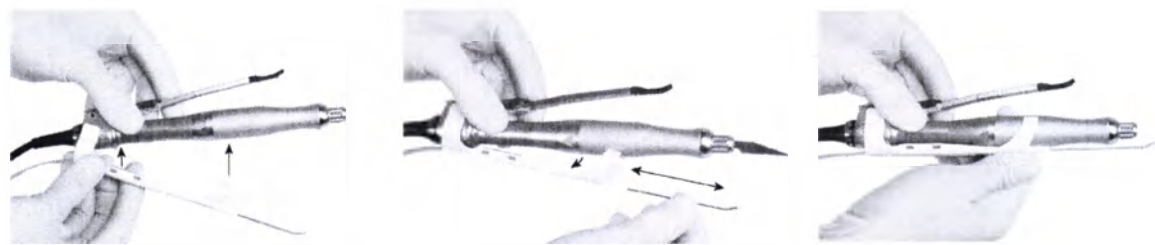


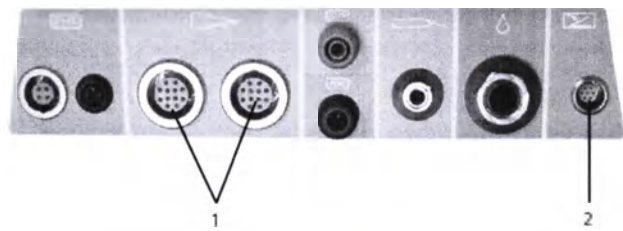
Figure 13-9. Finger-Controlled Microsaw Irrigation and Tubing Clip Assembly



CONNECT MICROSAW HANDPIECE TO IPC

On the IPC Console, locate a 12-pin port on the connector panel (Figure 13-10), align the mark on the connector to the mark on the console, then insert the connector.

Figure 13-10. Microsaws IPC Connection Ports



- 1    Microsaws handpiece connection port
- 2    Multifunction foot pedal connection port

MICROSAWS TOUCHSCREEN CONTROLS

**Important:** The IPC recognizes the connected saw, then displays the appropriate name and color ring.

- To adjust speed, in the Speed control box (Figure 13-11), press the plus button to increase maximum speed and the minus button to decrease maximum speed. Variable adjustment ranges from 0 % to 100 %.  
**Note:** When the Finger-Controlled Microsaw is in safe mode, the Speed control box displays SAFE (Figure 13-12). Refer to the Finger-Controlled Microsaw Safe Mode topic for additional information.
- To adjust the irrigation flow rate, in the Pump control box, press the plus button to increase flow rate or the minus button to decrease flow rate. If intermittent flow is available, pressing the plus or minus button progresses the system through intermittent and continuous flow. The system displays **Intermittent** when in intermittent mode.  
Default flow rate is 0 cc per minute. Maximum flow rate is 50 cc per minute.  
**Note:** To adjust flow rate, you can use the touchscreen or the Intelliflow Irrigation remote control.
- To switch between foot and finger control or to use both, in the Control control box, select the appropriate option. Finger-controlled saws can be operated via the lever on the handpiece, or the foot pedal.  
**Note:** This option is only available when using a finger-controlled handpiece.

FINGER-CONTROLLED MICROSAW SAFE MODE

When the handpiece is in safe mode, it is inoperable until the safety is turned off. The Speed control box on the Microsaws touchscreen displays SAFE when the handpiece is the active handpiece and in safe mode (Figure 13-12).

Switch the device to safe mode any time it is attached to the console, but not currently being used.

When more than one handpiece is attached to the console, use the safety switch of an inactive handpiece to activate that handpiece and make it ready for use.

Figure 13-11. Microsaws Touchscreen



Figure 13-12. Finger-Controlled Microsaw Safe Mode



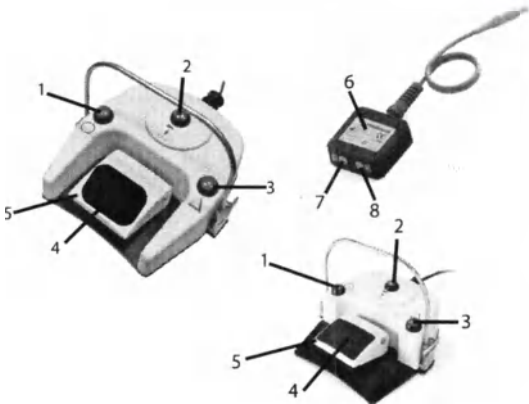
MICROSAW MULTIFUNCTION FOOT PEDAL CONTROLS

**Important:** By default, press each button on the foot pedal for at least 100 mS for the selection to become active. Use the IPC Settings screen to change the default value.

To use the multifunction foot pedal (Figure 13-13) to control the handpiece, do the following:

- To start or adjust the speed of a handpiece in variable mode, press the pedal.
- To toggle between the start/stop mode and variable-speed mode, press the control button.  
**Note:** Functionality of the control button may be changed in the handpiece Defaults menu to pause irrigation. Refer to Change System Settings in the Pre-Operating Instructions section.
- To change the active handpiece, press the handpiece button.  
**Note:** You can switch between finger-controlled handpieces by pressing the finger lever on the handpiece.

Figure 13-13. Multifunction Foot Pedal & Y-Splitter



- |                           |              |
|---------------------------|--------------|
| 1 Mode button             | 5 Foot pedal |
| 2 Handpiece button        | 6 Y-Splitter |
| 3 Control button          | 7 Port 1     |
| 4 Slip-resistant foot pad | 8 Port 2     |



MICROSAWS CLEANING AND STERILIZATION INSTRUCTIONS

Refer to document M000030A231 in the Cleaning and Sterilization section.

MICROSAWS TECHNICAL SPECIFICATIONS

|        |                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|--------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Size   | Reciprocating (ES200): 2.3 cm Width x 20.3 cm Length<br>Sagittal (ES300): 2.3 cm Width x 17.3 cm Length<br>Oscillating (ES100): 2.3 cm Width x 19.8 cm Length<br>Finger-Controlled Reciprocating (ES210): 2.3 cm Width x 3.2 cm Height x 20.3 cm Length<br>Finger-Controlled Sagittal (ES310): 2.3 cm Width x 3.2 cm Height x 17.8 cm Length<br>Finger-Controlled Oscillating (ES110): 2.3 cm Width x 3.2 cm Height x 21.0 cm Length |
| Weight | Reciprocating (ES200): 300 g<br>Sagittal (ES300): 250 g<br>Oscillating (ES100): 300 g<br>Finger-Controlled Reciprocating (ES210): 320 g<br>Finger-Controlled Sagittal (ES310): 300 g<br>Finger-Controlled Oscillating (ES110): 320 g                                                                                                                                                                                                 |
| Speed  | All Reciprocating: 1400-14000 cpm<br>All Sagittal: 2000-20000 cpm<br>All Oscillating: 1600-16000 cpm                                                                                                                                                                                                                                                                                                                                 |

Duty Cycle

≤ 20°C Ambient (one cut period = 20 seconds on / 20 seconds off)

Reciprocating: ≤ 15 cut periods<sup>1</sup>

Sagittal: ≤ 6 cut periods<sup>2</sup>

Oscillating: ≤ 4 cut periods<sup>3</sup>

> 20°C Ambient (one cut period = 20 seconds on / 40 seconds off)

Reciprocating: ≤ 5 cut periods<sup>4</sup>

Sagittal: ≤ 6 cut periods<sup>5</sup>

Oscillating: ≤ 3 cut periods<sup>6</sup>

Time for cool down after maximum number of cut periods listed above: 25 minutes.

<sup>1</sup>5 periods with Light Force (0.8 Lbf), 5 periods with Medium Force (2.1 Lbf), 5 periods with Heavy Force (3.9 Lbf)

<sup>2</sup>2 periods with Light Force (0.8 Lbf), 2 periods with Medium Force (1.5 Lbf), 2 periods with Heavy Force (3.0 Lbf)

<sup>3</sup>1 period with Light Force (0.7 Lbf), 2 periods with Medium Force (1.5 Lbf), 1 period with Heavy Force (2.6 Lbf)

<sup>4</sup>1 period with Light Force (0.8 Lbf), 2 periods with Medium Force (2.1 Lbf), 2 periods with Heavy Force (3.9 Lbf)

<sup>5</sup>2 periods with Light Force (0.8 Lbf), 2 periods with Medium Force (1.5 Lbf), 2 periods with Heavy Force (3.0 Lbf)

<sup>6</sup>1 period with Light Force (0.7 Lbf), 1 period with Medium Force (1.5 Lbf), 1 period with Heavy Force (2.6 Lbf)

# POWEEASE DRIVER

## DEVICE DESCRIPTION

The IPC POWEEASE System is specifically designed for drilling, tapping, and driving screws during spine surgery.

The IPC POWEEASE system consists of a POWEEASE Driver (Figure 14-1) that is powered by the IPC, along with the following POWEEASE driver compatible working end instruments:

- Taps
- Drill Bits
- Drivers
- Rod Cutter
- Post Cutter
- Set Screw Break-off Instrument (SSBO)

The POWEEASE System and accessories are compatible with the following implant systems:

- CD HORIZON SOLERA Spinal System
- TSRH 3Dx Spinal System

## ASSEMBLE THE IPC

**Important:** The manual start/stop button on the IPC console (Figure 1-2) does not function with the POWEEASE driver.

Note: The POWEEASE driver does not use the IPC pump system. The pumps are available for use with other accessories requiring irrigation or cooling.

1. Verify the wheels are locked on the IPC cart.
2. Inspect all components for damage and determine if the system is ready for use.
3. Mount the IPC and irrigation/collant bags on the I.V. pole.
 

**Important:** Mount the irrigant and coolant bags above the IPC to ensure adequate flow.
4. Plug the IPC into the power source. Position the IPC so that it does not obstruct the power source for the purpose of disconnecting the Main voltage by the power cord.
5. Locate the POWEEASE connection port on the IPC connector panel (Figure 14-2) and insert the connector from the POWEEASE driver.
6. If using the NIM-ECLIPSE with the IPC POWEEASE, assemble the IPC POWEEASE and the NIM-ECLIPSE system.
7. Turn on the IPC and do the following:
  - Verify the system passes the self-test.
  - Verify the POWEEASE screen appears on the IPC monitor.
8. Confirm the IPC POWEEASE System Operation.

## IPC POWEEASE MODE SELECT SWITCH

Use the mode select switch to change the handpiece from Forward, Reverse or Oscillate when the handpiece is the active handpiece. When the handpiece is the inactive handpiece, use the mode select switch to activate the handpiece.

## IPC POWEEASE SYSTEM OPERATION

1. On the POWEEASE driver, rotate the mode select switch (Figure 14-3) to Forward (F).
2. On the IPC touchscreen, verify the following:
  - The FWD Speed box is active and the default speed appears in white.
  - The Trigger Status is Ready For Use.

**Note:** If the trigger status is Locked, release and press the trigger to disengage the lock. Contact Customer Service if the trigger status does not change to Ready For Use.
3. On the POWEEASE driver, touch the trigger (Figure 14-4) and verify the speed in the FWD Speed box on the IPC touchscreen turns green.
4. On the POWEEASE driver, press the trigger and verify the following:
  - The speed increases as you increase pressure on the trigger.
  - The speed in the FWD Speed box on the IPC touchscreen turns yellow.
5. Remove finger from the POWEEASE driver trigger and verify the following:
  - The driver rotation stops.
  - The speed in the FWD Speed box on the IPC touchscreen turns white.
6. Repeat steps 1 through 5 for the Reverse (R) and Oscillate  modes.

Figure 14-1. POWEEASE Driver

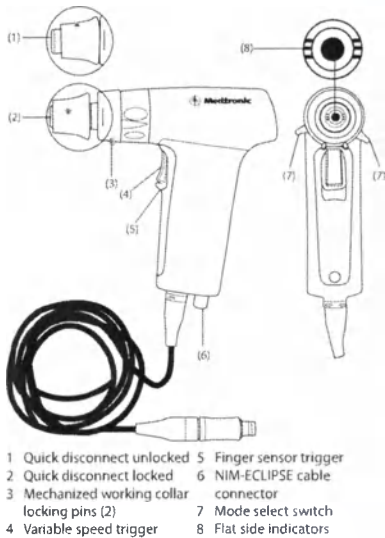


Figure 14-2. IPC POWEEASE Connection Ports

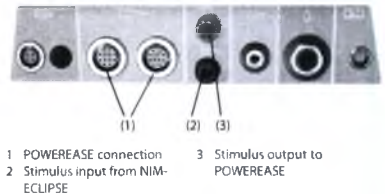


Figure 14-3. POWEEASE Mode Select Switch

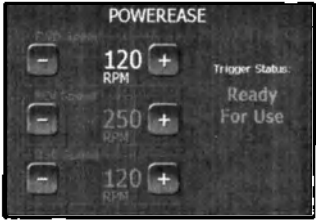


POWEEASE TOUCHSCREEN CONTROLS

To adjust the maximum speed of the driver using the IPC POWEEASE touchscreen (Figure 14-4), in the relevant speed control box, press the plus button to increase maximum speed or minus button to decrease maximum speed.

- Variable speed control:  
FWD Speed: variable adjustment from 10 to 250 rpm in increments of 10 rpm.  
REV Speed: variable adjustment from 10 to 250 rpm in increments of 10 rpm.  
OSC Speed: variable adjustment from 10 to 200 rpm in increments of 10 rpm.
- IPC POWEEASE touchscreen color codes:  
White: active speed at idle, finger off trigger.  
Green: active speed at idle, finger on trigger.  
Yellow: active speed in use.  
Gray: inactive
- Trigger Status:  
Ready For Use: Device is ready for use.  
Locked: In the case of a trigger control anomaly, the trigger is locked until the anomaly has cleared and use of the POWEEASE may resume.  
To disengage the lock, release and press the trigger. Contact Customer Service if the device does not return to Ready For Use.

Figure 14-4. IPC POWEEASE Touchscreen

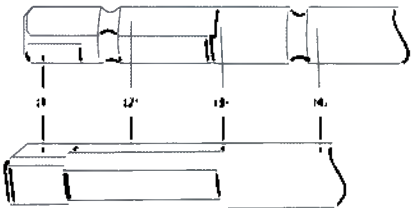


CLASSIC WORKING END ASSEMBLY AND OPERATION

**NOTE:** Please see the POWEEASE System Working Ends User's Manual and IFU for a listing of compatible working ends and further details regarding their proper use. Contact Customer Service or your sales representative for the most up-to-date version of the package insert or manual.

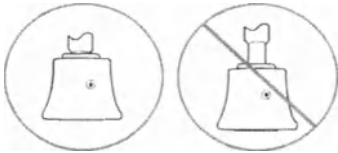
1. On the POWEEASE driver, pull back on and hold the quick disconnect to unlock the collet (Figure 14-1, 1).  
**Note:** The quick disconnect must be held in the unlocked position when inserting or removing tools.
2. Insert the classic working end drive shaft (Figure 14-5, 1) into the collet until fully seated. Fully seated is on or near the drive shaft shoulder (Figure 14-6).  
**Note:** If using a two sided shaft, align the flat sides on the drive shaft with the marks on the collet (Figure 14-1, 8).
3. Release the quick disconnect to place the working end in the locked position (Figure 14-1, 2).
4. To set the mode on the POWEEASE driver, rotate the mode select switch (Figure 14-3) to Forward (F), Reverse (R), or Oscillate .
  - Place mode select switch in Forward to drill, tap or insert screw.
  - Place mode select switch in Reverse to back out drill, back out tap or back out screw.
  - Place mode select switch in Oscillate to lock the tool in its current position. Refer to POWEEASE Driver Electronic Ratcheting for additional information.
5. To adjust the speed of the driver, increase pressure to increase speed or decrease pressure to decrease speed.  
**NOTE:** The IPC touchscreen displays the maximum speed for the selected mode.
6. Reverse procedure to remove the classic working end accessory.

Figure 14-5. Classic Working End



- 1 Four sided drive shaft
- 2 Flat Side
- 3 Drive shaft shoulder
- 4 Shaft

Figure 14-6. Classic Working End Seating



POWEEASE Driver Electronic Ratcheting

Ratcheting is intended to permit manual motion in one direction only.

- FWD Mode: With the trigger released, the handpiece functions as a ratchet allowing the handpiece to be turned in a clockwise direction while ratcheting in a counter clockwise direction.
- REV Mode: With the trigger released, the handpiece functions as a ratchet allowing the handpiece to be turned in a counter clockwise direction while ratcheting in a clockwise direction.
- OSC Mode: With trigger released, the handpiece locks the tool in its current position, and the surgeon can manually rotate the handpiece in a clockwise or counter-clockwise direction.

POWEEASE Ratchet Test

1. Load a drill, tap or screwdriver in the collet. Refer to Classic Working End Assembly and Operation for details.
2. On the POWEEASE driver, set the mode select switch to Forward (F), (Figure 14-3).
3. Hold the POWEEASE driver shaft firmly and verify the following:  
**Important: DO NOT** hold by the tool. **DO NOT** touch the trigger sensor.
  - The driver ratchets when rotated counter clockwise.
  - The driver does not ratchet when rotated clockwise.
4. Set the mode select switch to Reverse (R) and verify the following:
  - The driver ratchets when rotated clockwise.
  - The driver does not ratchet when rotated counter clockwise.
5. Set the mode select switch to Oscillate  and verify the driver does not ratchet when rotated clockwise or counter clockwise.

MECHANIZED WORKING END ASSEMBLY AND OPERATION

**NOTE:** Please see the POWEEASE System Working Ends User’s Manual and IFU for a complete listing of compatible working ends and further details regarding their proper use. Contact Customer Service or your sales representative for the most up-to-date version of the package insert or manual.

1.

On the POWEEASE driver, pull back on and hold the quick disconnect (Figure 14-1, 1) to unlock the collet.  
**Note:** The quick disconnect must be held in the unlocked position when inserting or removing tools.
2.

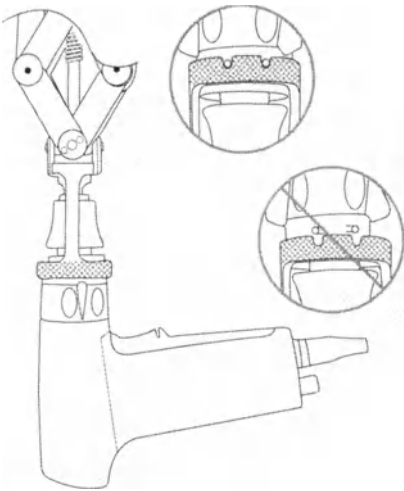
Align the slots on the working end collar with the mechanized working collar locking pins (Figure 14-7).
3.

To set the mode on the POWEEASE driver, rotate the mode select switch (Figure 14-3) to Forward (F), Reverse (R), or Oscillate .
  - Place the mode select switch in Forward to cut/shear implantable rods, cut vertical posts, break set screws.
  - Place the mode select switch in Reverse to open the tool.
  - Oscillate is intended as a rotational lock for classic working ends and has no function with mechanized working ends. However, if the trigger is pulled, the tool shaft will oscillate 60 ° clockwise and counter-clockwise.
4.

To adjust the speed of the driver, increase pressure to increase speed or decrease pressure to decrease speed.  
**NOTE:** The IPC touchscreen displays the maximum speed for the selected mode.
5.

Reverse this procedure to remove the classic working end accessory.

Figure 14-7. Mechanical Working End Seating



POWEEASE CLEANING AND STERILIZATION INSTRUCTIONS

Refer to document 68E4189 in the Cleaning and Sterilization section.

POWEEASE DRIVER TECHNICAL SPECIFICATIONS

POWEEASE Driver 2300000

|                                             |                                                                                                             |
|---------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| Size                                        | 175 mm Width x 160 mm Height x 42 mm Length                                                                 |
| Weight                                      | 900 g (1200 g including cable)                                                                              |
| Speed                                       | 0 to 250 rpm (variable)                                                                                     |
| Torque                                      | 7 Nm                                                                                                        |
| Cable Length (Driver)                       | 4.5 m                                                                                                       |
| Cable Length (IPC to Patient Interface Box) | 4.5 m                                                                                                       |
| Cable Length (Driver to IPC)                | 4.5 m                                                                                                       |
| Duty Cycle for Applied Part                 | For continuous operating room temperatures up to 33 °C, the POWEEASE driver rates for continuous operation. |
|                                             | For normal operating room temperatures (below 25 °C), the POWEEASE driver rates for continuous operation.   |

IPC POWEEASE WITH THE NIM-ECLIPSE SYSTEM

**Important:** Do not use the IPC POWEEASE - NIM-ECLIPSE System with multiple portable socket-outlet or extension cord.

The POWEEASE System is equipped with two cables that connect the IPC to the NIM-ECLIPSE. Wires within the POWEEASE make contact with the uncoated tool and carry stimulating current to the tool’s tip for nerve monitoring. Contact to your local NIM-ECLIPSE representative for more information.

**Important:** Only taps, screws and drills are available for nerve stimulation. Please see the POWEEASE System Working Ends User’s Manual and Instructions for Use for further details regarding the working ends available for use with nerve stimulation. When the IPC POWEEASE driver is used in combination with the NIM-ECLIPSE, the combination creates a medical electrical system. The system components are as follows:

- IPC
- POWEEASE with accessories
- NIM-ECLIPSE
- NIM cable set

## Assemble IPC POWEEASE and NIM-ECLIPSE System

**Important:** Refer to the NIM-ECLIPSE User's Guide for set up and use of the NIM-ECLIPSE system, including the laptop computer.

### Warnings:

- Only the POWEEASE handpiece with its accessories are intended to be used within the patient environment. The NIM-ECLIPSE cannot be used in the patient vicinity (1.5 meter radius from patient).
- Do not touch the patient and the enclosure parts of the NIM-ECLIPSE simultaneously.
- Dispose of the single-use NIM cables after each procedure.
- Any peripheral devices connected to the system must meet IEC60601-1 requirements. Consult with your biomedical engineering department to determine if the external devices meet this requirement.

1. Assemble the IPC and confirm IPC POWEEASE system operation.
2. Assemble the NIM-ECLIPSE according to the instructions in the NIM-ECLIPSE User's Guide. Verify the laptop computer power cord is plugged into the NIM-ECLIPSE 945ECLC Controller.
3. On the NIM-ECLIPSE stimulator extender, connect one end of the black NIM cable to the Stimulus Output connection port (Figure 14-8).
4. On the IPC connector panel, connect the other end of the black NIM cable to the Stimulus Input connection port (Figure 14-8).

**Important:** Route the wire so that it does not interfere with operating room personnel.

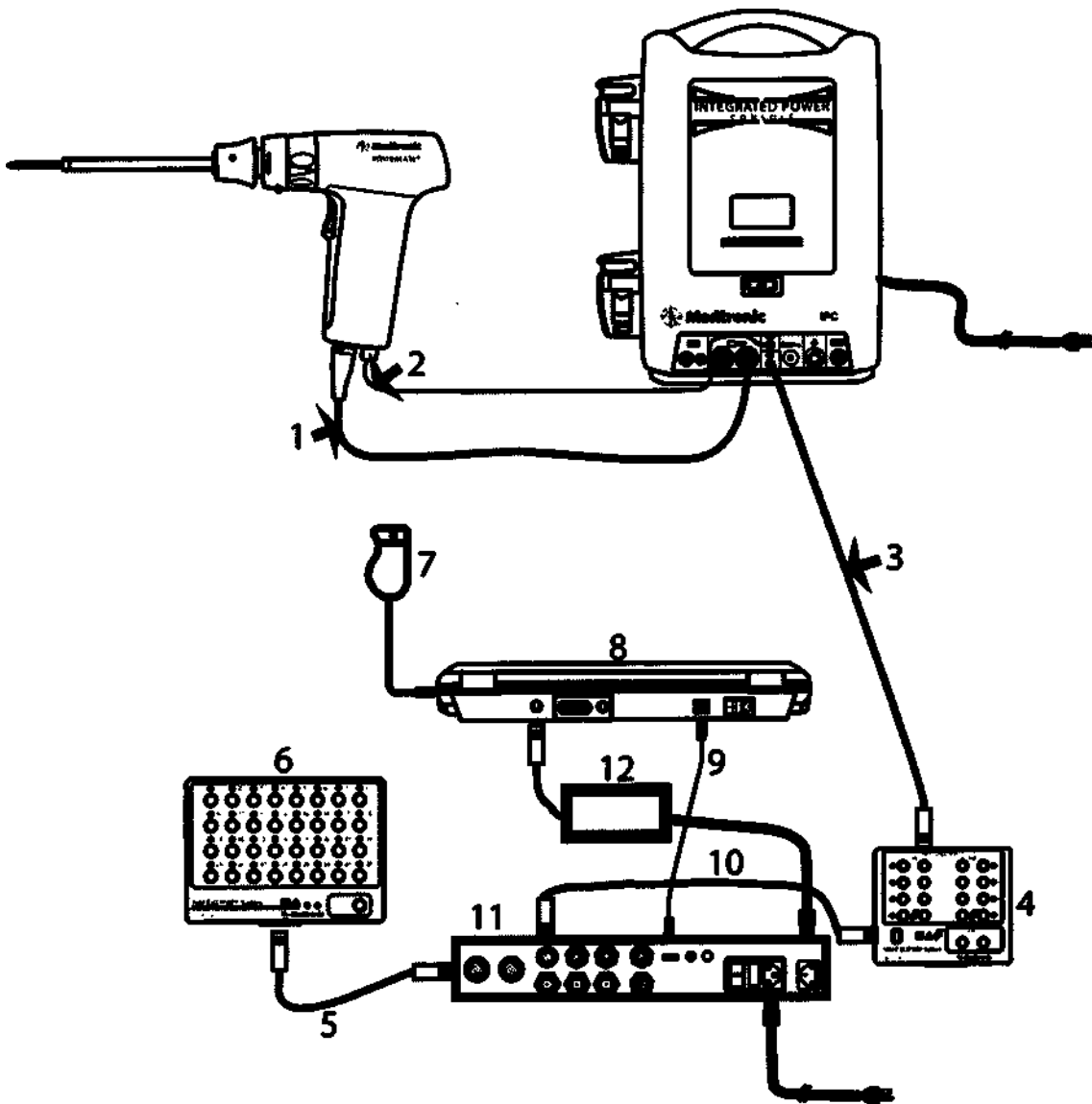
5. Connect one end of the blue NIM cable to the Stimulus Output IPC connector panel (Figure 14-8).

6. Connect the other end of the blue NIM cable to the NIM Stim Input on the POWEEASE driver.

**Important:** Route the wire so that it does not interfere with operating room personnel.



Figure 14-8. POWEREASE, IPC, NIM-ECLIPSE Connection



# NIM-ECLIPSE

- |                                        |                              |
|----------------------------------------|------------------------------|
| 1 Main POWEREASE Cable                 | 7 Mouse                      |
| 2 NIM Cable 2 (blue)                   | 8 Portable Notebook Computer |
| 3 NIM Cable (black)                    | 9 USB Interface Cable        |
| 4 Stimulator Extender                  | 10 Stimulator Cable          |
| 5 Digital Preamplifier Interface Cable | 11 Controller                |
| 6 Preamplifier Module                  | 12 Notebook Power Supply     |

# TROUBLESHOOTING AND ERROR CODES

For any troubleshooting items not corrected by the actions below, contact Customer Service.

## General System Troubleshooting

| Issue                                                         | Possible Cause                                          | Action                                                                                                                                              |
|---------------------------------------------------------------|---------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|
| Pump(s) does not run.                                         | Failed internal components.                             | Contact Customer Service                                                                                                                            |
| Little or no irrigation flow.                                 | Tubing Set improperly seated in pump.                   | Reposition tubing in pump, verify pump lid is fully closed with the fluid flow from left to right.                                                  |
|                                                               | Tubing is pinched or kinked.                            | Check tubing at side of pump, see Irrigation/Coolant Pumps.<br><br>Check remaining tubing for pinched or kinked areas, if necessary replace tubing. |
|                                                               | Tubing clamps are restricting flow.                     | Set tubing clamps in "open" position.                                                                                                               |
|                                                               | Irrigation flow rate setting low.                       | Adjust irrigation flow rate.                                                                                                                        |
|                                                               | Irrigator obstructed.                                   | Replace irrigator.                                                                                                                                  |
| Pump stall error.                                             | Tubing set improperly placed in pump.                   | Reposition tubing in pump, verify pump lid is fully closed with the fluid flow from left to right.                                                  |
|                                                               | Tubing is pinched or kinked.                            | Check tubing is not pinched or kinked on side of pump (see section on "Irrigation/Coolant Pumps").                                                  |
| Handpiece connected but console reads "Connect Handpiece."    | Moisture in cable conflicts with handpiece recognition. | Run a dry cycle when sterilizing.                                                                                                                   |
| Handpiece connected but console displays incorrect handpiece. |                                                         |                                                                                                                                                     |
| Console does not power up.                                    | Power cord not properly connected.                      | Connect power cord.                                                                                                                                 |
|                                                               | No power.                                               | Check power available (i.e. power strip is on, circuit breaker is closed, etc.).                                                                    |
|                                                               | Power Inlet Fuses blown.                                | Replace fuses with 5.00 A, 250 V, time delayed fuses (P/N 11270066 Fuse Kit 1898125 ).                                                              |
|                                                               | Failed internal components.                             | Contact Customer Service.                                                                                                                           |
| Power switch light is on but Touchscreen does not come on.    | Failed internal components.                             | Contact Customer Service.                                                                                                                           |
| Console does not power down.                                  | Power switch failure.                                   | Unplug power cord, Contact Customer Service.                                                                                                        |
| Touchscreen does not respond.                                 | Screen gasket displaced or failed internal components.  | Contact Customer Service.                                                                                                                           |
| Touchscreen does not work properly.                           | Touchscreen not calibrated.                             | Calibrate Touchscreen.                                                                                                                              |
| Console displays wrong handpiece / motor type.                | Console misidentified the handpiece / motor.            | Disconnect and reconnect the motor cable.<br>Turn console off then on.                                                                              |
|                                                               |                                                         | Change motor, motor cable, or console to isolate the problem.                                                                                       |
| Foot control unit buttons or pedal does not respond.          |                                                         | Run a dry cycle when sterilizing.                                                                                                                   |
|                                                               | Faulty Y-Splitter.                                      | Disconnect Y-Splitter and connect FCU to IPC directly.                                                                                              |
|                                                               | Incorrect use.                                          | Press and hold buttons for at least 1 second, wait for console confirmation beep.                                                                   |
|                                                               | Top button does not respond.                            | One (1) handpiece connected (top button has no function with 1 handpiece connected).                                                                |
|                                                               | Connector not fully inserted.                           | Disconnect and reconnect the FCU cable connector.<br>Try different FCU or console to isolate the problem.                                           |
| Handpiece fails to rotate.                                    | Internal component failure.                             | Contact Customer Service.                                                                                                                           |
|                                                               | Failed foot switch.                                     | Disconnect foot switch, use manual start/stop rocker switch on rear of console.                                                                     |
|                                                               | Failed handpiece motor or motor driver.                 | Contact Customer Service.                                                                                                                           |
|                                                               | Cables are not property connected.                      | Ensure handpiece cable is properly connected.                                                                                                       |
|                                                               | Cables are damaged.                                     | Check cables for cracks, splits, or bent connector pins.                                                                                            |

IPC TROUBLESHOOTING AND ERROR CODES

| Issue                               | Possible Cause                                                | Action                                                                                                                |
|-------------------------------------|---------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|
| Handpiece is too hot to touch/hold. | Blade, bur, and/or attachment transferring heat to handpiece. | Remove and reinstall or change blade, bur, and/or attachment. Ensure the part is properly seated before resuming use. |
|                                     | Inadequate irrigation and/or coolant.                         | Ensure adequate irrigation and/or coolant is present.                                                                 |

XOMED Blades or Burs

| Issue                                                                                      | Possible Cause                       | Action                                                                                                                                                                                                                                                                              |
|--------------------------------------------------------------------------------------------|--------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Appears to be damaged or defective.<br>Tool vibrates excessively, abnormal noise movement. | Damaged or defective.                | Remove and replace.                                                                                                                                                                                                                                                                 |
|                                                                                            | Tool is not firmly seated.           | Microdebridors, pull back locking collet and re-seat the tool.<br><br>Visao, unlock collar, check/re-seat notch, lock collar.                                                                                                                                                       |
| No suction.                                                                                | Blade opening is obstructed.         | Use stylet to clear blade.<br><br>Remove blade from surgical site and submerge the blade tip in sterile water with suction connected to the handpiece to evacuate the obstruction.                                                                                                  |
|                                                                                            | Tubing obstructed.                   | Remove and inspect suction tubing, and if obstructed, remove obstruction, reconnect tubing.                                                                                                                                                                                         |
| Tool is leaking irrigant.                                                                  | Tool not seated correctly in collet. | Check for proper tool insertion by pulling back locking collet, and re-seating tool.                                                                                                                                                                                                |
|                                                                                            | Low or no suction.                   | See Possible Cause, No Suction.                                                                                                                                                                                                                                                     |
| Tool wobbles in handpiece.                                                                 | Tool wobbles in handpiece.           | Reduce handpiece operating speeds.<br><br>Use tools that are rated for the console speed selected.<br><br>If necessary, use bur guard with burs medium, long and X-long.<br><br>Operate handpiece at 50 % of full speed for medium, long and X-long burs.<br><br>Select a new tool. |
|                                                                                            |                                      |                                                                                                                                                                                                                                                                                     |
| Tool vibrates excessively, abnormal noise movement.                                        | Tool is not firmly seated.           | Microdebridors, pull back locking collet and reseal the tool. If applicable for model, thumbwheel may be rotated slightly to check.<br>Visao, unlock collar, check/reseat notch, lock collar.                                                                                       |

Legend EHS, Legend EHS Stylus and Indigo Motors

| Issue                                           | Possible Cause                                       | Action                                                                                                                                                              |
|-------------------------------------------------|------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Motor is too hot to touch/hold.                 | Inadequate cool down period following sterilization. | Motor must be allowed to cool down following steam sterilization.                                                                                                   |
|                                                 | Attachment transferring heat to the motor.           | Switch attachments to determine whether the heat is being generated by the motor or the attachment.                                                                 |
|                                                 | Heavy side loading during dissection.                | Discontinue use and rest the motor by using it intermittently or wrap the motor with a moist sterile towel.                                                         |
|                                                 | Inadequate irrigation.                               | Ensure adequate irrigation to surgical site during bone dissection.                                                                                                 |
| Tool is difficult to remove from attachment.    | Aging of attachment.                                 | Contact Customer Service.                                                                                                                                           |
|                                                 | Use of reprocessed tools.                            |                                                                                                                                                                     |
|                                                 | Use of an unauthorized refurbisher.                  |                                                                                                                                                                     |
|                                                 | Improper cleaning.                                   | Clean the attachment thoroughly according to the instructions in this manual.<br><br>Change tool.                                                                   |
|                                                 |                                                      |                                                                                                                                                                     |
| Attachment will not seat properly on the motor. | Motor collet flats are not aligned.                  | Use the Legend motor wrench to rotate the flat closest to the motor case until its marker is aligned with the marker on the flat farthest away from the motor case. |
| Motor does not run.                             | Cables not properly connected.                       | Ensure motor and foot control cables are properly connected.                                                                                                        |
|                                                 | Speed setting is too low.                            | Ensure that a speed greater than 10000 rpm (EHS) or 3000 rpm (Stylus) is selected.                                                                                  |

| Issue                                                          | Possible Cause                                               | Action                                                                                                                       |
|----------------------------------------------------------------|--------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------|
| Motor with attachment rotates, but an abnormal noise is heard. | Attachment not properly installed and locked onto the motor. | Remove and reinstall the attachment and dissecting tool to ensure proper installation.                                       |
|                                                                | Internal failure of motor and/or console.                    | Change motor or console to isolate the problem.                                                                              |
|                                                                | Foot control not properly functioning.                       | Check for obstruction under the foot pedal.                                                                                  |
|                                                                | Cables damaged.                                              | Check cables for cracks, splits, or bent connector pins.                                                                     |
|                                                                | Bearings are worn.                                           | Change the attachment to isolate the location of the problem.                                                                |
|                                                                | Poor electrical connection.                                  | Check all connections from electrical source to console.<br><br>Ensure motor and foot control cables are properly connected. |
|                                                                | Internal failure of motor, console, or cable.                | Change motor, console, or cable to isolate the failing component.                                                            |
|                                                                | Attachment not properly installed.                           | Remove and reinstall the attachment and dissecting tool.                                                                     |

Stylus Touch Motors

| Issue               | Possible Cause                                            | Action                                                                                      |
|---------------------|-----------------------------------------------------------|---------------------------------------------------------------------------------------------|
| Motor does not run. | Finger switch not reaching maximum speed.                 | Check that the control lever ring is properly seated in one of the four possible positions. |
|                     | Finger switch not responding. Safety switch in safe mode. | Place switch in run mode.                                                                   |
|                     | Finger control damaged.                                   | Contact Customer Service.                                                                   |

Legend EHS, Legend EHS Stylus and Stylus Touch Attachments and Telescoping Tubes

| Issue                                                                         | Possible Cause                                                                                                                                                                                                                     | Action                                                                                                                                                                        |
|-------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Attachment or Telescoping Tube has uncomfortable temperature to touch/hold.   | Heat from worn attachment/tube bearings.                                                                                                                                                                                           | DO NOT use. Try another attachment/tube.<br><br>Telescoping Tubes are multi-use disposable. If problem is resolved with a new Telescoping Tube, discard the over heated tube. |
|                                                                               | Attachment/tube unclear due to improper cleaning procedures.                                                                                                                                                                       | Check that appropriate cleaning procedures are being followed.                                                                                                                |
|                                                                               | Heavy side loading during dissection.                                                                                                                                                                                              | Discontinue use and rest the attachment by using intermittently, try another identical attachment or wrap the attachment interface with a moist sterile towel.                |
| Attachment/telescoping tube is bent, loose, damaged or missing a component.   | Attachment mishandled, failed due to extended use or excessive force applied during use.                                                                                                                                           | DO NOT use. Dispose of telescoping tube. Telescoping Tubes are multi-use disposable. Contact Customer Service.                                                                |
| Color band on Attachment/Telescoping Tube fades or discolors.                 | Incorrect cleaning or sterilization method.                                                                                                                                                                                        | Use nomenclature markings on the attachment to match with a corresponding dissecting tool or Contact Customer Service.                                                        |
|                                                                               | Use of chlorine based or corrosive agents.                                                                                                                                                                                         |                                                                                                                                                                               |
|                                                                               | Aging.                                                                                                                                                                                                                             | Telescoping Tubes are multi-use disposable.                                                                                                                                   |
| Attachment has excess lubrication.                                            | Over lubrication during cleaning process.                                                                                                                                                                                          | Visually inspect and wipe excess lubrication.                                                                                                                                 |
| Footed attachment has a component missing from leg/foot area or foot is bent. | Attachment damaged by dissecting tool drilling out part or all of leg/foot area.                                                                                                                                                   | DO NOT use. Contact Customer Service.                                                                                                                                         |
|                                                                               | Bend caused by incorrect use.                                                                                                                                                                                                      |                                                                                                                                                                               |
| 16-MF contra-angle attachment is overheating.                                 | The contra-angle attachment operates by a set of internal gears to engage the drive shaft. It is normal for some heat to be generated approximately 2 cm from the distal end of the attachment and at the right of the angle head. | If heat continues or is excessive, Contact Customer Service.                                                                                                                  |

| Issue                                          | Possible Cause                            | Action                                              |
|------------------------------------------------|-------------------------------------------|-----------------------------------------------------|
| Smoke is generated by the attachment or motor. | Attachment is not in the locked position. | Make sure the attachment is in the locked position. |

Legend EHS, Legend EHS Stylus and Stylus Touch Tools

| Issue                                                          | Possible Cause                                                             | Action                                                                                                                                                                                         |
|----------------------------------------------------------------|----------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Tool wobbles.                                                  | A non-Legend tool is being used.                                           | Replace with a Legend tool.                                                                                                                                                                    |
|                                                                | Worn attachment or tube bearings.                                          | Try another attachment or tube to isolate the location of the problem.<br>If the attachment is failing, Contact Customer Service.<br>If the tube is failing, dispose of it and use a new tube. |
|                                                                | Attachment/tube and tool are not compatible.                               | Match color code on the tool packaging to the color code on the attachment/tube.                                                                                                               |
|                                                                | Motor is damaged.                                                          | Contact Customer Service.                                                                                                                                                                      |
|                                                                | Tool's size and geometry may contribute to wobbling at certain speeds.     | Adjust the speed by changing the pressure setting or foot/finger control. Do not use if wobbling persists.<br>Change tool.                                                                     |
| Tool vibrates excessively.                                     | Tool's size and geometry may create excessive vibration at certain speeds. | Adjust the speed.                                                                                                                                                                              |
|                                                                |                                                                            | Change tools.                                                                                                                                                                                  |
| Tool dull.                                                     | Extended use.                                                              | Change to a new tool.                                                                                                                                                                          |
|                                                                | Reprocessed tool was used.                                                 |                                                                                                                                                                                                |
|                                                                | Incorrect geometry.                                                        | Contact Customer Service.                                                                                                                                                                      |
| Tool will not seat properly in the motor or attachment collet. | Debris in collet of attachment or motor.                                   | Clean the attachment or motor thoroughly according to the instructions in this manual.<br>If cleaning does not correct the problem, Contact Customer Service.                                  |
|                                                                |                                                                            |                                                                                                                                                                                                |
|                                                                | A non-Legend tool is being used.                                           | Replace with a Legend tool.                                                                                                                                                                    |



ERROR CODES

| Code # | Title                                                                                                         | Cause                        | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|--------|---------------------------------------------------------------------------------------------------------------|------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1      | MCB does not report that it booted within 5 seconds of AI telling it to start and subsequent reattempts fail. | System Error.                | Power off. Wait 10 seconds. Power on. If error persists, call Customer Service.                                                                                                                                                                                                                                                                                                                                                                                     |
| 2      | NOT USED.                                                                                                     | NOT USED.                    | NOT USED                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 3      | UI-MCB Com Failure - Max resends exceeded.                                                                    | System Error.                | Power off. Wait 10 seconds. Power on. If error persists, call Customer Service.                                                                                                                                                                                                                                                                                                                                                                                     |
| 4      | UI-MCB Com Failure - Get answer failed.                                                                       |                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 5      | UI-MCB Com Failure - No status message received.                                                              |                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 6      | UI-MCB Com Failure - Serialization ID error.                                                                  |                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 7      | UI-MCB Com Failure - Timeout exception.                                                                       |                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 8      | UI-MCB Com Failure - Variable not recognized.                                                                 |                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 9      | Pump 1 stalled (no transitions on opto sensor).                                                               | Pump #1 stalled.             | Check tubing connection.                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 10     | Pump 2 stalled (no transitions on opto sensor).                                                               | Pump #2 stalled.             | Check tubing connection.                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 11     | Unrecognized/damaged handpiece plugged in on port 1 (first 12 pin).                                           | Handpiece.                   | Unplug handpiece and plug back in. If error persists, replace handpiece.                                                                                                                                                                                                                                                                                                                                                                                            |
| 12     | Unrecognized/damaged handpiece plugged in on port 2 (second 12 pin).                                          |                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 13     | Unrecognized/damaged handpiece plugged in on port 3 (4 pin).                                                  |                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 14     | Unrecognized/damaged handpiece plugged in on port 4 (Skeeter).                                                |                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 15     | Handpiece stalled.                                                                                            | Handpiece stalled.           | Check accessory.                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 16     | MCB motor overcurrent detected.                                                                               | Motor overcurrent.           | Unplug handpiece and plug back in. If error persists, replace handpiece.                                                                                                                                                                                                                                                                                                                                                                                            |
| 17     | Unrecognized/damaged multifunction foot pedal plugged in.                                                     | Foot Pedal Connection error. | <p>When using foot pedal only, unplug foot pedal and plug back in. If error persists, replace foot pedal or switch to manual control.</p> <p>When using Y-Splitter, disconnect foot pedal and Y-Splitter, then connect foot pedal directly to IPC. If after reconnecting foot pedal, the error goes away, replace Y-Splitter with another unit. If error persists, replace foot pedal and reconnect both Y-Splitter and foot pedal or switch to manual control.</p> |
| 18     | Damaged handpiece or finger lever base out of position.                                                       | Finger Control error.        | Stylus Touch - A finger control error has been detected. Check that the control lever ring is properly seated in one of the four possible positions. If error persists contact Customer Service. Press OK to use alternate control method. Triton/POWEEASE - Please check mode select switch to ensure a mode has been selected by rotating mechanism until it rests in a detent. If error persists, contact Customer Service.                                      |
| 19     | UI self test failure - culture (language) registry entry.                                                     | Self Test Failed.            | Power off. Wait 10 seconds. Power on. If error persists, call Customer Service.                                                                                                                                                                                                                                                                                                                                                                                     |
| 20     | UI self test failure - sector configuration registry entry.                                                   |                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 21     | UI self test failure - corrupt usage data file or unable to create usage data file.                           |                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 22     | NOT USED.                                                                                                     | NOT USED.                    | NOT USED.                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

IPC TROUBLESHOOTING AND ERROR CODES

|    |                                                     |                   |                                                                                 |
|----|-----------------------------------------------------|-------------------|---------------------------------------------------------------------------------|
| 23 | MCB non-specific self test failure.                 | Self Test Failed. | Power off. Wait 10 seconds. Power on. If error persists, call Customer Service. |
| 24 | MCB self test failure - port 1.                     |                   |                                                                                 |
| 25 | MCB self test failure - port 2.                     |                   |                                                                                 |
| 26 | MCB self test failure - port 3.                     |                   |                                                                                 |
| 27 | MCB self test failure - port 4.                     |                   |                                                                                 |
| 28 | MCB self test failure - bridge transitor 1 shorted. |                   |                                                                                 |
| 29 | MCB self test failure - bridge transitor 2 shorted. |                   |                                                                                 |
| 30 | MCB self test failure - bridge transitor 3 shorted. |                   |                                                                                 |
| 31 | MCB self test failure - bridge transitor 4 shorted. |                   |                                                                                 |
| 32 | MCB self test failure - bridge transitor 5 shorted. |                   |                                                                                 |
| 33 | MCB self test failure - bridge transitor 6 shorted. |                   |                                                                                 |
| 34 | MCB self test failure - A/D converter.              |                   |                                                                                 |
| 35 | MCB self test failure - motor error.                |                   |                                                                                 |
| 36 | MCB self test failure - 3.3 volt supply.            |                   |                                                                                 |
| 37 | MCB self test failure - 12 volt supply.             |                   |                                                                                 |
| 38 | MCB self test failure - 48 volt supply.             |                   |                                                                                 |
| 39 | MCB self test failure - FCU port.                   |                   |                                                                                 |

# CLEANING AND STERILIZATION

Reprocessing Instructions are subject to change. Refer to [manuals.medtronic.com](http://manuals.medtronic.com) for current Reprocessing Instructions.

## POST-OPERATIVE INSTRUCTIONS

### Disconnect Accessory Cable from Console

To disconnect non-silicone multi-pin cables from the console, push the cable toward the console and then pull out by the lock ring.

**Note:** Silicone insulated multi-pin and single pin cable connectors do not have a lock ring (1). Remove these types of cable connectors straight from the connector panel.

**Warning:** After disconnecting insulated connectors (see W79) from the console, connectors that have debris under the insulator must be



cleaned according to Cleaning and Sterilization instructions. If debris is still present after cleaning and sterilization, return for warranty servicing.

### Clean the Multifunction Foot Pedal

**Important:** If debris is present under the foot pedal's boot, return for warranty service.

DO NOT immerse or sterilize the foot pedal.

DO NOT use alcohol, other solvents or abrasive cleaners.

1. On the slip resistant foot pad ONLY, spray a neutral enzymatic detergent, pH 6.0-8.0, or a phenol based disinfectant, mixed according to manufacturer's instructions.
2. Leave the solution on the foot pad for approximately 10 minutes.
3. Dampen a cloth with a neutral enzymatic detergent, pH 6.0-8.0, or a phenol based disinfectant, mixed according to manufacturer's instructions.
4. Wipe the foot pedal with the damp cloth until visually clean.
5. Dry the unit with a clean, non-abrasive cloth.

### Clean the Y-Splitter

1. DO NOT immerse or sterilize the Y-Splitter.
2. DO NOT use alcohol, other solvents or abrasive cleaners.
3. Dampen a cloth with a neutral enzymatic detergent, pH 6.0 – 8.0, or a phenol based disinfectant, mixed according to manufacturer's instructions.
4. Wipe the Y-Splitter with a damp cloth until visually clean.
5. Dry the unit with a clean, non-abrasive cloth.



Medtronic

## Reprocessing Instructions

### Triton Electric High-Torque Handpiece

**Reprocessing Instructions**  
Cleaning and Sterilization instructions are subject to change.  
Up to date instructions are available online at **manuals.medtronic.com**.  
M000030A322 D

| Warnings and Precautions                                                      | <ul style="list-style-type: none"><li>Do not soak/submerge devices.</li><li>Do not use ultrasound to clean Triton High-Torque Handpiece.</li><li>Do not use chlorine based or corrosive cleaning agents such as bleach, lye, acetone, sodium hydroxide, formic acid, or solutions containing glutaraldehyde.</li><li>Allow an adequate cooling period after steam sterilization.</li><li>The use of a washer-disinfector for cleaning may cause a pre-mature degradation in performance.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                               |                   |                                         |              |                          |       |                    |                   |                                  |  |          |           |                |                |  |      |           |       |                                         |  |       |          |               |                |
|-------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|-------------------|-----------------------------------------|--------------|--------------------------|-------|--------------------|-------------------|----------------------------------|--|----------|-----------|----------------|----------------|--|------|-----------|-------|-----------------------------------------|--|-------|----------|---------------|----------------|
| Limitations                                                                   | Verify functionality prior to re-use, by connecting the handpiece to the IPC and pressing the trigger. Verify that the drive shaft rotates.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                               |                   |                                         |              |                          |       |                    |                   |                                  |  |          |           |                |                |  |      |           |       |                                         |  |       |          |               |                |
| Point of Use                                                                  | Disconnect device from the IPC. Remove and discard disposables.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                               |                   |                                         |              |                          |       |                    |                   |                                  |  |          |           |                |                |  |      |           |       |                                         |  |       |          |               |                |
| Containment and Transportation                                                | It is recommended that devices are reprocessed as soon as is practical following use.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                               |                   |                                         |              |                          |       |                    |                   |                                  |  |          |           |                |                |  |      |           |       |                                         |  |       |          |               |                |
| Preparation for Decontamination                                               | Disconnect device from the IPC. Remove and discard disposables.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                               |                   |                                         |              |                          |       |                    |                   |                                  |  |          |           |                |                |  |      |           |       |                                         |  |       |          |               |                |
| Cleaning: Automated (Do NOT use ultrasonic washer)                            | <p>Handpiece and Attachments</p> <ul style="list-style-type: none"><li>Prior to placing devices in the automated washer, manually rinse under tap water, until no visible soil is noticed.</li><li>Move any moveable parts back and forth to allow water to reach hard-to-rinse areas.</li><li>Transfer the devices into the washer for processing. Place the devices in the washer to facilitate drainage.</li><li>Verify that devices are visually clean after automated cleaning.</li></ul> <table><tr><th>Recommended Washer Cycle</th><th>Phase</th><th>Recirculation Time</th><th>Water Temperature</th><th>Detergent Type and Concentration</th></tr><tr><td></td><td>Pre-Wash</td><td>2 minutes</td><td>Cold tap water</td><td>Not applicable</td></tr><tr><td></td><td>Wash</td><td>5 minutes</td><td>66 °C</td><td>Neutral enzymatic detergent, pH 6.0-8.0</td></tr><tr><td></td><td>Rinse</td><td>1 minute</td><td>Hot tap water</td><td>Not applicable</td></tr></table>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                               |                   |                                         |              | Recommended Washer Cycle | Phase | Recirculation Time | Water Temperature | Detergent Type and Concentration |  | Pre-Wash | 2 minutes | Cold tap water | Not applicable |  | Wash | 5 minutes | 66 °C | Neutral enzymatic detergent, pH 6.0-8.0 |  | Rinse | 1 minute | Hot tap water | Not applicable |
| Recommended Washer Cycle                                                      | Phase                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Recirculation Time                                                                                                            | Water Temperature | Detergent Type and Concentration        |              |                          |       |                    |                   |                                  |  |          |           |                |                |  |      |           |       |                                         |  |       |          |               |                |
|                                                                               | Pre-Wash                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 2 minutes                                                                                                                     | Cold tap water    | Not applicable                          |              |                          |       |                    |                   |                                  |  |          |           |                |                |  |      |           |       |                                         |  |       |          |               |                |
|                                                                               | Wash                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 5 minutes                                                                                                                     | 66 °C             | Neutral enzymatic detergent, pH 6.0-8.0 |              |                          |       |                    |                   |                                  |  |          |           |                |                |  |      |           |       |                                         |  |       |          |               |                |
|                                                                               | Rinse                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 1 minute                                                                                                                      | Hot tap water     | Not applicable                          |              |                          |       |                    |                   |                                  |  |          |           |                |                |  |      |           |       |                                         |  |       |          |               |                |
| Cleaning: Manual                                                              | <p>Handpiece and Attachments</p> <ol style="list-style-type: none"><li>Rinse the entire device, including cable, thoroughly under running water.</li><li>Wipe all external surfaces of the device and cable with a cloth dampened with a neutral enzymatic detergent pH 6.0-8.0 (henceforth referred to as "cleaning solution").</li><li>Scrub the device thoroughly with a soft bristled brush that has been dampened with the cleaning solution, paying close attention to rough surfaces, crevices, and difficult to reach areas. Move any moveable parts, to allow the solution to reach all areas.</li><li>Clean central cannulation shaft of the handpiece with a cleaning brush (P/N 120-028-1 or equivalent) dampened with the cleaning solution.</li><li>Insert the cleaning brush into the cannulation from the front and make at least 6 passes with the brush. If residual soil is seen on the cleaning brush in between strokes, rinse it off in the cleaning solution.</li><li>Repeat the step above from the back side of the handpiece.</li><li>Flush approximately 30 mL of cleaning solution from a syringe into the central cannulation shaft.</li><li>Flush approximately 30 mL of cleaning solution from a syringe into the trigger and Forward / Reverse switch, while moving moveable parts.</li><li>Repeat the flushing in steps 7 and 8, using water instead of cleaning solution.</li><li>Rinse the entire device under running water. Move any moveable parts, to allow the water to reach all areas. Also, allow water to thoroughly clean the central cannulation shaft. Rinse until there is no visible evidence of soil or debris.</li><li>Dry the entire device with a towel.</li></ol> <p>Sagittal and Reciprocating Saw Attachments</p> <ol style="list-style-type: none"><li>Rinse the entire device thoroughly under running water.</li><li>Wipe all external surfaces of the device with a cloth dampened with a neutral enzymatic detergent pH 6.0-8.0 (henceforth referred to as "cleaning solution").</li><li>Scrub the device thoroughly with a soft bristled brush that has been dampened with the cleaning solution, paying close attention to rough surfaces, crevices, and difficult to reach areas. Ensure to brush the blade opening, the gaps/details between and around the blade jaws.</li><li>Dip the distal end of the saw body (up to approximately 1.25 inches from the distal end) into cleaning solution and agitate it for 10-15 seconds.</li><li>Flush approximately 30 mL of cleaning solution from a syringe into the blade opening and the gaps and details between and around two jaws. Repeat the flushing using water, instead of cleaning solution.</li><li>Repeat the previous step one more time.</li><li>Rinse the device under running water. Allow water to thoroughly rinse the gaps and details between and around blade jaws. Rinse until there is no visible evidence of soil or debris.</li><li>Dry the device with a towel.</li></ol> |                                                                                                                               |                   |                                         |              |                          |       |                    |                   |                                  |  |          |           |                |                |  |      |           |       |                                         |  |       |          |               |                |
| Disinfection                                                                  | Follow hospital procedures.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                               |                   |                                         |              |                          |       |                    |                   |                                  |  |          |           |                |                |  |      |           |       |                                         |  |       |          |               |                |
| Packaging                                                                     | For sterilization, place devices in instrument tray. Devices may be unwrapped, or wrapped with up to two layers of 1-ply polypropylene wrap                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                               |                   |                                         |              |                          |       |                    |                   |                                  |  |          |           |                |                |  |      |           |       |                                         |  |       |          |               |                |
| Sterilization (Temperatures are minimum required, times are minimum required) | Steam Sterilization                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                               |                   |                                         |              |                          |       |                    |                   |                                  |  |          |           |                |                |  |      |           |       |                                         |  |       |          |               |                |
|                                                                               | Cycle                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Gravity                                                                                                                       | Pre-Vac           | Pre-Vac (FR/WHO)                        | Pre-Vac (UK) |                          |       |                    |                   |                                  |  |          |           |                |                |  |      |           |       |                                         |  |       |          |               |                |
|                                                                               | Temperature                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 132 °C                                                                                                                        | 132 °C            | 134 °C                                  | 134 °C       |                          |       |                    |                   |                                  |  |          |           |                |                |  |      |           |       |                                         |  |       |          |               |                |
|                                                                               | Time                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 25 minutes                                                                                                                    | 4 minutes         | 18 minutes                              | 3 minutes    |                          |       |                    |                   |                                  |  |          |           |                |                |  |      |           |       |                                         |  |       |          |               |                |
|                                                                               | Drying                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 30 minutes                                                                                                                    | 20 minutes        | 30 minutes                              | 25 minutes   |                          |       |                    |                   |                                  |  |          |           |                |                |  |      |           |       |                                         |  |       |          |               |                |
|                                                                               | STERMAD                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Do not use low temperature hydrogen peroxide gas plasma sterilization due to lumen internal diameter and length restrictions. |                   |                                         |              |                          |       |                    |                   |                                  |  |          |           |                |                |  |      |           |       |                                         |  |       |          |               |                |
|                                                                               | STEMS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Not applicable.                                                                                                               |                   |                                         |              |                          |       |                    |                   |                                  |  |          |           |                |                |  |      |           |       |                                         |  |       |          |               |                |
|                                                                               | 100% ETO Sterilization Parameters                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                               |                   |                                         |              |                          |       |                    |                   |                                  |  |          |           |                |                |  |      |           |       |                                         |  |       |          |               |                |
|                                                                               | Preconditioning                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 51-59 °C, 70 ±5 % relative humidity, 30 min.                                                                                  |                   |                                         |              |                          |       |                    |                   |                                  |  |          |           |                |                |  |      |           |       |                                         |  |       |          |               |                |
|                                                                               | Sterilization                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Temperature                                                                                                                   | 51-59 °C          |                                         |              |                          |       |                    |                   |                                  |  |          |           |                |                |  |      |           |       |                                         |  |       |          |               |                |
| Relative Humidity                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 70 +/- 5 %                                                                                                                    |                   |                                         |              |                          |       |                    |                   |                                  |  |          |           |                |                |  |      |           |       |                                         |  |       |          |               |                |
| Ethylene oxide concentration                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 725 +/- 25 mg/L                                                                                                               |                   |                                         |              |                          |       |                    |                   |                                  |  |          |           |                |                |  |      |           |       |                                         |  |       |          |               |                |
| Gas exposure time (full-cycle)                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 4 hours                                                                                                                       |                   |                                         |              |                          |       |                    |                   |                                  |  |          |           |                |                |  |      |           |       |                                         |  |       |          |               |                |
| Aeration                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 51-59 °C, 18 hours                                                                                                            |                   |                                         |              |                          |       |                    |                   |                                  |  |          |           |                |                |  |      |           |       |                                         |  |       |          |               |                |
| Maintenance, Inspection and Testing                                           | <ul style="list-style-type: none"><li>Inspect devices for any damage before and after each use. If damage is observed, do not use the device until it is repaired.</li><li>Verify functionality prior to re-use.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                               |                   |                                         |              |                          |       |                    |                   |                                  |  |          |           |                |                |  |      |           |       |                                         |  |       |          |               |                |
| Storage                                                                       | Store in a clean, dry area.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                               |                   |                                         |              |                          |       |                    |                   |                                  |  |          |           |                |                |  |      |           |       |                                         |  |       |          |               |                |
| Additional Information                                                        | None                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                               |                   |                                         |              |                          |       |                    |                   |                                  |  |          |           |                |                |  |      |           |       |                                         |  |       |          |               |                |

**Note:** The Pre-Vac (FR/WHO) and Pre-Vac (UK) sterilization cycles are not considered by the United States Food and Drug Administration (US FDA) to be standard sterilization cycles. Users should only use sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization containers) that have been cleared by the US FDA for the selected sterilization cycle specifications (time and temperature).

**Note:** The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing the product for re-use. It remains the responsibility of the processor to ensure that the reprocessing is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

**Note:** All validations performed per current AAMI TIR12, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers. Medtronic recommends incineration of devices that have directly contacted patients suspected or confirmed with Transmissible Spongiform Encephalopathy (TSE)/ CJD diagnosis.



Medtronic

## Reprocessing Instructions Endo-Scrub 2 Finger Switch

### Reprocessing Instructions

Cleaning and Sterilization instructions are subject to change. Up to date instructions are available online at [manuals.medtronic.com](https://manuals.medtronic.com).  
68E4005 D

|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                      |           |              |
|-------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|-----------|--------------|
| Warnings and Precautions                                                      | Disconnect the finger switch from the Endo-Scrub 2 pump before cleaning.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                      |           |              |
| Limitations                                                                   | After cleaning and sterilization, verify functionality prior to re-use.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                      |           |              |
| Point of Use                                                                  | <ul style="list-style-type: none"><li>• This product is provided non-sterile and must be cleaned and sterilized before the first use and any reuse.</li><li>• After use, remove the finger switch from the sheath and disconnect the plug from the pump.</li><li>• Thoroughly rinse with water following use.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                      |           |              |
| Containment and Transportation                                                | It is recommended that devices are reprocessed as soon as is practical following use.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                      |           |              |
| Preparation for Decontamination                                               | Promptly and thoroughly rinse with deionized water after each use.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                      |           |              |
| Cleaning: Automated (Do NOT use ultrasonic washer)                            | Not validated                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                      |           |              |
| Cleaning: Manual                                                              | <ul style="list-style-type: none"><li>• Dip the finger switch housing in a diluted mixture of mild (pH 7.0 - 8.5) enzymatic detergent. (Follow detergent manufacturer's instructions for proper dilution.)</li><li>• Thoroughly clean the housing with a soft instrument brush to remove any blood and tissue.</li><li>• Rinse the housing thoroughly with tap water and wipe dry.</li><li>• Note: If wiping the cord dry, be sure to hold the cord and not the housing to avoid stressing or breaking the electrical connections located inside the housing.</li></ul>                                                                                                                                                                                                                                                                                                                                          |                                      |           |              |
| Disinfection                                                                  | Do not cold soak in glutaraldehyde, chlorine, or ammonium solutions, or dry heat sterilize, as damage to the instrument finish may occur.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                      |           |              |
| Packaging                                                                     | <ul style="list-style-type: none"><li>• A standard, sterilization wrap may be used. In the US, an FDA approved surgical wrap must be used. Ensure that the pack is large enough to contain the instrument without stressing the seals.</li><li>• In sets: Instruments may be loaded into dedicated instruments trays or general purpose sterilization trays. Ensure that cutting edges are protected. Wrap trays using appropriate method.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                      |           |              |
| Sterilization (Temperatures are minimum required, times are minimum required) | <ul style="list-style-type: none"><li>• Check the cleanliness and operation of the instrument. Clean again if debris is present and remove from use any damaged instrument. Close instruments with catches and racks on the first notch. Arrange the instruments in sterilization containers with perforations on the top and bottom, and on supports such as those used in microsurgery. Follow the appropriate cycle listed in the table below.</li><li>• The sterilization parameters given below should be used for devices that are fully disassembled when disassembly is possible. Use basic aseptic technique during post-sterilization assembly to maintain the sterility of the instruments.</li><li>• All steam cycles have been validated in the wrapped configuration and can be sterilized wrapped or unwrapped. These devices have only been validated for steam sterilization methods.</li></ul> |                                      |           |              |
|                                                                               | Steam Sterilization                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                      |           |              |
|                                                                               | Cycle                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Gravity                              | Pre-Vac   | Pre-vac (UK) |
|                                                                               | Temperature                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 132 °C                               | 132 °C    | 134 °C       |
|                                                                               | Time                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 10 minutes                           | 4 minutes | 3 minutes    |
|                                                                               | Drying                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 15-30 minutes, or until visibly dry. |           |              |
|                                                                               | STERRAD                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Not validated.                       |           |              |
|                                                                               | 100% EtO Sterilization Parameters                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Not validated.                       |           |              |
| Maintenance, Inspection and Testing                                           | <ul style="list-style-type: none"><li>• Inspect finger switch for any damage before and after each use. If damage is observed do not use the finger switch until it is repaired or replaced.</li><li>• After cleaning and sterilization, verify functionality prior to re-use.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                      |           |              |
| Storage                                                                       | Store in a clean, dry area.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                      |           |              |
| Additional Information                                                        | None                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                      |           |              |

**Note:** The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing the product for re-use. It remains the responsibility of the processor to ensure that the reprocessing is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

**Note:** All validations performed per current AAMI TIR12, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.

Medtronic recommends incineration of devices that have directly contacted patients suspected or confirmed with Transmissible Spongiform Encephalopathy (TSE)/ CJD diagnosis.





## Reprocessing Instructions Microdebridors

StraightShot M5, StraightShot M4, StraightShot Magnum II, StraightShot III or  
Midas Rex Spine Shaver

### Reprocessing Instructions

Cleaning and Sterilization instructions are subject to change. Up to date instructions are available online at [manuals.medtronic.com](http://manuals.medtronic.com).  
68E3282 F

#### Warnings and Precautions

- Disconnect the power before cleaning.
- Do not fully immerse, or ultrasonically clean, this instrument.
- Do not cold soak sterilize this instrument in glutaraldehyde. This will void the warranty.
- Do not use organic solvents to clean the bur chuck.
- For Microdebrider handpiece cleaning, cover handpiece cable connector end with one of the following handpiece cable caps:
  - Handpiece Cleaning Cap, Universal - catalog number 3318520.
  - Handpiece Cable Cap, Small - catalog number 3318510.
  - Use 3318520 for StraightShot M4, Spine Shaver, StraightShot Magnum II, and StraightShot III.
  - Using 3318520 is optional for StraightShot M5.
  - Use Catalog number 3318510 for other Microdebridors.
- After completion of the cleaning steps, remove Handpiece Cable Cap or other protective components installed prior to cleaning.

#### Limitations

After cleaning and sterilization, verify functionality prior to re-use.

#### Point of Use

- This product is provided non-sterile and must be cleaned and sterilized before the first use and any reuse.
- To remove occasional residual buildup on handpiece cable connector, use a soft brush and isopropyl alcohol.

#### Containment and Transportation

It is recommended that instruments are reprocessed as soon as is practical following use.

#### Preparation for Decontamination

Remove the bur from the handpiece, otherwise disassembly is not required.

#### Cleaning: Automated (Do NOT use ultrasonic washer)

- Remove instruments and equipment from any instrument trays.
  - Use alkaline (pH  $\leq 10.5$ ) or neutral pH detergent.
  - Do not immerse the handpiece.
- Auto Wash Pre-Cleaning Instructions - Neutral Detergent**
- Manually rinse the handpiece, cable, and tubing management clips with running tap water to remove all visible soil from the device. Using a soft bristled brush and a neutral detergent solution, gently and thoroughly clean the entire open lumen of the device. Actuate the collet while rinsing and turn the thumbwheel. Hold the handpiece with collet end down when rinsing and run stream of water through the suction port.
  - Place devices in the washer with the collet facing downward to facilitate drainage.

##### Auto wash Cycle - Neutral Enzymatic Detergent

| Phase         | Minimum Time | Temperature    | Detergent                                                                |
|---------------|--------------|----------------|--------------------------------------------------------------------------|
| Pre-wash 1    | 02:00        | Cold tap water | Not applicable                                                           |
| Enzyme wash   | 05:00        | < 50°C         | neutral pH enzymatic detergent, manufacturer's recommended concentration |
| Rinse 1       | 01:00        | Hot tap water  | Not applicable                                                           |
| Thermal rinse | 01:00        | 82°C minimum   | Not applicable                                                           |

Visually examine for cleanliness.

##### Auto Wash Pre-Cleaning Instructions - Alkaline Detergent

- Manually rinse the handpiece, cable, and tubing management clips with running tap water to remove all visible soil from the device. Using a soft bristled brush and a neutral detergent solution, gently and thoroughly brush the entire open lumen of the device. Actuate the collet while rinsing and turn the thumbwheel. Hold the handpiece with collet end down when rinsing and run stream of water through the suction port.
- Place devices in the washer with the collet facing downward to facilitate drainage.

##### Auto wash Cycle - Alkaline Detergent

| Phase         | Minimum Time | Temperature      | Detergent                         |
|---------------|--------------|------------------|-----------------------------------|
| Pre-wash 1    | 02:00        | Cold tap water   | Not applicable                    |
| Wash 1        | 05:00        | 66°C (set point) | alkaline detergent pH $\leq 10.5$ |
| Rinse 1       | 01:00        | Hot tap water    | Not applicable                    |
| Thermal rinse | 01:00        | 82°C minimum     | Not applicable                    |

Visually examine for cleanliness.

#### Cleaning: Manual

- Remove instruments and equipment from instrument tray.
  - Do not immerse the handpiece.
  - Wipe the handpiece and cable with neutral detergent applied to a clean, non-abrasive cloth.
  - Manually rinse the handpiece, cable, and tubing management clips with running tap water to remove all visible soil from the device. Hold the handpiece with collet end down when rinsing and run stream of water through the suction port.
  - Use an enzymatic detergent solution to loosen and remove collected tissues from the unit.
  - Using an enzymatic detergent solution and a soft cloth dampened with the detergent, wipe the motor and cable. Gently clean the handpiece, cable, and tubing management clips with a soft bristle brush wetted with the enzymatic detergent. Using a soft bristled brush, gently and thoroughly clean the entire open lumen of the device. Actuate the collet while cleaning and turn the thumbwheel. Use the brush to thoroughly clean the tubing management clips.
  - Manually rinse the handpiece, cable, and tubing management clips with running tap water to remove all visible soil from the device.
  - Hold the handpiece with collet end down when rinsing the lumen thoroughly.\*
- \* Additional Cleaning Instructions for XPS Straightshot M5/M4/Spine Shaver Microdebrider:
- During the normal cleaning cycle, run a gentle stream of warm water into the collet (front end), and into the lock lever of the Straightshot M4/Spine Shaver handpiece.
  - While warm water is running into the collet, rotate the mechanism for several revolutions (rotate the wheel); and while water is running into the lock lever, actuate the lock lever several times (locking and unlocking).
  - Shake excess water from the handpiece.
  - PRECAUTION: Ensure the use of a very gentle stream of warm clean water during this additional cleaning step.

#### Drying and Lubrication

- Dry the handpiece and cable with a lint-free towel. Make sure to dry off the electrical connection on the cable ends.
- Apply a small amount of silicone spray into the front-end collet and outside of the handpiece.
- Sterilize the handpiece immediately after cleaning.



Medtronic

## Reprocessing Instructions Microdebriders

StraightShot M5, StraightShot M4, StraightShot Magnum II, StraightShot III or  
Midas Rex Spine Shaver

**Reprocessing Instructions**  
Cleaning and Sterilization instructions are  
subject to change. Up to date instructions  
are available online at **manuals.**  
**medtronic.com.**  
68E3282 F

|                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                      |                                         |               |           |                  |              |
|----------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|---------------|-----------|------------------|--------------|
| Disinfection                                                                     | Do not cold soak in glutaraldehyde.                                                                                                                                                                                                                                                                                                                                                  |                                         |               |           |                  |              |
| Packaging                                                                        | <ul style="list-style-type: none"><li>A standard, sterilization wrap may be used. In the US, an FDA approved surgical wrap must be used. Ensure that the pack is large enough to contain the instrument without stressing the seals.</li><li>In sets: Instruments may be loaded into dedicated instrument trays. Wrap trays using appropriate method.</li></ul>                      |                                         |               |           |                  |              |
| Sterilization<br>(Temperatures are minimum required, times are minimum required) | The sterilization parameters given below should be used for devices that are fully disassembled when disassembly is possible. Use basic aseptic technique during post-sterilization assembly to maintain the sterility of the instrument(s). All steam sterilization cycles have been validated in the wrapped configuration and instruments can be sterilized wrapped or unwrapped. |                                         |               |           |                  |              |
|                                                                                  | Steam Sterilization                                                                                                                                                                                                                                                                                                                                                                  |                                         |               |           |                  |              |
|                                                                                  | Cycle                                                                                                                                                                                                                                                                                                                                                                                | Gravity*                                | Gravity       | Pre-Vac   | Pre-Vac (FR/WHO) | Pre-vac (UK) |
|                                                                                  | Temperature                                                                                                                                                                                                                                                                                                                                                                          | 121°C                                   | 132°C         | 132°C     | 134°C            | 134°C        |
|                                                                                  | Time                                                                                                                                                                                                                                                                                                                                                                                 | 40 minutes                              | 15 minutes    | 4 minutes | 18 minutes       | 3 minutes    |
|                                                                                  | Drying                                                                                                                                                                                                                                                                                                                                                                               | 25 minutes, or until visibly dry        |               |           |                  |              |
|                                                                                  | 100% EtO Sterilization Parameters (set points)                                                                                                                                                                                                                                                                                                                                       |                                         |               |           |                  |              |
|                                                                                  | Preconditioning                                                                                                                                                                                                                                                                                                                                                                      | 54°C, 60% relative humidity, 60 minutes |               |           |                  |              |
|                                                                                  | Sterilization                                                                                                                                                                                                                                                                                                                                                                        | Temperature                             |               |           | 54°C             |              |
|                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                      | Relative Humidity                       |               |           | 60%              |              |
|                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                      | Ethylene oxide concentration            |               |           | 725 mg/L         |              |
|                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                      | Gas exposure time (full-cycle)          |               |           | 120 minutes      |              |
| Aeration                                                                         |                                                                                                                                                                                                                                                                                                                                                                                      |                                         | 54°C, 8 hours |           |                  |              |
| Maintenance, Inspection and Testing                                              | <ul style="list-style-type: none"><li>Inspect components for any damage before and after each use. If damage is observed do not use the instrument until it is repaired.</li><li>After cleaning and sterilization, verify functionality prior to re-use.</li></ul>                                                                                                                   |                                         |               |           |                  |              |
| Storage                                                                          | It is extremely important that the handpiece be rapidly and completely vacuum dried before storage to prevent corrosion and residue deposits in the bearing and motor.                                                                                                                                                                                                               |                                         |               |           |                  |              |
| Additional Information                                                           | Increase temperatures higher than those stated when necessary to satisfy governmental or health care facility requirements so long as the temperature does not exceed 149° C. Heating above 149° C may damage the handpiece and will void the warranty.                                                                                                                              |                                         |               |           |                  |              |

\* This 40 minutes and 121°C gravity sterilization cycle is not considered by the United States Food and Drug Administration (USFDA) to be a standard sterilization cycle. Users should only use sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization containers) that have been cleared by the USFDA for the selected sterilization cycle specifications (40 minutes and 121°C).

**Note:** The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing the product for re-use. It remains the responsibility of the processor to ensure that the reprocessing is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

**Note:** All validations performed per current AAMI TIR12, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.

Medtronic recommends incineration of devices that have directly contacted patients suspected or confirmed with Transmissible Spongiform Encephalopathy (TSE)/ CJD diagnosis.



**Medtronic**

## Reprocessing Instructions

### Legend EHS and Legend EHS Stylus

#### Reprocessing Instructions

Cleaning and Sterilization instructions are subject to change. Up to date instructions are available online at [manuals.medtronic.com](https://manuals.medtronic.com).  
M000030A234 C

|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                               |                    |                    |                                         |
|-------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|--------------------|--------------------|-----------------------------------------|
| Warnings and Precautions                                                      | <ul style="list-style-type: none"><li>Do not soak/submerge devices.</li><li>Do not use ultrasound to clean devices.</li><li>Do not use chlorine based or corrosive cleaning agents such as bleach, lye, acetone, sodium hypochlorite/bleach, sodium hydroxide, formic acid, or solutions containing glutaraldehyde.</li><li>The use of a washer-disinfector for cleaning may cause a degradation in performance.</li><li>Allow an adequate cooling period after steam sterilization.</li></ul>           |                                                                                                                               |                    |                    |                                         |
| Limitations                                                                   | Verify functionality prior to re-use.                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                               |                    |                    |                                         |
| Point of Use                                                                  | Follow hospital procedures.                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                               |                    |                    |                                         |
| Containment and Transportation                                                | It is recommended that devices are reprocessed as soon as is practical following use.                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                               |                    |                    |                                         |
| Preparation for Decontamination                                               | Follow hospital procedures.                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                               |                    |                    |                                         |
| Cleaning: Automated (Do NOT use ultrasonic washer)                            | <ul style="list-style-type: none"><li>Review the washer-disinfector warning above, before using this cleaning method.</li><li>Remove devices from instrument trays before placing into washer baskets.</li><li>Orient devices following recommendations of the washer/disinfector manufacturers.</li></ul>                                                                                                                                                                                               |                                                                                                                               |                    |                    |                                         |
|                                                                               | Recommended Washer Cycle                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Phase                                                                                                                         | Recirculation Time | Water Temperature  | Detergent Type and Concentration        |
|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Pre-Wash                                                                                                                      | 2 minutes          | Cold tap water     | Not applicable                          |
|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Wash                                                                                                                          | 5 minutes          | 66 °C (set point)  | Neutral enzymatic detergent, pH 6.0-8.0 |
|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Final Rinse                                                                                                                   | 1 minute           | Hot tap water      | Not applicable                          |
| Cleaning: Manual                                                              | <ul style="list-style-type: none"><li>Wipe all external surfaces of the motor and cable with a cloth dampened with a neutral enzymatic detergent, pH 6.0-8.0.</li><li>Brush motor case and collet with a nylon brush dampened with a neutral enzymatic detergent.</li><li>Rinse motor thoroughly under running water, collet end pointed down. Dry collet and motor with towel.</li><li>Verify that devices are visually clean after manual cleaning.</li><li>Rinse thoroughly with tap water.</li></ul> |                                                                                                                               |                    |                    |                                         |
| Disinfection                                                                  | Follow hospital procedures.                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                               |                    |                    |                                         |
| Packaging                                                                     | For sterilization, place devices in instrument tray. Devices may be unwrapped, or wrapped with up to two layers of 1-ply polypropylene wrap.                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                               |                    |                    |                                         |
| Sterilization (Temperatures are minimum required, times are minimum required) | Steam Sterilization                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                               |                    |                    |                                         |
|                                                                               | Cycle                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Gravity                                                                                                                       | Pre-Vac            | Pre-Vac            |                                         |
|                                                                               | Temperature                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 132 °C                                                                                                                        | 132 °C             | 134 °C             |                                         |
|                                                                               | Time                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 25 minutes                                                                                                                    | 4 minutes          | 3 minutes          |                                         |
|                                                                               | Drying                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 15 minutes                                                                                                                    | 15 minutes         | 10 minutes         |                                         |
|                                                                               | STERRAD                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Do not use low temperature hydrogen peroxide gas plasma sterilization due to lumen internal diameter and length restrictions. |                    |                    |                                         |
|                                                                               | STERIS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Do not use liquid peracetic acid sterilization due to immersion procedure.                                                    |                    |                    |                                         |
|                                                                               | 100% EtO Sterilization Parameters                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                               |                    |                    |                                         |
|                                                                               | Preconditioning                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 51-59 °C, 70 ±5 % relative humidity, 30 min.                                                                                  |                    |                    |                                         |
|                                                                               | Sterilization                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Temperature                                                                                                                   |                    | 51-59 °C           |                                         |
|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Relative Humidity                                                                                                             |                    | 70 +/- 5 %         |                                         |
|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Ethylene oxide concentration                                                                                                  |                    | 725 +/- 25 mg/L    |                                         |
|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Gas exposure time (full-cycle)                                                                                                |                    | 4 hours            |                                         |
|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Aeration                                                                                                                      |                    | 51-59 °C, 18 hours |                                         |
| Maintenance, Inspection and Testing                                           | <ul style="list-style-type: none"><li>Inspect devices for any damage before and after each use. If damage is observed, do not use the device until it is repaired.</li><li>Verify functionality prior to re-use.</li></ul>                                                                                                                                                                                                                                                                               |                                                                                                                               |                    |                    |                                         |
| Storage                                                                       | Store with other sterile devices.                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                               |                    |                    |                                         |
| Additional Information                                                        | None                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                               |                    |                    |                                         |

**Note:** The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing the product for re-use. It remains the responsibility of the processor to ensure that the reprocessing is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

**Note:** All validations performed per current AAMI TIR12, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.

Medtronic recommends incineration of devices that have directly contacted patients suspected or confirmed with Transmissible Spongiform Encephalopathy (TSE)/ CJD diagnosis.



**Medtronic**

## Reprocessing Instructions Stylus Touch

### Reprocessing Instructions

Cleaning and Sterilization instructions are subject to change. Up to date instructions are available online at [manuals.medtronic.com](http://manuals.medtronic.com).  
68E4132 D

|                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                             |                           |                          |                                         |
|--------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|---------------------------|--------------------------|-----------------------------------------|
| <b>Warnings and Precautions</b>                                                      | <ul style="list-style-type: none"><li>• Do not soak/submerge devices.</li><li>• Do not use ultrasound to clean devices.</li><li>• Do not use chlorine based or corrosive cleaning agents such as bleach, lye, acetone, sodium hypochlorite/bleach, sodium hydroxide, formic acid, or solutions containing glutaraldehyde.</li><li>• The use of a washer-disinfector for cleaning may cause a degradation in performance.</li><li>• Allow an adequate cooling period after steam sterilization.</li></ul> |                                                                             |                           |                          |                                         |
| <b>Limitations</b>                                                                   | Verify functionality prior to re-use.                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                             |                           |                          |                                         |
| <b>Point of Use</b>                                                                  | This product is provided non-sterile and must be cleaned and sterilized before the first use and any reuse.                                                                                                                                                                                                                                                                                                                                                                                              |                                                                             |                           |                          |                                         |
| <b>Containment and Transportation</b>                                                | It is recommended that devices are reprocessed as soon as is practical following use.                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                             |                           |                          |                                         |
| <b>Preparation for Decontamination</b>                                               | Follow hospital procedures.                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                             |                           |                          |                                         |
| <b>Cleaning: Automated (Do NOT use ultrasonic washer)</b>                            | Review the washer-disinfector warning above, before using this cleaning method. Remove devices from instrument trays before placing into washer baskets. Orient devices following recommendations of the washer/disinfector manufacturers. Verify that devices are visually clean after automated cleaning.                                                                                                                                                                                              |                                                                             |                           |                          |                                         |
|                                                                                      | <b>Recommended Washer Cycle</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>Phase</b>                                                                | <b>Recirculation Time</b> | <b>Water Temperature</b> | <b>Detergent Type and Concentration</b> |
|                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>Pre-Wash</b>                                                             | 2 minutes                 | Cold tap water           | Not applicable                          |
|                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>Wash</b>                                                                 | 5 minutes                 | 66 °C (set point)        | Neutral enzymatic detergent, pH 6.0-8.0 |
|                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>Rinse</b>                                                                | 1 minute                  | Hot tap water            | Not applicable                          |
| <b>Cleaning: Manual</b>                                                              | <ul style="list-style-type: none"><li>• Wipe all external surfaces with a cloth dampened with a neutral enzymatic detergent, pH 6.0-8.0.</li><li>• Brush motor case and collet with a nylon brush dampened with a neutral enzymatic detergent.</li><li>• Rinse motor thoroughly under running water, collet end pointed down.</li><li>• Dry with towel.</li><li>• Verify that devices are visually clean after manual cleaning.</li></ul>                                                                |                                                                             |                           |                          |                                         |
| <b>Disinfection</b>                                                                  | Follow hospital procedures.                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                             |                           |                          |                                         |
| <b>Packaging</b>                                                                     | For sterilization, place devices in instrument tray. Devices may be unwrapped, or wrapped with up to two layers of 1-ply polypropylene wrap.                                                                                                                                                                                                                                                                                                                                                             |                                                                             |                           |                          |                                         |
| <b>Sterilization (Temperatures are minimum required, times are minimum required)</b> | <b>Steam Sterilization</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                             |                           |                          |                                         |
|                                                                                      | <b>Cycle</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>Pre-Vac</b>                                                              | <b>Gravity</b>            | <b>Pre-Vac</b>           | <b>Pre-Vac</b>                          |
|                                                                                      | <b>Temperature</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 132 °C                                                                      | 132 °C                    | 134 °C                   | 134 °C                                  |
|                                                                                      | <b>Time</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 4 minutes                                                                   | 25 minutes                | 3 minutes                | 18 minutes                              |
|                                                                                      | <b>Drying</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 15 minutes                                                                  | 15 minutes                | 10 minutes               | 20 minutes                              |
|                                                                                      | <b>STERRAD</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Not validated                                                               |                           |                          |                                         |
|                                                                                      | <b>100% EtO Sterilization Parameters</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                             |                           |                          |                                         |
|                                                                                      | <b>Preconditioning</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 55 °C, 70 % relative humidity, Vacuum Set Point: 1.3 psia, Time: 30 minutes |                           |                          |                                         |
|                                                                                      | <b>Sterilization</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>Temperature</b>                                                          |                           | 55 °C +/- 4° C           |                                         |
|                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>Relative Humidity</b>                                                    |                           | 70 +/- 5 %               |                                         |
|                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>Ethylene oxide concentration</b>                                         |                           | 725 +/- 25 mg/L          |                                         |
|                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>Gas exposure time (full-cycle)</b>                                       |                           | 4 hours                  |                                         |
|                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>Aeration</b>                                                             |                           | 55 °C +/- 4 °C, 12 hours |                                         |
| <b>Maintenance, Inspection and Testing</b>                                           | <ul style="list-style-type: none"><li>• Inspect devices for any damage before and after each use. If damage is observed, do not use the device until it is repaired.</li><li>• After cleaning and sterilization, verify functionality prior to re-use.</li></ul>                                                                                                                                                                                                                                         |                                                                             |                           |                          |                                         |
| <b>Storage</b>                                                                       | Store with other sterile devices.                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                             |                           |                          |                                         |
| <b>Additional Information</b>                                                        | None                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                             |                           |                          |                                         |

**Note:** The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing the product for re-use. It remains the responsibility of the processor to ensure that the reprocessing is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

**Note:** All validations performed per current AAMI TIR12, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.

Medtronic recommends incineration of devices that have directly contacted patients suspected or confirmed with Transmissible Spongiform Encephalopathy (TSE)/ CJD diagnosis.





**Medtronic**

## Reprocessing Instructions Legend Attachments/Tubes

### Reprocessing Instructions

Cleaning and Sterilization instructions are subject to change. Up to date instructions are available online at [manuals.medtronic.com](https://manuals.medtronic.com).  
M000030A235 D

|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                               |                    |                   |                                         |
|-------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|--------------------|-------------------|-----------------------------------------|
| Warnings and Precautions                                                      | <ul style="list-style-type: none"><li>Do not soak/submerge devices.</li><li>Do not use ultrasound to clean devices.</li><li>Do not use chlorine based or corrosive cleaning agents such as bleach, lye, acetone, sodium hypochlorite/bleach, sodium hydroxide, formic acid, or solutions containing glutaraldehyde.</li><li>The use of a washer-disinfector for cleaning may cause a pre-mature degradation in performance.</li><li>Allow an adequate cooling period after steam sterilization.</li><li>Use ONLY nylon cleaning brushes. Non-nylon cleaning brushes leave residue that may prevent the tool from being secured properly in the handpiece.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                               |                    |                   |                                         |
| Limitations                                                                   | Verify functionality prior to re-use.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                               |                    |                   |                                         |
| Point of Use                                                                  | Follow hospital procedures.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                               |                    |                   |                                         |
| Containment and Transportation                                                | It is recommended that devices are reprocessed as soon as is practical following use.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                               |                    |                   |                                         |
| Preparation for Decontamination                                               | Follow hospital procedures.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                               |                    |                   |                                         |
| Cleaning: Automated (Do NOT use ultrasonic washer)                            | <ul style="list-style-type: none"><li>Review the washer-disinfector warning above, before using this cleaning method.</li><li>Manually rinse attachments/tubes under tap water, until no visible soil is noticed, before placing them into the automatic washer.</li><li>Remove devices from instrument trays before placing into washer baskets.</li><li>Orient devices following recommendations of the washer/disinfector manufacturers.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                               |                    |                   |                                         |
|                                                                               | Recommended Washer Cycle                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Phase                                                                                                                         | Recirculation Time | Water Temperature | Detergent Type and Concentration        |
|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Pre-Wash                                                                                                                      | 2 minutes          | Cold tap water    | Not applicable                          |
|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Wash                                                                                                                          | 5 minutes          | 66 °C (set point) | Neutral enzymatic detergent, pH 6.0-8.0 |
|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Rinse                                                                                                                         | 1 minute           | Hot tap water     | Not applicable                          |
| Cleaning: Manual                                                              | <ol style="list-style-type: none"><li>Wipe all attachments and telescoping tubes with a cloth, dampened with a surgical instrument cleaning solution.</li><li>Immerse the head of Contra-Angle attachments in surgical instrument cleaning solution and run the motor for 1 minute.</li><li>Other attachments and tubes may be mechanically agitated in cleaning solution, but not soaked or immersed.</li><li>A nylon brush dampened with a surgical instrument cleaning solution may be used to clean the external surfaces and internal connecting surfaces of the attachments and tubes.</li><li>Straight attachments, footed attachments and telescoping straight tubes have special cleaning brushes sized to the attachment's or telescoping tube's internal diameter. Push the brush wet with surgical instrument cleaning solution through the attachment or telescoping tube from rear to front to loosen and remove debris trapped inside.</li><li>Move any moveable parts back and forth to allow solution to thoroughly clean attachment, for example, sleeve on footed attachment, perforator attachment.</li><li>Rinse thoroughly with tap water.</li></ol> |                                                                                                                               |                    |                   |                                         |
| Drying and Lubrication                                                        | <ol style="list-style-type: none"><li>Thoroughly dry attachments. An air gun may be used to blow moisture out from rear to front of attachment.</li></ol> <p><b>Note:</b> Medtronic no longer recommends using the Legend attachment cleaning nozzle (PA120), as this may cause some attachments to overheat.</p> <ol style="list-style-type: none"><li>Using an aerosol spray lubricant (such as Pana Spray), perform the following steps to lubricate attachments:<ul style="list-style-type: none"><li>Holding the can approximately 10-15 cm (3-6 inches) away from the attachment, spray all components that move, rotate, or slide with three quick squirts.</li><li>Articulate movable components to ensure proper lubrication.</li><li>Remove excess lubricant with a clean cloth.</li></ul></li></ol>                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                               |                    |                   |                                         |
| Disinfection                                                                  | Follow hospital procedures.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                               |                    |                   |                                         |
| Packaging                                                                     | For sterilization, place devices in instrument tray. Devices may be unwrapped, or wrapped with up to two layers of 1-ply polypropylene wrap.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                               |                    |                   |                                         |
| Sterilization (Temperatures are minimum required, times are minimum required) | Steam Sterilization                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                               |                    |                   |                                         |
|                                                                               | Cycle                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Gravity                                                                                                                       | Pre-Vac            | Pre-Vac (FR/WHO)  | Pre-vac (UK)                            |
|                                                                               | Temperature                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 132 °C                                                                                                                        | 132 °C             | 134 °C            | 134 °C                                  |
|                                                                               | Time                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 25 minutes                                                                                                                    | 4 minutes          | 18 minutes        | 3 minutes                               |
|                                                                               | Drying                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 15 minutes                                                                                                                    | 15 minutes         | 20 minutes        | 10 minutes                              |
|                                                                               | STERAD                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Do not use low temperature hydrogen peroxide gas plasma sterilization due to lumen internal diameter and length restrictions. |                    |                   |                                         |
|                                                                               | STERIS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Do not use liquid peracetic acid sterilization due to immersion procedure.                                                    |                    |                   |                                         |
|                                                                               | 100% EtO Sterilization Parameters                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                               |                    |                   |                                         |
|                                                                               | Preconditioning                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 51-59 °C, 70 ±5% relative humidity, 30 min                                                                                    |                    |                   |                                         |
|                                                                               | Sterilization                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Temperature                                                                                                                   | 51-59 °C           |                   |                                         |
|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Relative Humidity                                                                                                             | 70 ±5 %            |                   |                                         |
|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Ethylene oxide concentration                                                                                                  | 725 +/- 25 mg/L    |                   |                                         |
|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Gas exposure time (full-cycle)                                                                                                | 4 hours            |                   |                                         |
|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Aeration                                                                                                                      | 51-59 °C, 18 hours |                   |                                         |
| Maintenance, Inspection and Testing                                           | <ul style="list-style-type: none"><li>Inspect devices for any damage before and after each use. If damage is observed, do not use the device until it is repaired.</li><li>Verify functionality prior to re-use.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                               |                    |                   |                                         |
| Storage                                                                       | Store with other sterile devices.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                               |                    |                   |                                         |
| Additional Information                                                        | None                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                               |                    |                   |                                         |

**Note:** The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing the product for re-use. It remains the responsibility of the processor to ensure that the reprocessing is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

**Note:** All validations performed per current AAMI TIR12, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.

Medtronic recommends incineration of devices that have directly contacted patients suspected or confirmed with Transmissible Spongiform Encephalopathy (TSE)/ CJD diagnosis.



**Medtronic**

## Reprocessing Instructions for Reusable Instruments Skeeter Oto-Flex Burs

### Reprocessing Instructions

Cleaning and Sterilization instructions are subject to change. Up to date instructions are available online at [manuals.medtronic.com](http://manuals.medtronic.com).  
68E3968 F

|                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                 |                          |                                |                         |
|--------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|--------------------------|--------------------------------|-------------------------|
| <b>Warnings and Precautions</b>                                                      | <ul style="list-style-type: none"><li>Remove bur from handpiece before reprocessing of bur and/or handpiece.</li><li>Before sterilization, carefully inspect the bur tips.</li><li>Burs exhibiting the following conditions should be replaced:<ul style="list-style-type: none"><li>nicks on cutting surfaces</li><li>noticeable wear on PTFE bearings</li><li>severe bends or crimps on bur shaft</li></ul></li><li>Cold soak in glutaraldehyde, chlorine, or ammonium solutions, or dry heat sterilization is not recommended as damage to the bur may occur.</li><li>Store burs in a clean, dry area.</li></ul>                                                                                                                                                                                                        |                                                                                 |                          |                                |                         |
| <b>Limitations</b>                                                                   | Discard any burs that shows signs of damage or wear.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                 |                          |                                |                         |
| <b>Point of Use</b>                                                                  | <ul style="list-style-type: none"><li>Remove burs from the handpiece before cleaning and sterilizing.</li><li>Promptly and thoroughly rinse instruments with deionized water after each use.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                 |                          |                                |                         |
| <b>Containment and Transportation</b>                                                | It is recommended that instruments are reprocessed as soon as is practical following use.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                 |                          |                                |                         |
| <b>Preparation for Decontamination</b>                                               | Promptly and thoroughly rinse instruments with deionized water after each use.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                 |                          |                                |                         |
| <b>Cleaning: Automated</b>                                                           | <ul style="list-style-type: none"><li>Remove burs from any instrument trays before placing into washer baskets.</li><li>Orient burs following recommendations of washer/disinfector manufacturers.</li><li>Use alkaline or neutral pH detergent recommended by washer/disinfector or detergent manufacturers.</li><li>Following cleaning, apply a light coating of silicone spray or Pana Spray in the following manner: grasp the PTFE bearing and rotate the bur to assure application of the spray inside the bearing.</li></ul>                                                                                                                                                                                                                                                                                        |                                                                                 |                          |                                |                         |
|                                                                                      | <b>Phase</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Recirculation Time</b>                                                       | <b>Water Temperature</b> | <b>Detergent Type</b>          |                         |
|                                                                                      | Pre-wash 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 3 minutes                                                                       | Cold tap water           | Not applicable                 |                         |
|                                                                                      | Enzyme Wash                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 5 minutes                                                                       | Hot tap water            | Neutral pH enzymatic detergent |                         |
|                                                                                      | Wash 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 5 minutes                                                                       | 66 °C set point          | Neutral pH detergent           |                         |
|                                                                                      | Rinse 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 3 minutes                                                                       | Hot tap water            | Not applicable                 |                         |
| <b>Cleaning: Manual</b> <ul style="list-style-type: none"><li></li></ul>             | <ul style="list-style-type: none"><li>Soak in lukewarm (less than 43 °C), mild (pH 7.0 - 8.5), enzymatic detergent and deionized water for a minimum of 2 minutes.</li><li>Then clean ultrasonically in lukewarm solution of mild detergent (less than 43 °C; pH 7.0 - 8.5) and deionized water for at least 10 minutes.</li><li>Rinse thoroughly with deionized water and wipe dry.</li><li>Following cleaning, apply a light coating of silicone spray or Pana Spray in the following manner: grasp the PTFE bearing and rotate the bur to assure application of the spray inside the bearing.</li></ul> <p><b>Note:</b> When using an ultrasonic cleaner or a spray washing machine, follow the manufacturer's recommendations, particularly with regard to articulated instruments and positioning of instruments.</p> |                                                                                 |                          |                                |                         |
| <b>Disinfection</b>                                                                  | Do not cold soak in glutaraldehyde.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                 |                          |                                |                         |
| <b>Packaging</b>                                                                     | <ul style="list-style-type: none"><li>A standard sterilization wrap may be used. In the US, an FDA approved surgical wrap is required. Ensure that the pack is large enough to contain the instrument without stressing the seals.</li><li>In sets: Instruments may be loaded into dedicated Medtronic Xomed instrument trays. Ensure that cutting edges are protected. Wrap trays using appropriate method.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                 |                          |                                |                         |
| <b>Sterilization (Temperatures are minimum required; times are minimum required)</b> | <ul style="list-style-type: none"><li>The sterilization parameters given below should be used for devices that are fully disassembled when disassembly is possible. Use basic aseptic technique during post-sterilization assembly to maintain the sterility of the instrument(s).</li><li>All steam cycles have been validated in the wrapped configuration and can be sterilized wrapped or unwrapped</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                 |                          |                                |                         |
|                                                                                      | <b>Cycle</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <b>Gravity</b>                                                                  | <b>Gravity</b>           | <b>Pre-Vac</b>                 | <b>Pre-Vac (FR/WHO)</b> |
|                                                                                      | <b>Temperature</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 121 °C                                                                          | 132 °C                   | 132 °C                         | 134 °C                  |
|                                                                                      | <b>Time</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 30 minutes                                                                      | 10 minutes               | 4 minutes                      | 18 minutes              |
|                                                                                      | <b>Drying</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 15 minutes, or until visibly dry                                                |                          |                                |                         |
|                                                                                      | <b>STERAD</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Not validated.                                                                  |                          |                                |                         |
|                                                                                      | <b>100 % EtO Sterilization Parameters</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                 |                          |                                |                         |
|                                                                                      | <b>Conditioning in Chamber</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                 |                          | <b>Sterilization</b>           |                         |
|                                                                                      | Temperature                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 54 +/- 2 °C                                                                     |                          | Temperature                    | 54 +/- 2 °C             |
|                                                                                      | Relative Humidity                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 60 +/- 5 %                                                                      |                          | Relative Humidity              | 60 +/- 5 %              |
|                                                                                      | Vacuum Set Point                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 1.3 psia                                                                        |                          | Ethylene Oxide Concentration   | 600 +/- 25 mg/L         |
|                                                                                      | Preconditioning Time                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 30 minutes                                                                      |                          | Gas Exposure Time (full cycle) | 120 minutes             |
|                                                                                      | <b>Aeration</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 8 hours heated aeration at 48-52 °C or 24 hours aeration at ambient temperature |                          |                                |                         |
| <b>Maintenance, Inspection and Testing</b>                                           | Discard any burs that shows signs of damage or wear.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                 |                          |                                |                         |
| <b>Storage</b>                                                                       | Store burs in a clean, dry area.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                 |                          |                                |                         |
| <b>Additional Information</b>                                                        | None                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                 |                          |                                |                         |

**Note:** The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing the product for re-use. It remains the responsibility of the processor to ensure that the reprocessing is performed using validated equipment to achieve the desired result. This normally requires validation and routine monitoring of the process.

Some devices have specific assembly instructions. In this case, refer to the assembly insert provided with the device for additional instructions.

All validations performed per current AAMI TIR12, "Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers."

Medtronic recommends incineration of devices that have directly contacted patients suspected or confirmed with Transmissible Spongiform Encephalopathy (TSE)/ CJD diagnosis.

|                                                                                                   |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                 |                                                                                                                                                                                                                                    |                                |                         |                     |
|---------------------------------------------------------------------------------------------------|--|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------|-------------------------|---------------------|
|  <b>Medtronic</b> |  | <b>Reprocessing Instructions</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                 | <b>Reprocessing Instructions</b><br>Cleaning and Sterilization instructions are subject to change. Up to date instructions are available online at <a href="http://manuals.medtronic.com">manuals.medtronic.com</a> .<br>68E3969 G |                                |                         |                     |
| <b>Warnings and Precautions</b>                                                                   |  | <ul style="list-style-type: none"><li>• Disconnect the power before cleaning.</li><li>• Do not fully immerse, or ultrasonically clean, this instrument.</li><li>• Do not use any cleaning instruments in the cannulated shaft of the handpiece.</li><li>• Do not cold soak sterilize this instrument in glutaraldehyde. This will void the warranty.</li><li>• Do not use organic solvents to clean the bur chuck.</li></ul>                                                                                                                                                                                                                                                   |                                                                                 |                                                                                                                                                                                                                                    |                                |                         |                     |
| <b>Limitations</b>                                                                                |  | After cleaning and sterilization, verify functionality prior to re-use.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                 |                                                                                                                                                                                                                                    |                                |                         |                     |
| <b>Point of Use</b>                                                                               |  | <ul style="list-style-type: none"><li>• This product is provided non-sterile and must be cleaned and sterilized before the first use and any reuse.</li><li>• To remove occasional residual buildup on handpiece cable connector, use a soft brush and isopropyl alcohol.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                 |                                                                                                                                                                                                                                    |                                |                         |                     |
| <b>Containment and Transportation</b>                                                             |  | It is recommended that instruments are reprocessed as soon as is practical following use.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                 |                                                                                                                                                                                                                                    |                                |                         |                     |
| <b>Preparation for Decontamination</b>                                                            |  | Disassembly not required, other than removal of the bur.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                 |                                                                                                                                                                                                                                    |                                |                         |                     |
| <b>Cleaning: Automated (Do NOT use ultrasonic washer)</b>                                         |  | <ul style="list-style-type: none"><li>• Remove instruments and equipment from any sterilization trays before placing into washer baskets.</li><li>• Orient devices following recommendations of washer/disinfector manufacturers.</li><li>• Use alkaline or neutral pH detergent recommended by washer/disinfector or detergent manufacturers.</li><li>• These products have been validated for effective cleaning using an automatic washer/disinfector cycle consisting of a minimum 44 minutes total time, including a pre-wash, main wash &amp; rinse, and thermal rinse. The thermal rinse shall be at least 10 minutes long at a minimum temperature of 60 °C.</li></ul> |                                                                                 |                                                                                                                                                                                                                                    |                                |                         |                     |
| <b>Cleaning: Manual</b>                                                                           |  | <ul style="list-style-type: none"><li>• Carefully clean with an enzymatic detergent. Do not fully immerse.</li><li>• The cannulated needle nose should be cleaned by immersing in the detergent solution up to the level of the Bur Release button. Do not use any cleaning instruments in the cannulated shaft of the handpiece.</li><li>• Rinse by immersing the distal end of the handpiece (up to the Bur Release button) in distilled water, using a gentle swirling motion to flush away residual cleaning solution.</li></ul>                                                                                                                                           |                                                                                 |                                                                                                                                                                                                                                    |                                |                         |                     |
| <b>Drying and Lubrication</b>                                                                     |  | <ul style="list-style-type: none"><li>• Avoid water accumulation in the motor housing by shaking excess water out with a downward motion.</li><li>• Silicone spray or Pana Spray should be sprayed into the cannulated shaft of the handpiece prior to sterilization. Apply silicone spray or Pana Spray until surplus lubricant is noted on the outside of the Bur Release Button. Wipe away excess lubricant from the handpiece. Following this procedure will ensure that the bur release mechanism is well lubricated for proper functioning.</li><li>• Sterilize the handpieces immediately after cleaning.</li></ul>                                                     |                                                                                 |                                                                                                                                                                                                                                    |                                |                         |                     |
| <b>Disinfection</b>                                                                               |  | Do not cold soak in glutaraldehyde.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                 |                                                                                                                                                                                                                                    |                                |                         |                     |
| <b>Packaging</b>                                                                                  |  | <ul style="list-style-type: none"><li>• A standard, sterilization wrap may be used. In the US, an FDA approved surgical wrap must be used. Ensure that the pack is large enough to contain the instrument without stressing the seals.</li><li>• In sets: Instruments may be loaded into dedicated instrument trays or general purpose sterilization trays. Wrap trays using appropriate method.</li></ul>                                                                                                                                                                                                                                                                     |                                                                                 |                                                                                                                                                                                                                                    |                                |                         |                     |
| <b>Sterilization (Temperatures are minimum required, times are minimum required)</b>              |  | <ul style="list-style-type: none"><li>• The sterilization parameters given below should be used for devices that are fully disassembled when disassembly is possible. Use basic aseptic technique during post-sterilization assembly to maintain the sterility of the instrument(s).</li><li>• All steam sterilization cycles have been validated in the wrapped configuration and instruments can be sterilized wrapped or unwrapped.</li></ul>                                                                                                                                                                                                                               |                                                                                 |                                                                                                                                                                                                                                    |                                |                         |                     |
|                                                                                                   |  | <b>Steam Sterilization</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                 |                                                                                                                                                                                                                                    |                                |                         |                     |
|                                                                                                   |  | <b>Cycle</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <b>Gravity</b>                                                                  | <b>Gravity</b>                                                                                                                                                                                                                     | <b>Pre-vac</b>                 | <b>Pre-vac (FR/WHO)</b> | <b>Pre-vac (UK)</b> |
|                                                                                                   |  | <b>Temperature</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 121 °C                                                                          | 132 °C                                                                                                                                                                                                                             | 132 °C                         | 134 °C                  | 134 °C              |
|                                                                                                   |  | <b>Time</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 30 minutes                                                                      | 10 minutes                                                                                                                                                                                                                         | 4 minutes                      | 18 minutes              | 3 minutes           |
|                                                                                                   |  | <b>Drying</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 15 minutes, or until visibly dry.                                               |                                                                                                                                                                                                                                    |                                |                         |                     |
|                                                                                                   |  | <b>STERRAD</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 100S Compatible                                                                 |                                                                                                                                                                                                                                    |                                |                         |                     |
|                                                                                                   |  | <b>100% EtO Sterilization Parameters</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                 |                                                                                                                                                                                                                                    |                                |                         |                     |
|                                                                                                   |  | <b>Conditioning in Chamber</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                 |                                                                                                                                                                                                                                    | <b>Sterilization</b>           |                         |                     |
|                                                                                                   |  | Temperature                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 54 +/- 2 °C                                                                     |                                                                                                                                                                                                                                    | Temperature                    | 54 +/- 2 °C             |                     |
|                                                                                                   |  | Relative Humidity                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 60 +/- 5 %                                                                      |                                                                                                                                                                                                                                    | Relative Humidity              | 60 +/- 5 %              |                     |
|                                                                                                   |  | Vacuum Set Point                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 1.3 psia                                                                        |                                                                                                                                                                                                                                    | Ethylene Oxide Concentration   | 600 +/- 25 mg/L         |                     |
|                                                                                                   |  | Preconditioning Time                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 30 minutes                                                                      |                                                                                                                                                                                                                                    | Gas Exposure Time (full cycle) | 120 minutes             |                     |
|                                                                                                   |  | <b>Aeration</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 8 hours heated aeration at 48-52 °C or 24 hours aeration at ambient temperature |                                                                                                                                                                                                                                    |                                |                         |                     |
| <b>Maintenance, Inspection and Testing</b>                                                        |  | <ul style="list-style-type: none"><li>• Inspect components for any damage before and after each use. If damage is observed do not use the instrument until it is repaired.</li><li>• After cleaning and sterilization, verify functionality prior to re-use.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                 |                                                                                                                                                                                                                                    |                                |                         |                     |
| <b>Storage</b>                                                                                    |  | It is extremely important that the handpiece be rapidly and completely dried before storage to prevent corrosion and residue deposits in the bearing and motor.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                 |                                                                                                                                                                                                                                    |                                |                         |                     |
| <b>Additional Information</b>                                                                     |  | None                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                 |                                                                                                                                                                                                                                    |                                |                         |                     |

**Note:** The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing the product for re-use. It remains the responsibility of the processor to ensure that the reprocessing is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

**Note:** All validations performed per current AAMI TIR12, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.

Medtronic recommends incineration of devices that have directly contacted patients suspected or confirmed with Transmissible Spongiform Encephalopathy (TSE)/ CJD diagnosis.



**Medtronic**

## Reprocessing Instructions

Visao

### Reprocessing Instructions

Cleaning and Sterilization instructions are subject to change. Up to date instructions are available online at [manuals.medtronic.com](http://manuals.medtronic.com). 68E3281 F

|                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                       |                |                         |                     |
|--------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|----------------|-------------------------|---------------------|
| <b>Warnings and Precautions</b>                                                      | <ul style="list-style-type: none"><li>• Disconnect the power before cleaning.</li><li>• Do not fully immerse, or ultrasonically clean, this instrument.</li><li>• Do not cold soak sterilize this instrument in glutaraldehyde. This will void the warranty.</li><li>• Do not use organic solvents to clean the bur chuck.</li><li>• For Visao handpiece cleaning (and Xcalibur Hi-Speed with angled cable), cover handpiece cable connector end with Handpiece Cleaning Cap, Universal, catalog number 3318520.</li><li>• After completion of the cleaning steps, remove Handpiece Cable Cap or other protective components installed prior to cleaning.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                     |                                       |                |                         |                     |
| <b>Limitations</b>                                                                   | After cleaning and sterilization, verify functionality prior to re-use.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                       |                |                         |                     |
| <b>Point of Use</b>                                                                  | <ul style="list-style-type: none"><li>• This product is provided non-sterile and must be cleaned and sterilized before the first use and any reuse.</li><li>• To remove occasional residual buildup on handpiece cable connector, use a soft brush and isopropyl alcohol.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                       |                |                         |                     |
| <b>Containment and Transportation</b>                                                | It is recommended that instruments are reprocessed as soon as is practical following use.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                       |                |                         |                     |
| <b>Preparation for Decontamination</b>                                               | Remove the bur from the handpiece, otherwise disassembly is not required.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                       |                |                         |                     |
| <b>Cleaning: Automated</b>                                                           | <ul style="list-style-type: none"><li>• Remove instruments and equipment from any sterilization trays before placing into washer baskets. Orient devices following recommendations of washer/disinfector manufacturers.</li><li>• Use alkaline or neutral pH detergent recommended by washer/disinfector or detergent manufacturers.</li><li>• These products have been validated for effective cleaning using an automatic washer/disinfector cycle consisting of a minimum 44 minutes total time, including a pre-wash, main wash &amp; rinse, and thermal rinse. The thermal rinse shall be at least 10 minutes long at a minimum temperature of 60°C.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                     |                                       |                |                         |                     |
| <b>Cleaning: Manual</b>                                                              | <ul style="list-style-type: none"><li>• After surgery, clean the irrigation sleeves and bur guards with an enzymatic detergent solution. Wipe the handpiece and cable with disinfectant applied to a clean, non-abrasive cloth.</li><li>• A chuck brush cleaner (REF 3112500) or an appropriately sized small (plastic bristle) bore brush may be inserted into the distal end of the Visao handpiece, irrigation sleeves and bur guards to assist in removing fluids, tissue, or bone fragments, making sure to clean all passages. Use an enzymatic detergent solution to loosen and remove collected tissues from the unit.</li><li>• Rinse out the distal end of the handpiece. Shake excess water from the handpiece.</li><li>• Ensure all water is drained from the cooling housing. If saline was used for cooling during surgery, use distilled water to rinse the housing prior to draining.</li><li>• Using distilled water, rinse saline from the irrigation nozzles. Drain the nozzle of all water.</li><li>• Sterilize the handpiece immediately after cleaning.</li></ul> |                                       |                |                         |                     |
| <b>Disinfection</b>                                                                  | Do not cold soak in glutaraldehyde.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                       |                |                         |                     |
| <b>Packaging</b>                                                                     | <ul style="list-style-type: none"><li>• A standard, sterilization wrap may be used. In the US, an FDA approved surgical wrap must be used. Ensure that the pack is large enough to contain the instrument without stressing the seals.</li><li>• In sets: Instruments may be loaded into dedicated instrument trays or general purpose sterilization trays. Wrap trays using appropriate method.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                       |                |                         |                     |
| <b>Sterilization (Temperatures are minimum required, times are minimum required)</b> | The sterilization parameters given below should be used for devices that are fully disassembled when disassembly is possible. Use basic aseptic technique during post-sterilization assembly to maintain the sterility of the instrument(s). All steam sterilization cycles have been validated in the wrapped configuration and instruments can be sterilized wrapped or unwrapped.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                       |                |                         |                     |
|                                                                                      | <b>Steam Sterilization</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                       |                |                         |                     |
|                                                                                      | <b>Cycle</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <b>Gravity</b>                        | <b>Pre-Vac</b> | <b>Pre-Vac (FR/WHO)</b> | <b>Pre-vac (UK)</b> |
|                                                                                      | <b>Temperature</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 121 °C                                | 132 °C         | 134 °C                  | 134 °C              |
|                                                                                      | <b>Time</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 40 minutes                            | 4 minutes      | 18 minutes              | 3 minutes           |
|                                                                                      | <b>Drying</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 8 minutes, or until visibly dry       |                |                         |                     |
|                                                                                      | <b>STERRAD</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 100S Compatible (Handpiece Only)      |                |                         |                     |
|                                                                                      | <b>100% EtO Sterilization Parameters</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                       |                |                         |                     |
|                                                                                      | <b>Preconditioning</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                       |                |                         |                     |
|                                                                                      | <b>Sterilization</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>Temperature</b>                    |                | 54-55 °C                |                     |
|                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Relative Humidity</b>              |                | 60 +/- 5 %              |                     |
|                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Ethylene oxide concentration</b>   |                | 600 +/- 25 mg/L         |                     |
|                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Gas exposure time (full-cycle)</b> |                | 120 minutes             |                     |
|                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Aeration</b>                       |                | 48-52 °C, 8 hours       |                     |
| <b>Maintenance, Inspection and Testing</b>                                           | <ul style="list-style-type: none"><li>• Inspect components for any damage before and after each use. If damage is observed do not use the instrument until it is repaired.</li><li>• After cleaning and sterilization, verify functionality prior to re-use.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                       |                |                         |                     |
| <b>Storage</b>                                                                       | It is extremely important that the handpiece be rapidly and completely vacuum dried before storage to prevent corrosion and residue deposits in the bearing and motor.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                       |                |                         |                     |
| <b>Additional Information</b>                                                        | Increase temperatures higher than those stated when necessary to satisfy governmental or health care facility requirements so long as the temperature does not exceed 149 °C. Heating above 149 °C may damage the handpiece and will void the warranty.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                       |                |                         |                     |

**Note:** The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing the product for re-use. It remains the responsibility of the processor to ensure that the reprocessing is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

**Note:** All validations performed per current AAMI TIR12, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.

Medtronic recommends incineration of devices that have directly contacted patients suspected or confirmed with Transmissible Spongiform Encephalopathy (TSE)/ CJD diagnosis.



# Reprocessing Instructions

## Indigo High-Speed Otologic Drill

**Reprocessing Instructions**  
Cleaning and Sterilization instructions are subject to change. Up to date instructions are available online at [manuals.medtronic.com](https://manuals.medtronic.com).  
68E4187 D

|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                           |                    |                    |                                                           |
|-------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|--------------------|--------------------|-----------------------------------------------------------|
| Warnings and Precautions                                                      | <ul style="list-style-type: none"><li>Do not soak/submerge devices.</li><li>Do not use ultrasound to clean devices.</li><li>Do not use chlorine based or corrosive cleaning agents such as bleach, lye, acetone, sodium hypochlorite/bleach, sodium hydroxide, formic acid, or solutions containing glutaraldehyde.</li><li>The use of a washer-disinfector for cleaning may cause a pre mature degradation in performance.</li><li>Allow an adequate cooling period after steam sterilization.</li></ul>                                                                                                                                                                                                                                    |                                           |                    |                    |                                                           |
| Limitations                                                                   | Verify functionality prior to re-use.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                           |                    |                    |                                                           |
| Point of Use                                                                  | This product is provided non-sterile and must be cleaned and sterilized before the first use and any reuse.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                           |                    |                    |                                                           |
| Containment and Transportation                                                | It is recommended that devices are reprocessed as soon as is practical following use.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                           |                    |                    |                                                           |
| Preparation for Decontamination                                               | Follow hospital procedures.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                           |                    |                    |                                                           |
| Cleaning: Detergent                                                           | Use a cleaning agent that is suitable for use on aluminum surfaces. A neutral enzymatic to mild alkaline agent (pH 6.0 to 10.5) is preferred. If a washer-disinfector is used, see the instructions supplied with the washer-disinfector machine to select the recommended cleaning agent.                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                           |                    |                    |                                                           |
| Cleaning: Automated (Do NOT use ultrasonic washer)                            | <ul style="list-style-type: none"><li>Remove devices from instrument trays before placing into washer baskets.</li><li>Prior to cleaning, cover the drill cable connector end with Handpiece Cleaning Cap, catalog number 3318520.</li><li>Orient devices following recommendations of the washer/disinfector manufacturers.</li><li>After completion of the cleaning steps, remove Handpiece Cleaning Cap or other protective components prior to sterilization.</li></ul>                                                                                                                                                                                                                                                                  |                                           |                    |                    |                                                           |
|                                                                               | Recommended Washer Cycle                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Phase                                     | Recirculation Time | Water Temperature  | Detergent Type and Concentration                          |
|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Pre-Wash                                  | 2 minutes          | Cold tap water     | Not applicable                                            |
|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Wash                                      | 5 minutes          | 66 °C (set point)  | Neutral enzymatic to mild alkaline detergent, pH 6.0-10.5 |
|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Rinse                                     | 1 minute           | Hot tap water      | Not applicable                                            |
| Cleaning: Manual                                                              | <ul style="list-style-type: none"><li>Prior to cleaning, cover the drill cable connector end with Handpiece Cleaning Cap, catalog number 3318520.</li><li>Wipe all external surface of the motor and cable with a cloth dampened with the detergent prepared with lukewarm tap water.</li><li>Brush motor case and collet with a nylon brush dampened with a neutral enzymatic detergent.</li><li>Rinse motor thoroughly under running water, collet end pointed down.</li><li>Dry collet and motor with lint free towel</li><li>After completion of the cleaning steps, remove Handpiece Cleaning Cap or other protective components prior to sterilization.</li><li>Verify that devices are visually clean after manual cleaning</li></ul> |                                           |                    |                    |                                                           |
| Disinfection                                                                  | Follow hospital procedures.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                           |                    |                    |                                                           |
| Packaging                                                                     | Place devices in instrument tray, and double wrap instrument case with 1-ply polypropylene wrap. In the US, an FDA approved surgical wrap must be used.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                           |                    |                    |                                                           |
| Sterilization (Temperatures are minimum required, times are minimum required) | Steam Sterilization                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                           |                    |                    |                                                           |
|                                                                               | Cycle                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Gravity                                   | Pre-Vac            | Pre-Vac (FR/WHO)   | Pre-vac (UK)                                              |
|                                                                               | Temperature                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 132 °C                                    | 132 °C             | 134 °C             | 134 °C                                                    |
|                                                                               | Time                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 25 minutes                                | 4 minutes          | 18 minutes         | 3 minutes                                                 |
|                                                                               | Drying                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 20 minutes                                |                    |                    |                                                           |
|                                                                               | STERRAD                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Not validated                             |                    |                    |                                                           |
|                                                                               | 100% EtO Sterilization Parameters                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                           |                    |                    |                                                           |
|                                                                               | Preconditioning                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 55 °C, 70 % relative humidity, 30 minutes |                    |                    |                                                           |
|                                                                               | Sterilization                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Temperature                               |                    | 55 °C              |                                                           |
|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Relative Humidity                         |                    | 70 %               |                                                           |
|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Ethylene oxide concentration              |                    | 725 mg/L           |                                                           |
|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Gas exposure time (full-cycle)            |                    | 240 minutes        |                                                           |
|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Aeration                                  |                    | 53-57 °C, 18 hours |                                                           |
| Maintenance, Inspection and Testing                                           | <ul style="list-style-type: none"><li>Inspect components for any damage before and after each use. If damage is observed do not use the instrument until it is repaired.</li><li>After cleaning and sterilization, verify functionality prior to re-use.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                           |                    |                    |                                                           |
| Storage                                                                       | Store with other sterile devices.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                           |                    |                    |                                                           |
| Additional Information                                                        | None                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                           |                    |                    |                                                           |

**Note:** The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing the product for re-use. It remains the responsibility of the processor to ensure that the reprocessing is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

**Note:** All validations performed per current AAMI TIR12, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.

Medtronic recommends incineration of devices that have directly contacted patients suspected or confirmed with Transmissible Spongiform Encephalopathy (TSE)/ CJD diagnosis.



**Medtronic**

# Reprocessing Instructions

## Indigo High-Speed Otologic Drill Attachments

**Reprocessing Instructions**

Cleaning and Sterilization instructions are subject to change. Up to date instructions are available online at [manuals.medtronic.com](http://manuals.medtronic.com).  
68E4188 D

|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                           |                    |                    |                                                           |
|-------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|--------------------|--------------------|-----------------------------------------------------------|
| Warnings and Precautions                                                      | <ul style="list-style-type: none"><li>Do not soak/submerge devices.</li><li>Do not use ultrasound to clean devices.</li><li>Do not use chlorine based or corrosive cleaning agents such as bleach, lye, acetone, sodium hypochlorite/bleach, sodium hydroxide, formic acid, or solutions containing glutaraldehyde.</li><li>The use of a washer-disinfector for cleaning may cause a pre-mature degradation in performance.</li><li>Allow an adequate cooling period after steam sterilization.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                           |                    |                    |                                                           |
| Limitations                                                                   | Verify functionality prior to re-use.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                           |                    |                    |                                                           |
| Point of Use                                                                  | This product is provided non-sterile and must be cleaned and sterilized before the first use and any reuse.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                           |                    |                    |                                                           |
| Containment and Transportation                                                | It is recommended that devices are reprocessed as soon as is practical following use.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                           |                    |                    |                                                           |
| Preparation for Decontamination                                               | Follow hospital procedures.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                           |                    |                    |                                                           |
| Cleaning: Detergent                                                           | A neutral enzymatic to mild alkaline agent (pH 6.0 to 10.5) is preferred. If a washer-disinfector is used, see the instructions supplied with the washer-disinfector machine to select the recommended cleaning agent.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                           |                    |                    |                                                           |
| Cleaning: Automated (Do NOT use ultrasonic washer)                            | <ul style="list-style-type: none"><li>All attachments must be thoroughly rinsed manually with tap water, ensuring all hard to reach areas are rinsed, prior to transfer to automatic washer for processing.</li><li>Remove devices from instrument trays before placing into washer baskets.</li><li>Orient devices following recommendations of the washer/disinfector manufacturers.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                           |                    |                    |                                                           |
|                                                                               | Recommended Washer Cycle                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Phase                                     | Recirculation Time | Water Temperature  | Detergent Type and Concentration                          |
|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Pre-Wash                                  | 2 minutes          | Cold tap water     | Not applicable                                            |
|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Wash                                      | 5 minutes          | 66°C (set point)   | Neutral enzymatic to mild alkaline detergent, pH 6.0-10.5 |
|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Rinse                                     | 1 minute           | Hot tap water      | Not applicable                                            |
| Cleaning: Manual                                                              | <ul style="list-style-type: none"><li>Use the detergent, prepared with lukewarm tap water for the cleaning process.</li><li>Thoroughly wipe the straight and angled attachments with a cloth dampened with the detergent.</li><li>Wipe entire attachment until all gross soil has been removed.</li><li>Using a brush wetted with the detergent, brush the attachments to clean the external surfaces and internal connecting surfaces.</li><li>For the angled attachment: Wet an appropriately sized cleaning brush (Ø 2.4mm) with the detergent. Insert the brush into the bore at the front of the attachment. Brush the bore to loosen debris trapped inside. Rinse the bore to remove debris.</li><li>For the straight attachment: Wet an appropriately sized cleaning brush (Ø 2.4mm) with the detergent. Push the brush through the straight attachment from the rear to front to loosen and remove debris trapped inside. Rinse bore to remove debris.</li><li>Place one half of the straight or angled attachment into the detergent. Do not immerse the entire attachment. Gently agitate the attachments in the detergent and actuate any moveable parts.</li><li>Place the other half of the attachment into the detergent and repeat. Do not immerse the entire attachment.</li><li>Rinse the attachment thoroughly with tap water. Flush both ends to remove detergent.</li></ul> |                                           |                    |                    |                                                           |
| Drying and Lubrication                                                        | <ul style="list-style-type: none"><li>Thoroughly dry the attachments. An air gun may be used on the straight attachment to blow moisture out from the rear to front.</li><li>Using an aerosol spray lubricant (such as Pana Spray), perform the following steps to lubricate attachments:<ul style="list-style-type: none"><li>Holding the can approximately 10-15 cm (3-6 inches) away from the attachment, spray all components that move, rotate, or slide with three quick squirts.</li><li>Articulate movable components to ensure proper lubrication.</li><li>Remove excess lubricant with a clean cloth.</li></ul></li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                           |                    |                    |                                                           |
| Disinfection                                                                  | Follow hospital procedures.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                           |                    |                    |                                                           |
| Packaging                                                                     | Place devices in instrument tray, and double wrap instrument case with 1-ply polypropylene wrap. In the US, an FDA approved surgical wrap must be used.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                           |                    |                    |                                                           |
| Sterilization (Temperatures are minimum required, times are minimum required) | Steam Sterilization                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                           |                    |                    |                                                           |
|                                                                               | Cycle                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Gravity                                   | Pre-Vac            | Pre-Vac (FR/WHO)   | Pre vac (UK)                                              |
|                                                                               | Temperature                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 132 °C                                    | 132 °C             | 134 °C             | 134 °C                                                    |
|                                                                               | Time                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 25 minutes                                | 4 minutes          | 18 minutes         | 3 minutes                                                 |
|                                                                               | Drying                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 20 minutes                                |                    |                    |                                                           |
|                                                                               | STERRAD                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Not validated                             |                    |                    |                                                           |
|                                                                               | 100% EtO Sterilization Parameters                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                           |                    |                    |                                                           |
|                                                                               | Preconditioning                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 55 °C, 70 % relative humidity, 30 minutes |                    |                    |                                                           |
|                                                                               | Sterilization                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Temperature                               |                    | 55 °C              |                                                           |
|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Relative Humidity                         |                    | 70 %               |                                                           |
|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Ethylene oxide concentration              |                    | 725 mg/L           |                                                           |
|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Gas exposure time (full-cycle)            |                    | 240 minutes        |                                                           |
|                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Aeration                                  |                    | 53-57 °C, 18 hours |                                                           |
| Maintenance, Inspection and Testing                                           | <ul style="list-style-type: none"><li>Inspect components for any damage before and after each use. If damage is observed do not use the instrument until it is repaired.</li><li>After cleaning and sterilization, verify functionality prior to re-use.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                           |                    |                    |                                                           |
| Storage                                                                       | Store with other sterile devices.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                           |                    |                    |                                                           |
| Additional Information                                                        | None                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                           |                    |                    |                                                           |

**Note:** The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing the product for re-use. It remains the responsibility of the processor to ensure that the reprocessing is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

**Note:** All validations performed per current AAMI TIR12, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.

Medtronic recommends incineration of devices that have directly contacted patients suspected or confirmed with Transmissible Spongiform Encephalopathy (TSE)/ CJD diagnosis.



|                                                                                      |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                               |                                                                                                                                                                                                                                        |                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  |
|--------------------------------------------------------------------------------------|--|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|      |  | <h1>Reprocessing Instructions</h1> <h2>Microsaws</h2>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                               | <b>Reprocessing Instructions</b><br>Cleaning and Sterilization instructions are subject to change. Up to date instructions are available online at <a href="http://manuals.medtronic.com">manuals.medtronic.com</a> .<br>M000030A231 D |                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  |
| <b>Warnings and Precautions</b>                                                      |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                               |                                                                                                                                                                                                                                        |                          | <ul style="list-style-type: none"><li>Do not soak/submerge devices.</li><li>Do not use ultrasound to clean Midas Rex Microsaw devices.</li><li>Do not use chlorine-based or corrosive cleaning agents such as bleach, lye, acetone, sodium hypochlorite/bleach, sodium hydroxide, formic acid, or solutions containing glutaraldehyde.</li><li>Allow an adequate cooling period after steam sterilization.</li><li>The use of a washer-disinfector for cleaning may cause a premature degradation in performance.</li></ul>                                      |  |
| <b>Limitations</b>                                                                   |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                               |                                                                                                                                                                                                                                        |                          | Verify functionality prior to reuse.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |  |
| <b>Point of Use</b>                                                                  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                               |                                                                                                                                                                                                                                        |                          | Follow hospital procedures.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |  |
| <b>Containment and Transportation</b>                                                |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                               |                                                                                                                                                                                                                                        |                          | It is recommended that devices are reprocessed as soon as is practical following use.                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |  |
| <b>Preparation for Decontamination</b>                                               |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                               |                                                                                                                                                                                                                                        |                          | <ul style="list-style-type: none"><li>Disconnect handpiece from console.</li><li>Remove irrigation tubing/clips, saw blade, and cable management clamps.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                               |  |
| <b>Cleaning: Automated (Do NOT use ultrasonic washer)</b>                            |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                               |                                                                                                                                                                                                                                        |                          | <ul style="list-style-type: none"><li>Prior to placing the saws in the automated washer, manually rinse the saw body with the distal end pointed down under tap water, until no visible soil is noticed.</li><li>Move any movable parts back and forth to allow water to reach hard to-rinse areas.</li><li>Transfer the devices into the washer for processing, making sure that the oscillating saw collet is open. Place the devices in the washer to facilitate drainage.</li><li>Verify that devices are visually clean after automated cleaning.</li></ul> |  |
|                                                                                      |  | <b>Recommended Washer Cycle</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <b>Phase</b>                                                                                                                  | <b>Recirculation Time</b>                                                                                                                                                                                                              | <b>Water Temperature</b> | <b>Detergent Type and Concentration</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |  |
|                                                                                      |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <b>Pre-Wash</b>                                                                                                               | 2 minutes                                                                                                                                                                                                                              | Cold tap water           | Not applicable                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |  |
|                                                                                      |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <b>Wash</b>                                                                                                                   | 5 minutes                                                                                                                                                                                                                              | 66 ° (set point)         | Neutral enzymatic detergent, pH 6.0-8.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |  |
|                                                                                      |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <b>Rinse</b>                                                                                                                  | 1 minute                                                                                                                                                                                                                               | Hot tap water            | Not applicable                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |  |
| <b>Cleaning: Manual</b>                                                              |  | <ul style="list-style-type: none"><li>Rinse the device thoroughly under running water, with the collet end pointed down.</li><li>Wipe the saw body and cable with a cloth dampened with a neutral enzymatic detergent, pH 6.0-8.0 (henceforth referred to as "cleaning solution").</li><li>With the blade collet end pointed down, brush saw body, blade-release button, and extended lever tip (if applicable) with a nylon brush that has been dipped in cleaning solution.</li><li>Sagittal Only:<ol style="list-style-type: none"><li>Dip the distal end of the saw in cleaning solution and agitate for 10-15 seconds.</li><li>Press and hold the blade-release button, then repeat step 1.</li><li>With the blade-release button pressed, flush approximately 15 mL of cleaning solution from a syringe into the blade opening.</li><li>Flush all ports with 15 mL of cleaning solution.</li><li>Repeat steps 1-4 using water instead of cleaning solution.</li></ol></li><li>Reciprocating Only:<ol style="list-style-type: none"><li>With the distal end facing up, squeeze 30 mL of cleaning solution from a syringe into the distal end of the device so that the solution thoroughly reaches the inside of the collet.</li><li>While the device is in the vertical position, rotate the collet knob back and forth three times.</li><li>Dump the solution from the device.</li><li>Repeat steps 1-3 a second time with cleaning solution.</li><li>Repeat steps 1-3 a third time with water.</li></ol></li><li>Rinse the device under running water, ensuring that water enters all ports/openings. Move any moveable parts to allow the solution to reach all areas. Rinse until there is no visible evidence of soil or debris.</li></ul> |                                                                                                                               |                                                                                                                                                                                                                                        |                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  |
| <b>Drying and Lubrication</b>                                                        |  | <ul style="list-style-type: none"><li>Dry the entire device with a lint-free towel.</li><li>Reciprocating and Oscillating Only: If desired, complete the following steps using Pana Spray to lubricate the saw collet:<ol style="list-style-type: none"><li>Holding the can approximately 10-15 cm (4-6 inches) away from the saw collet, spray into the hole of the shaft (reciprocating saw) or onto the proximal/bottom portion of the collet near the locked/unlocked indicators (oscillating saw) with three quick squirts.</li><li>Articulate the collet to ensure proper lubrication.</li><li>Remove excess lubricant with a clean cloth.</li></ol></li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                               |                                                                                                                                                                                                                                        |                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  |
| <b>Disinfection</b>                                                                  |  | Follow hospital procedures.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                               |                                                                                                                                                                                                                                        |                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  |
| <b>Packaging</b>                                                                     |  | For sterilization, place devices in instrument tray. Devices may be unwrapped, or wrapped with up to two layers of 1-ply polypropylene wrap.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                               |                                                                                                                                                                                                                                        |                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  |
| <b>Sterilization (Temperatures are minimum required, times are minimum required)</b> |  | <b>Steam Sterilization</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                               |                                                                                                                                                                                                                                        |                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  |
|                                                                                      |  | <b>Cycle</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>Pre-Vac</b>                                                                                                                | <b>Pre-Vac (FR/WHO)</b>                                                                                                                                                                                                                | <b>Pre-Vac (UK)</b>      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  |
|                                                                                      |  | <b>Temperature</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 132 °C                                                                                                                        | 134 °C                                                                                                                                                                                                                                 | 134 °C                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  |
|                                                                                      |  | <b>Time</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 4 minutes                                                                                                                     | 18 minutes                                                                                                                                                                                                                             | 3 minutes                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  |
|                                                                                      |  | <b>Drying</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 20 minutes                                                                                                                    | 30 minutes                                                                                                                                                                                                                             | 22 minutes               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  |
|                                                                                      |  | <b>STERRAD</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Do not use low temperature hydrogen peroxide gas plasma sterilization due to lumen internal diameter and length restrictions. |                                                                                                                                                                                                                                        |                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  |
|                                                                                      |  | <b>STERIS</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Do not use liquid peracetic acid sterilization due to immersion procedure.                                                    |                                                                                                                                                                                                                                        |                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  |
| <b>Maintenance, Inspection and Testing</b>                                           |  | <ul style="list-style-type: none"><li>Inspect components for any damage before and after each use. If damage is observed, do not use the instrument until it is repaired.</li><li>After cleaning and sterilization, verify functionality prior to reuse.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                               |                                                                                                                                                                                                                                        |                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  |
| <b>Storage</b>                                                                       |  | Store with other sterile devices.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                               |                                                                                                                                                                                                                                        |                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  |
| <b>Additional Information</b>                                                        |  | <b>None</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                               |                                                                                                                                                                                                                                        |                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  |

**Note:** The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing the product for reuse. It remains the responsibility of the processor to ensure that the reprocessing is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

**Note:** All validations performed per current AAMI TIR12, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.

Medtronic recommends incineration of devices that have directly contacted patients suspected or confirmed with Transmissible Spongiform Encephalopathy (TSE)/ CJD diagnosis.

**Medtronic**

## Reprocessing Instructions

### POWEEASE Driver

**Reprocessing Instructions**

Cleaning and Sterilization instructions are subject to change. Up to date instructions are available online at [manuals.medtronic.com](http://manuals.medtronic.com). 68E4189 C

|                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                |                           |                          |                                         |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|---------------------------|--------------------------|-----------------------------------------|
| <b>Warnings and Precautions</b>                                                      | <ul style="list-style-type: none"><li>Do not soak/submerge devices.</li><li>Do not use ultrasound to clean devices.</li><li>Do not use chlorine based or corrosive cleaning agents such as bleach, lye, acetone, sodium hypochlorite/bleach, sodium hydroxide, formic acid, or solutions containing glutaraldehyde.</li><li>The use of a washer-disinfector for cleaning may cause a pre-mature degradation in performance.</li><li>Allow an adequate cooling period after steam sterilization.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                |                           |                          |                                         |
| <b>Limitations</b>                                                                   | Verify functionality prior to re-use.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                |                           |                          |                                         |
| <b>Point of Use</b>                                                                  | No particular requirements.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                |                           |                          |                                         |
| <b>Containment and Transportation</b>                                                | It is recommended that devices are reprocessed as soon as is practical following use.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                |                           |                          |                                         |
| <b>Preparation for Decontamination</b>                                               | Disconnect handpiece from console.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                |                           |                          |                                         |
| <b>Cleaning: Manual</b>                                                              | <ul style="list-style-type: none"><li>Rinse tap water through the open lumen of the handpiece, collet pointed down, until all evidence of soil and debris is removed. Actuate and rinse collet.</li><li>Wipe external surface of the motor and cable with a cloth dampened with neutral enzymatic detergent, pH 6.0-8.0.</li><li>Thoroughly clean the motor case, collet, and trigger area with a nylon brush dampened with neutral enzymatic detergent, pH 6.0-8.0. Actuate the collet and trigger while brushing.</li><li>Use a lumen brush to brush the entire length of the lumen.</li><li>Rinse entire device, with collet pointed down, under running tap water.</li><li>Immerse the collet portion of the device into neutral enzymatic detergent, pH 6.0-8.0 for a minimum of 2 minutes. Actuate and thoroughly brush the collet while immersed. A syringe should be used to flush hard to reach areas.</li><li>Rinse entire device, with collet pointed down, under running tap water. A syringe should be used to rinse hard to reach areas.</li><li>Dry with lint free cloth.</li><li>Verify that device is visually clean.</li></ul>                        |                |                           |                          |                                         |
| <b>Cleaning: Automated (Do NOT use ultrasonic washer)</b>                            | The POWEREASE must undergo the manual cleaning process prior to processing in a washer/disinfector.<br>1. Rinse tap water through the open lumen of the handpiece, collet pointed down until all evidence of soil and debris is removed. Actuate and rinse collet.<br>2. Wipe external surface of the motor and cable with a cloth dampened with neutral enzymatic detergent.<br>3. Brush motor case, collet, and trigger area with a nylon brush dampened with neutral enzymatic detergent. Actuate the collet and trigger while brushing.<br>4. Use a lumen brush to brush the entire length of the lumen.<br>5. Rinse entire device, with the collet pointed down, under running tap water.<br>6. Immerse the collet portion of the device into neutral enzymatic detergent for a minimum of 2 minutes. Actuate and brush the collet while immersed. A syringe should be used to flush hard to reach areas.<br>7. Rinse entire device, with the collet pointed down, under running tap water. A syringe should be used to rinse hard to reach areas.<br>8. Place POWEREASE into a suitable washer/disinfector basket and process through a washer/disinfector cycle. |                |                           |                          |                                         |
|                                                                                      | <b>Recommended Washer Cycle</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Phase</b>   | <b>Recirculation Time</b> | <b>Water Temperature</b> | <b>Detergent Type and Concentration</b> |
|                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Pre-Wash       | 2 minutes                 | Cold tap water           | Not applicable                          |
|                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Wash           | 5 minutes                 | 66 °C (set point)        | Neutral enzymatic detergent, pH 6.0-8.0 |
|                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Rinse          | 1 minute                  | Hot tap water            | Not applicable                          |
| <b>Disinfection</b>                                                                  | Follow hospital procedures.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                |                           |                          |                                         |
| <b>Packaging</b>                                                                     | Steam sterilization may be performed wrapped or unwrapped. If wrapped, in the US, an FDA approved surgical wrap must be used.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                |                           |                          |                                         |
| <b>Sterilization (Temperatures are minimum required, times are minimum required)</b> | <b>Steam Sterilization</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                |                           |                          |                                         |
|                                                                                      | <b>Cycle</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <b>Gravity</b> | <b>Pre-Vac</b>            | <b>Pre-Vac (FR/WHO)</b>  | <b>Pre-Vac (UK)</b>                     |
|                                                                                      | <b>Temperature</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 132 °C         | 132 °C                    | 134 °C                   | 134 °C                                  |
|                                                                                      | <b>Time</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 25 minutes     | 4 minutes                 | 18 minutes               | 3 minutes                               |
|                                                                                      | <b>Drying</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 40 minutes     |                           |                          |                                         |
|                                                                                      | <b>STERRAD</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Not validated  |                           |                          |                                         |
|                                                                                      | <b>STERIS</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Not validated  |                           |                          |                                         |
|                                                                                      | <b>100% EtO Sterilization Parameters</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Not validated  |                           |                          |                                         |
| <b>Maintenance, Inspection and Testing</b>                                           | <ul style="list-style-type: none"><li>Inspect devices for any damage before and after each use. If damage is observed, do not use the device until it is repaired.</li><li>After cleaning and sterilization, verify functionality prior to re-use.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                |                           |                          |                                         |
| <b>Storage</b>                                                                       | Store with other sterile devices.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                |                           |                          |                                         |
| <b>Additional Information</b>                                                        | None                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                |                           |                          |                                         |

**Note:** The instructions provided above have been validated by the manufacturer as being CAPABLE of preparing the product for re-use. It remains the responsibility of the processor to ensure that the reprocessing is actually performed using equipment, materials and personnel in the reprocessing facility to achieve the desired result. This normally requires validation and routine monitoring of the process.

**Note:** All validations performed per current AAMI TIR12, Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers.

Medtronic recommends incineration of devices that have directly contacted patients suspected or confirmed with Transmissible Spongiform Encephalopathy (TSE)/ CJD diagnosis.

SYMBOLS

The following symbols can appear on this device and related packaging.

|  |                           |  |                                                                      |  |                                                 |  |                                                                                                                                                                                                                                                                                                                                                                             |
|--|---------------------------|--|----------------------------------------------------------------------|--|-------------------------------------------------|--|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | On/Off Button             |  | Package Contents                                                     |  | Follow Instructions For Use                     |  | Conforms to ANSI/AAMI ES60601-1, Certified to CAN/CSA-C22.2 No.60601-1, IEC/EN 60601-1                                                                                                                                                                                                                                                                                      |
|  | EMC Compliance Mark       |  | Do Not Oil                                                           |  | Do Not Immerse                                  |  | Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.                                                                                                                                                                                                                                                                                 |
|  | Fuse                      |  | IPX1 Protected Against Vertical Water Drops                          |  | Oscillate                                       |  | Authorized Representative in the European Community                                                                                                                                                                                                                                                                                                                         |
|  | Use By Date               |  | IPX7 Protected Against The Effects Of Temporary Immersion In Water   |  | Forward                                         |  | Precaution: Pinch Hazard. Keep Fingers Clear Of Rollers                                                                                                                                                                                                                                                                                                                     |
|  | Accessory                 |  | Type BF Applied Part                                                 |  | Reverse                                         |  | Contains DEHP (di-2-ethyl hexyl phthalate)                                                                                                                                                                                                                                                                                                                                  |
|  | AC Power                  |  | Start/Stop                                                           |  | Foot Pedal Connector                            |  | Protective Earth                                                                                                                                                                                                                                                                                                                                                            |
|  | Output                    |  | RF Transmitter (Interference May Occur)                              |  | Fine Irrigant Adjustment                        |  | Equipotential Ground Connector                                                                                                                                                                                                                                                                                                                                              |
|  | Is Approximately Equal To |  | Consult Instructions for Use                                         |  | Left Foot Control Unit Button / Mode Button     |  | Use With                                                                                                                                                                                                                                                                                                                                                                    |
|  | Non Sterile               |  | Stim Bur Connector                                                   |  | Right Foot Control Unit Button / Control Button |  | RoHS - Environmental friendly use period - China (SJ/T 11364-2006)                                                                                                                                                                                                                                                                                                          |
|  | Non Sterile               |  | NIM Console Connector                                                |  | Top Foot Control Unit Button / Handpiece Button |  | Do Not Dispose Of This Product In The Unsorted Municipal Waste Stream. Dispose Of This Product According to Local Regulations. See Recycling.Medtronic.com for Instructions On Proper Disposal Of This Product.                                                                                                                                                             |
|  | Quantity                  |  | Electrical High Speed Handpiece Connector                            |  | Locked                                          |  | If the single use symbol is on the device label then this device is designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death. |
|  | Not Greater Than 120vac   |  | World Wide Standard for Medical Tubing Diameter                      |  | Unlocked                                        |  |                                                                                                                                                                                                                                                                                                                                                                             |
|  | Caution                   |  | Date of Manufacture                                                  |  | Handpiece                                       |  | Accessory                                                                                                                                                                                                                                                                                                                                                                   |
|  | Applied Part Duty Cycle   |  | Manufacturer                                                         |  | Shaver                                          |  | Adapter                                                                                                                                                                                                                                                                                                                                                                     |
|  | Catalog Number            |  |                                                                      |  |                                                 |  | Attachment                                                                                                                                                                                                                                                                                                                                                                  |
|  | Lot Number                |  | Sterilized using Irradiation                                         |  | Pump Head 1                                     |  | Bone Mill                                                                                                                                                                                                                                                                                                                                                                   |
|  | Serial Number             |  | Temperature Limitation Outer Limits -- Transport Inner Limits -- Use |  | Pump Head 2                                     |  | Brush                                                                                                                                                                                                                                                                                                                                                                       |
|  | USA Only                  |  | Ergonomically Engineered                                             |  | Refurbished                                     |  | Control Unit                                                                                                                                                                                                                                                                                                                                                                |
|  |                           |  |                                                                      |  |                                                 |  | Dissecting Tool                                                                                                                                                                                                                                                                                                                                                             |
|  |                           |  |                                                                      |  |                                                 |  | Instrument Case                                                                                                                                                                                                                                                                                                                                                             |
|  |                           |  |                                                                      |  |                                                 |  | Lubricant/Diffuser                                                                                                                                                                                                                                                                                                                                                          |
|  |                           |  |                                                                      |  |                                                 |  | Motor                                                                                                                                                                                                                                                                                                                                                                       |
|  |                           |  |                                                                      |  |                                                 |  | Multi-Use Disposable Attachment                                                                                                                                                                                                                                                                                                                                             |
|  |                           |  |                                                                      |  |                                                 |  | Regulator                                                                                                                                                                                                                                                                                                                                                                   |

The information contained in this document is accurate at time of publication. Medtronic reserves the right to make changes to the product described in this manual. Refer to [manuals.medtronic.com](http://manuals.medtronic.com) for the current version.



68E4066 N  
2016-06

© 2016 Medtronic, Inc.



# Medtronic

[medtronic.com](http://medtronic.com)  
[manuals.medtronic.com](http://manuals.medtronic.com)



Medtronic Xomed, Inc.  
6743 Southpoint Drive North  
Jacksonville, Florida USA 32216  
800 874 5797



Medtronic B.V.  
Earl Bakkenstraat 10  
6422 PJ Heerlen  
The Netherlands  
011 31 45 566 8000



# Система объединенного пульта управления электроприводами (IPC®)

МОДЕЛЬ: 1898001



## Руководство пользователя

RxOnly



## ОТДЕЛ РАБОТЫ С КЛИЕНТАМИ

Для получения более подробной информации об использовании изделия или для того, чтобы сообщить о любых проблемах, обратитесь в корпорацию Medtronic используя сведения, приведенные на синей и белой карточках с контактной информацией, которые идут в комплекте с каждым устройством, или обратитесь к региональному дистрибьютору.

Medtronic Xomed, Inc.  
6743 Southpoint Drive North  
Jacksonville, Florida 32216 США  
[www.medtronic.com](http://www.medtronic.com)

Справочная телефонная линия (США)  
800 874 5797

Международная сервисная служба  
Заказчикам из других стран, кроме США, необходимо обращаться в региональный офис Medtronic Xomed.

Ниже перечислены товарные знаки или зарегистрированные товарные знаки, принадлежащие корпорации Medtronic, Inc. в США и других странах: CD HORIZON®, Endo-Scrub®, Hydrodebrider®, Indigo™, Intelliflow®, IPC®, Legend®, Legend EHS®, Legend EHS Stylus®, Magnum®, Midas Rex®, Mednext®, NIM®, NIM-ECLIPSE®, POWEREASE®, Skeeter®, SOLERA®, StraightShot®, Stylus Touch®, Triton®, TSRH® 3Dx™, Visao® и XPS®. Все другие товарные знаки, знаки обслуживания, зарегистрированные товарные знаки или зарегистрированные знаки обслуживания являются собственностью их владельцев в США и других странах.

# СОДЕРЖАНИЕ

|                                                                                               |      |
|-----------------------------------------------------------------------------------------------|------|
| ГЛОССАРИЙ .....                                                                               | 1-1  |
| ПОКАЗАНИЯ К ПРИМЕНЕНИЮ .....                                                                  | 1-1  |
| ОПИСАНИЕ УСТРОЙСТВА.....                                                                      | 1-1  |
| ПРОТИВОПОКАЗАНИЯ .....                                                                        | 1-1  |
| ПРЕДУРЕЖДЕНИЯ.....                                                                            | 1-1  |
| Предупреждения, относящиеся к системе.....                                                    | 1-1  |
| Предупреждения, относящиеся к компонентам .....                                               | 1-2  |
| Предупреждения, относящиеся к одноразовым компонентам .....                                   | 1-2  |
| МЕРЫ ПРЕДОСТОРОЖНОСТИ .....                                                                   | 1-3  |
| ТРЕБОВАНИЯ К СИСТЕМЕ И ЕЕ ТЕХНИЧЕСКИЕ ХАРАКТЕРИСТИКИ.....                                     | 1-5  |
| Технические характеристики пульта управления.....                                             | 1-5  |
| Серийные номера шнуров питания.....                                                           | 1-5  |
| ЗВУКОВАЯ СИГНАЛИЗАЦИЯ СИСТЕМЫ И РИСУНКИ.....                                                  | 1-6  |
| ДЕЙСТВИЯ ДО НАЧАЛА ЭКСПЛУАТАЦИИ СИСТЕМЫ.....                                                  | 1-9  |
| При получении системы.....                                                                    | 1-9  |
| Настройка IPC .....                                                                           | 1-9  |
| Установка картриджей помп или ирригационных трубок .....                                      | 1-9  |
| Подготовка IPC к эксплуатации.....                                                            | 1-9  |
| Калибровка сенсорного экрана .....                                                            | 1-9  |
| Изменение настроек системы .....                                                              | 1-10 |
| Установка и наполнение помп.....                                                              | 1-11 |
| Конфигурации помп по умолчанию.....                                                           | 1-11 |
| Подтверждение функциональности системы .....                                                  | 1-11 |
| КОМПОНЕНТЫ IPC.....                                                                           | 1-12 |
| Подключение пульта управления к дополнительному источнику питания .....                       | 1-12 |
| Многофункциональная ножная педаль .....                                                       | 1-12 |
| У-образный делитель сигнала .....                                                             | 1-12 |
| Пульт дистанционного управления ирригацией Intelliflow.....                                   | 1-12 |
| РЕКОМЕНДАЦИИ И ЗАЯВЛЕНИЕ ПРОИЗВОДИТЕЛЯ ПО УСТОЙЧИВОСТИ К<br>ЭЛЕКТРОМАГНИТНОМУ ИЗЛУЧЕНИЮ ..... | 1-13 |
| ОГРАНИЧЕННАЯ ГАРАНТИЯ.....                                                                    | 1-16 |
| КАСАТЕЛЬНО КОМПОНЕНТОВ, ЗАРАЖЕННЫХ ВОЗБУДИТЕЛЯМИ ТГЭ.....                                     | 1-16 |
| ЭЛЕКТРОРУКОЯТКА TRITON С ВЫСОКИМ КРУТЯЩИМ МОМЕНТОМ.....                                       | 2-1  |
| АСПИРАЦИОННЫЙ ИРРИГАТОР.....                                                                  | 3-1  |
| ENDO-SCRUB 2.....                                                                             | 4-1  |
| РУКОЯТКА СПИНАЛЬНОГО ШЕЙВЕРА (SC1).....                                                       | 5-1  |
| STRAIGHTSHOT M5, STRAIGHTSHOT M4, STRAIGHTSHOT MAGNUM II И STRAIGHTSHOT III.....              | 6-1  |
| LEGEND EHS И LEGEND EHS STYLUS .....                                                          | 7-1  |
| STYLUS TOUCH.....                                                                             | 8-1  |
| НАСАДКИ LEGEND EHS, LEGEND EHS STYLUS И STYLUS TOUCH .....                                    | 9-1  |
| СВЕРХЛЕГКИЙ ОТОЛОГИЧЕСКИЙ ИНСТРУМЕНТ SKEETER.....                                             | 10-1 |
| ВЫСОКОСКОРОСТНАЯ ДРЕЛЬ VISAO .....                                                            | 11-1 |
| ВЫСОКОСКОРОСТНАЯ ОТОЛОГИЧЕСКАЯ ДРЕЛЬ INDIGO .....                                             | 12-1 |

|                                                                                                              |                    |
|--------------------------------------------------------------------------------------------------------------|--------------------|
| <b>МИКРОПИЛЫ MIDAS REX .....</b>                                                                             | <b>13-1</b>        |
| <b>ЭЛЕКТРОПРИВОД POWEREASE .....</b>                                                                         | <b>14-1</b>        |
| <b>УСТРАНЕНИЕ НЕПОЛАДОК И КОДЫ ОШИБОК .....</b>                                                              | <b>A-1</b>         |
| <b>ОЧИСТКА И СТЕРИЛИЗАЦИЯ.....</b>                                                                           | <b>B-1</b>         |
| Действия после окончания работы с системой .....                                                             | <b>B-1</b>         |
| Электрорукоятка Triton с высоким крутящим моментом .....                                                     | <b>M000030A322</b> |
| Пальцевой переключатель Endo-Scrub 2 .....                                                                   | <b>68E4005</b>     |
| Спинальные шейверы StraightShot M5, StraightShot M4, StraightShot Magnum II, StraightShot III и Midas Rex .. | <b>68E3282</b>     |
| .....                                                                                                        |                    |
| Legend EHS и Legend EHS Stylus .....                                                                         | <b>M000030A234</b> |
| Stylus Touch.....                                                                                            | <b>68E4132</b>     |
| Насадки и трубки Legend .....                                                                                | <b>M000030A235</b> |
| Боры Skeeter Oto-flex .....                                                                                  | <b>68E3968</b>     |
| Рукоятка Skeeter .....                                                                                       | <b>68E3969</b>     |
| Visao .....                                                                                                  | <b>68E3281</b>     |
| Высокоскоростная отолгическая дрель Indigo .....                                                             | <b>68E4187</b>     |
| Насадки для высокоскоростной отолгической дрели Indigo.....                                                  | <b>68E4188</b>     |
| Микропилы .....                                                                                              | <b>M000030A231</b> |
| Электропривод POWEREASE.....                                                                                 | <b>68E4189</b>     |
| <b>СИМВОЛЫ .....</b>                                                                                         | <b>C</b>           |

## ГЛОССАРИЙ

В данном руководстве могут использоваться следующие слова и сокращения.

|             |                                                                                                                                                                                      |
|-------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| FCU         | Foot Control Unit (Блок ножного управления)                                                                                                                                          |
| FWD         | Вперед — вращение по часовой стрелке                                                                                                                                                 |
| I.V.        | Внутривенно                                                                                                                                                                          |
| IPC         | Integrated Power Console (Объединенный пульт управления электроприводами)                                                                                                            |
| NIM         | Nerve Integrity Monitor (Монитор целостности нерва) — один или несколько из следующих мониторов целостности нерва: NIM-Response 2.0, NIM-Neuro 2.0, NIM-Response 3.0 и NIM-Neuro 3.0 |
| NIM-ECLIPSE | Монитор целостности нерва, используемый в спинальной хирургии                                                                                                                        |
| OSC         | Колебание                                                                                                                                                                            |
| REV         | Назад — вращение против часовой стрелки                                                                                                                                              |
| XPS         | Система электропитания Xomed                                                                                                                                                         |

## ПОКАЗАНИЯ К ПРИМЕНЕНИЮ

Система IPC используется для рассечения (разрезания), удаления, сверления и распиливания мягких и твердых тканей и костных структур головы, шеи и ЛОР-органов, в том числе в ходе отоларингологических, неврологических, нейроотоларингологических, синусовых, риноларингологических, носоглоточных, гортанных, а также стоматологических, челюстно-лицевых, пластических, реконструктивных и эстетических хирургических процедур.

## ОПИСАНИЕ УСТРОЙСТВА

Система IPC — это оснащенное электроприводом устройство с микродебридером, дрелью и пилой, предназначенное для удаления мягкой, твердой и костной ткани во время хирургических операций. Система состоит из пульта управления электроприводами, ножной педали, соединительных кабелей и набора рукояток, приводящих в действие различные боры, лезвия, дрели, скребки, канюли и пилы. В ее состав входят встроенные помпы для ирригации лезвий и боров, а также для охлаждающей жидкости электродвигателя.

Помимо рукояток и помп, имеется разъем для продолжительной стимуляции прямыми борами Visao, которые позволяют контролировать целостность нерва в ходе хирургических операций. Монитор целостности нерва (NIM) представляет собой отдельное устройство для стимуляции и контроля целостности нерва. Система имеет разъемы, позволяющие подключить NIM к рукоятке Visao и защите стимулирующего бора, что дает возможность стимулировать и мониторинга целостности нерва в операционном поле с помощью NIM.

Данное устройство предназначено для использования врачами, которые обучены выполнению описанных процедур.

С помощью данной системы можно очищать кончик жесткого стержневого эндоскопа для поддержания хорошей визуализации в ходе эндоскопических процедур без извлечения эндоскопа из операционного поля.

## ПРОТИВОПОКАЗАНИЯ

Нет.

## ПРЕДУПРЕЖДЕНИЯ

### Предупреждения, относящиеся к системе

- W1 Оператору системы IPC необходимо ознакомиться с руководством пользователя, содержащимися в нем мерами предосторожности, процедурами и сведениями по безопасности.
- W2 Запрещается пользоваться системой IPC в присутствии огнеопасных анестетиков. Следует избегать возможности воспламенения или взрыва газов.
- W3 Если рукоятка не используется, необходимо устранить возможность случайного срабатывания ножного управления. Во избежание непреднамеренного рассечения ткани, кости или нерва следует контролировать усилие, прилагаемое к рукоятке, и скорость ее работы.
- W4 Во избежание общего поражения электрическим током следует отключать питание системы IPC перед очисткой.
- W5 Во избежание общего поражения электрическим током запрещается подсоединять к системе IPC не утвержденные производителем компоненты.
- W6 Во избежание поражения электрическим током необходимо надежно и правильно подключить заземление. Систему IPC следует подключать только к специализированным розеткам для больниц.
- W7 Это медицинское устройство соответствует требованиям стандарта безопасности EN 60601-1-2 к электромагнитной совместимости, электромагнитному излучению и прохождению контрольных испытаний. Тем не менее, если данное оборудование эксплуатируется в присутствии электромагнитных помех высокого уровня или высокочувствительного оборудования, возможно возникновение помех, и необходимо предпринять все необходимые меры по уменьшению помех или устранению их источника. Ухудшение рабочих характеристик может привести к увеличению продолжительности операции на пациенте под наркозом.
- W8 Медицинское электрооборудование требует особых мер предосторожности в отношении ЭМС и должно устанавливаться и вводиться в эксплуатацию с учетом сведений по ЭМС, приведенных в данном руководстве.
- W9 На работу медицинского электрооборудования может оказывать помехи портативное и мобильное РЧ коммуникационное оборудование.
- W10 Запрещается эксплуатировать систему IPC в присутствии устройств для магнитно-резонансной томографии.
- W11 Разрешается использовать только принадлежности и кабели, указанные и продаваемые корпорацией Medtronic. В противном случае возможно повышение излучения и снижение помехоустойчивости данного устройства.
- W12 Систему IPC нельзя использовать вблизи другого оборудования, ставить ее на другие устройства и использовать как подставку для других устройств. Если систему IPC необходимо разместить рядом с другим оборудованием, над или под ним, необходимо убедиться, что система нормально работает в предполагаемой конфигурации.
- W13 Запрещается запускать рукоятку системы IPC непосредственно после обработки в автоклаве. Нужно подождать, пока она остынет (обычно 1 час).
- W14 Перед работой с системой IPC следует прочитать вкладыш, прилагаемый к костной мельнице Legend.
- W15 Правила техники безопасности при рассечении металла.
  - W15a Необходимо использовать средства защиты глаз.
  - W15b Необходимо охлаждать режущие поверхности, тщательно промывая их.
  - W15c Область раны должна быть защищена от металлических обрезков.
  - W15d Подвижные фрагменты любого разрезаемого металлического компонента необходимо удерживать фиксатором или зажимом.

## ОБЪЕДИНЕННЫЙ ПУЛЬТ УПРАВЛЕНИЯ ЭЛЕКТРОПРИВОДАМИ (IPC)

- W16 Запрещается работать с системой IPC без средств защиты глаз.
- W17 Все работы по техническому обслуживанию должны выполняться только квалифицированными специалистами корпорации Medtronic.
- W18 Работы по ремонту или модернизации системы IPC должны выполняться только квалифицированными специалистами сервисной службы. Иначе возможно значительное ухудшение рабочих характеристик устройства или аннулирование гарантии на оборудование.

### Предупреждения, относящиеся к компонентам

- W19 Запрещается использовать любые детали, кроме утвержденных компонентов системы Medtronic. Иначе возможно повреждение устройства или нарушение стандартных рабочих характеристик.
- W20 До и после работы следует осматривать устройство на предмет повреждения. В случае обнаружения повреждения запрещается использовать вышедшую из строя деталь, пока она не будет отремонтирована или заменена. Металлические стружки от поврежденных деталей могут попасть в операционное поле.
- W21 Когда требуется точно расположить кончик лезвия, следует включить стопор вращения на рукоятке и затем откалибровать и проверить положение кончика лезвия с помощью эндовидеохирургической системы (IGS). При работе с невращающимися лезвиями всегда нужно блокировать рукоятку M4, чтобы сохранять их калибровку в системе IGS.
- W22 При использовании вращающихся инструментов с электроприводом следует прибегать к помощи визуализации, в том числе, к средствам формирования изображения (например, рентгеноскопии, эндовидеохирургии). Если визуализация операционного поля недостаточна, необходимо прервать работу с электроприводными инструментами.
- W23 Насадки Midas Rex с переменной длиной выступающей части. Прежде чем пользоваться инструментами для рассечения, хирурги должны ознакомиться с их рабочими характеристиками и выяснить, как различная длина выступающих частей инструментов влияет на стабильность рассечения. В случае чрезмерного треска, вибрации или подвижности инструмента следует уменьшить длину его выступающей части.
- W24 При продолжительном использовании возможен выход из строя электродвигателя и насадок, детали которых могут отсоединиться и выпасть, причинив травму пациенту.
- W25 Перед началом работы электрические контакты должны быть сухими.
- W26 Интенсивные боковые нагрузки и/или длительное функционирование могут привести к перегреву устройства.
- W27 Не используйте перегретое устройство, поскольку это может привести к термической травме пациента или врача.
- W28 Применяйте надлежащую ирригацию. Применение инструмента без ирригации может привести к чрезмерному нагреву и термической травме ткани. В зависимости от объема ирригации температура сверл и лезвий пил может превысить 50 °C.
- W29 Запрещается менять инструмент для препарирования, лезвия пилы или насадку во время работы электродвигателя, а также в случае перегрева электродвигателя или насадки.
- W30 Не погружайте компоненты системы в жидкость, за исключением особых указаний.
- W31 Во время хирургической операции запрещается класть электродвигатель, насадку или инструмент на пациента или неподготовленное место.
- W32 Запрещается использовать неправильно работающую систему до проведения всех необходимых ремонтных работ и последующего испытания на соответствие рабочих характеристик техническим требованиям корпорации Medtronic.
- W33 Номенклатура и цветовой код на упаковке инструмента и на насадке должны совпадать.
- W34 После каждой регулировки длины выступающей части инструмента необходимо убедиться, что насадка остается в заблокированном положении, поскольку попытка сильного увеличения длины выступающей части инструмента может привести к случайному разблокированию насадки.
- W35 Электродвигатели Midas Rex Legend EHS и Midas Rex Legend EHS Stylus разрешается включать только при заблокированной насадке. При попытке включить электродвигатель Midas Rex Legend EHS Stylus с разблокированной насадкой возможно застопоривание электродвигателя.
- W36 Если насадка не зафиксирована, возможно появление дыма и/или перегрев насадки. Это может привести к термическому ожогу хирурга или персонала.
- W37 Пока насадка не будет зафиксирована надлежащим образом, электродвигатели Indigo и Legend EHS не будут работать правильно.
- W38 Во избежание нанесения рваных ран пользователю и перекрестного инфицирования через порванную перчатку ЗАПРЕЩАЕТСЯ менять насадку на включенной рукоятке.
- W39 Насадки Legend на ножке должны извлекаться осторожно и медленно в соответствии с инструкциями, чтобы не нанести травму оператору.
- W40 ЗАПРЕЩАЕТСЯ изменять конструкцию инструментов, используемых с рукоятками. Изменение инструментов может привести к ухудшению рабочих характеристик.
- W41 Безопасность использования системы Endo-Scrub 2 в операциях с применением хирургических лазеров не подтверждена клинически.
- W42 Для обеспечения соответствия требованиям стандарта IEC 60601-1 необходимо использовать силовой кабель, утвержденный корпорацией Medtronic.
- W43 Во избежание поражения электрическим током данное оборудование необходимо подключать только к электрическим сетям с защитным заземлением.
- W44 Размещайте кабель датчика подавления помех NIM в стороне от кабелей системы IPC.
- W45 Многоразовые устройства подлежат обязательной стерилизации перед каждым использованием. Запрещается использовать нестерилизованные устройства.

### Предупреждения, относящиеся к одноразовым компонентам

- W46 Имеются инструменты для резекции мягкой ткани и кости во время хирургических операций. Выбор используемых инструментов зависит от их предназначения и потребностей пациента. Режущие инструменты с электроприводом вызывают кровотечение и приводят к удалению значительного объема ткани или кости.
- W47 Во время хирургических операций с повышенным риском следует использовать соответствующие способы остановки кровотечения в операционном поле для обеспечения безопасности пациента.
- W48 Режущую зону инструмента/лезвие пилы всегда следует держать на расстоянии от пальцев и неплотно прилегающих частей одежды. Во избежание рваных ран и перекрестного инфицирования оператора системы не допускайте нарушения целостности хирургических перчаток.
- W49 Инструмент должен включаться только после подтверждения соответствующей анатомической привязки и осуществления доступа к операционному полю.
- W50 При использовании инструментов с электроприводом необходимо внимательно следить за тем, чтобы подвижный режущий кончик инструмента был активирован в строгом соответствии с анатомическими ориентирами в пределах операционного поля.
- W51 Вставка металлических предметов в наконечник инструмента может разрушить его, а осколки при этом могут попасть в рану. Эти осколки могут оказаться трудноудаляемыми и привести к раздражению, воспалению и реакции организма на инородное тело в операционном поле.
- W52 Сгибание или попытка действовать инструментом как рычагом может разрушить его и нанести травмы пациенту или персоналу.
- W53 При выполнении иссечения запрещается с излишним усилием поддевать или толкать кость с помощью насадки, инструмента или лезвия.
- W54 В зависимости от размера и геометрии инструмента на определенных скоростях может возникнуть чрезмерная вибрация. В этом случае необходимо увеличить или уменьшить скорость на пульте управления. Во избежание непреднамеренного удаления ткани пациента следует заменить инструмент на новый.



- W55 Перед использованием инструмента его нужно проверить на предмет вибрации при требуемой скорости. Если кончик инструмента начинает вибрировать, необходимо прервать работу и заменить инструмент, чтобы не допустить непреднамеренного удаления ткани пациента.
- W56 Колебания оси вращения инструмента могут привести к его вибрации и, как следствие, к излишнему разрушению ткани и кости, а также нарушению слуха.
- W57 Чрезмерный шум вблизи улитки или цепочки косточек среднего уха, создаваемый инструментом во время сверления, может нарушить слух.
- W58 Рекомендованные скорости для черепного перфоратора СМОТРИТЕ на его этикетке.
- W59 Инструменты с меткой «L» — это удлинённые инструменты, предназначенные для рассечения легких костей. Увеличенная конструкция головки и рукоятки инструмента может влиять на устойчивость рассечения.
- W60 Бороздки инструментов и зубья лезвий имеют острые края и могут повредить хирургические перчатки. При установке и извлечении инструментов/лезвий их можно захватывать кровоостанавливающими зажимами.
- W61 ЗАПРЕЩАЕТСЯ повторно затачивать использованные инструменты. Изношенные инструменты нужно часто заменять новыми, чтобы обеспечить эффективное контролируемое рассечение.
- W62 Перед каждым использованием и после него следует тщательно осматривать инструменты на предмет чрезмерного износа, расщепления, нарушения целостности или иных дефектов. Инструменты, вызывающие подозрение, необходимо заменить новыми, прежде чем приступать к работе.
- W63 При чрезмерном нажиме бор может переломиться. В случае перелома инструмента необходимо с особой тщательностью извлечь и удалить из пациента все осколки инструмента. Неудаленные осколки инструмента могут повредить ткани пациента.
- W64 Запрещается обрабатывать кость инструментами для резки металла.
- W65 Разрешается использовать только вращающиеся инструменты, специально предназначенные для данного сверлильного оборудования.
- W66 При работе с невращающимися инструментами во избежание непреднамеренного вращения следует убедиться, что блокировка вращения включена.
- W67 Применение инструментов с возвратно-поступательным движением, имеющих электропривод, может привести к вибрации и связанной с ней травме.
- W68 Лезвия с электроприводом должны эксплуатироваться только в режиме колебаний. При работе в режиме прямой резки возможно повреждение лезвия.
- W69 Не пытайтесь стерилизовать одноразовые устройства. Одноразовые компоненты в упаковке являются стерильными. Они не предназначены для повторного использования. Чтобы предотвратить микробное загрязнение, используйте их только один раз.
- W70 Любые трубки или иные средства защиты кончиков рукояток, используемые во время доставки, необходимо удалить перед очисткой и стерилизацией.
- W71 Запрещается использовать инструменты из поврежденной или вскрытой упаковки. При нарушенной герметизации защита от перекрестного инфицирования не может быть обеспечена.
- W72 Необходимо правильно утилизировать одноразовые устройства, извлеченные из стерильной упаковки. При извлечении из упаковки устройства теряют стерильность.
- W73 Запрещается использовать затупленные, поврежденные или изогнутые инструменты. Использование затупленных инструментов снижает эффективность рукоятки и приводит к ее нагреванию.
- W74 Лезвия T&A. Осторожно извлеките внутреннюю трубку из внешней трубки. При этом внутренняя трубка может растянуться. Это может привести к неправильной фиксации внутренней трубки в рукоятке или ненадлежащей работе лезвия.
- W75 Лезвия T&A. Чтобы не повредить внутреннее уплотнение во время вставки и извлечения внутренней трубки из внешней трубки, ее нужно поворачивать. В случае повреждения уплотнения жидкость из лезвия будет протекать в рукоятку.
- W76 Перед включением системы всегда нужно убедиться, что дрель надежно зафиксирована в рукоятке.
- W77 Перед использованием каждого инструмента в рукоятке всегда нужно проверять его работу.
- W78 Боры и дрели с электроприводом должны работать только в режиме прямой резки.
- W79 В данной системе требуются изолированные разъемы для микродебридеров StraightShot M4, StraightShot Magnum II, StraightShot III, рукояток Midas Rex SC1, Visao или Skeeter и многофункционального модуля ножного управления.
- W80 Перед хранением системы нужно простерилизовать и высушить многоразовые устройства. Своевременная стерилизация снижает вероятность перекрестного инфицирования.
- W81 После каждой процедуры необходимо правильно очистить все многоразовые компоненты системы.
- W82 Дополнительная розетка электропитания с защитной крышкой предназначена только для подключения пультов управления Hydrodebrider или костной мельницы.
- W83 Когда устройство Stylus Touch не используется, переводите его в безопасный режим.
- W84 Не вносите рукоятку Stylus Touch в магнитные поля, например, в поля магнитных ковриков и МРТ оборудования, чтобы предотвратить случайное включение рукоятки.
- W85 Не применяйте чрезмерную боковую нагрузку. Чрезмерная боковая нагрузка может привести к случайной разблокировке изогнутых насадок и их отсоединению от электродвигателя.

## МЕРЫ ПРЕДОСТОРОЖНОСТИ

- P1 Функция наполнения PRIME/FLUSH (НАПОЛНИТЬ/ПРОМЫТЬ) предназначена для продувки воздуха из комплекта трубок во время настройки оборудования. При первом нажатии кнопки Prime (Наполнить) или Flush (Промыть) помпа 1 и/или 2 включается на достаточно длительное время, чтобы продуть воздух из комплектов трубок. При включении и выключении питания происходит сброс функции PRIME (НАПОЛНИТЬ). После однократного нажатия все кнопки Prime (Наполнить) становятся кнопками Flush (Промыть).
- P2 Для предотвращения повреждения изогнутых инструментов необходимо отсоединить аспирационную трубку, прежде чем менять инструмент в ходе операции.
- P3 При работе с угловой насадкой держите узел рукоятки за насадку, чтобы она случайно не выпала из рукоятки.
- P4 Только для инструментов Legend:  
Если упаковка инструмента вскрыта, но инструмент не использовался и не загрязнен, его можно повторно стерилизовать. Извлеките инструмент из оригинальной упаковки и поместите его в соответствующий контейнер для автоклавирования. Стерилизация паром:  
паровая стерилизация с высоким вакуумом 132 °C в течение 5 минут;  
паровая стерилизация с гравитационным вытеснением 132 °C в течение 15 минут.  
Повторно стерилизованный инструмент необходимо использовать сразу после стерилизации. Если после повторной стерилизации появляется ржавчина или коррозия, инструмент не подлежит использованию.
- P5 ЗАПРЕЩАЕТСЯ использовать насадку 16-MF с рабочей скоростью свыше 62 000 об./мин. Это может привести к перегреву и повреждению внутренних шестерен насадки.
- P6 ЗАПРЕЩАЕТСЯ использовать спиральную дрель или контрголовой инструмент с рабочей скоростью свыше 62 000 об./мин.
- P7 Запрещается отсоединять кабель от электродвигателя Midas Rex Legend EHS Stylus.
- P8 Запрещается перегибать кабели. Следует проверять кабели и штырьки разъемов на предмет отсутствия трещин, следов износа или коррозии.
- P9 Запрещается наносить средство против запотевания стекол на эндоскоп или чехол, так как это может привести к запотеванию или протечке.

## ОБЪЕДИНЕННЫЙ ПУЛЬТ УПРАВЛЕНИЯ ЭЛЕКТРОПРИВОДАМИ (IPC)

- P10 Перед стерилизацией необходимо отсоединить кабель от электродвигателя Midas Rex Legend EHS.
- P11 Применение мойки-дезинфектора эндоскопов может привести к преждевременному ухудшению рабочих характеристик.
- P12 Прежде чем помещать устройства в мойку-дезинфектор эндоскопов, их нужно извлечь из футляра для инструментов, затем им надо дать обсохнуть.
- P13 Устройства должны размещаться в мойке-дезинфекторе эндоскопов с соблюдением ориентации, рекомендованной производителем.
- P14 Из-за ограниченного внутреннего диаметра просвета и длины трубки ЗАПРЕЩАЕТСЯ применять стерилизацию в низкотемпературной газовой плазме перекиси водорода.
- P15 ЗАПРЕЩАЕТСЯ стерилизовать в низкотемпературной жидкой надуксусной кислоте, так как эта процедура включает погружение.
- P16 ЗАПРЕЩАЕТСЯ стерилизовать чистящее сопло насадки Legend паром или этиленоксидом.
- P17 Выведение из эксплуатации и утилизация насадок должны осуществляться в соответствии с местными нормативными актами, регулирующими утилизацию зараженных материалов.
- P18 Одноразовые устройства предназначены только для однократного использования.
- P19 Очистка электродвигателя и кабеля выполняется без отсоединения их друг от друга. Это снижает вероятность попадания загрязнений внутрь электродвигателя.
- P20 Разрешается использовать ТОЛЬКО рекомендованные чистящие средства.
- P21 Запрещается с излишним усилием вставлять эндоскоп в чехол Endo-Scrub 2. Это может привести к повреждению эндоскопа и чехла Endo-Scrub 2.
- P22 Если кончик эндоскопа выступает за кончик чехла Endo-Scrub 2, значит чехол поврежден. Поврежденный продукт нужно незамедлительно выбросить.
- P23 При использовании У-образного делителя сигнала одновременно может быть активна только одна многофункциональная ножная педаль.
- P24 Одновременно можно использовать только один У-образный делитель сигнала.
- P25 Убедитесь, что лезвие или бор полностью установлены в микродебридер. Для лезвий: перед использованием убедитесь, что кончик полностью контактирует с внешней канюлей.

ТРЕБОВАНИЯ К СИСТЕМЕ И ЕЕ ТЕХНИЧЕСКИЕ ХАРАКТЕРИСТИКИ

Технические характеристики пульта управления

Действующие стандарты для электрических систем

|                         |                                                                                                                                                                                                                                                                                                                        |                         |
|-------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|
| ANSI/AAMI ES60601-1     | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (Медицинская электроаппаратура, часть 1 «Общие требования к основным средствам безопасности и необходимым рабочим характеристикам»)                                                                             | 2005 г.                 |
| IEC 60601-1             | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (Медицинская электроаппаратура, часть 1 «Общие требования к основным средствам безопасности и необходимым рабочим характеристикам»)                                                                             | 2005 г.                 |
| EN - 60601-1            | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (Медицинская электроаппаратура, часть 1 «Общие требования к основным средствам безопасности и необходимым рабочим характеристикам») (IEC 60601-1:2005)                                                          | 2006 г.                 |
| IEC 60601-1-4           | Medical electrical equipment - Part 1: General Requirements for Safety, Part 4: Programmable Electrical Medical Systems (Медицинская электроаппаратура, часть 1 «Общие требования к безопасности», часть 4 «Программируемые электрические медицинские системы»)                                                        | 2000 г.                 |
| EN 60601-1-2            | Medical electrical equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests (Медицинская электроаппаратура, часть 1-2 «Общие требования к безопасности». Дополнительный стандарт «Электромагнитная совместимость — требования и испытания») | 2001 г./<br>A1: 2006 г. |
| CAN/CSA C22.2 № 60601-1 | Medical electrical equipment - Part 1: General Requirements for Safety (Изделия медицинские электрические. Часть 1. Общие требования к основной безопасности и основным функциональным характеристикам)                                                                                                                | 2005 г.                 |

Физические размеры

|        |                                      |
|--------|--------------------------------------|
| Размер | 277 мм х 353 мм х 267 мм (Ш х В х Г) |
| Масса  | 7,3 кг                               |

Условия эксплуатации

|                      |                                       |
|----------------------|---------------------------------------|
| Температура          | от +10 до +33 °С                      |
| Влажность            | относительная влажность от 30 до 75 % |
| Атмосферное давление | от 700 до 1 060 гПа                   |

Условия транспортировки и хранения

|                      |                                       |
|----------------------|---------------------------------------|
| Температура          | от -40 до +70 °С                      |
| Влажность            | относительная влажность от 10 до 95 % |
| Атмосферное давление | от 500 до 1 060 гПа                   |

Дисплей и сенсорный экран

|            |                                                                                  |
|------------|----------------------------------------------------------------------------------|
| Тип        | высококонтрастный цифровой цветной графический дисплей, видимый в полной темноте |
| Разрешение | размер экрана по диагонали — 21 см, разрешение 480 х 640 пикселей                |

Тип выводимого звукового сигнала

|                                         |                                                     |
|-----------------------------------------|-----------------------------------------------------|
| Уровень громкости базового аудиосигнала | минимальный уровень звукового давления 60 дБА (1 м) |
|-----------------------------------------|-----------------------------------------------------|

Электрические характеристики

|                                                                           |                                                               |
|---------------------------------------------------------------------------|---------------------------------------------------------------|
| Входное напряжение                                                        | 100 В–240 В ± 10 %                                            |
| Частота                                                                   | 50/60 Гц                                                      |
| Потребляемая мощность                                                     | 500 ВА                                                        |
| Дополнительный выход переменного тока                                     | 200 ВА макс.                                                  |
| Внутренний предохранитель                                                 | 5 х 20 мм Т. L. 5 А, 250 В                                    |
|                                                                           | Medtronic Xomed, номер детали 11270066                        |
| Рабочий цикл деталей, находящихся в непосредственном контакте с пациентом | Максимальное время нахождения во включенном состоянии — 120 с |
|                                                                           | Минимальное время нахождения в выключенном состоянии — 180 с  |

Серийные номера шнуров питания

|                                                                                                                                                                                   |                                                                                             |                                                                                                                                                                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Северная Америка:<br>Барбадос, Белиз, Боливия, Венесуэла, Канада, Колумбия, США, Эквадор<br>Стандарт — номер детали EA600 или 1895820<br>6 метров — номер детали EA650 или 189721 | Великобритания,<br>Гонконг, Ирландия, Малайзия, Сингапур<br>Номер детали: EA606 или 1895821 | Континентальная Европа:<br>Австрия, Бельгия, Германия, Греция, Испания, Корея, Люксембург, Нидерланды, Норвегия, Португалия, Финляндия, Франция, Швеция<br>Номер детали: EA602 или 1895822 |
| Китай<br>Номер детали: EA604                                                                                                                                                      | Индия, ЮАР<br>Номер детали: EA607                                                           | Швейцария<br>Номер детали: EA601                                                                                                                                                           |
| Аргентина<br>Номер детали: EA608                                                                                                                                                  | Израиль<br>Номер детали: EA609                                                              | Дания<br>Номер детали: EA610                                                                                                                                                               |
| Австралия, Новая Зеландия<br>Номер детали: EA605                                                                                                                                  | Япония<br>Номер детали: EA603 или 1895823                                                   | Италия, Чили<br>Номер детали: EA611                                                                                                                                                        |

## ЗВУКОВАЯ СИГНАЛИЗАЦИЯ СИСТЕМЫ И РИСУНКИ

### Звуковые предупреждающие и информирующие сигналы

Пользователь пульта управления IPC может услышать следующие сигналы тревоги и звуковые сигналы.

#### Звуковой сигнал тревоги

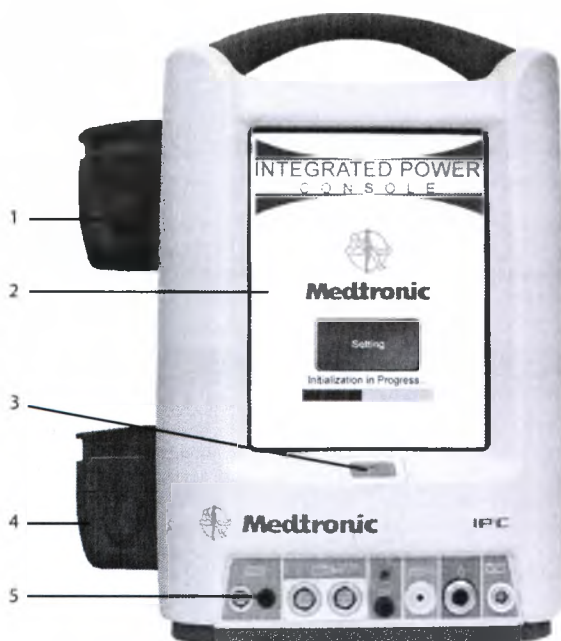
При обнаружении системой ошибки на сенсорном экране появляется сообщение, и система издает три последовательных звуковых сигнала.

#### Звуковые сигналы

| Сигнал IPC              | Причина(-ы)                                                                                                                                                                                                                                                                                                            |
|-------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 сигнал                | <ul style="list-style-type: none"> <li>Подтверждение нажатия кнопки переключения.</li> <li>Изменение режима работы с прямого на режим колебаний.</li> <li>Изменение активной рукоятки.</li> </ul>                                                                                                                      |
| 2 сигнала               | Изменение режима работы с колебаний на прямой.                                                                                                                                                                                                                                                                         |
| 3 сигнала               | <ul style="list-style-type: none"> <li>Звуковой сигнал тревоги. Обнаружена ошибка. См. сообщение об ошибке на экране.</li> <li>Активная рукоятка переведена в режим вращения в обратном направлении и нажата ножная педаль.</li> <li>Первое изменение направления работы инструмента с прямого на обратный.</li> </ul> |
| Длинный звуковой сигнал | Смена рукоятки на дрель.                                                                                                                                                                                                                                                                                               |

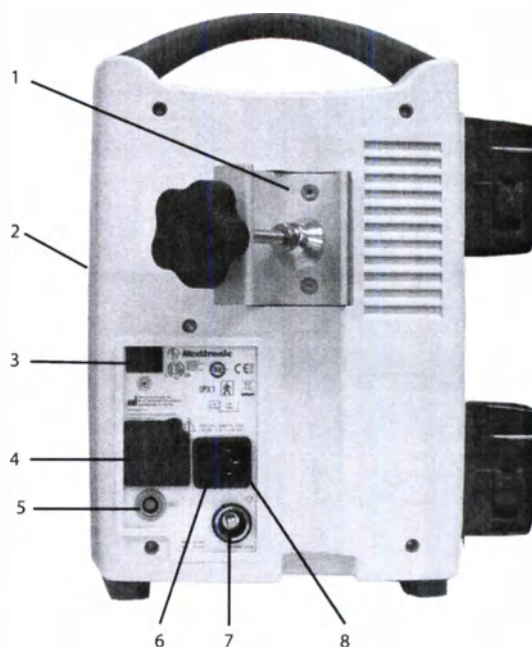
### Рисунки с изображениями системы

Рис. 1-1. Пульт управления IPC, вид спереди



- 1 Помпа 1: охлаждение, очистка линзы или ирригация
- 2 Сенсорный экран
- 3 Выключение и включение питания
- 4 Помпа 2: ирригация или очистка линзы
- 5 Панель разъемов пульта управления для подключения периферийных устройств

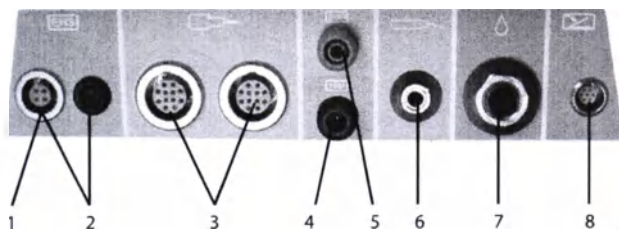
Рис. 1-2. Пульт управления IPC, вид сзади



- 1 Зажим для крепления к стойке
- 2 Порт для компактной флэш-карты (для использования специалистами Medtronic)
- 3 Запуск/остановка вручную
- 4 Дополнительная розетка электропитания
- 5 Разъем для Endo-Scrub 2
- 6 Доступ к предохранителю
- 7 Разъем для эквипотенциального заземления. Используйте проводник для выравнивания потенциала.
- 8 Разъем для шнура питания, предназначенного для медицинских учреждений

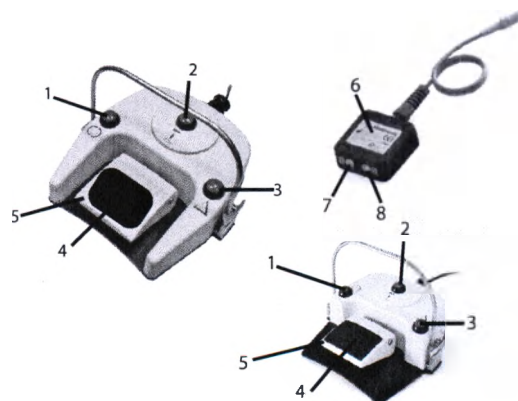


Рис. 1-3. Панель разъемов пульта управления ИРС



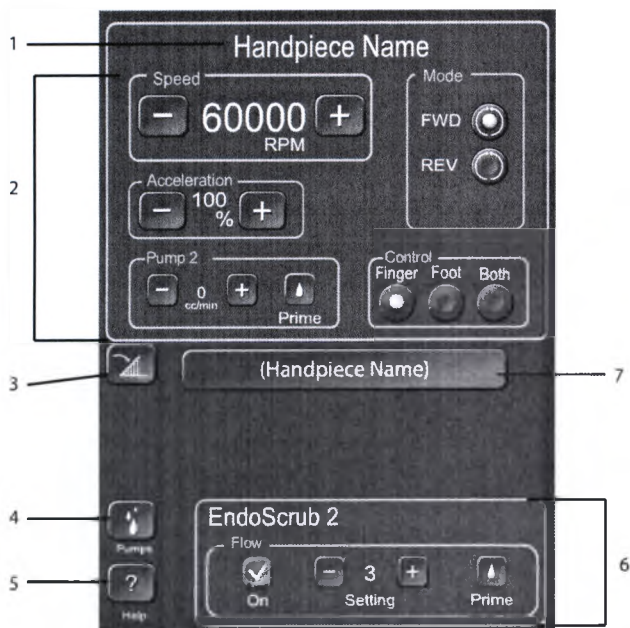
- |                                                                                                                                                                                                                                                                 |                                                                                                                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|
| 1 Электродвигатель Legend EHS                                                                                                                                                                                                                                   | 4 Входной порт для стимулирующего сигнала от блока интерфейса пациента (NIM или NIM-ECLIPSE)                                               |
| 2 Электродвигатель Legend EHS Stylus                                                                                                                                                                                                                            | 5 Выходной порт для стимулирующего сигнала к защитному устройству стимулирующего бора или POWEREASE                                        |
| 3 Рукоятка спинального шейвера, Микродебридер StraightShot M5, Микродебридер StraightShot M4, Микродебридер StraightShot Magnum II, Микродебридер StraightShot III, Электродвигатель Stylus Touch, Дрель Visao, Дрель Indigo, Микропилы Midas Rex, Дрель Triton | 6 Рукоятка Skeeter                                                                                                                         |
|                                                                                                                                                                                                                                                                 | 7 Пальцевой переключатель системы Endo-Scrub 2, Ножная педаль системы Endo-Scrub 2, Пульт дистанционного управления ирригацией IntelliFlow |
|                                                                                                                                                                                                                                                                 | 8 Многофункциональная ножная педаль                                                                                                        |

Рис. 1-4. Многофункциональная ножная педаль и У-образный делитель сигнала



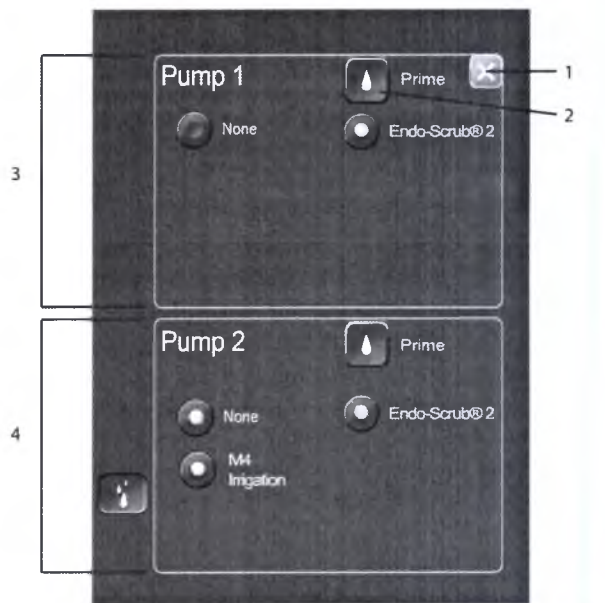
- |                              |                               |
|------------------------------|-------------------------------|
| 1 Кнопка переключения режима | 5 Ножная педаль               |
| 2 Кнопка рукоятки            | 6 У-образный делитель сигнала |
| 3 Кнопка управления          | 7 Порт 1                      |
| 4 Нескользкая подкладка      | 8 Порт 2                      |

Рис. 1-5. Сенсорный экран ИРС



- |                                                 |                                                                                    |
|-------------------------------------------------|------------------------------------------------------------------------------------|
| 1 Отображение активной рукоятки                 | 5 Открывает экран Help (Справка)                                                   |
| 2 Панель управления инструментом                | 6 Панель управления инструмента для ирригации                                      |
| 3 Управление переменной скоростью ножной педали | 7 Неактивная рукоятка                                                              |
| 4 Открывает экран Pumps (Помпы)                 | 8 Служит для установки настроек активной рукоятки в качестве настроек по умолчанию |

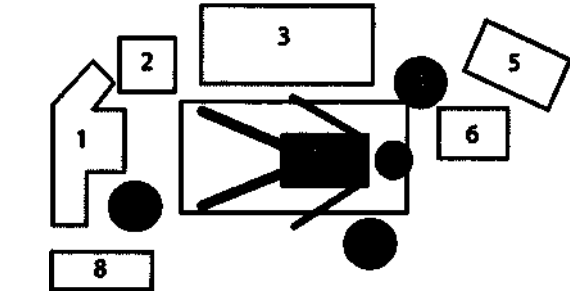
Рис. 1-6. Экран ИРС Pumps (Помпы)



- |                                         |                                                  |
|-----------------------------------------|--------------------------------------------------|
| 1 Закрыть панель помп                   | 3 Панель имеющихся инструментов Pump 1 (Помпа 1) |
| 2 Prime/Flush (Наполнить/Промыть) помпу | 4 Панель имеющихся инструментов Pump 2 (Помпа 2) |

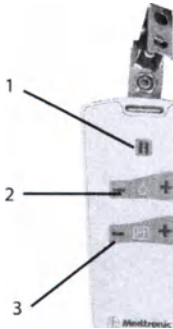


Рис. 1-7. Подготовка операционной



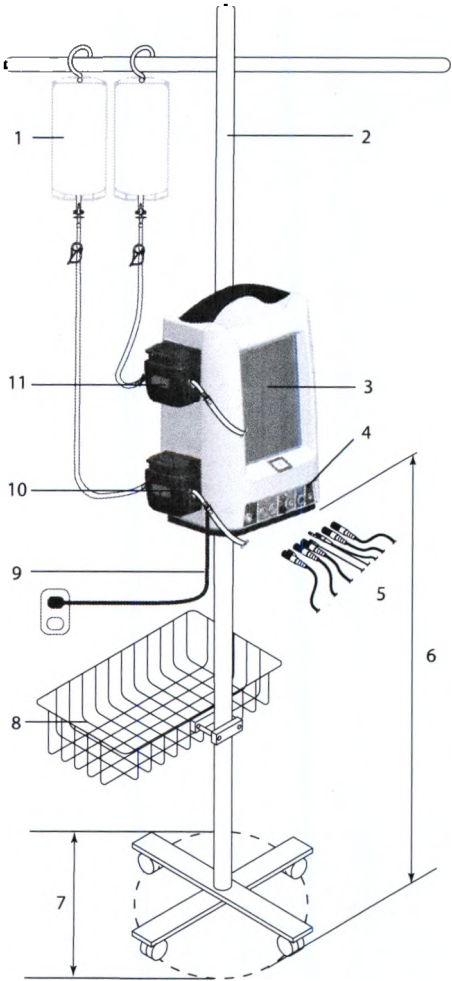
- |   |                                                               |    |                              |
|---|---------------------------------------------------------------|----|------------------------------|
| 1 | Оборудование для анестезии                                    | 6  | Микроскоп                    |
| 2 | Система IPC                                                   | 7  | Хирург                       |
| 3 | Хирургические расходные материалы / хирургические инструменты | 8  | Электрохирургический аппарат |
| 4 | Операционная сестра                                           | 9  | Анестезиолог                 |
| 5 | Монитор NIM                                                   | 10 | Пациент                      |

Рис. 1-9. Пульт дистанционного управления IntelliFlow



- |   |                                                                                                                                            |
|---|--------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Пауза/включение-выключение                                                                                                                 |
| 2 | Больше и меньше при тонкой регулировке                                                                                                     |
| 3 | Больше и меньше при грубой регулировке ИЛИ выбор размера (французского калибра) трубки из нержавеющей стали для аспирационного ирригатора. |

Рис. 1-8. Конфигурация системы IPC



- |   |                                               |    |                                                |
|---|-----------------------------------------------|----|------------------------------------------------|
| 1 | Пакеты с жидкостью для ирригации и охлаждения | 7  | Диаметр основания стойки для системы ирригации |
| 2 | Стойка для системы ирригации                  | 8  | Корзина стойки для системы ирригации           |
| 3 | Пульт управления IPC                          | 9  | Шнур питания                                   |
| 4 | Многоволоконный разъем пульта управления      | 10 | Помпа 2                                        |
| 5 | Кабели принадлежностей                        | 11 | Помпа 1                                        |
| 6 | Высота пульта управления                      |    |                                                |

## ДЕЙСТВИЯ ДО НАЧАЛА ЭКСПЛУАТАЦИИ СИСТЕМЫ

Ниже приведены общие инструкции по обращению с IPC до начала эксплуатации. Инструкции по эксплуатации отдельных рукояток и дополнительных принадлежностей приведены в других разделах данной инструкции по применению.

### При получении системы

- Убедитесь в том, что содержимое коробки соответствует перечню. При некомплекте или повреждении компонентов сообщите об этом в службу технической поддержки Medtronic.
- Если контейнер поврежден или амортизирующий материал имеет следы сдавливания, уведомьте об этом транспортную компанию и службу технической поддержки Medtronic. Сохраните упаковочный материал для осмотра представителем транспортной компании.
- Сохраните картонные коробки и упаковочный материал. Транспортная упаковка обеспечивает должную защиту устройства при перевозке.

### Настройка IPC

Подробные инструкции содержатся в соответствующих тематических разделах документации.

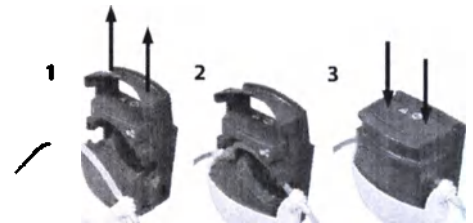
1. Установите картриджи помп или ирригационные трубки.
2. Подготовьте IPC к эксплуатации.
3. Если необходимо, проведите калибровку сенсорного экрана.
4. Если необходимо, измените настройки системы.
5. Настройте и заполните жидкостью помпы.
6. Подтвердите функциональность системы.
7. Нажмите несколько раз кнопку ручного запуска и остановки на задней стороне пульта управления (Рис. 1-2) и убедитесь в том, что вы можете запустить и остановить рукоятку, процесс ирригации и/или поток охлаждающей жидкости.

### Установка картриджей помп или ирригационных трубок

1. Найдите нужную помпу и поднимите фиксатор (Рис. 1-10).  
Помпа 1: охлаждение, очистка линзы или ирригация.  
Помпа 2: ирригация.  
**Важная информация!** Номер помпы должен соответствовать номеру, указанному на картридже (или 1/1, или 2/2). Если на картридже не указан номер, воспользуйтесь экраном Pump Setup (Настройка помпы) для установки картриджа.
2. Вставьте картридж помпы.
3. Закройте фиксатор со щелчком.

**Предупреждение!** Убедитесь в том, что картридж помпы не сдавливает трубку.

Рис. 1-10. Установка картриджа помпы



### Подготовка IPC к эксплуатации

1. Убедитесь в надлежащей подготовке операционной (Рис. 1-7). У хирурга могут быть свои предпочтения в отношении расположения и обзора компонентов.
2. Убедитесь в том, что все колеса на тележке IPC заблокированы.
3. Проверьте все компоненты на предмет повреждений и определите, готова ли система к работе.
4. Укрепите IPC и пакеты с жидкостью для ирригации и охлаждения на стойке для внутривенных вливаний (Рис. 1-8).  
**Важная информация!**
  - Укрепите пакеты с жидкостью для ирригации и охлаждения выше IPC, чтобы обеспечить надлежащий поток.
  - Рекомендуется использовать стойку для системы ирригации с диаметром основания не менее 53 см и закреплять все компоненты как можно ниже, чтобы повысить устойчивость во время использования.
  - При транспортировке или установке на неровном полу с уклоном более 10 градусов высота установки пульта управления не должна превышать 38 см, если пакеты с жидкостью для ирригации и охлаждения закреплены на высоте полностью раздвинутой стойки.
5. Подключите IPC к источнику электропитания. IPC нужно установить так, чтобы источник электропитания оставался доступным и позволял отключиться от электросети с помощью шнура питания.
6. Найдите на панели разъемов (Рис. 1-3) порт для подключения ножной педали или дополнительной принадлежности, совместите отметки на разъеме и пульте управления и затем вставьте разъем.
7. Подсоедините трубки для аспирации, охлаждения и/или ирригации.
8. Включите IPC и убедитесь в том, что система успешно выполняет самодиагностику.  
**Примечание.** Если IPC не обнаруживает рукоятку или ножную педаль, появится экран Connect Handpiece/Connect Footswitch (Подключение рукоятки/ножного переключателя). Выполните следующие действия:
  - Убедитесь в том, что кабель подсоединен к правильному порту.
  - Нажмите **[OK]** в информационном окне Connect Handpiece/Connect Footswitch (Подключение рукоятки/ножного переключателя), чтобы продолжить использование IPC без ножной педали или рукоятки.

### Калибровка сенсорного экрана

**Примечание.** Этот этап не обязателен.

1. Включите пульт управления IPC.
2. Во время запуска системы нажмите **[Settings]** (Настройки) в экране Splash (Начальный).
3. В экране Settings (Настройки) нажмите **Touch Screen Calibration** (Калибровка сенсорного экрана) и следуйте указаниям на экране.

Изменение настроек системы

Примечание. Во время хирургического вмешательства настройки системы можно перезаписать.

- 1. Включите пульт управления IPC.
- 2. Во время запуска системы нажмите [Settings] (Настройки) в экране Splash (Начальный).
- 3. Чтобы сменить язык, нажмите на название соответствующего языка.
- 4. Чтобы изменить настройки по умолчанию, нажмите [Default] (По умолчанию).
  - В экране Default (По умолчанию) нажмите стрелки вперед и назад, чтобы изменить выбранный инструмент.
  - Измените настройки по умолчанию.
  - Чтобы подтвердить выбранные настройки системы и вернуться в экран Splash (Начальный), нажмите [OK].
- 5. При работе с дополнительными принадлежностями, снабженными звуковой сигнализацией, нажмите кнопку управления звуковыми сигналами REV (Назад), чтобы обеспечить следующее:
  - система подает одну серию звуковых сигналов обратного вращения при активации режима реверса;
  - система подает одну серию звуковых сигналов обратного вращения при первом использовании дрели в режиме реверса после активации режима реверса.
- 6. Чтобы подтвердить выбранные настройки системы и вернуться к сенсорному экрану IPC, нажмите [OK].
- 7. Чтобы восстановить заводские настройки по умолчанию, нажмите [Restore] (Восстановить).

Настройки по умолчанию для рукоятки

Конфигурация системы зависит от подсоединенной к пульту управления рукоятки(-ок). В таблице ниже приведены конфигурации по умолчанию, настройки по умолчанию (X) и опции по умолчанию (O).

Примечание. Для обновления настроек активной рукоятки по умолчанию во время использования нажмите кнопку set active handpiece settings as default settings (Установка настроек активной рукоятки в качестве настроек по умолчанию) (рис. 1-5).

| Таблица 1. Конфигурации сенсорного экрана IPC по умолчанию |          |            |     |                                |           |       |      |           |            |        |       |           |                    |
|------------------------------------------------------------|----------|------------|-----|--------------------------------|-----------|-------|------|-----------|------------|--------|-------|-----------|--------------------|
| Рукоятка                                                   | Скорость |            |     | Режим или переключатель режима |           |       |      | Ускорение | Замедление | Размер | Поток | Ирригация | Управление         |
|                                                            | об./мин  | циклов/мин | %   | Вперед                         | Колебание | Назад |      |           |            |        |       |           |                    |
| Visao                                                      | 80 000   |            |     | X                              |           | O     |      |           |            |        |       | 30        |                    |
| Indigo                                                     | 52000    |            |     | X                              |           | O     |      |           |            |        |       | 30        |                    |
| Midas Rex SC1                                              |          | 3400       |     | O                              | X         |       |      |           |            |        |       | 60        |                    |
| StraightShot M5                                            | 5000     |            |     | O                              | X         |       |      |           |            |        |       | 05        |                    |
| StraightShot M4                                            | 5000     |            |     | O                              | X         |       |      |           |            |        |       | 05        |                    |
| StraightShot III, Magnum II                                | 5000     |            |     | O                              | X         |       |      |           |            |        |       | 30        |                    |
| Legend EHS Stylus                                          | 60 000   |            |     | X                              |           | O     | 45 % | 45 %      |            |        |       | 0         |                    |
| Legend EHS                                                 | 70 000   |            |     | X                              |           | O     |      |           |            |        |       | 0         |                    |
| Stylus Touch                                               | 60 000   |            |     | X                              |           | O     | 80 % | 100 %     |            |        |       | 0         | Управление пальцем |
| Skeeter                                                    | 16 000   |            |     | X                              |           | O     |      |           |            |        |       | 0         |                    |
| Endo-Scrub 2                                               |          |            |     |                                |           |       |      |           |            |        | 3     |           |                    |
| Аспирационный ирригатор                                    |          |            |     |                                |           |       |      |           |            | 8      | 50 %  |           |                    |
| Triton                                                     |          |            | 100 | X                              |           |       |      |           |            |        |       |           |                    |
|                                                            |          |            | 100 |                                |           | X     |      |           |            |        |       |           |                    |
| Микропилы Midas Rex                                        |          |            | 100 |                                |           |       |      |           |            |        |       | 0         |                    |
| POWEREASE                                                  | 120      |            |     | X                              |           |       |      |           |            |        |       |           |                    |
|                                                            | 120      |            |     |                                | X         |       |      |           |            |        |       |           |                    |
|                                                            | 250      |            |     |                                |           | X     |      |           |            |        |       |           |                    |

Установка и наполнение помп

- Пульт управления IPC включает помпу 1 и/или 2 на достаточно продолжительное время, необходимое для вытеснения воздуха из трубок при однократном нажатии на кнопку заполнения.
- При включении и выключении питания IPC происходит сброс функции наполнения помпы.
- После наполнения помпы кнопка наполнения приобретает функции промывки помпы.
  1. Подсоедините трубки картриджа IPC к трубкам для ирригационной или охлаждающей жидкости на инструменте.
  2. Переведите зажим ирригационной трубки в положение OPEN (Открыто).
  3. Если в инструменте есть прозрачная капельница (Visao), заполните прозрачную камеру капельницы охлаждающей жидкостью. Сжимайте и отпускайте камеру до полного заполнения.
  4. На сенсорном экране IPC (Рис. 1-5) нажмите кнопку помпы.

**Примечание.** Экран управления помпами доступен также из экрана Connect Handpiece/Connect Footswitch (Подключение рукоятки/ножного переключателя), который отображается при подготовке IPC к работе, если система не обнаруживает рукоятку или ножной переключатель.
  5. В экране управления помпами IPC (Рис. 1-6) выберите инструмент для каждой помпы.
  6. Для каждой помпы нажмите кнопку наполнения и убедитесь в выполнении следующих условий.
    - Помпа(-ы) работает(-ют) до полного вытеснения воздуха из трубок.
    - Небольшое количество lubricанта вытекает из кончика ирригационного устройства.
    - Помпа(-ы) выключается(-ются).
  7. Нажмите кнопку, закрывающую экран.

Конфигурации помп по умолчанию

Конфигурация помпы зависит от подсоединенной к пульту управления рукоятки(-ок). В таблице ниже приведены настройки помп по умолчанию (X) и опции по умолчанию (O).

| Таблица 2. Конфигурации по умолчанию в экране Pumps (Помпы) пульта управления IPC |            |           |           |              |         |                         |         |
|-----------------------------------------------------------------------------------|------------|-----------|-----------|--------------|---------|-------------------------|---------|
| Рукоятка                                                                          | Помпа 1    |           | Помпа 2   | Endo-Scrub 2 |         | Аспирационный ирригатор |         |
|                                                                                   | Охлаждение | Ирригация | Ирригация | Помпа 1      | Помпа 2 | Помпа 1                 | Помпа 2 |
| Visao                                                                             | X          |           | X         |              | O       |                         | O       |
| Indigo                                                                            |            | O         | X         | O            | O       | O                       | O       |
| Midas Rex SC1                                                                     |            | O         | X         | O            | O       |                         |         |
| StraightShot M5                                                                   |            | O         | X*        | X            | O       |                         |         |
| StraightShot M4                                                                   |            | O         | X*        | X            | O       |                         |         |
| StraightShot III, Magnum II                                                       |            | O         | X*        | X            | O       |                         |         |
| Legend EHS Stylus                                                                 |            | X         | O*        | O            | O       | O                       | O       |
| Legend EHS                                                                        |            | X         | O         | O            | O       | O                       | O       |
| Stylus Touch                                                                      |            | X         | O         | O            | O       | O                       | O       |
| Skeeter                                                                           |            |           |           | O            | O       | O                       | O       |
| Endo-Scrub 2                                                                      |            | X         | O         | X            | O       |                         |         |
| Аспирационный ирригатор                                                           |            | O         | O         |              |         | O                       | O       |
| Микропилы Midas Rex                                                               |            | O         | X         | O            | O       | O                       | O       |
| POWEREASE                                                                         |            |           |           | O            | O       | O                       | O       |

\* Когда IPC обнаруживает и StraightShot M4 или StraightShot M5, и рукоятку Legend EHS Stylus Touch, по умолчанию система устанавливает помпу 2 как «общую» ирригационную помпу. Необходимо вручную подсоединить ирригационные трубки к активной рукоятке.

Подтверждение функциональности системы

1. Убедитесь в том, что при нажатии педали ирригации активируется рукоятка и появляется ирригационная жидкость. Убедитесь в том, что в поле Speed (Скорость) на сенсорном экране скорость изменяется от белого до желтого цвета.
2. Убедитесь в том, что кнопки ножной педали работают. Для получения подробной информации см. «Многофункциональная ножная педаль».
3. Убедитесь в том, что вы можете выполнять все описанные ниже действия на сенсорном экране.
  - Регулирование скорости: в поле Speed (Скорость) нажимайте кнопки со знаками «плюс» и «минус».
  - Изменение режимов: в поле Mode (Режим) нажмите кнопку любого режима.
  - Регулирование потока: в поле Irrigation (Ирригация) нажимайте кнопки со знаками «плюс» и «минус».

## КОМПОНЕНТЫ IPC

### Подключение пульта управления к дополнительному источнику питания

**Предупреждение!** Дополнительная розетка электропитания предназначена только для подключения пультов IPC для Hydrodebrider и костной мельницы (см. W82). Дополнительная розетка электропитания предназначена только для подключения к сетям с напряжением  $\leq 120$  В переменного тока.

### Многофункциональная ножная педаль

Многофункциональную ножную педаль (Рис. 1-4) можно использовать для запуска и остановки наконечника, управления скоростью работы наконечника, выбора наконечника и рабочего режима. Специальные указания по использованию каждого наконечника и управлению им см. в теме, посвященной элементам управления многофункциональной ножной педалью.

### У-образный делитель сигнала

У-образный делитель сигнала (Рис. 1-4) позволяет использовать не более двух многофункциональных ножных педалей, подсоединенных к одному IPC (см. P23 и P24). В этой конфигурации У-образный делитель сигнала должен быть подключен к IPC, а многофункциональные ножные педали — к У-образному делителю сигнала. При подсоединении одной ножной педали к У-образному делителю сигнала можно использовать порт 1 или 2.

### Пульт дистанционного управления ирригацией IntelliFlow

Пульт дистанционного управления ирригацией IntelliFlow (Рис. 1-9) используется для запуска, остановки и изменения потока ирригационной жидкости в стерильном поле.

При использовании рукоятки для ирригации:

- для паузы ирригационного потока нажимайте кнопку паузы/включения-выключения;
- для регулирования ирригационного потока нажимайте кнопки «больше» и «меньше» в поле тонкой регулировки или грубой регулировки.

При использовании аспирационного ирригатора:

- для паузы, включения и выключения аспирационного ирригатора нажимайте кнопку паузы/включения-выключения;
- для регулирования ирригационного потока нажимайте кнопки «больше» и «меньше» в поле тонкой регулировки;
- для выбора размера (французского калибра) трубки из нержавеющей стали нажимайте кнопку выбора размера трубки из нержавеющей стали.



РЕКОМЕНДАЦИИ И ЗАЯВЛЕНИЕ ПРОИЗВОДИТЕЛЯ ПО УСТОЙЧИВОСТИ К ЭЛЕКТРОМАГНИТНОМУ ИЗЛУЧЕНИЮ  
Часть I

| ИРС предназначен для использования в электромагнитной обстановке, описанной ниже. Заказчик или пользователь ИРС должен убедиться в соответствии обстановки данным условиям. |                                                                         |                                                                         |                                                                                                                                                                                                                                                                                           |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|-------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Испытание на устойчивость к электромагнитному излучению                                                                                                                     | Уровень испытания IEC/EN60601-1-2                                       | Уровень соответствия                                                    | Электромагнитная обстановка — рекомендации                                                                                                                                                                                                                                                |
| Электростатический разряд (ЭСР)                                                                                                                                             | ± 6 кВ при контакте                                                     | ± 6 кВ при контакте                                                     | Полы в помещении должны быть выполнены из дерева, цемента или выложены керамической плиткой. Если полы покрыты синтетическим материалом, относительная влажность должна составлять не менее 30 %.                                                                                         |
| IEC 61000-4-2                                                                                                                                                               | ± 8 кВ по воздуху                                                       | ± 8 кВ по воздуху                                                       |                                                                                                                                                                                                                                                                                           |
| Испытание на помехоустойчивость к быстрым электрическим переходным процессам или всплескам IEC 61000-4-4                                                                    | ± 2 кВ для линий электропитания<br>± 1 кВ для входных/выходных линий    | ± 2 кВ для линий электропитания<br>± 1 кВ для входных/выходных линий    | Мощность, потребляемая от сети, должна соответствовать типичным условиям коммерческого учреждения или больницы.                                                                                                                                                                           |
| Испытание на помехоустойчивость к всплеску напряжения в сети электропитания IEC 61000-4-5                                                                                   | ± 1 кВ при дифференциальном включении<br>± 2 кВ при синфазном включении | ± 1 кВ при дифференциальном включении<br>± 2 кВ при синфазном включении | Мощность, потребляемая от сети, должна соответствовать типичным условиям коммерческого учреждения или больницы.                                                                                                                                                                           |
| Испытание на помехоустойчивость к провалам, прерываниям электропитания и колебаниям напряжения во входных линиях электропитания IEC 61000-4-11                              | < 5 % UT (падение > 95 % UT) в течение 0,5 цикла                        | < 5 % UT (падение > 95 % UT) в течение 0,5 цикла                        | Мощность, потребляемая от сети, должна соответствовать типичным условиям коммерческого учреждения или больницы. Если оператору ИРС необходимо продолжить работу при перебоях в электропитании, рекомендуется использовать источник бесперебойного электропитания или аккумулятор для ИРС. |
|                                                                                                                                                                             | 40 % UT (падение 60 % UT) в течение 5 циклов                            | 40 % UT (падение 60 % UT) в течение 5 циклов                            |                                                                                                                                                                                                                                                                                           |
|                                                                                                                                                                             | 70 % UT (падение 30 % UT) в течение 25 циклов                           | 70 % UT (падение 30 % UT) в течение 25 циклов                           |                                                                                                                                                                                                                                                                                           |
|                                                                                                                                                                             | < 5 % UT (падение > 95 % UT) в течение 5 сек                            | < 5 % UT (падение > 95 % UT) в течение 5 сек                            |                                                                                                                                                                                                                                                                                           |
| Магнитное поле с частотой сети электропитания (50/60 Гц) IEC 61000 4-8                                                                                                      | 3 А/м                                                                   | 3 А/м                                                                   | Магнитные поля с частотой питающей сети должны соответствовать требованиям к коммерческим помещениям или медицинским учреждениям.                                                                                                                                                         |
| Примечание. UT — напряжение в сети переменного тока до применения испытательного уровня.                                                                                    |                                                                         |                                                                         |                                                                                                                                                                                                                                                                                           |

| Рекомендации и заявление производителя по электромагнитному излучению                                                                                                       |               |                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ИРС предназначен для использования в электромагнитной обстановке, описанной ниже. Заказчик или пользователь ИРС должен убедиться в соответствии обстановки данным условиям. |               |                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Испытание на излучение                                                                                                                                                      | Соответствие  | Электромагнитная обстановка — рекомендации                                                                                                                                                                                                                                                                                                                                                                          |
| РЧ-излучение CISPR 11                                                                                                                                                       | Группа 1      | ИРС использует РЧ-энергию исключительно для осуществления внутренних функций. Поэтому РЧ-излучение очень низкое, и маловероятно, что оно вызовет какие-либо помехи в работе окружающего электронного оборудования.<br><br>ИРС пригоден для эксплуатации в любых помещениях, кроме жилых и непосредственно подключенных к бытовой электросети низкого напряжения, используемой для электроснабжения жилых помещений. |
| РЧ-излучение CISPR 11                                                                                                                                                       | Класс А       |                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Гармоническое излучение IEC 61000-3-2                                                                                                                                       | Класс А       |                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Колебания напряжения IEC 61000-3-3                                                                                                                                          | Соответствует |                                                                                                                                                                                                                                                                                                                                                                                                                     |

| Рекомендуемое разделяющее расстояние между портативным и мобильным РЧ коммуникационным оборудованием и ИРС                                                                                                                                                                                                                                                                                                                                   |                                                                     |                                           |                                            |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|-------------------------------------------|--------------------------------------------|
| ИРС предназначен для использования в электромагнитной обстановке с контролируемым уровнем РЧ-помех. Заказчик или оператор ИРС может способствовать профилактике электромагнитного взаимодействия, обеспечивая минимальное расстояние между портативным и мобильным РЧ коммуникационным оборудованием (передатчиками) и ИРС как рекомендуется ниже, в соответствии с максимальной мощностью выходного сигнала коммуникационного оборудования. |                                                                     |                                           |                                            |
| Номинальная<br>максимальная выходная<br>мощность передатчика,<br>Вт                                                                                                                                                                                                                                                                                                                                                                          | Разделяющее расстояние в соответствии с частотой передатчика, метры |                                           |                                            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                              | от 150 кГц до 80 МГц<br>$d = 1,2\sqrt{P}$                           | от 80 МГц до 800 МГц<br>$d = 1,2\sqrt{P}$ | от 800 МГц до 2,5 ГГц<br>$d = 2,3\sqrt{P}$ |
| 0,01                                                                                                                                                                                                                                                                                                                                                                                                                                         | 0,12                                                                | 0,12                                      | 0,23                                       |
| 0,10                                                                                                                                                                                                                                                                                                                                                                                                                                         | 0,38                                                                | 0,38                                      | 0,73                                       |
| 1,00                                                                                                                                                                                                                                                                                                                                                                                                                                         | 1,20                                                                | 1,20                                      | 2,30                                       |
| 10,00                                                                                                                                                                                                                                                                                                                                                                                                                                        | 3,80                                                                | 3,80                                      | 7,30                                       |
| 100,00                                                                                                                                                                                                                                                                                                                                                                                                                                       | 12,00                                                               | 12,00                                     | 23,0                                       |

Для передатчиков с максимальной выходной мощностью, не соответствующей перечисленным выше, рекомендуемое разделяющее расстояние  $d$  в метрах (м) можно рассчитать по уравнению, применимому к частоте передатчика, где  $P$  — максимальная номинальная выходная мощность передатчика в ваттах (Вт), по данным производителя передатчика.

ПРИМЕЧАНИЕ 1. Для передатчиков с рабочей частотой 80 МГц и 800 МГц применяется расстояние, соответствующее более высокому частотному диапазону.

ПРИМЕЧАНИЕ 2. Данные рекомендации могут применяться не во всех ситуациях. На распространение электромагнитного излучения влияют его поглощение и отражение конструкциями, предметами и людьми.

## Часть II

| IPC предназначен для использования в электромагнитной обстановке, описанной ниже.<br>Заказчик или пользователь IPC должен убедиться в соответствии обстановки данным условиям.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                   |                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Испытание на устойчивость к электромагнитному излучению                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Уровень испытания IEC/EN60601-1-2 | Уровень соответствия | Электромагнитная обстановка — рекомендации                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                   |                      | Портативное и мобильное РЧ коммуникационное оборудование следует использовать на расстоянии от любой части IPC, включая кабели, не меньшем, чем рекомендуемое разделяющее расстояние, которое рассчитывается по уравнению, соответствующему рабочей частоте передатчика.<br>Рекомендуемое разделяющее расстояние                                                                                                                                                                                                                                                                         |
| Испытания на устойчивость к кондуктивным помехам, наведенным радиочастотными электромагнитными полями                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 3 В ср. кв.                       | 3 В ср. кв.          | $d = 1,2 \sqrt{P}$                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| IEC 61000-4-6                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | от 150 кГц до 80 МГц              |                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Испытания на устойчивость к радиочастотному электромагнитному полю                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 3 В/м                             | 3 В/м                | $d = 1,2 \sqrt{P}$ от 80 МГц до 800 МГц                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| IEC 61000-4-3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | от 80 МГц до 2,5 ГГц              |                      | $d = 2,3 \sqrt{P}$ от 800 МГц до 2,5 ГГц                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                   |                      | Где $P$ — максимальная номинальная выходная мощность передатчика в ваттах (Вт) по данным производителя передатчика, а $d$ — рекомендуемое разделяющее расстояние в метрах (м).<br><br>Напряженность поля стационарных радиочастотных передатчиков, определяемая по данным электромагнитного мониторинга <sup>a</sup> , не должна превышать допустимого уровня во всех диапазонах частот <sup>b</sup> .<br><br>Рядом с оборудованием, помеченным следующим символом, возможно возникновение помех:<br> |
| ПРИМЕЧАНИЕ 1. Для передатчиков с рабочей частотой 80 МГц и 800 МГц применяется расстояние, соответствующее более высокому частотному диапазону.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                   |                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| ПРИМЕЧАНИЕ 2. Данные рекомендации могут применяться не во всех ситуациях. На распространение электромагнитного излучения влияют его поглощение и отражение конструкциями, предметами и людьми.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                   |                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| ПРИМЕЧАНИЕ 3. При эксплуатации системы IPC с рукояткой Stylus Touch допустимый уровень составляет 3 В/м, за исключением диапазона от 88 МГц до 91 МГц, где допустимый уровень составляет 1 В/м. Формула расчета разделяющего расстояния для системы IPC и Stylus Touch составляет $d = 3,5 \sqrt{P}$ в данном частотном диапазоне.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                   |                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| а Напряженность поля стационарных передатчиков, например базовых станций мобильной связи (беспроводных и сотовых телефонов), наземных мобильных радиостанций, любительских радиопередатчиков, радиовещательных станций в AM и FM диапазонах и телепередатчиков, невозможно точно определить теоретическими методами. Для оценки электромагнитной обстановки в помещении со стационарными радиочастотными передатчиками следует рассмотреть возможность проведения электромагнитной разведки. Если измеренная напряженность поля в помещении, в котором эксплуатируется IPC, превышает указанный выше применимый уровень соответствия, следует наблюдать за работой IPC для подтверждения его нормального функционирования. Если наблюдаются отклонения в работе IPC, могут потребоваться дополнительные меры, например, переориентация или перемещение устройства. |                                   |                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| б В частотном диапазоне от 150 кГц до 80 МГц напряженность полей не должна превышать 3 В/м.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                   |                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |

## ОГРАНИЧЕННАЯ ГАРАНТИЯ

- A. Настоящая ограниченная гарантия предоставляется покупателю системы IPC производства Medtronic. Настоящая ограниченная гарантия распространяется только на покупателя, который приобрел систему IPC непосредственно у корпорации Medtronic или у дочерней компании, либо у официального дистрибьютора или представителя корпорации. Система IPC включает пульт управления, электродвигатель или рукоятку, ножную педаль, кабели электродвигателя, контейнеры и лотки для инструментов (далее Компоненты Системы), прямые и изогнутые насадки для электродвигателей (далее Насадки), защитные устройства для боров и телескопические трубки (далее Многоразовые компоненты) и инструменты для препарирования, трубки для ирригационных и охлаждающих жидкостей и пульт управления Intelliflow (далее Одноразовые компоненты); все вместе перечисленные компоненты далее обозначаются как Система IPC, если не указано иное.
- i. Если Компонент системы в течение срока действия этой ограниченной гарантии (в течение 1 [одного] года со дня продажи нового Компонента системы или в течение 90 [девяноста] дней со дня продажи восстановленного или подержанного Компонента системы) окажется не в состоянии функционировать в соответствии с заявленными компанией Medtronic характеристиками, то компания Medtronic произведет ремонт либо замену Компонента электродвигателя или любых его частей.
  - ii. Если Насадка в течение срока действия этой ограниченной гарантии (в течение 90 [девяноста] дней со дня продажи новой Насадки) окажется не в состоянии функционировать в соответствии с заявленными компанией Medtronic характеристиками, то компания Medtronic произведет ремонт либо замену этой Насадки или любых ее частей.
  - iii. Если Частично многократно применяемый компонент в течение срока действия этой ограниченной гарантии (в течение 30 [тридцати] дней со дня продажи нового Частично многократно применяемого компонента) окажется не в состоянии функционировать в соответствии с заявленными компанией Medtronic характеристиками, то компания Medtronic произведет замену этого Частично многократно применяемого компонента или любых его частей.
  - iv. Если Одноразовый компонент до истечения срока его годности (Использовать до) окажется не в состоянии функционировать в соответствии с заявленными корпорацией Medtronic характеристиками, то корпорация Medtronic произведет замену этого Одноразового компонента.
- B. Для получения права на данную ограниченную гарантию должны выполняться следующие условия.
- i. Продукт должен быть использован до истечения срока годности (в случае его наличия).
  - ii. Продукт должен использоваться в соответствии с обозначениями и не должен модифицироваться, использоваться неправильно или не по назначению. Продукт не должен быть поврежден или подвергнут ненадлежащему обращению.
  - iii. Корпорацию Medtronic следует оповестить в письменной форме в течение тридцати (30) дней после обнаружения дефекта.
  - iv. Продукт должен быть возвращен в корпорацию Medtronic в течение тридцати (30) дней после получения в корпорации Medtronic уведомления в соответствии с пунктом 3.
  - v. В зависимости от результатов исследования продукта специалистами корпорации Medtronic, корпорацией Medtronic должно быть определено, что: (i) Продукт не подвергался ремонту или изменению конструкции силами лиц, не относящихся к корпорации Medtronic или ее уполномоченным представителям, (ii) Продукт не эксплуатировался в условиях, отличных от стандартных, и (iii) надлежащее периодическое техническое обслуживание. Продукт проводилось, если это применимо.
- C. Данная ограниченная гарантия имеет ограничения в виде оговоренных условий. НАСТОЯЩАЯ ОГРАНИЧЕННАЯ ГАРАНТИЯ ЗАМЕНЯЕТ ВСЕ ОСТАЛЬНЫЕ ГАРАНТИИ, ПРЯМЫЕ ИЛИ ОПОСРЕДОВАННЫЕ, КАК РЕГЛАМЕНТИРУЕМЫЕ ЗАКОНОДАТЕЛЬСТВОМ, ТАК И ИНЫЕ, В ТОМ ЧИСЛЕ ЛЮБЫЕ ПОДРАЗУМЕВАЕМЫЕ ГАРАНТИИ КОММЕРЧЕСКОЙ ВЫГОДЫ ИЛИ СООТВЕТСТВИЯ КАКОЙ-ЛИБО КОНКРЕТНОЙ ЦЕЛИ. Ни при каких обстоятельствах корпорация Medtronic не несет ответственности за любой случайный, опосредованный, предполагаемый или иной аналогичный ущерб, являющийся следствием дефекта, сбоя или неисправности Продукта, независимо от того, основана ли претензия на гарантийных обязательствах, контракте, небрежного обращения с Продуктом или иных основаниях.
- D. Исключения и ограничения, указанные выше, не подразумевают противоречие обязательным положениям применимых правовых норм и не должны расцениваться как таковые. Пользователи могут воспользоваться обязательными правами на гарантию согласно законам, регламентирующим реализацию товаров широкого потребления. Если какая-либо часть или условие данной ограниченной гарантии определяются судом компетентной юрисдикции как незаконные, не имеющие возможности служить основанием для иска или противоречащие применяемым правовым нормам, оставшаяся часть ограниченной гарантии будет считаться имеющей юридическую силу и все права и обязательства будут толковаться и принудительно обеспечиваться, как если бы данная ограниченная гарантия не содержала отдельных частей или условий, которые считаются не имеющими юридической силы.

## КАСАТЕЛЬНО КОМПОНЕНТОВ, ЗАРАЖЕННЫХ ВОЗБУДИТЕЛЯМИ ТГЭ

Политика возврата предметов, потенциально зараженных возбудителем трансмиссивной губчатой энцефалопатии (ТГЭ)

Корпорация Medtronic не будет санкционировать или принимать возврат продуктов, имевших непосредственный контакт с пациентами или загрязненных биологическими жидкостями пациентов, в отношении которых имеются подозрения или подтвержден диагноз трансмиссивной губчатой энцефалопатии или болезни Крейтцфельда-Якоба.

Приводящиеся ниже рекомендации не имеют строго обязательного характера и могут изменяться в зависимости от конкретных особенностей политики и процедур, применяемых в различных медицинских учреждениях. По вопросам текущих процедур и правил обработки многоразового оборудования в случае возникновения подозрений о заражении болезнью Крейтцфельда-Якоба или возбудителями трансмиссивной губчатой энцефалопатии больничному персоналу следует обращаться к специалистам, ответственным за профилактику инфекционных заболеваний в лечебном учреждении.

Инструменты для препарирования, боры или лезвия Medtronic, использованные в операциях на пациентах, у которых подозревается болезнь Крейтцфельда-Якоба или трансмиссивная губчатая энцефалопатия, следует сжигать. Многоразовое оборудование, использованное на пациентах, у которых подозревается болезнь Крейтцфельда-Якоба или трансмиссивная губчатая энцефалопатия, должны подвергаться карантину и не использоваться повторно, пока не будет подтвержден или опровергнут диагноз. Многоразовое оборудование следует переводить на карантин после очистки, обеззараживания, стерилизации и упаковки в жесткий герметичный контейнер до получения окончательного диагноза. Если диагноз болезни Крейтцфельда-Якоба или трансмиссивной губчатой энцефалопатии не подтверждается, находящееся на карантине многоразовое оборудование можно вернуть в эксплуатацию после соответствующей очистки, обеззараживания и стерилизации.

Компания Medtronic рекомендует сжигать все изделия Medtronic, использованные на пациентах с подтвержденным диагнозом трансмиссивной губчатой энцефалопатии. По вопросам приобретения заменяющей продукции или получения надежного оборудования во временное пользование обращайтесь к своему торговому представителю.

За дополнительными сведениями обращайтесь в отдел по работе с клиентами.



# ЭЛЕКТРОРУКОЯТКА TRITON С ВЫСОКИМ КРУТЯЩИМ МОМЕНТОМ

## ОПИСАНИЕ УСТРОЙСТВА

Электрорукоятка Triton с высоким крутящим моментом позволяет удалять твердые и мягкие ткани, просверливать базовые отверстия, закручивать винты, вставлять проволоки и штифты при спинальных и краниальных хирургических вмешательствах и операциях на костных структурах малых размеров, которые выполняются имеющими специальную подготовку хирургами в условиях операционных.

Приведенные ниже инструкции, касающиеся электрорукоятки Triton с высоким крутящим моментом, дополняют общие инструкции по сборке, приведенные в разделе «Настройка IPC». Выполните все этапы настройки IPC и перейдите к инструкциям, приведенным ниже.

## ПЕРЕД ПРИМЕНЕНИЕМ

Перед первым применением очистите и простерилизуйте устройство. Дополнительную информацию см. в инструкциях по обработке в данном руководстве.

## СБОРКА САГИТТАЛЬНОЙ ПИЛЫ TRITON

**Предупреждение!** Насадки с пилами Triton должны применяться только с лезвиями для пил Triton производства компании Medtronic. Дополнительная информация по лезвиям для пил Triton приведена в Triton Quick Reference Saw Blade Guide (Кратком справочном руководстве по лезвиям к пиле Triton (LIT200017)).

1. Вставьте насадку с сагиттальной пилой в рукоятку так, чтобы легко было ввести ключ для сагиттальной пилы (Рис. 2-1).

**Примечание.** Для обеспечения надлежащего хирургического доступа можно вставить насадку в 12 различных положениях.

Рис. 2-1. Сборка сагиттальной пилы



2. Вставьте ключ для сагиттальной пилы в насадку и поверните его против часовой стрелки до ощущения слабого сопротивления.
3. Вставьте лезвие в пространство между двумя зажимами и убедитесь в том, что лезвие установлено до упора.
4. Чтобы зафиксировать лезвие, поверните ключ для сагиттальной пилы по часовой стрелке. Активируйте инструмент на короткое время и еще раз затяните лезвие.

**Внимание!** Не затягивайте лезвие слишком сильно.

## РАЗБОРКА САГИТТАЛЬНОЙ ПИЛЫ TRITON

Чтобы снять лезвие для пилы Triton, вставьте ключ для сагиттальной пилы в насадку и поверните его против часовой стрелки.

## СБОРКА РЕЦИПРОКНОЙ ПИЛЫ TRITON

**Предупреждение!** Насадки с пилами Triton должны применяться только с лезвиями для пил Triton производства компании Medtronic. Дополнительная информация по лезвиям для пил Triton приведена в Triton Quick Reference Saw Blade Guide (Кратком справочном руководстве по лезвиям к пиле Triton (LIT200017)).

1. Открутите гайку зажимного патрона и вставьте лезвие до упора (Рис. 2-2).

**Примечание.** Насадку можно устанавливать в различных положениях для обеспечения надлежащего хирургического доступа.

2. Затяните гайку зажимного патрона вручную. Активируйте инструмент на короткое время и еще раз затяните гайку.

Рис. 2-2. Сборка реципрокной пилы



## РАЗБОРКА РЕЦИПРОКНОЙ ПИЛЫ TRITON

Чтобы снять лезвие для реципрокной пилы Triton, открутите гайку зажимного патрона.

## СБОРКА ЦАНГОВЫХ ПАТРОНОВ TRITON AO/SYNTHES И TRINKLE

1. Чтобы установить перовое сверло, оттяните назад кольцо на насадке (Рис. 2-3).
2. Вставьте перовое сверло и отпустите кольцо.

Рис. 2-3. Сборка цанговых патронов AO/Synthes и Trinkle



## РАЗБОРКА ЦАНГОВЫХ ПАТРОНОВ TRITON AO/SYNTHES И TRINKLE

1. Чтобы снять перовое сверло, оттяните назад кольцо на насадке.
2. Выньте перовое сверло и отпустите кольцо.



### СБОРКА ЦАНГОВОГО ПАТРОНА TRITON JACOBS

1. Чтобы установить перовое сверло, поверните ключ, чтобы открыть патрон или поверните патрон, если используется насадка с патроном, не требующим ключа (Рис. 2-4).
2. Вставьте перовое сверло.

Рис. 2-4. Сборка цангового патрона Jacobs



### РАЗБОРКА ЦАНОВОГО ПАТРОНА TRITON JACOBS

1. Чтобы снять перовое сверло, поверните ключ, чтобы открыть патрон или поверните патрон, если используется насадка с патроном, не требующим ключа.
2. Выньте перовое сверло.

### СБОРКА ЦАНГОВЫХ ПАТРОНОВ TRITON HUDSON И ZIMMER

Чтобы установить инструмент, оттяните назад кольцо на насадке и вставьте вставной конец инструмента в зажимной патрон (рис. 2-5).

Рис. 2-5. Сборка цанговых патронов Hudson и Zimmer



### РАЗБОРКА ЦАНГОВЫХ ПАТРОНОВ TRITON HUDSON И ZIMMER

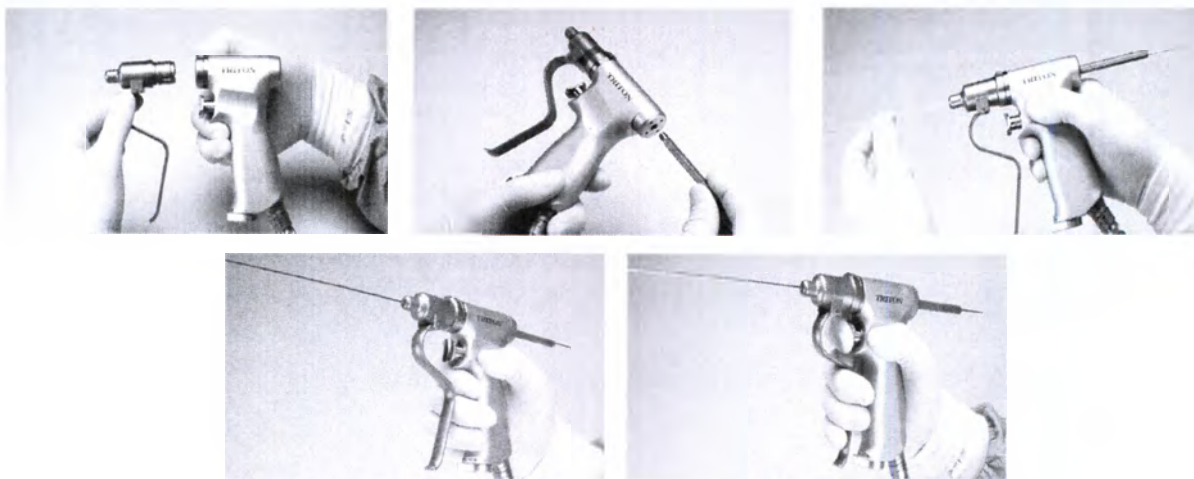
Чтобы снять инструмент, оттяните назад кольцо на насадке и выньте вставной конец инструмента из цангового патрона.

### СБОРКА ЗАЖИМНОГО ПАТРОНА ДЛЯ ПРОВОЛОКИ И ШТИФТА TRITON

К зажимному патрону для проволоки подходит проволока диаметром до 1,6 мм. К зажимному патрону для штифта подходят штифты диаметром до 3,2 мм.

1. Вставьте зажимной патрон для проволоки или штифта (Рис. 2-6), переведя рукоятку в БЕЗОПАСНЫЙ режим (Рис. 2-7).
2. Вкрутите канюлированный удлинитель с задней стороны рукоятки, чтобы обеспечить защиту для хирурга от укола проволокой или штифтом, насколько это необходимо.
3. Вставьте проволоку или штифт спереди или сзади рукоятки.
4. Переведите инструмент в РАБОЧЕЕ положение, расположив кнопку-регулятор вертикально.
5. Поверните переключатель режима на основании рукоятки в положение ВПЕРЕД.
6. Зажмите рукой рычаг выдвижения проволоки/штифта и удерживайте его.
7. Нажмите кнопку-регулятор, чтобы привести в движение проволоку/штифт. Кнопка-регулятор чувствительна к силе нажатия, что обеспечивает переменную скорость работы.
8. Чтобы использовать дополнительную длину проволоки/штифта, разблокируйте проволоку/штифт.
9. Выдвиньте рычаг и кнопку-регулятор.
10. Оттяните рукоятку к себе по вставленному инструменту.
11. Зажмите рычаг выдвижения проволоки/штифта и кнопку-регулятор, чтобы привести в движение проволоку.

Рис. 2-6. Сборка зажимного патрона для проволоки и штифта



РАЗБОРКА ЗАЖИМНОГО ПАТРОНА ДЛЯ ПРОВОЛОКИ И ШТИФТА TRITON

Чтобы вынуть вставленную в ткань проволоку/штифт, переведите переключатель режима в положение НАЗАД, зажмите рычаг выдвижения проволоки/штифта и нажмите кнопку-регулятор.

ЭКСПЛУАТАЦИЯ ЭЛЕКТРУКОУЯТКИ TRITON С ВЫСОКИМ КРУТЯЩИМ МОМЕНТОМ

В насадку можно вставить инструмент перед присоединением ее к рукоятке.

**Внимание!** При присоединении всех насадок переведите рукоятку в БЕЗОПАСНОЕ положение (Рис. 2-7).

**Примечание.** В рукоятке есть дополнительная ручка, которая вкручивается в заднюю часть рукоятки. Дополнительная ручка обеспечивает баланс и возможность задействовать обе руки при различных работах по сверлению отверстий и резке.

1. Переведя рукоятку в БЕЗОПАСНОЕ положение (Рис. 2-7), вставьте насадку с инструментом, нажав кнопку быстрой разблокировки на верхней поверхности рукоятки. Закрепите насадку в рукоятке, слегка повернув ее до полной посадки.
2. Переведите рукоятку в РАБОЧЕЕ положение, повернув кнопку-регулятор вертикально. Переключатель режима внизу рукоятки должен быть переведен в положение ВПЕРЕД.
3. После окончания работы верните кнопку-регулятор в БЕЗОПАСНОЕ положение до того, как отсоединить насадку.
4. Снимите насадку, нажав кнопку быстрой разблокировки на верхней поверхности рукоятки.

Безопасное положение

В БЕЗОПАСНОМ положении рукоятка не работает. Чтобы начать работу с рукояткой, активируйте и нажмите кнопку-регулятор.

Рис. 2-7. Безопасное и рабочее положения рукоятки Triton



БЕЗОПАСНОЕ ПОЛОЖЕНИЕ: поверните кнопку-регулятор в любую сторону, чтобы перевести рукоятку в БЕЗОПАСНЫЙ режим.

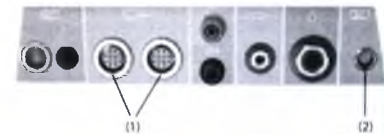
РАБОЧЕЕ ПОЛОЖЕНИЕ: кнопка-регулятор в вертикальном положении позволяет активировать рукоятку.

ПОДСОЕДИНЕНИЕ ЭЛЕКТРУКОУЯТКИ TRITON С ВЫСОКИМ КРУТЯЩИМ МОМЕНТОМ К IPC

Найдите нужный порт для подключения электрукоутки Triton с высоким крутящим моментом на панели разъемов (Рис. 2-8) и вставьте разъем.

**Примечание.** Чтобы вставить многотырьковые разъемы (такие разъемы обозначены серебряной или красной меткой), совместите метку на разъеме с меткой на пульте управления и вставьте разъем.

Рис. 2-8. Порты для подключения Triton к IPC



1 Подключение Triton

2 Подключение ножной педали

ЭЛЕМЕНТЫ УПРАВЛЕНИЯ ЭЛЕКТРУКОУЯТКОЙ TRITON С ВЫСОКИМ КРУТЯЩИМ МОМЕНТОМ НА СЕНСОРНОМ ЭКРАНЕ

Чтобы настроить переменную скорость работы электрукоутки Triton с высоким крутящим моментом, в поле управления FWD Speed (Скорость вращения вперед) или REV Speed (Скорость вращения назад) (Рис. 2-9) на сенсорном экране IPC нажимайте кнопки со знаками «плюс» для увеличения переменной скорости и «минус» для снижения переменной скорости.

Рис. 2-9. Сенсорный экран Triton



ПЕРЕКЛЮЧАТЕЛЬ РЕЖИМА ЭЛЕКТРУКОУЯТКИ TRITON С ВЫСОКИМ КРУТЯЩИМ МОМЕНТОМ

Переключатель режима используется для изменения направления работы рукоятки с прямого на обратное, если рукоятка является активной. Когда рукоятка не активна, используйте переключатель режима для включения рукоятки.

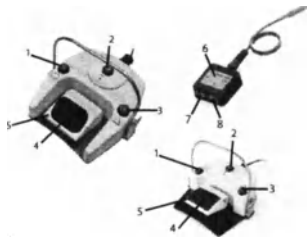
ЭЛЕМЕНТЫ УПРАВЛЕНИЯ ЭЛЕКТРОРУКОЯТКОЙ TRITON С ВЫСОКИМ КРУТЯЩИМ МОМЕНТОМ НА МНОГОФУНКЦИОНАЛЬНОЙ НОЖНОЙ ПЕДАЛИ

**Важная информация!** По умолчанию, для активирования выбранного действия необходимо нажимать каждую кнопку не менее 100 мсек. Изменить это значение по умолчанию можно в экране Settings (Настройки) на сенсорном экране IPC. Для управления рукояткой с помощью многофункциональной ножной педали (Рис. 2-10) выполните следующие действия.

- Чтобы переключиться между режимом пуска/остановки и режимом переменной скорости, нажмите кнопку управления.
- Чтобы сменить рукоятку, нажмите кнопку рукоятки.



Рис. 2-10. Многофункциональная ножная педаль и У-образный делитель сигнала



- 1 Кнопка переключения режима
- 2 Кнопка рукоятки
- 3 Кнопка управления
- 4 Нескользящая подкладка
- 5 Ножная педаль
- 6 У-образный делитель сигнала
- 7 Порт 1
- 8 Порт 2

Управление вращением электрорукоятки Triton с высоким крутящим моментом в обратном направлении с помощью многофункциональной ножной педали

При подсоединении к пульту управления IPC дополнительной ножной педали она может использоваться как альтернативный метод активации режима обратного вращения (без помощи переключателя режима снизу рукоятки). При подключении педали на экране появляется поле управления Reverse Pedal (Педаль обратного вращения) (Рис. 2-11).

**Примечание.** По умолчанию, педаль отключена (OFF (Выкл.)).

1. Чтобы воспользоваться педалью, нажмите ON (Вкл.) в поле управления Reverse Pedal (Педаль обратного вращения) на сенсорном экране IPC.
2. Если педаль включена, нажмите ногой на ножную педаль, чтобы рукоятка начала вращаться в обратном направлении (независимо от положения переключателя режима).

**ПРИМЕЧАНИЕ.** Для активирования рукоятки кнопка-регулятор должна быть нажата, даже если вы давите на ножную педаль.

3. Чтобы вернуть рукоятку в режим работы, определенный положением переключателя режима внизу рукоятки, уберите ногу с педали.

Рис. 2-11. Поле управления Reverse Pedal (Педаль обратного вращения)



ИНСТРУКЦИИ ПО ОЧИСТКЕ И СТЕРИЛИЗАЦИИ ЭЛЕКТРОРУКОЯТКИ TRITON С ВЫСОКИМ КРУТЯЩИМ МОМЕНТОМ

См. документ M000030A322 в разделе, посвященном очистке и стерилизации.

ТЕХНИЧЕСКИЕ ХАРАКТЕРИСТИКИ ЭЛЕКТРОРУКОЯТКИ TRITON С ВЫСОКИМ КРУТЯЩИМ МОМЕНТОМ

Электрорукоятка Triton с высоким крутящим моментом ED500

|                                                                           |                                                                                                                                                                                                                                                                                                                      |
|---------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Размер                                                                    | Д 8,9 см х В 13,7 см х Ш 2,8 см                                                                                                                                                                                                                                                                                      |
| Масса                                                                     | 0,9 кг                                                                                                                                                                                                                                                                                                               |
| Скорость                                                                  | 180–1800 циклов/мин (фактическая скорость зависит от используемой насадки)                                                                                                                                                                                                                                           |
| Рабочий цикл деталей, находящихся в непосредственном контакте с пациентом | Длительность цикла: максимум 20 секунд во включенном состоянии / минимум 20 секунд в выключенном состоянии<br>Максимальное количество рабочих циклов перед перерывом в работе рукоятки: 6<br>Максимальное количество рабочих циклов перед перерывом в работе насадки: 3<br>Минимальная длительность перерыва: 25 мин |

# АСПИРАЦИОННЫЙ ИРРИГАТОР

Приведенные ниже инструкции, касающиеся аспирационного ирригатора, дополняют общие инструкции по сборке, приведенные в разделе «Настройка IPC». Выполните все этапы настройки IPC и перейдите к инструкциям, приведенным ниже.

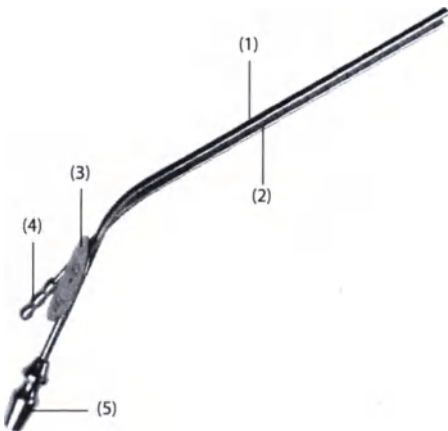
## СБОРКА АСПИРАЦИОННОГО ИРРИГАТОРА

- 1. Соедините механизм отсоса и патрубок для системы отсоса на аспирационном ирригаторе с помощью трубки отсоса (Рис. 3-1).
- 2. На сенсорном экране IPC (Рис. 1-5) нажмите кнопку помпы.
- 3. В экране управления помпами IPC (Рис. 1-6) выберите помпу для аспирационного ирригатора.  
**Примечание.** При использовании рукоятки, которая подсоединяется к помпе, IPC автоматически задействует аспирационный ирригатор с помпой, которая не используется рукояткой.
- 4. Соедините картридж IPC (Рис. 1-8) и ирригационный патрубок на аспирационном ирригаторе (Рис. 3-1) с помощью ирригационной трубки.
- 5. Переведите зажим ирригационной трубки в положение OPEN (Открыто).

## НАБОР АДАПТЕРА АСПИРАЦИОННОГО ИРРИГАТОРА

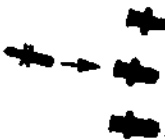
- 1. Подсоедините адаптер к высокоскоростной ирригационной трубке (синий адаптер) или к трубке IPC (белый адаптер).
- 2. Подсоедините адаптер к соединительной ирригационной трубке (Рис. 3-2).
- 3. Подсоедините соединительную ирригационную трубку к ирригационному патрубку на аспирационном ирригаторе.

Рис. 3-1. Аспирационный ирригатор



- |                           |                                  |
|---------------------------|----------------------------------|
| 1 Трубка отсоса           | 4 Ирригационный<br>патрубок      |
| 2 Ирригационная<br>трубка | 5 Патрубок для системы<br>отсоса |
| 3 Размер трубки           |                                  |

Рис. 3-2. Набор адаптера аспирационного ирригатора





АСПИРАЦИОННЫЙ ИРРИГАТОР В АВТОНОМНОМ РЕЖИМЕ

Аспирационный ирригатор может работать как автономное устройство, для чего необходимо изменить настройки по умолчанию системы IPC

- 1. В меню Defaults (По умолчанию) (рис. 3-3) в поле Stand Alone (Автономно) выберите **Suction Irrigator** (Аспирационный ирригатор) и нажмите **[OK]**.
- 2. На экране Handpiece Connection (Подключение рукоятки) (рис. 3-4) в поле Suction Irrigator (Аспирационный ирригатор) нажмите **[OK]**.

Рис. 3-3. Меню настроек по умолчанию системы IPC General (Общие)

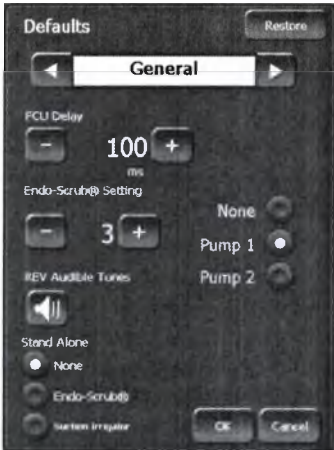


Рис. 3-4. Экран подключения наконечника



ЭЛЕМЕНТЫ УПРАВЛЕНИЯ АСПИРАЦИОННЫМ ИРРИГАТОРОМ НА СЕНСОРНОМ ЭКРАНЕ

Чтобы задать или настроить элементы управления аспирационным ирригатором, выполните следующие действия на сенсорном экране IPC в поле управления Suction Irrigator (Аспирационный ирригатор) (Рис. 3-5).

- Чтобы задать размер трубки, в поле управления Size (Размер) нажимайте кнопки со знаками «плюс» и «минус».
- Примечание.** По умолчанию в системе задано значение 8.
- Чтобы включить или отключить ирригацию, в поле управления Flow (Поток) выберите окошко On/Off (Вкл./Выкл.).
- Чтобы регулировать скорость потока, в поле управления Flow (Поток) нажимайте кнопки со знаками «плюс» и «минус».

Рис. 3-5. Сенсорный экран Suction Irrigator (Аспирационный ирригатор)





# ENDO-SCRUB 2

Приведенные ниже инструкции, касающиеся Endo-Scrub 2, дополняют общие инструкции по сборке, приведенные в разделе «Настройка IPC». Выполните все этапы настройки IPC и перейдите к инструкциям, приведенным ниже. Дополнительную информацию см. в документах Endo-Scrub 2 System Instructions for Use (Инструкция по эксплуатации системы Endo-Scrub 2), Endo-Scrub Sheaths Instructions for Use (Инструкция по эксплуатации чехлов Endo-Scrub) и Endo-Scrub 2 Finger Switch Instructions for Use (Инструкция по эксплуатации пальцевого переключателя Endo-Scrub 2).

В системе IPC реализована функция Endo-Scrub 2, которая обеспечивается применением ирригационной помпы номер один (1) и управлением ее работой с помощью сенсорного экрана и внешнего ножного переключателя или пальцевого переключателя.

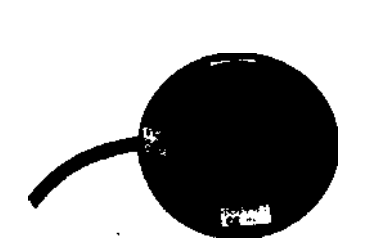
ЗАПРЕЩАЕТСЯ использовать систему Endo-Scrub 2 для инфузий, для дезинфицирования или стерилизации эндоскопа, для аспирационного удаления крови и остатков органических веществ.

Чехол Endo-Scrub 2 разрешается использовать только с эндоскопами, перечисленными на этикетке чехла. В противном случае возможно нарушение работоспособности или ухудшение рабочих характеристик изделий.

Рис. 4-1. Пальцевой переключатель Endo-Scrub 2



Рис. 4-2. Ножная педаль Endo-Scrub 2



## СБОРКА ENDO-SCRUB 2

- Смочите эндоскоп.
- Медленно введите эндоскоп утвержденного типа в чехол Endo-Scrub 2 (Рис. 4-3).
- Подсоедините ирригационную трубку и источник света (Рис. 4-4).

Рис. 4-3. Сборка Endo-Scrub 2

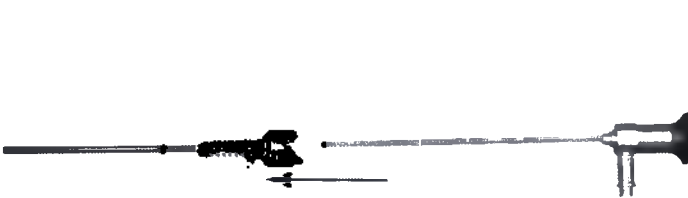
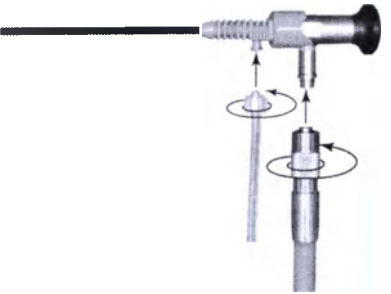


Рис. 4-4. Сборка Endo-Scrub 2



## СБОРКА ПАЛЬЦЕВОГО ПЕРЕКЛЮЧАТЕЛЯ ENDO-SCRUB 2

При использовании пальцевого переключателя Endo-Scrub 2 выполните указанные ниже действия.

- Наденьте пальцевой переключатель на чехол Endo-Scrub 2 (Рис. 4-1). Совместите вырез на кольце с люэровским разъемом на комплекте трубок. Пальцевой переключатель установлен верно, если вырез на кольце расположен точно напротив люэровского разъема.
- Активируйте помпу, нажав кнопку-активатор на пальцевом переключателе.

## ПАЛЬЦЕВОЙ ПЕРЕКЛЮЧАТЕЛЬ ENDO-SCRUB 2

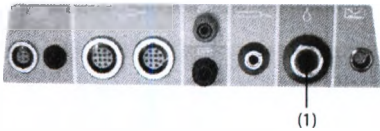
Примечание. Описанная ниже процедура применима и при использовании многофункциональной ножной педали.

- Чтобы активировать цикл промывки Endo-Scrub, нажмите и отпустите пальцевой переключатель.
- Чтобы начать постоянную ирригацию, нажмите и удерживайте пальцевой переключатель.

ПОДКЛЮЧЕНИЕ ENDO-SCRUB 2 К ПУЛЬТУ УПРАВЛЕНИЯ IPC

- 1. Найдите крышку разъема для Endo-Scrub 2 на задней поверхности пульта управления IPC (Рис. 1-2).
- 2. Вставьте маленькую отвертку в углубление на крышке разъема для кабеля и потяните крышку.
- 3. Подсоедините кабель переключателя к разъему для кабеля.
- 4. Подсоедините пальцевой переключатель Endo-Scrub 2 (Рис. 4-1) или ножную педаль (Рис. 4-2) к пульта управления (Рис. 4-5).

Рис. 4-5. Порт IPC для подключения Endo-Scrub 2



1 Порт для подключения ножного переключателя или ножной педали

ЭЛЕМЕНТЫ УПРАВЛЕНИЯ ENDO-SCRUB 2 НА СЕНСОРНОМ ЭКРАНЕ

Чтобы задать или настроить элементы управления Endo-Scrub 2, выполните следующие действия на сенсорном экране IPC в разделе Flow (Поток) поля управления Endo-Scrub 2 (Рис. 4-6).

- Чтобы включить Endo-Scrub 2, нажмите окошко On/Off (Вкл./Выкл.).
- Чтобы отрегулировать скорость ирригации, следует нажать соответственно на кнопки «плюс» для увеличения ирригационного потока или «минус» для его уменьшения.  
- Чтобы наполнить помпу, нажмите кнопку наполнения. 

Рис. 4-6. Сенсорный экран Endo-Scrub 2

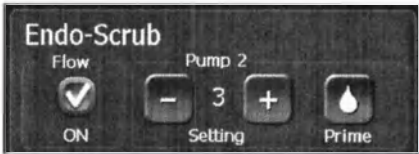
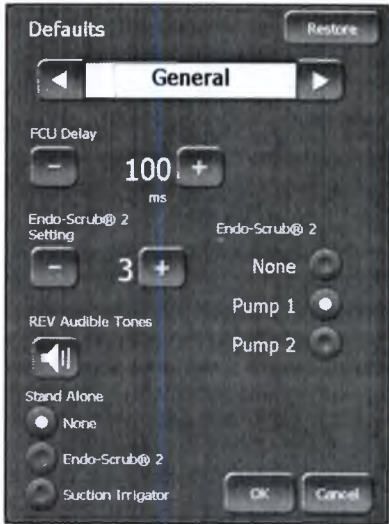


Рис. 4-7. Меню настроек по умолчанию системы IPC General (Общие)



ENDO-SCRUB 2 В АВТОНОМНОМ РЕЖИМЕ

Endo-Scrub 2 может работать как автономное устройство, для чего необходимо изменить настройки по умолчанию системы IPC.

- 1. В меню Defaults (По умолчанию) (рис. 4-7) в поле Stand Alone (Автономно) выберите **Endo-Scrub** и нажмите **[OK]**.
- 2. На экране Handpiece Connection (Подключение рукоятки) (рис. 4-8) в поле Endo-Scrub нажмите **[OK]**.

ИНСТРУКЦИИ ПО ОЧИСТКЕ И СТЕРИЛИЗАЦИИ ENDO-SCRUB 2

См. документ 68E4005 в разделе, посвященном очистке и стерилизации.

Очистка ножной педали Endo-Scrub 2

**Важная информация!** Если под защитным чехлом кабеля ножной педали есть загрязнения, верните педаль на гарантийное обслуживание.

ЗАПРЕЩАЕТСЯ погружать ножную педаль в жидкость или стерилизовать.

ЗАПРЕЩАЕТСЯ использовать спирт, другие растворители или абразивные чистящие средства.

- 1. Протрите ножную педаль системы Endo-Scrub 2 тканью, смоченной в нейтральном ферментативном моющем составе (pH 6,0–8,0) или дезинфицирующем средстве на основе фенола.
- 2. Протрите педаль насухо чистой неабразивной тканью.

Рис. 4-8. Экран подключения наконечника



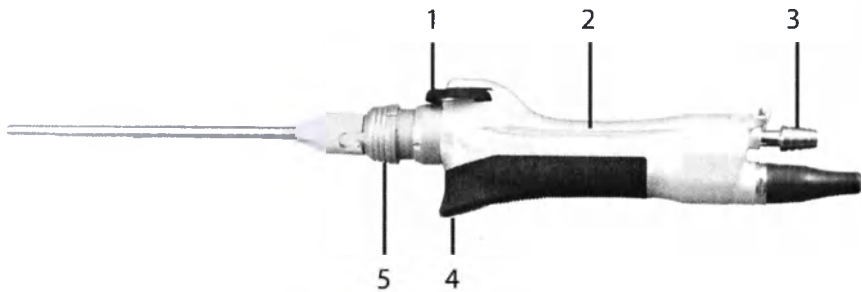
# РУКОЯТКА СПИНАЛЬНОГО ШЕЙВЕРА (SC1)

## ОПИСАНИЕ УСТРОЙСТВА

Приведенные ниже инструкции, касающиеся рукоятки спинального шейвера (SC1), дополняют общие инструкции по сборке, приведенные в разделе «Настройка IPC». Выполните все этапы настройки IPC и перейдите к инструкциям, приведенным ниже. Дополнительную информацию см. в Midas Rex User's Guide (Руководство пользователя Midas Rex).

В пульте управления IPC спинальный шейвер Midas Rex (SC1) используется с помпой 2. Работой спинального шейвера Midas Rex (SC1) можно управлять с сенсорного экрана IPC и с помощью многофункциональной ножной педали.

Рис. 5-1. Рукоятка спинального шейвера (SC1)



- |                                           |                                            |
|-------------------------------------------|--------------------------------------------|
| 1 Колесико для управления пальцем         | 4 Фиксатор колесика для управления пальцем |
| 2 Паз для ирригационной трубки            | 5 Запорное кольцо                          |
| 3 Патрубок с бородками для системы отсоса |                                            |

## УСТАНОВКА ЛЕЗВИЯ ИЛИ БОРА СПИНАЛЬНОГО ШЕЙВЕРА (SC1)

1. Вставьте инструмент, совмещая выступы с углублениями (Рис. 5-2). Сориентируйте патрубок с бородками для ирригационной системы влево или вправо.  
**Примечание.** В StraightShot M4 используется система выравнивания, состоящая из четырех выступов.
  - Для обеспечения вращения прямых лезвий сориентируйте патрубок с бородками для ирригационной системы в положение 3 часов для хирургов-правшей и в положение 9 часов для хирургов-левшей.
  - Для обеспечения вращения изогнутых лезвий сориентируйте патрубок с бородками для ирригационной системы в положение 3 часов.
2. Нажмите запорное кольцо (Рис. 5-3).
3. Отпустите запорное кольцо.  
**Примечание.** Если кольцо не возвращается назад до конца, отрегулируйте его положение с помощью колесика, слегка вращая его пальцем назад и вперед, пока кольцо не поднимется полностью.
4. Проверьте фиксацию лезвия или бора, потянув его, и визуально убедитесь, что дистальный кончик внутреннего лезвия соприкасается с дистальным концом внешней канюли (Рис. 5-4).

Рис. 5-2. Сборка спинального шейвера (SC1)

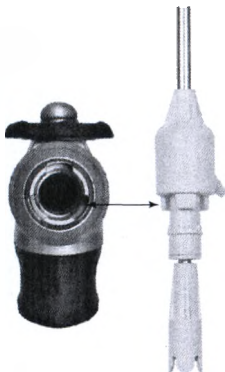


Рис. 5-3. Сборка спинального шейвера (SC1)

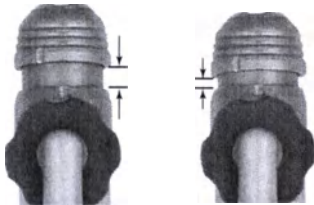
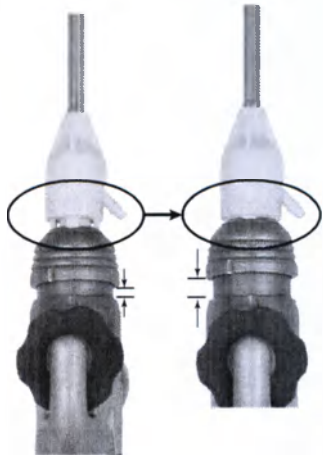


Рис. 5-4. Сборка спинального шейвера (SC1)



ПОДСОЕДИНЕНИЕ ТРУБОК ОТСОСА И ИРРИГАЦИИ К СПИНАЛЬНОМУ ШЕЙВЕРУ (SC1)

- 1. Подсоедините трубку отсоса к механизму отсасывания (Рис. 5-5), а ирригационную трубку к патрубку с бородками для ирригационной системы (Рис. 5-5).
- 2. Закрепите трубки отсоса и ирригации в пазу для ирригационной трубки на рукоятке (Рис. 5-6).

Рис. 5-5. Подсоединение трубок отсоса и ирригации к спинальному шейверу (SC1)

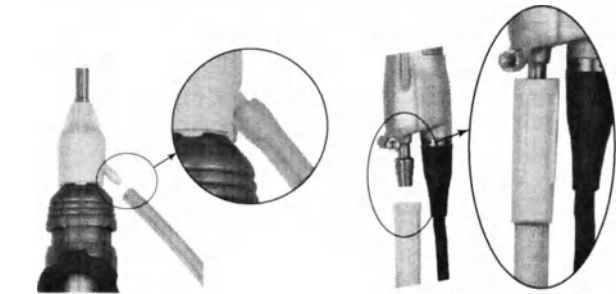
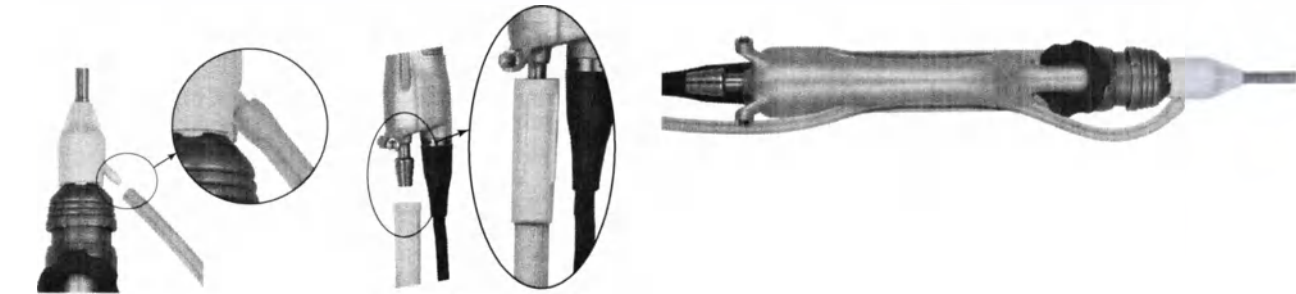


Рис. 5-6. Подсоединение трубок отсоса и ирригации к спинальному шейверу (SC1)

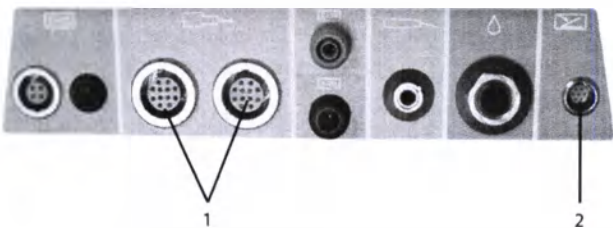


ПОДСОЕДИНЕНИЕ СПИНАЛЬНОГО ШЕЙВЕРА (SC1) К ПУЛЬТУ УПРАВЛЕНИЯ ИРС

Найдите порт для подключения спинального шейвера (SC1) на панели разъемов (Рис. 5-7) и вставьте разъем.

**Примечание.** Чтобы вставить многорыльковые разъемы (такие разъемы обозначены серебряной или красной меткой), совместите метку на разъеме с меткой на пульте управления и вставьте разъем.

Рис. 5-7. Порты для подключения спинального шейвера (SC1) к ИРС



- 1 Порт для подключения рукоятки спинального шейвера (SC1)
- 2 Порт для подключения многофункциональной ножной педали

ЭЛЕМЕНТЫ УПРАВЛЕНИЯ СПИНАЛЬНЫМ ШЕЙВЕРОМ (SC1) НА СЕНСОРНОМ ЭКРАНЕ

Чтобы задать или настроить элементы управления спинальным шейвером (SC1), выполните следующие действия в поле управления на сенсорном экране ИРС (Рис. 5-8).

- Для изменения направления вращения в поле управления Mode (Режим) выберите OSC (Колебания) или FWD (Вперед).
- Чтобы увеличить или уменьшить скорость, следует нажать в поле управления Speed (Скорость) соответственно на кнопки «плюс» или «минус».

Режим прямого вращения: по умолчанию, 12 000 циклов/мин; возможна настройка в пределах от 50 до 12 000 циклов/мин.  
Режим колебаний: по умолчанию, 3 400 циклов/мин; возможна настройка в пределах от 50 до 5 000 циклов/мин.

- Чтобы увеличить или уменьшить интенсивность ирригации, следует нажать в поле управления Pump (Помпа) соответственно на кнопки «плюс» или «минус». Если в системе есть функция прерывистой ирригации, нажатие кнопки «плюс» или «минус» переключает режим ирригации между прерывистой и постоянной. В режиме прерывистой ирригации система отображает надпись «Intermittent» (Прерывистый).

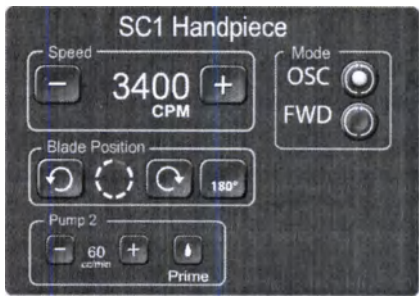
Режим прямого вращения: по умолчанию выставлено значение 30 куб. см. в минуту.  
Режим колебаний: по умолчанию, 60 куб. см. в минуту.

**Примечание.** Для регулирования интенсивности ирригации можно использовать сенсорный экран или пульт дистанционного управления ирригацией Intelliflow.

- Только в режиме колебаний** можно выполнить любые следующие действия в поле управления Blade Position (Положение лезвия):

- для вращения внутреннего лезвия на 180° нажмите кнопку со значком «дельта»;
  - для вращения внутреннего лезвия с небольшим шагом нажимайте кнопки со стрелками, направленными по и против часовой стрелки.
- Примечание. Индикатор направления движения указывает направление вращения лезвия.
- Для вращения внешнего лезвия вращайте колесико пальцем (Рис. 5-1).

Рис. 5-8. Сенсорный экран спинального шейвера (SC1)



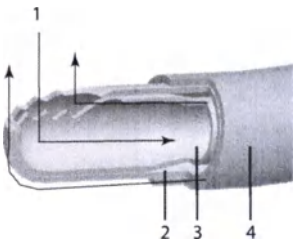


УПРАВЛЕНИЕ РЕЗЦОМ СПИНАЛЬНОГО ШЕЙВЕРА (SC1)

**Примечание.** Периодически погружайте кончик лезвия в стерильную воду, не выключая аспирации, чтобы на протяжении всего вмешательства лезвия оставались чистыми.

- Для вращения внешнего лезвия (Рис. 5-9) вращайте колесико пальцем (Рис. 5-1).
- Для вращения внутреннего лезвия воспользуйтесь настройками в поле управления Blade Position (Положение лезвия) на сенсорном экране IPC. Для получения подробной информации см. темы, посвященные управлению соответствующим инструментом.

Рис. 5-9. Лезвия в разрезе



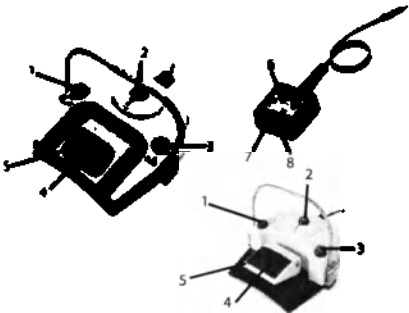
- 1 Направление отсоса внутри внутреннего лезвия  
Ирригационный поток между внутренним и внешним лезвиями
- 2 Внешнее лезвие
- 3 Внутреннее лезвие
- 4 Внешний патрубок

ЭЛЕМЕНТЫ УПРАВЛЕНИЯ СПИНАЛЬНЫМ ШЕЙВЕРОМ (SC1) НА МНОГОФУНКЦИОНАЛЬНОЙ НОЖНОЙ ПЕДАЛИ

**Важная информация!** По умолчанию, для активирования выбранного действия необходимо нажимать каждую кнопку не менее 100 мсек. Изменить это значение по умолчанию можно в экране Settings (Настройки) на сенсорном экране IPC. Для управления рукояткой с помощью многофункциональной ножной педали (Рис. 5-10) выполните следующие действия.

- Чтобы выбрать режим прямого вращения или режим колебаний, нажмите кнопку режима.
- Чтобы активировать рукоятку или настроить ее скорость в режиме переменной скорости, нажмите ножную педаль.
- Чтобы повернуть внутреннее лезвие на 180°, нажмите кнопку управления.
- Чтобы сменить рукоятку, нажмите кнопку рукоятки.

Рис. 5-10. Многофункциональная ножная педаль и U-образный делитель сигнала



- 1 Кнопка переключения режима
- 2 Кнопка рукоятки
- 3 Кнопка управления
- 4 Нескользкая подкладка
- 5 Ножная педаль
- 6 U-образный делитель сигнала
- 7 Порт 1
- 8 Порт 2

ИНСТРУКЦИИ ПО ОЧИСТКЕ И СТЕРИЛИЗАЦИИ СПИНАЛЬНОГО ШЕЙВЕРА (SC1)

См. документ 68E3282 в разделе, посвященном очистке и стерилизации.

ТЕХНИЧЕСКИЕ ХАРАКТЕРИСТИКИ СПИНАЛЬНОГО ШЕЙВЕРА (SC1)

Спинальный шейвер (SC1) ED100

|                                                                           |                                                                                                                             |
|---------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------|
| Размер                                                                    | длина — 14,3 см, ширина — 1,8 см (ED100)                                                                                    |
| Масса                                                                     | 228 г (ED100)                                                                                                               |
| Скорость                                                                  | 50–5 000 циклов/мин при колебательном движении<br>50–12 000 циклов/мин в прямом направлении                                 |
| Рабочий цикл деталей, находящихся в непосредственном контакте с пациентом | Максимальное время нахождения во включенном состоянии — 60 с<br>Минимальное время нахождения в выключенном состоянии — 30 с |



# STRAIGHTSHOT M5, STRAIGHTSHOT M4, STRAIGHTSHOT MAGNUM II, И STRAIGHTSHOT III

## ОПИСАНИЕ УСТРОЙСТВА

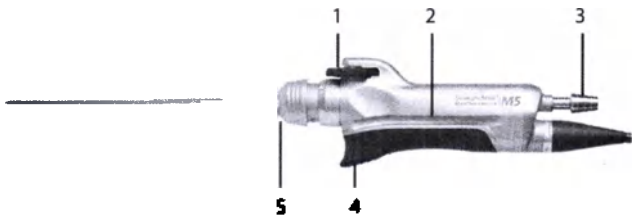
**Примечание.** StraightShot III не предназначен для продажи в США.

Приведенные ниже инструкции, касающиеся StraightShot M4, StraightShot M5, StraightShot Magnum II и StraightShot III, дополняют общие инструкции по сборке, приведенные в разделе «Настройка IPC». Выполните все этапы настройки IPC и перейдите к инструкциям, приведенным ниже.

IPC задействует микродебридер с помпой 2. Работой микродебридера можно управлять с сенсорного экрана IPC и с помощью многофункциональной ножной педали.

Если IPC обнаруживает подсоединение рукояток и StraightShot M4 или StraightShot M5, и Legend EHS Stylus, параметр помпы 2 по умолчанию становится **Shared** (Общая). Необходимо вручную подсоединить трубки для ирригационной жидкости к активной рукоятке. В экране помп можно перезадать параметр по умолчанию **Shared** (Общая), выбрав для помпы 1 рукоятку StraightShot M4 или Legend EHS Stylus. Более подробная информация содержится в разделе «Установка и наполнение помп».

Рис. 6-1. Рукоятка StraightShot M5



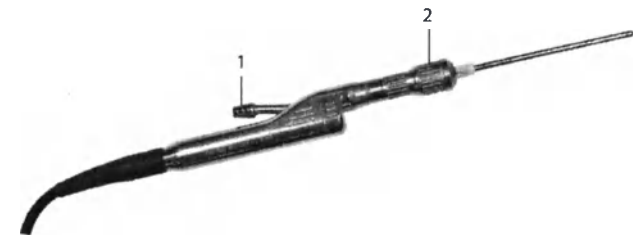
- 1 Колесико для управления пальцем

2 Паз для ирригационной трубки

3 Патрубок с бородками для системы отсоса
- 4 Фиксатор колесика для управления пальцем

5 Запорное кольцо

Рис. 6-2. Рукоятки StraightShot Magnum II и III



- 1 Патрубок с бородками для системы отсоса
- 2 Запорное кольцо

## УСТАНОВКА ЛЕЗВИЯ ИЛИ БОРА В STRAIGHTSHOT M4 И STRAIGHTSHOT M5

- Вставьте инструмент, совмещая выступы с углублениями (Рис. 6-3). Сориентируйте патрубок с бородками для ирригационной системы влево или вправо.  
**Примечание.** В StraightShot M4 и StraightShot M5 используется система выравнивания, состоящая из четырех выступов.
    - Для обеспечения вращения прямых лезвий сориентируйте патрубок с бородками для ирригационной системы в положение 3 часов для хирургов-правшей и в положение 9 часов для хирургов-левшей.
    - Для обеспечения вращения изогнутых лезвий сориентируйте патрубок с бородками для ирригационной системы в положение 3 часов.
    - Для вращающихся лезвий: поворачивайте колесико пальцем вперед и назад с небольшой амплитудой до полной установки лезвия.
  - Нажмите запорное кольцо (Рис. 6-4).
  - Отпустите запорное кольцо.
- Примечание.** Если кольцо не возвращается назад до конца, отрегулируйте его положение с помощью колесика, слегка вращая его пальцем назад и вперед, пока кольцо не поднимется полностью.
- Проверьте фиксацию лезвия или бора, потянув его, и визуально убедитесь, что дистальный кончик внутреннего лезвия соприкасается с дистальным концом внешней канюли (Рис. 6-5).

Рис. 6-3. Установка лезвия или бора

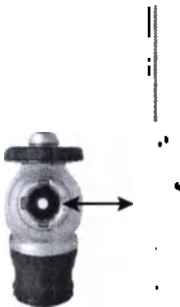


Рис. 6-4. Установка лезвия или бора

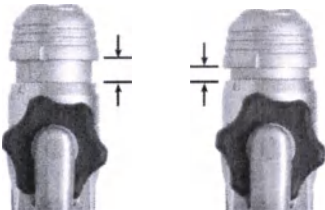
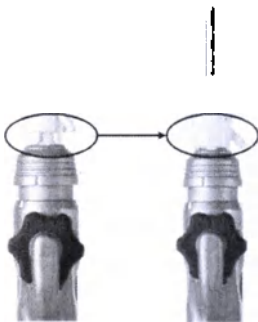


Рис. 6-5. Установка лезвия или бора

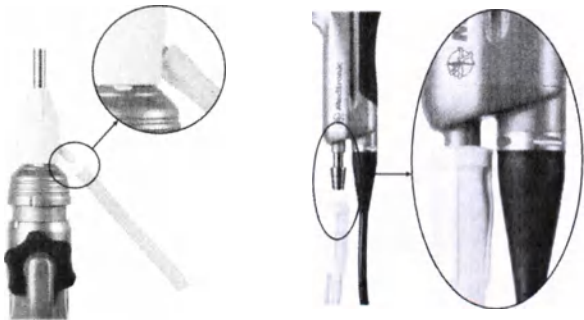


**ПОДСОЕДИНЕНИЕ АСПИРАЦИОННЫХ И ИРРИГАЦИОННЫХ ТРУБОК К STRAIGHTSHOT M4 И STRAIGHTSHOT M5**

- 1. Подсоедините трубку отсоса к механизму отсасывания, а ирригационную трубку к патрубку с бородками для ирригационной системы (Рис. 6-6).
- 2. Закрепите трубки отсоса и ирригации в пазу для ирригационной трубки на рукоятке (Рис. 6-7).

Рис. 6-6. Подсоединение трубок отсоса и ирригации

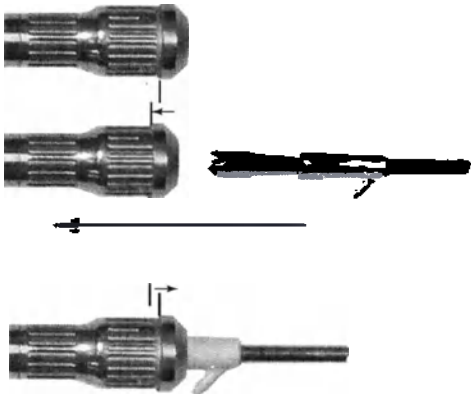
Рис. 6-7. Подсоединение трубок отсоса и ирригации



**УСТАНОВКА ЛЕЗВИЯ И БОРА В STRAIGHTSHOT MAGNUM II И STRAIGHTSHOT III**

- 1. Нажмите втулку и вставьте лезвие во втулку (Рис. 6-8).
- 2. Отпустите втулку (Рис. 6-8).
- 3. Проверьте фиксацию инструмента, потянув его, и убедитесь, что дистальный кончик внутреннего лезвия соприкасается с дистальным концом внешней канюли.

Рис. 6-8. Установка лезвия и бора в StraightShot II и III



**ПОДСОЕДИНЕНИЕ ТРУБОК ОТСОСА И ИРРИГАЦИИ К STRAIGHTSHOT MAGNUM II И STRAIGHTSHOT III**

- 1. Подсоедините трубку отсоса к механизму отсасывания, а ирригационную трубку к патрубку с бородками для ирригационной системы (Рис. 6-9).
- 2. Закрепите трубки отсоса и ирригации зажимами.

Рис. 6-9. Подсоединение трубок отсоса и ирригации к StraightShot II и III

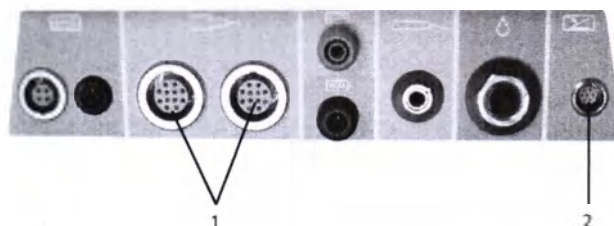


## ПОДКЛЮЧЕНИЕ STRAIGHTSHOT К ПУЛЬТУ УПРАВЛЕНИЯ IPC

Найдите порт для подключения StraightShot на панели разъемов (Рис. 6-10) и вставьте разъем.

**Примечание.** Чтобы вставить многоштырьковые разъемы (такие разъемы обозначены серебряной или красной меткой), совместите метку на разъеме с меткой на пульте управления и вставьте разъем.

Рис. 6-10. Порты для подключения



- 1 Порт для подключения рукоятки
- 2 Порт для подключения многофункциональной ножной педали

## ЭЛЕМЕНТЫ УПРАВЛЕНИЯ STRAIGHTSHOT M4, STRAIGHTSHOT MAGNUM II И STRAIGHTSHOT III НА СЕНСОРНОМ ЭКРАНЕ

**Примечание.** Элементы управления в экранах управления рукоятками StraightShot M4, StraightShot Magnum II и StraightShot III такие же, как изображенные в поле управления StraightShot M4.

**Примечание.** Если вы останавливаете вращение лезвия, происходит одно из следующих действий.

- Если на сенсорном экране видна кнопка IPC, внутреннее лезвие вернется в положение, с которого было начато вращение.
- Если на сенсорном экране видна кнопка XPS, внутреннее лезвие остановится в текущем положении.

Чтобы задать или настроить элементы управления StraightShot, выполните следующие действия на сенсорном экране IPC в поле управления рукояткой StraightShot (Рис. 6-11).

- Для изменения направления вращения выберите OSC (колебания) или FWD (вперед).

**Примечание.** Система отображает значение скорости по умолчанию для режима вращения вперед или режима колебаний.

- Чтобы настроить скорость, следует нажать в поле управления Speed (Скорость) на кнопки «плюс» или «минус».
  - Режим прямого вращения: по умолчанию, 12 000 об./мин.; возможна настройка в пределах от 50 до 12 000 об./мин.
  - Режим колебаний: по умолчанию, 5000 об./мин.; возможна настройка в пределах от 50 до 5000 об./мин.
- Чтобы увеличить или уменьшить скорость ирригационного потока, следует нажимать кнопки «плюс» или «минус» в поле управления Pump (Помпа) соответственно. Если в системе есть функция прерывистой ирригации, нажатие кнопки «плюс» или «минус» переключает режим ирригации между прерывистым и постоянным. В режиме прерывистой ирригации система отображает надпись **Intermittent** (Прерывистый).
- Режим Forward (Прямая резка): значение по умолчанию, 30 куб. см/мин.
- Режим Oscillate (Колебания): значение по умолчанию, 5 куб. см/мин.

**Примечание.** Для регулирования скорости потока можно использовать сенсорный экран или пульт дистанционного управления ирригацией IntelliFlow.

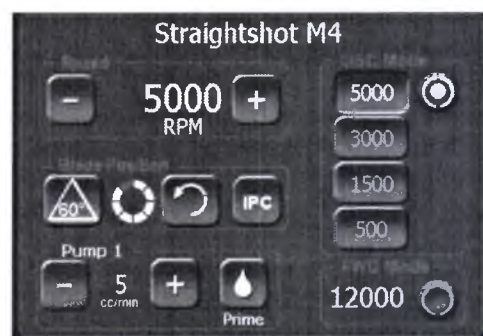
- Для вращения внешнего лезвия вращайте колесико пальцем (Рис. 6-1).
- **Только в режиме колебаний** можно выполнить любые следующие действия в поле управления Blade Position (Положение лезвия):

**Примечание.** Индикатор направления движения указывает направление вращения лезвия.

Чтобы включить опцию поворота лезвия с помощью многофункциональной ножной педали, нажмите кнопку со знаком «дельта».

Для вращения внутреннего лезвия с небольшим шагом нажимайте кнопки со стрелками, направленными по и против часовой стрелки.

Рис. 6-11. Сенсорный экран StraightShot на IPC



ЭЛЕМЕНТЫ УПРАВЛЕНИЯ STRAIGHTSHOT M5 НА СЕН-  
СОРНОМ ЭКРАНЕ

**Примечание.** Если вы останавливаете вращение лезвия, происходит одно из следующих действий.

- Если на сенсорном экране видна кнопка IPC, внутреннее лезвие вернется в положение, с которого было начато вращение.
- Если на сенсорном экране видна кнопка XPS, внутреннее лезвие остановится в текущем положении.

Чтобы задать или настроить элементы управления StraightShot, выполните следующие действия на сенсорном экране IPC в поле управления рукояткой StraightShot (рис. 6-12).

- Для изменения направления вращения выберите OSC (Колебания) или FWD (Вперед).

Примечание. Система отображает значение скорости по умолчанию для режима вращения вперед или режима колебаний.

- Чтобы увеличить или уменьшить скорость, следует нажать в поле управления Speed (Скорость) соответственно на кнопки «плюс» или «минус».

Режим прямого вращения: по умолчанию — 12 000 об./мин.; возможна настройка в пределах от 50 до 30 000 об./мин.

Режим колебаний: по умолчанию — 5 000 об./мин.; возможна настройка в пределах от 50 до 7 500 об./мин.

- Чтобы увеличить или уменьшить интенсивность ирригации, следует нажать в поле управления Pump (Помпа) соответственно на кнопки «плюс» или «минус». Если в системе есть функция прерывистой ирригации, нажатие кнопки «плюс» или «минус» переключает режим ирригации между прерывистым и постоянным. В режиме прерывистой ирригации система отображает надпись «Intermittent» (Прерывистый).

Режим прямого вращения: по умолчанию выставлено значение 30 куб. см в минуту.

Режим колебаний: по умолчанию выставлено значение 5 куб. см в минуту.

Примечание. Для регулирования интенсивности ирригации можно использовать сенсорный экран или пульт дистанционного управления ирригацией Intelliflow.

- Для вращения внешнего лезвия вращайте колесико пальцем (рис. 6-1).

**Только в режиме колебаний** можно выполнить любые следующие действия в поле управления Blade Position (Положение лезвия).

**Примечание.** Индикатор направления движения указывает направление вращения лезвия.

Чтобы включить опцию поворота лезвия с помощью многофункциональной ножной педали, нажмите кнопку со знаком «дельта».

Для вращения внутреннего лезвия с небольшим шагом нажимайте кнопку со стрелкой, направленной против часовой стрелки.



Рис. 6-12. Сенсорный экран StraightShot M5

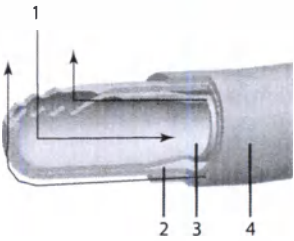
УПРАВЛЕНИЕ ЛЕЗВИЕМ МИКРОДЕБРИДЕРА

**Важная информация!** Если при вмешательствах на дыхательных путях засорится лезвие, то пациент может аспирировать в дыхательные пути 1—5 куб. см ирригационного раствора до обнаружения засора.

**Примечание.** Периодически погружайте кончик лезвия в стерильную воду, не выключая аспирации, чтобы на протяжении всего вмешательства лезвия оставались чистыми.

- Для вращения внешнего лезвия (Рис. 6-13) вращайте колесико пальцем (Рис. 6-1).
- Для вращения внутреннего лезвия воспользуйтесь настройками в поле управления Blade Position (Положение лезвия) на сенсорном экране IPC. Для получения подробной информации см. темы, посвященные управлению соответствующим инструментом.

Рис. 6-13. Лезвия в разрезе



- 1 Направление отсоса внутри внутреннего лезвия  
Ирригационный поток между внутренним и внешним лезвиями
- 2 Внешнее лезвие
- 3 Внутреннее лезвие
- 4 Внешний патрубок

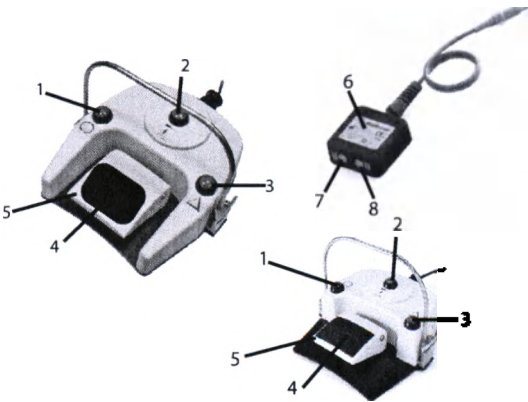


ЭЛЕМЕНТЫ УПРАВЛЕНИЯ  
НА МНОГОФУНКЦИОНАЛЬНОЙ НОЖНОЙ ПЕДАЛИ

**Важная информация!** По умолчанию, для активирования выбранного действия необходимо нажимать каждую кнопку не менее 100 мсек. Изменить это значение по умолчанию можно в экране Settings (Настройки) на сенсорном экране IPC. Для управления рукояткой с помощью многофункциональной ножной педали (Рис. 6-14) выполните следующие действия.

- Чтобы выбрать режим прямого вращения или режим колебаний, нажмите кнопку режима. 
- Чтобы активировать рукоятку или настроить ее скорость в режиме переменной скорости, нажмите ножную педаль.
- Чтобы повернуть внутреннее лезвие (на 60° или 180°), нажмите кнопку управления. 
- Чтобы сменить рукоятку, нажмите кнопку рукоятки. 

Рис. 6-14. Многофункциональная ножная педаль и У-образный делитель сигнала



- |                              |                               |
|------------------------------|-------------------------------|
| 1 Кнопка переключения режима | 5 Ножная педаль               |
| 2 Кнопка рукоятки            | 6 У-образный делитель сигнала |
| 3 Кнопка управления          | 7 Порт 1                      |
| 4 Нескользкая подкладка      | 8 Порт 2                      |

ИНСТРУКЦИИ ПО ОЧИСТКЕ И СТЕРИЛИЗАЦИИ

См. документ 68E3282 в разделе, посвященном очистке и стерилизации.

ТЕХНИЧЕСКИЕ ХАРАКТЕРИСТИКИ STRAIGHTSHOT M4

StraightShot M4 1898200T

|                                                                           |                                                                                                                                                                                                                                                 |
|---------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Размер                                                                    | длина — 14,3 см, ширина — 1,8 см (1898200T)                                                                                                                                                                                                     |
| Масса                                                                     | 228 г 1898200T                                                                                                                                                                                                                                  |
| Скорость                                                                  | 50–5 000 об./мин в режиме колебаний<br>50–12 000 об./мин в режиме вращения вперед                                                                                                                                                               |
| Рабочий цикл деталей, находящихся в непосредственном контакте с пациентом | При полной нагрузке рукоятка StraightShot M4 рассчитана на перемежающийся режим работы со следующими показателями.<br>Максимальное время нахождения во включенном состоянии: 60 с<br>Минимальное время нахождения в выключенном состоянии: 30 с |

ТЕХНИЧЕСКИЕ ХАРАКТЕРИСТИКИ STRAIGHTSHOT M5

StraightShot M5 1899200

|                                                                           |                                                                                                                                                                                                                                                 |
|---------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Размер                                                                    | длина — 12,5 см, ширина — 2,0 см                                                                                                                                                                                                                |
| Вес                                                                       | 203 г (1899200)                                                                                                                                                                                                                                 |
| Скорость                                                                  | 50–7 500 об./мин при колебательном движении<br>50–30 000 об./мин в прямом направлении                                                                                                                                                           |
| Рабочий цикл деталей, находящихся в непосредственном контакте с пациентом | При полной нагрузке рукоятка StraightShot M5 рассчитана на перемежающийся режим работы со следующими показателями:<br>Максимальное время нахождения во включенном состоянии: 60 с<br>Минимальное время нахождения в выключенном состоянии: 30 с |



ТЕХНИЧЕСКИЕ ХАРАКТЕРИСТИКИ STRAIGHTSHOT MAGNUM II И STRAIGHTSHOT III

StraightShot Magnum II 1897200

StraightShot III 1897201

|                                                                                    |                                                                                                                                                                                                                                 |
|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Размер                                                                             | длина — 17 см, ширина — 1,6 см (1897200/1897201)                                                                                                                                                                                |
| Масса                                                                              | 240 г 1897200, 1897201<br>254 г 1897200T                                                                                                                                                                                        |
| Скорость                                                                           | 50–5 000 об./мин в режиме колебаний<br>50–12 000 об./мин в режиме вращения вперед                                                                                                                                               |
| Рабочий цикл<br>деталей, находящихся<br>в непосредственном контакте<br>с пациентом | При полной нагрузке рукоятки рассчитаны на перемежающийся режим работы со следующими показателями.<br>Максимальное время нахождения во включенном состоянии: 60 с<br>Минимальное время нахождения в выключенном состоянии: 30 с |

# LEGEND EHS И LEGEND EHS STYLUS

Legend EHS (Рис. 7-1) — это высокоскоростной реверсивный электродвигатель с высоким крутящим моментом, используемый для рассечения кости и биоматериалов со скоростью, которую можно выбрать в диапазоне от 200 до 75 000 об./мин.

Legend EHS Stylus (Рис. 7-2) — это небольшой компактный высокоскоростной реверсивный электродвигатель с высоким крутящим моментом, используемый для рассечения кости и биоматериалов со скоростью, которую можно выбрать в диапазоне от 200 до 75 000 об./мин.

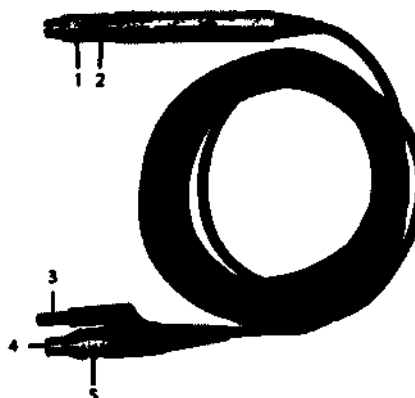
Приведенные ниже инструкции, касающиеся Legend EHS и Legend EHS Stylus, дополняют общие инструкции по сборке, приведенные в разделе «Настройка IPC». Выполните все этапы настройки IPC и перейдите к инструкциям, приведенным ниже.

Рис. 7-1. Электродвигатель Legend EHS



- 1 Вращающийся зажимной патрон
- 2 Неподвижный зажимной патрон
- 3 Кабельный 4-штырьковый разъем

Рис. 7-2. Электродвигатель Legend EHS Stylus



- 1 Неподвижный зажимной патрон
- 2 Вращающийся зажимной патрон
- 3 Разъем для заземления
- 4 Кабельный 4-штырьковый разъем
- 5 Запорная гильза

## СБОРКА НАСАДОК LEGEND EHS И LEGEND EHS STYLUS

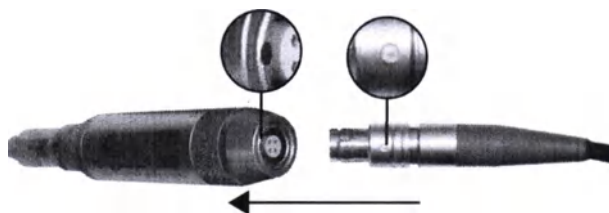
Инструкции по сборке насадок см. в разделе «Legend EHS, Legend EHS Stylus and Stylus Touch Attachments» (Насадки Legend EHS, Legend EHS Stylus и Stylus Touch).

## ПОДСОЕДИНЕНИЕ КАБЕЛЯ LEGEND EHS К ЭЛЕКТРОДВИГАТЕЛЮ

**Примечание.** Кабель электродвигателя Legend EHS Stylus встроен в рукоятку и неотделим от электродвигателя.

Чтобы подсоединить кабель Legend EHS к электродвигателю Legend EHS, совместите метку на кабеле с красной меткой на электродвигателе (Рис. 7-3) и соедините обе части.

Рис. 7-3. Подсоединение кабеля Legend EHS к электродвигателю

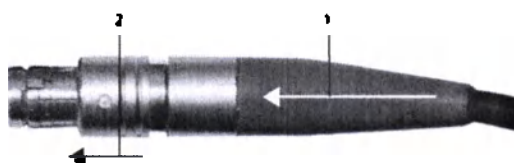


## ОТСОЕДИНЕНИЕ КАБЕЛЯ LEGEND EHS ОТ ЭЛЕКТРОДВИГАТЕЛЯ

**Примечание.** Кабель электродвигателя Legend EHS Stylus встроен в рукоятку и неотделим от электродвигателя.

Чтобы отсоединить кабель Legend EHS от электродвигателя Legend EHS, (1) прижмите кабель к электродвигателю, затем (2) вытяните кабель, держа его ТОЛЬКО за стопорное кольцо (Рис. 7-4).

Рис. 7-4. Отсоединение кабеля Legend EHS от электродвигателя



ПОДСОЕДИНЕНИЕ LEGEND EHS ИЛИ LEGEND EHS STYLUS К IPC

Найдите нужный порт для подключения Legend EHS или Legend EHS Stylus на панели разъемов (Рис. 7-5) и вставьте разъем.

**Примечание.** Чтобы вставить многотырьковые разъемы (такие разъемы обозначены серебряной или красной меткой), совместите метку на разъеме с меткой на пульте управления и вставьте разъем.

При использовании Legend EHS или Legend EHS Stylus IPC задействует ирригацию через помпу 1. Если система обнаруживает подсоединение Legend EHS или Legend EHS Stylus, параметр помпы 2 по умолчанию становится **None** (Нет).

Если IPC обнаруживает подсоединение и рукоятки Legend EHS Stylus, и StraightShot M4, параметр помпы 2 по умолчанию становится **Shared** (Общая). Необходимо вручную подсоединить трубки для ирригационной жидкости к активной рукоятке. В экране помп можно перезадать параметр по умолчанию **Shared** (Общая), выбрав для помпы 1 рукоятку StraightShot M4 или Legend EHS Stylus. Более подробная информация содержится в разделе «Установка и наполнение помп».

Работой Legend EHS или Legend EHS Stylus можно управлять с сенсорного экрана IPC и с помощью многофункциональной ножной педали.

Рис. 7-5. Порты для подключения Legend EHS и Legend EHS Stylus



- 1 Порт для подключения электродвигателя Legend EHS
- 2 Порт для подключения электродвигателя Legend EHS Stylus
- 3 Порт для подключения многофункциональной ножной педали

Рис. 7-6. Сенсорный экран Legend EHS Stylus



ЭЛЕМЕНТЫ УПРАВЛЕНИЯ LEGEND EHS И LEGEND EHS STYLUS НА СЕНСОРНОМ ЭКРАНЕ

Чтобы задать или настроить элементы управления Legend EHS и Legend EHS Stylus, выполните следующие действия в поле управления (Рис. 7-6).

- Для изменения направления вращения в поле управления Mode (Режим) выберите FWD (вперед) или REV (назад).  
**Важная информация!** Конфигурация системы может отличаться от настроек по умолчанию. Если кнопка REV (назад) кажется отжатой (Рис. 7-7) и не имеет селективной кнопки, режим вращения в обратном направлении выбрать нельзя. Если кнопка REV (назад) кажется нажатой (Рис. 7-7) и имеет селективную кнопку, режим вращения в обратном направлении можно выбрать с помощью сенсорного экрана или многофункциональной ножной педали.
- Чтобы увеличить или уменьшить скорость в режиме вращения вперед (FWD) и назад (REV), следует нажать в поле управления Speed (Скорость) соответственно на кнопки «плюс» или «минус». По умолчанию, выставлена скорость 70000 об./мин.; возможна настройка в пределах от 200 до 75 000 об./мин.
- Чтобы увеличить или уменьшить интенсивность ирригации, следует нажать в поле управления Pump (Помпа) соответственно на кнопки «плюс» или «минус». Если в системе есть функция прерывистой ирригации, нажатие кнопки «плюс» или «минус» переключает режим ирригации между прерывистым и постоянным. В режиме прерывистой ирригации система отображает надпись **«Intermittent»** (Прерывистый). По умолчанию, выставлено значение 0 куб. см. в минуту для режимов вращения вперед и назад.

Рис. 7-7. Режим Legend EHS или Legend EHS Stylus

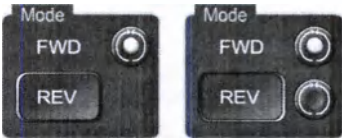


Рис. 7-8. Меню настроек по умолчанию Stylus (Стилус)



**Примечание.** Пока используются настройки меню Defaults (По умолчанию), выбранные значения ускорения и замедления применяться не будут, поскольку электродвигатель не будет работать. Чтобы подобрать необходимые значения, регулируйте ускорение и замедление во время работы электродвигателя, отмечая для себя предпочитаемые значения.

- Чтобы разрешить регулировку ускорения и замедления во время работы рукоятки и включить отображение параметров настройки ускорения и замедления на рабочем экране электродвигателя, в меню Defaults (По умолчанию) выберите **Show On Screen** (Показывать на экране) и нажмите **[OK]**. Чтобы выключить отображение параметров «Ускорение» и «Замедление» во время работы рукоятки, в меню Defaults (По умолчанию) отмените выбор **Show On Screen** (Показывать на экране).

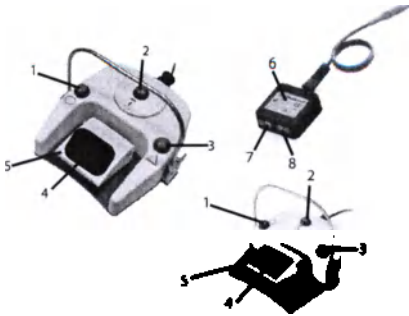
ЭЛЕМЕНТЫ УПРАВЛЕНИЯ LEGEND EHS И LEGEND EHS STYLUS НА МНОГОФУНКЦИОНАЛЬНОЙ НОЖНОЙ ПЕДАЛИ

**Важная информация!** По умолчанию, для активирования выбранного действия необходимо нажимать каждую кнопку не менее 100 мсек. Изменить это значение по умолчанию можно в экране Settings (Настройки) на сенсорном экране IPC.

Для управления рукояткой с помощью многофункциональной ножной педали (Рис. 7-9) выполните следующие действия.

- Чтобы выбрать режим прямого или обратного вращения, нажмите кнопку режима.
  - Чтобы активировать рукоятку или настроить ее скорость в режиме переменной скорости, нажмите ножную педаль.
  - Чтобы переключиться между режимом пуска/остановки и режимом переменной скорости, нажмите кнопку управления.
- Примечание.** В меню рукоятки по умолчанию можно изменить функцию кнопки управления на приостановку ирригации. См. «Изменение настроек системы» в разделе «Действия до начала эксплуатации системы».
- Чтобы сменить рукоятку, нажмите кнопку рукоятки.

Рис. 7-9. Многофункциональная ножная педаль и У-образный делитель сигнала



- |   |                            |   |                             |
|---|----------------------------|---|-----------------------------|
| 1 | Кнопка переключения режима | 5 | Ножная педаль               |
| 2 | Кнопка рукоятки            | 6 | У-образный делитель сигнала |
| 3 | Кнопка управления          | 7 | Порт 1                      |
| 4 | Нескользкая подкладка      | 8 | Порт 2                      |

ИНСТРУКЦИИ ПО ОЧИСТКЕ И СТЕРИЛИЗАЦИИ LEGEND EHS И LEGEND EHS STYLUS

См. документы M000030A234 и M000030A235 в разделе, посвященном очистке и стерилизации.

ТЕХНИЧЕСКИЕ ХАРАКТЕРИСТИКИ LEGEND EHS

Legend EHS EM100-A

|                                                                           |                                                                                                                                                                        |
|---------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Размер                                                                    | длина — 9,02 см, диаметр — 2,03 см                                                                                                                                     |
| Масса                                                                     | 180 г                                                                                                                                                                  |
| Скорость                                                                  | 75 000 об./мин в прямом и обратном направлении                                                                                                                         |
| Рабочий цикл деталей, находящихся в непосредственном контакте с пациентом | Электродвигатель Legend EHS рассчитан на непрерывную резку в течение 3 минут на скорости 70 000 об./мин при комнатной температуре до 40 °C.                            |
|                                                                           | При нормальной комнатной температуре (обычно 20 °C) электродвигатель Legend EHS рассчитан на непрерывную резку в течение 10 минут с последующим перерывом на 25 минут. |
|                                                                           | В режиме работы с перерывами электродвигатель Legend EHS рассчитан на неограниченное число включений и выключений (по 20 секунд каждое) при скорости 70 000 об./мин.   |

ТЕХНИЧЕСКИЕ ХАРАКТЕРИСТИКИ LEGEND EHS STYLUS

Legend EHS Stylus EM200

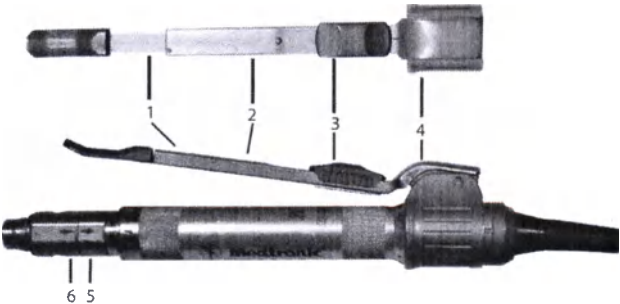
|                                                                           |                                                                                                                                                                                            |
|---------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Размер                                                                    | длина — 7,77 см, диаметр — 1,65 см                                                                                                                                                         |
| Масса                                                                     | 90 г                                                                                                                                                                                       |
| Скорость                                                                  | 75 000 об./мин в прямом и обратном направлении                                                                                                                                             |
| Рабочий цикл деталей, находящихся в непосредственном контакте с пациентом | Электродвигатель Legend EHS Stylus рассчитан на работу в течение 3 минут на скорости 60 000 об./мин при температуре в помещении от комнатной до 40 °C с последующим перерывом на 25 минут. |
|                                                                           | При нормальной комнатной температуре (обычно 20 °C) электродвигатель Legend EHS Stylus рассчитан на резку в течение неограниченного времени при скорости 60 000 об./мин.                   |

# STYLUS TOUCH

Stylus Touch (Рис. 8-1) — это небольшой компактный высокоскоростной реверсивный электродвигатель с высоким крутящим моментом, используемый для рассечения кости и биоматериалов с различной скоростью от 200 до 75 000 об./мин. Электродвигатель Stylus Touch снабжен вращающимся пальцевым рычагом, повторяющим функции многофункциональной ножной педали.

Приведенные ниже инструкции, касающиеся Stylus Touch, дополняют общие инструкции по сборке, приведенные в разделе «Настройка IPC». Выполните все этапы настройки IPC и перейдите к инструкциям, приведенным ниже.

Рис. 8-1. Электродвигатель Stylus Touch



- 1 Телескопический упор для пальца
- 2 Пальцевой рычаг
- 3 Переключатель безопасного режима пальцевого рычага
- 4 Кольцо рычага управления
- 5 Неподвижный зажимной патрон
- 6 Вращающийся зажимной патрон

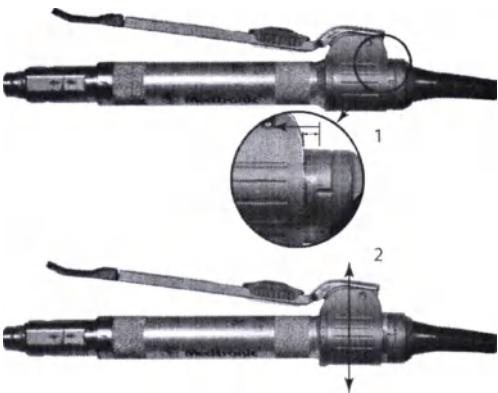
## СБОРКА НАСАДОК STYLUS TOUCH

Инструкции по сборке насадок см. в разделе «Legend EHS, Legend EHS Stylus and Stylus Touch Attachments» (Насадки Legend EHS, Legend EHS Stylus и Stylus Touch).

## ВРАЩЕНИЕ ПАЛЬЦЕВОГО РЫЧАГА STYLUS TOUCH

- 1. Сдвиньте кольцо рычага управления вперед (Рис. 8-2).
- 2. Поворачивайте рычаг по или против часовой стрелки до его фиксации в новом положении.

Рис. 8-2. Вращение пальцевого рычага Stylus Touch



## ПОДКЛЮЧЕНИЕ STYLUS TOUCH К ПУЛЬТУ УПРАВЛЕНИЯ IPC

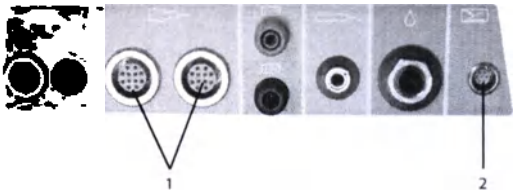
Найдите порт для подключения Stylus Touch на панели разъемов (Рис. 8-3) и вставьте разъем.

**Примечание.** Чтобы вставить многоштырьковые разъемы (такие разъемы обозначены серебряной или красной меткой), совместите метку на разъеме с меткой на пульте управления и вставьте разъем.

IPC задействует Stylus Touch с помпой 1. Если вы не применяете ирригацию при работе со Stylus Touch, вручную измените выбор помпы с помпы 1 на **None** (Нет). Более подробная информация содержится в разделе «Установка и наполнение помп».

Работой Stylus Touch можно управлять с сенсорного экрана IPC и с помощью многофункциональной ножной педали.

Рис. 8-3. Порты для подключения Stylus Touch



- 1 Порт для подключения Stylus Touch
- 2 Порт для подключения многофункциональной ножной педали



## ЭЛЕМЕНТЫ УПРАВЛЕНИЯ STYLUS TOUCH НА СЕНСОРНОМ ЭКРАНЕ

Чтобы задать или настроить элементы управления Stylus Touch, выполните следующие действия в поле управления (рис. 8-4) на сенсорном экране IPC:

- Для изменения направления вращения в поле управления Mode (Режим) выберите FWD (forward) (Вперед) или REV (reverse) (Назад).  
**Важная информация!** Конфигурация системы может отличаться от настроек по умолчанию. Если кнопка REV (reverse) (Назад) кажется отжатой (рис. 8-7) и не имеет селективной кнопки, режим вращения в обратном направлении выбрать нельзя. Если кнопка REV (Назад) кажется нажатой (рис. 8-7) и имеет селективную кнопку, режим вращения в обратном направлении можно выбрать с помощью сенсорного экрана или многофункциональной ножной педали.
- Чтобы увеличить или уменьшить скорость, следует нажать в поле управления Speed (Скорость) соответственно на кнопки «плюс» или «минус». По умолчанию выставлена скорость 60 000 rpm; возможна настройка в пределах от 200 до 75 000 rpm.  
**Примечание.** При работе с рукояткой в безопасном режиме в поле управления Speed (Скорость) появляется надпись «SAFE» (Безопасный режим) (рис. 8-6). Дополнительную информацию см. в разделе, посвященном работе со Stylus Touch в безопасном режиме.
- Чтобы увеличить или уменьшить скорость ирригационного потока, следует нажать в поле управления Pump (Помпа) соответственно на кнопки «плюс» или «минус». Если в системе есть функция прерывистой ирригации, нажатие кнопки «плюс» или «минус» переключает режим ирригации между прерывистым и постоянным. В режиме прерывистой ирригации система отображает надпись «Intermittent» (Прерывистый). По умолчанию выставлено значение 0 куб. см. в минуту.

**Примечание.** Для регулирования скорости потока можно использовать сенсорный экран или пульт дистанционного управления ирригацией IntelliFlow.

- Чтобы настроить ускорение и замедление, следует нажать в меню Defaults (По умолчанию) (рис. 8-5) соответственно на кнопки «плюс» или «минус». Acceleration (Ускорение) — скорость, с которой электродвигатель набирает обороты для достижения заданного значения. Deceleration (Замедление) — скорость, с которой электродвигатель сбрасывает обороты для достижения заданного значения или остановки.

**Примечание.** Пока используются настройки меню по умолчанию, выбранные значения ускорения и замедления применяться не будут, поскольку электродвигатель не будет работать. Чтобы подобрать необходимые значения, регулируйте ускорение и замедление во время работы электродвигателя, отмечая для себя предпочитаемые значения.

- Чтобы разрешить регулировку ускорения и замедления во время работы рукоятки и включить отображение параметров настройки Acceleration (Ускорение) и Deceleration (Замедление) на рабочем экране электродвигателя, в меню Defaults (По умолчанию) выберите **Show On Screen** (Показывать на экране) и нажмите **[OK]**. Чтобы выключить отображение параметров Acceleration (Ускорение) и Deceleration (Замедление) во время работы рукоятки, в меню Defaults (По умолчанию) отмените выбор **Show On Screen** (Показывать на экране).

## АВАРИЙНЫЙ ПЕРЕКЛЮЧАТЕЛЬ STYLUS TOUCH

Когда рукоятка находится в безопасном режиме, она не поддается управлению до отключения безопасного режима. Когда рукоятка является активной и находится в безопасном режиме (рис. 8-6), в поле управления Speed (Скорость) на сенсорном экране Stylus Touch отображается надпись SAFE (БЕЗОПАСНЫЙ).

Всегда переводите устройство в безопасный режим, когда оно подключено к пульту управления, но не используется. Чтобы перевести Stylus Touch в безопасный режим, переведите пальцевой рычаг безопасного режима на рукоятке Stylus Touch (рис. 8-1) в положение «Вкл».

Если к пульту управления подключено несколько рукояток, активируйте предохранительный переключатель неактивной рукоятки, чтобы активировать эту рукоятку и подготовить ее к работе.

Рис. 8-4. Сенсорный экран Stylus Touch



Рис. 8-5. Меню настроек по умолчанию Stylus Touch (Сенсорный стилус)



Рис. 8-6. Безопасный режим Stylus Touch



Рис. 8-7. Режим вращения Stylus Touch



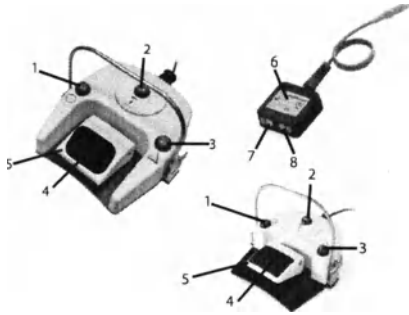
ЭЛЕМЕНТЫ УПРАВЛЕНИЯ STYLUS TOUCH НА МНОГО-
ФУНКЦИОНАЛЬНОЙ НОЖНОЙ ПЕДАЛИ

Важная информация! По умолчанию, для активирования выбранного
действия необходимо нажимать каждую кнопку не менее 100 мсек. Изменить
это значение по умолчанию можно в экране Settings (Настройки) на сенсорном
экране IPC.

Для управления рукояткой с помощью многофункциональной ножной педали
(Рис. 8-8) выполните следующие действия.

- Чтобы выбрать режим прямого или обратного вращения, нажмите кнопку
режима.
  - Чтобы активировать рукоятку или настроить ее скорость в режиме
переменной скорости, нажмите ножную педаль.
  - Чтобы переключиться между режимом пуска/остановки и режимом
переменной скорости, нажмите кнопку управления.
- Примечание. В меню рукоятки по умолчанию можно изменить функцию
кнопки управления на приостановку ирригации. См. «Изменение настроек
системы» в разделе «Действия до начала эксплуатации системы».
- Чтобы сменить рукоятку, нажмите кнопку рукоятки.

Рис. 8-8. Многофункциональная ножная педаль и У-образный
делитель сигнала



- 1

Кнопка переключения
режима
- 2

Кнопка рукоятки
- 3

Кнопка управления
- 4

Нескользящая
подкладка
- 5

Ножная педаль
- 6

У-образный делитель
сигнала
- 7

Порт 1
- 8

Порт 2

ИНСТРУКЦИИ ПО ОЧИСТКЕ И СТЕРИЛИЗАЦИИ STYLUS TOUCH

См. документы 68E4132 и M000030A235 в разделе, посвященном очистке и стерилизации.

ТЕХНИЧЕСКИЕ ХАРАКТЕРИСТИКИ STYLUS TOUCH

Stylus Touch EM210

|                                                                           |                                                                                                                                                                                                  |
|---------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Размер                                                                    | длина — 15,26 см, диаметр — 1,65 см                                                                                                                                                              |
| Масса                                                                     | 130 г                                                                                                                                                                                            |
| Скорость                                                                  | 75 000 об./мин в прямом и обратном направлении                                                                                                                                                   |
| Рабочий цикл деталей, находящихся в непосредственном контакте с пациентом | Электродвигатель Legend EHS Stylus Touch рассчитан на работу в течение 3 минут на скорости 60 000 об./мин при температуре в помещении от комнатной до 40 °С с последующим перерывом на 25 минут. |
|                                                                           | При нормальной комнатной температуре (обычно 20 °С) электродвигатель Legend EHS Stylus Touch рассчитан на резку в течение неограниченного времени при скорости 60 000 об./мин.                   |

# НАСАДКИ LEGEND EHS, LEGEND EHS STYLUS И STYLUS TOUCH

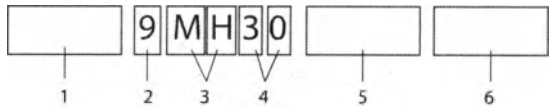
Приведенные ниже инструкции по применению насадок Legend EHS, Legend EHS Stylus и Stylus Touch дополняют информацию в разделе «Настройка IPC» и общие инструкции по применению отдельных электродвигателей. Выполните все этапы настройки IPC, инструкции по применению конкретного электродвигателя и перейдите к инструкциям, приведенным ниже.

## НОМЕНКЛАТУРА ИНСТРУМЕНТОВ ДЛЯ ПРЕПАРИРОВАНИЯ

**Примечание.** Номенклатура и цветовой код на упаковке инструмента для препарирования и на насадке должны совпадать.

Номера деталей инструментов для препарирования составлены по стандартной схеме (Рис. 9-1). Основной номер детали состоит из пяти символов, представляющих длину соответствующей насадки, форму головки инструмента и диаметр головки инструмента. Кроме того, номера деталей могут включать в себя различные префиксы, определяющие конкретный тип насадки, а также различные суффиксы, содержащие дополнительные сведения об инструменте для препарирования. Номера инструментов, дизайн которых соответствует линии Mednext, имеют дополнительный суффикс «-MN».

Рис. 9-1. Схема составления номенклатуры инструментов для препарирования



- 1. Дополнительный префикс
- 2. Длина насадки
- 3. Форма головки инструмента
- 4. Диаметр головки инструмента (x x миллиметров)
- 5. Дополнительный суффикс
- 6. Дополнительный суффикс «-MN»

## Префиксы номеров инструментов

- F Для использования с насадками на ножке.
- MC Для использования с насадками для резки металла.
- T Для использования с телескопическими насадками.

## Формы головки инструмента

- |                   |                      |
|-------------------|----------------------|
| AC В форме желудя | MH Спичечная головка |
| BA Шаровая        | OV Овальная          |
| CY Цилиндрическая | RT Обратный конус    |
| NM Дырокол        | TA Коническая        |
| HS Кольцевая пила | TD Спиральная дрель  |

## Суффиксы номеров инструментов

**Примечание.** В одном номере детали могут применяться несколько суффиксов.

- |                        |                                  |
|------------------------|----------------------------------|
| L Длинный              | S Спиральный                     |
| D Алмазный             | SH Короткий                      |
| X Высшего качества     |                                  |
| F Для тонкой обработки | DC Алмазный для грубой обработки |
| C Твердосплавный       | DX Алмазный, сверхгрубый         |

## ВЫРАВНИВАНИЕ ЗАЖИМНОГО ПАТРОНА ЭЛЕКТРОДВИГАТЕЛЯ

**Примечание.** Насадка не будет верно установлена на электродвигателе Legend EHS, Legend EHS Stylus и Stylus Touch, если стрелки на гранях зажимного патрона электродвигателя не совмещены.

1. Удостоверьтесь в выравнивании стрелок на гранях зажимного патрона электродвигателя. До установки насадки и инструмента для препарирования на электродвигатель Legend EHS, Legend EHS Stylus или Stylus Touch проверьте совмещение стрелок на гранях зажимного патрона. (Рис. 9-2).

2. Если стрелки не совмещены (Рис. 9-3), нужно с помощью гаечного ключа (Рис. 9-4) электродвигателя поворачивать вращающийся зажимной патрон, пока его стрелка не совместится со стрелкой на неподвижном зажимном патроне.

**Примечание.** Для выравнивания стрелок на гранях зажимного патрона электродвигателя ЗАПРЕЩАЕТСЯ использовать какие-либо другие компоненты, кроме гаечного ключа электродвигателя.

Рис. 9-2. Правильное совмещение



Рис. 9-3. Неправильное совмещение



Рис. 9-4. Гаечный ключ



## СБОРКА ПРЯМЫХ НАСАДОК

**Предупреждения!** См. предупреждения W36 и W54.

**Внимание!** Номенклатура и цветовой код на упаковке инструмента и на насадке должны совпадать.

### Примечания.

- Насадка не будет верно установлена на электродвигателе, если стрелки на гранях зажимного патрона электродвигателя не совмещены.
- Пока насадка не зафиксирована надлежащим образом, электродвигатель Legend EHS не будет работать правильно.
- Если насадка не зафиксирована, возможно появление дыма и/или перегрев насадки. Это может привести к термическому ожогу хирурга или персонала.

1. Надвиньте прямую насадку на зажимной патрон электродвигателя, совмещая треугольные стрелки на насадке и корпусе электродвигателя (Рис. 9-5). Вы услышите и почувствуете щелчок, который подтверждает, что инструмент полностью встал на свое место.

Рис. 9-5. Сборка прямых насадок



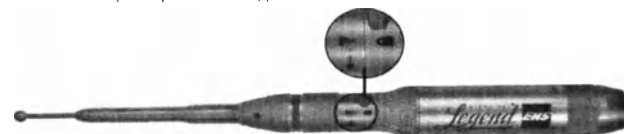
2. Вставьте инструмент в насадку легким вращением (Рис. 9-6). Вы услышите и почувствуете щелчок, который подтверждает, что инструмент полностью встал на свое место.

Рис. 9-6. Сборка прямых насадок



3. Поворачивайте насадку в указанном стрелкой направлении, пока метка совмещения на насадке не окажется на одной линии с символом блокировки (Рис. 9-7). Во время вращения насадки будут слышны два щелчка.

Рис. 9-7. Сборка прямых насадок



4. Слегка потяните инструмент, чтобы удостовериться в том, что он зафиксирован в рукоятке.

**Примечание.** Инструмент должен вращаться свободно. В противном случае разблокируйте насадку, заново вставьте инструмент и снова зафиксируйте насадку.

## РАЗБОРКА ПРЯМЫХ НАСАДОК

1. Возьмите электродвигатель в руку. Вращательным движением разблокируйте насадку.
2. Снимите инструмент для препарирования с насадки и выбросьте инструмент.
3. С помощью большого и указательного пальцев отделите насадку от электродвигателя.

## СБОРКА УГЛОВЫХ НАСАДОК

**Внимание!** При работе с угловой насадкой держите узел рукоятки за насадку, чтобы она случайно не выпала из рукоятки.

### Примечания.

- Прежде чем устанавливать угловую насадку на электродвигатель, в нее можно вставить и зафиксировать инструмент для препарирования.
- С угловыми и прямыми насадками одной и той же длины и с одинаковой буквенной и цветовой маркировкой используются одни и те же инструменты для препарирования.
- Пока насадка не зафиксирована надлежащим образом, электродвигатель Legend EHS не будет работать правильно.
- Если насадка не зафиксирована, возможно появление дыма и/или перегрев насадки. Это может привести к термическому ожогу хирурга или персонала.



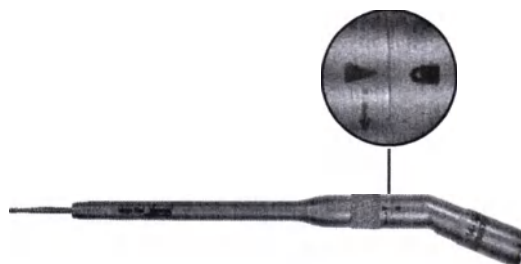
1. Вставьте инструмент с разблокированным фиксатором в угловую насадку, немного вращая его (Рис. 9-8). Вы услышите и почувствуете щелчок, который подтверждает, что инструмент полностью встал на свое место.

Рис. 9-8. Сборка угловых насадок



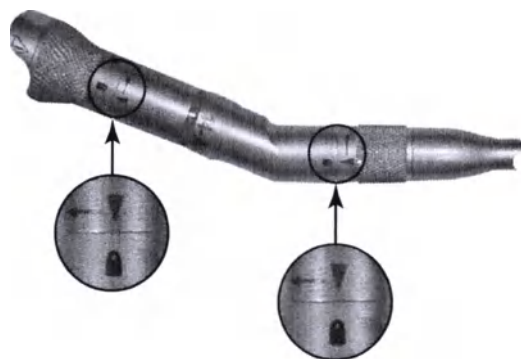
2. Поворачивайте фиксатор инструмента в указанном стрелкой направлении, пока метка совмещения фиксатора инструмента не окажется на одной линии с символом блокировки (Рис. 9-9).

Рис. 9-9. Сборка угловых насадок



3. Слегка потяните инструмент, чтобы удостовериться в том, что он зафиксирован в рукоятке.  
**Примечание.** Инструмент должен вращаться свободно. В противном случае разблокируйте насадку, заново вставьте инструмент и снова зафиксируйте насадку.
4. Надвиньте угловую насадку на зажимной патрон электродвигателя, совмещая треугольные стрелки на насадке и корпусе электродвигателя. Вы услышите и почувствуете щелчок, который подтверждает, что инструмент полностью встал на свое место.
5. Поворачивайте насадку в указанном стрелкой направлении, пока метка совмещения на насадке не окажется на одной линии с символом блокировки. Во время вращения насадки будут слышны два щелчка.
6. Убедитесь в том, что и метка совмещения насадки с электродвигателем, и метка совмещения фиксатора инструмента находятся на одной линии с символом блокировки (Рис. 9-10).

Рис. 9-10. Сборка угловых насадок



## РАЗБОРКА УГЛОВЫХ НАСАДОК

1. Чтобы снять инструмент с насадки, поверните фиксатор инструмента в положение разблокировки.
2. Поверните насадку, чтобы перевести ее в положение разблокировки и отделить от электродвигателя.



## СБОРКА ФИКСИРОВАННЫХ НАСАДОК НА НОЖКЕ

**Предупреждение!** См. предупреждение W37.

1. Вставьте инструмент для препарирования в зажимной патрон электродвигателя легким вращением (Рис. 9-11). Вы услышите и почувствуете щелчок, который подтверждает, что инструмент полностью встал на свое место.

Рис. 9-11. Сборка насадок на ножке



2. Надвиньте насадку на ножке поверх инструмента для препарирования на электродвигатель, совмещая треугольные стрелки на насадке и корпусе электродвигателя (Рис. 9-12).

Рис. 9-12. Сборка насадок на ножке



3. Нажмите на насадку на ножке по направлению к электродвигателю и поверните насадку, чтобы заблокировать ее на корпусе электродвигателя (Рис. 9-13).

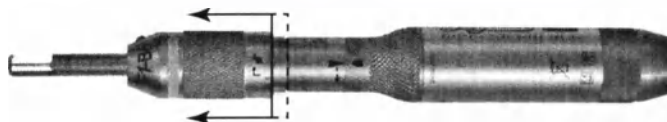
Рис. 9-13. Сборка насадок на ножке



## РАЗБОРКА ФИКСИРОВАННЫХ НАСАДОК НА НОЖКЕ

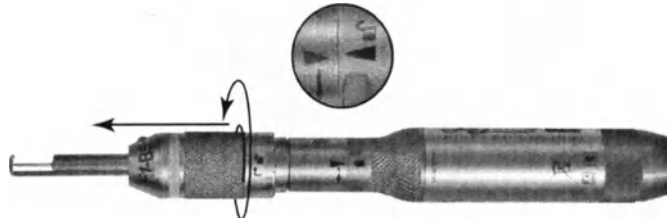
1. Чтобы снять насадку на ножке, возьмите электродвигатель в руку. Толкайте втулку насадки на ножке в дистальном направлении, поворачивая насадку на электродвигателе в положение разблокировки. Отпустите втулку (Рис. 9-14).

Рис. 9-14. Разборка насадок на ножке



2. Во избежание травмирования инструментом для препарирования с помощью большого и указательного пальцев осторожно и медленно отделите насадку от электродвигателя и снимите ее с инструмента для препарирования (Рис. 9-15).

Рис. 9-15. Разборка насадок на ножке



3. Вытяните инструмент для препарирования из зажимного патрона электродвигателя и выбросьте инструмент (Рис. 9-16).

Рис. 9-16. Разборка насадок на ножке



**СБОРКА ВРАЩАЮЩИХСЯ НАСАДОК НА НОЖКЕ**

**Предупреждения!** См. предупреждения W20 и W52.

**Примечания.**

- С вращающимися и фиксированными насадками на ножке одной и той же длины и с одинаковой буквенной и цветовой маркировкой используются одни и те же инструменты для препарирования.
- Конец насадки, на которой расположена ножка, свободно вращается на 360°.

Установка вращающихся насадок на ножке выполняется в соответствии с инструкциями по сборке фиксированных насадок на ножке.

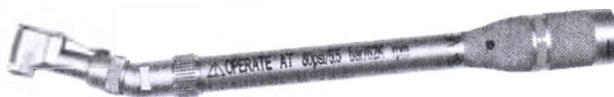
**РАЗБОРКА ВРАЩАЮЩИХСЯ НАСАДОК НА НОЖКЕ**

Отсоединение вращающихся насадок на ножке выполняется в соответствии с инструкциями по разборке фиксированных насадок на ножке.

**СБОРКА КОНТРУГЛОВОЙ НАСАДКИ 16-MF**

1. На сенсорном экране IPC выставьте скорость 62 000 об./мин. с помощью кнопок управления скоростью.
2. Надвиньте контругловую насадку на зажимной патрон электродвигателя, совмещая треугольные стрелки на насадке и корпусе электродвигателя. Вы услышите и почувствуете щелчок, который подтверждает, что инструмент полностью встал на свое место.
3. Поверните насадку в положение блокировки на корпусе электродвигателя (Рис. 9-17).

Рис. 9-17. Сборка контругловых насадок



4. Поверните рычаг головки насадки латерально в открытое положение и вставьте инструмент для препарирования (Рис. 9-18).
5. Закройте рычаг (Рис. 9-19).
6. Осторожно потяните инструмент, чтобы убедиться в правильности его установки.

Рис. 9-18. Сборка контругловых насадок

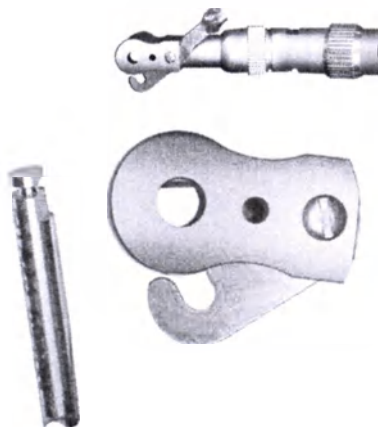


Рис. 9-19. Сборка контругловых насадок

**РАЗБОРКА КОНТРУГЛОВОЙ НАСАДКИ 16-MF**

1. Поверните рычаг головки насадки латерально, чтобы удалить инструмент для препарирования.
2. Выбросьте инструмент для препарирования.
3. Поверните насадку 16-MF, чтобы перевести ее в положение разблокировки и отделить от электродвигателя.

## СБОРКА НАСАДОК ДЛЯ РЕЗКИ МЕТАЛЛА

**Предупреждение!** См. предупреждение W15.

**Важная информация!** С насадками для резки металла используются вольфрамокарбидные инструменты для препарирования или инструменты с алмазными режущими дисками. В номенклатуре всех инструментов для резки металла имеется префикс «МС» (например, МС254, МС30). Инструменты для резки металла нельзя вставлять ни в какие другие насадки.

- Надвиньте насадку для резки металла на зажимной патрон электродвигателя, совмещая треугольные маркеры на насадке и корпусе электродвигателя. Вы услышите и почувствуете щелчок, который подтверждает, что инструмент полностью встал на свое место.
- Поверните насадку в положение блокировки на корпусе электродвигателя.
- Удерживайте насадку направленной ВВЕРХ и, открутив фиксатор инструмента на несколько оборотов, вставьте инструмент для препарирования в насадку (Рис. 9-20).
- Поверните инструмент для препарирования так, чтобы он плотно вошел в свое место. Вы почувствуете щелчок, который означает, что инструмент плотно посажен (Рис. 9-20).

Рис. 9-20. Сборка насадок для резки металла



## РАЗБОРКА НАСАДОК ДЛЯ РЕЗКИ МЕТАЛЛА

- Открутите фиксатор инструмента на несколько оборотов и выньте инструмент для препарирования.
- Поверните насадку, чтобы перевести ее в положение разблокировки и отделить от электродвигателя.

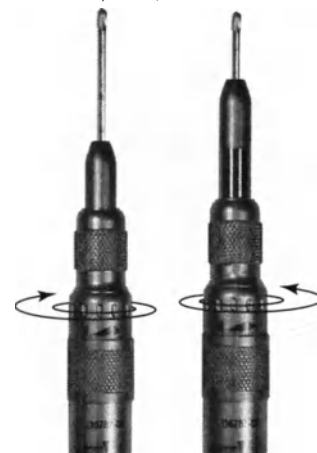
## СБОРКА НАСАДОК С ПЕРЕМЕННОЙ ДЛИНОЙ ВЫСТУПАЮЩЕЙ ЧАСТИ

**Предупреждения!** См. предупреждения W23, W34, W53 и W57.

Насадки с переменной длиной выступающей части отличаются от стандартных насадок двойной цветовой маркировочной полосой. Цвет полосы на насадке должен совпадать с цветом маркировки на упаковке инструмента для препарирования.

- Сборка насадки выполняется в соответствии с инструкциями по сборке прямых насадок.
- После сборки длина выступающей части инструмента для препарирования регулируется с помощью регулировочного кольца ТРУБКИ (Рис. 9-21). Чтобы увеличить длину трубки и, соответственно, уменьшить длину выступающей части инструмента, поверните регулировочное кольцо вправо, держа инструмент в направлении от себя. При повороте кольца влево длина трубки уменьшается, а длина выступающей части инструмента увеличивается.

Рис. 9-21. Насадка с переменной длиной выступающей части



## РАЗБОРКА НАСАДОК С ПЕРЕМЕННОЙ ДЛИНОЙ ВЫСТУПАЮЩЕЙ ЧАСТИ

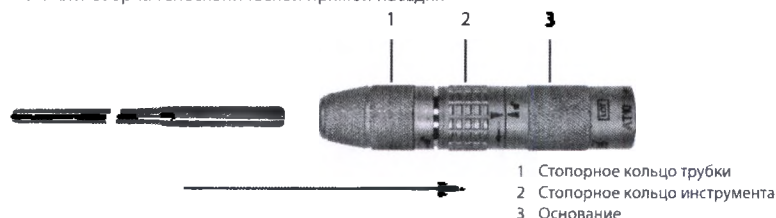
Отсоединение насадок с переменной длиной выступающей части выполняется в соответствии с инструкциями по разборке прямых насадок.

## СБОРКА ТЕЛЕСКОПИЧЕСКОЙ ПРЯМОЙ НАСАДКИ AT10

- Сборка насадки выполняется в соответствии с инструкциями по сборке прямых насадок.
- Вставьте основание выбранной телескопической трубки в насадку.
- Чтобы заблокировать трубку, поворачивайте пальцами стопорное кольцо ТРУБКИ до упора по часовой стрелке (Рис. 9-22).

**Примечание.** ЗАПРЕЩАЕТСЯ перетягивать кольцо.

Рис. 9-22. Сборка телескопической прямой насадки



- Убедитесь в том, что стопорное кольцо ИНСТРУМЕНТА разблокировано. Вставьте инструмент для препарирования в телескопическую трубку (Рис. 9-23). При полной посадке инструмента для препарирования вы почувствуете защелкивание.

Рис. 9-23. Сборка телескопической прямой насадки



5. Заблокируйте стопорное кольцо ИНСТРУМЕНТА, повернув его (Рис. 9-24).

Рис. 9-24. Сборка телескопической прямой насадки



6. Убедитесь, что инструмент встал на место, слегка потянув его.
7. Если возникает необходимость в изменении положения трубки, поверните стопорное кольцо ТРУБКИ в сторону разблокировки, переустановите трубку и поверните стопорное кольцо ТРУБКИ в заблокированное положение.
8. Чтобы убедиться в правильности установки, осторожно потяните сначала инструмент для препарирования, а потом трубку.

## СБОРКА ТЕЛЕСКОПИЧЕСКОЙ ИЗОГНУТОЙ НАСАДКИ AT10

1. Сборка насадки выполняется в соответствии с инструкциями по сборке прямых насадок.
2. Вставьте основание изогнутого бора в насадку, чтобы втулка вошла до упора. Чтобы заблокировать бор, поворачивайте пальцами стопорное кольцо ТРУБКИ до упора по часовой стрелке (Рис. 9-25).

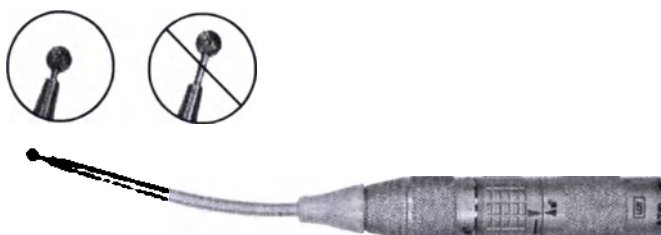
**Примечание.** ЗАПРЕЩАЕТСЯ перетягивать кольцо.

Рис. 9-25. Сборка телескопической изогнутой насадки



3. Убедитесь, что втулка встала на место, слегка потянув инструмент.
4. Задвиньте инструмент в стопорное кольцо инструмента, немного прижав бор по направлению внутрь насадки (Рис. 9-26). Вы услышите и почувствуете щелчок, который подтверждает, что инструмент полностью встал на свое место.

Рис. 9-26. Сборка телескопической изогнутой насадки



5. Поворачивайте стопорное кольцо инструмента, пока метка совмещения фиксатора инструмента не окажется на одной линии с символом блокировки (Рис. 9-27).

Рис. 9-27. Сборка телескопической изогнутой насадки



Рис. 9-28. Охлаждение изогнутого бора



6. Убедитесь, что бор встал на место, слегка потянув его.
7. Перед первым использованием смочите охлаждающий рукав, погрузив его в емкость с солевым раствором или деионизированной водой (Рис. 9-28).
8. Во время работы поддерживайте обильную ирригацию охлаждающего рукава и бора, пуская тонкую струйку физраствора или деионизированной воды по всей длине охлаждающего рукава.



СБОРКА НАСАДКИ ТЕЛЕСКОПИЧЕСКОЙ ТРУБКИ

- 1. Установите насадку на электродвигатель в соответствии с инструкциями по сборке прямых насадок.
- 2. Вставьте основание инструмента в насадку, чтобы втулка вошла до упора. Для блокировки поворачивайте пальцами стопорное кольцо ТРУБКИ до упора (Рис. 9-27).

Примечание. ЗАПРЕЩАЕТСЯ перетягивать.

- 3. Убедитесь, что втулка встала на место, слегка потянув инструмент.
- 4. Задвиньте инструмент в стопорное кольцо инструмента, немного прижав бор по направлению внутрь насадки (Рис. 9-27). Будет слышен ощутимый щелчок, который подтверждает, что инструмент полностью встал на свое место.

РАЗБОРКА ТЕЛЕСКОПИЧЕСКОЙ НАСАДКИ AT10

- 1. Поверните стопорное кольцо ТРУБКИ в положение разблокировки.
- 2. Поверните стопорное кольцо ИНСТРУМЕНТА в положение разблокировки.
- 3. Вытяните телескопическую трубку из насадки.
- 4. Поверните насадку, чтобы перевести ее в положение разблокировки на корпусе электродвигателя и отделить от электродвигателя.

СБОРКА НАСАДОК ПЕРФОРАТОРОВ AD01 И AD03

Предупреждение! См. предупреждение W56.

Примечание. Черепной перфоратор можно установить в насадку до ее установки на электродвигатель.

| Настройка пульта управления | Максимальная скорость                        |                                              |
|-----------------------------|----------------------------------------------|----------------------------------------------|
|                             | Скорость вращения выходного вала AD01 (МАКС) | Скорость вращения выходного вала AD03 (МАКС) |
| 60000 об./мин               | 645 об./мин                                  | 830 об./мин                                  |
| 70000 об./мин               | 745 об./мин                                  | 965 об./мин                                  |
| 72000 об./мин               | 770 об./мин                                  | 995 об./мин                                  |
| 74000 об./мин               | 790 об./мин                                  | 1020 об./мин                                 |
| 75000 об./мин               | 805 об./мин                                  | 1035 об./мин                                 |

- 1. Сборка насадки выполняется в соответствии с инструкциями по сборке прямых насадок.
- 2. Чтобы установить черепной перфоратор с наконечником Hudson, потяните в проксимальном направлении кольцо на насадке перфоратора. Вставьте устройство и отпустите кольцо, чтобы оно вернулось на свое место (Рис. 9-29).

Рис. 9-29. Сборка насадки перфоратора с наконечником Hudson



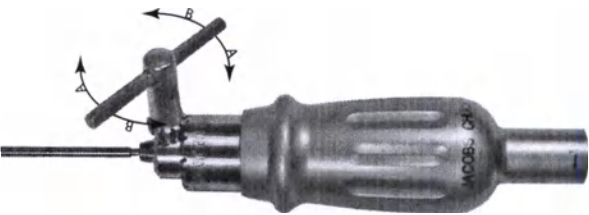
РАЗБОРКА НАСАДОК ПЕРФОРАТОРОВ AD01 И AD03

Чтобы снять черепной перфоратор, оттяните кольцо в проксимальном направлении на насадке перфоратора. Поверните насадку перфоратора, чтобы перевести ее в положение разблокировки и отделить от электродвигателя.

СБОРКА НАСАДКИ С ЦАНГОВЫМ ПАТРОНОМ JACOBS

- 1. Сборка насадки выполняется в соответствии с инструкциями по сборке прямых насадок.
- 2. Чтобы установить перовое сверло, поверните торцевой ключ для насадки с цанговым патроном Jacobs, чтобы открыть зубчатую обойму. Вставьте перовое сверло и затяните обойму ключом (Рис. 9-30).

Рис. 9-30. Сборка насадки с цанговым патроном Jacobs



РАЗБОРКА НАСАДКИ С ЦАНГОВЫМ ПАТРОНОМ JACOBS

Откройте зубчатую обойму с помощью ключа для насадки с цанговым патроном Jacobs. Снимите перовое сверло и выбросьте его в соответствующий контейнер. Поверните насадку с цанговым патроном Jacobs, чтобы перевести ее в положение разблокировки и отделить от электродвигателя.

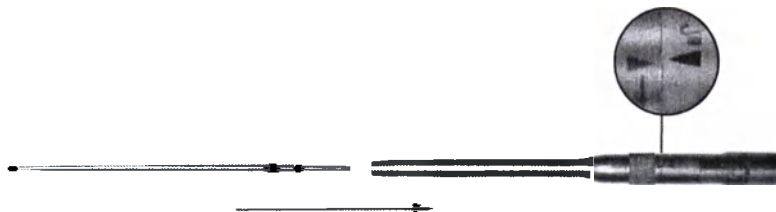


## СБОРКА УГЛОВЫХ НАСАДОК С ДВОЙНОЙ ФИКСАЦИЕЙ

### Примечания.

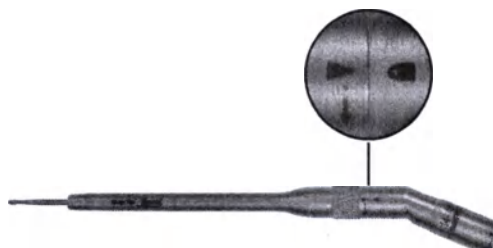
- С угловыми насадками одной и той же длины и с одинаковой буквенной и цветовой маркировкой используются одни и те же инструменты для препарирования.
- Прежде чем устанавливать угловую насадку на электродвигатель, в нее можно вставить и зафиксировать инструмент.
  - Сборка насадки выполняется в соответствии с инструкциями по сборке прямых насадок.
  - Вставьте инструмент в насадку легким вращением. Вы услышите и почувствуете щелчок, который подтверждает, что инструмент полностью встал на свое место (Рис. 9-31).

Рис. 9-31. Сборка угловых насадок с двойной фиксацией



- Поворачивайте фиксатор инструмента в указанном стрелкой направлении, пока метка совмещения фиксатора инструмента не окажется на одной линии с символом блокировки (Рис. 9-32).

Рис. 9-32. Сборка угловых насадок с двойной фиксацией

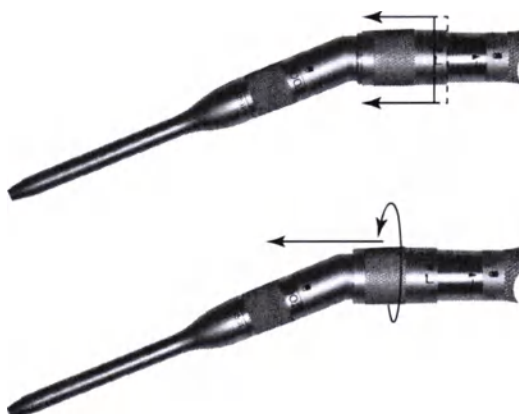


- Потяните инструмент, чтобы удостовериться в том, что он зафиксирован в рукоятке.
- Инструмент должен свободно вращаться. В противном случае разблокируйте насадку, заново вставьте инструмент и снова зафиксируйте насадку.
- Убедитесь, что метка совмещения насадки с двигателем и метка фиксатора инструмента находятся на одной линии с символом блокировки.

## РАЗБОРКА УГЛОВЫХ НАСАДОК С ДВОЙНОЙ ФИКСАЦИЕЙ

- Чтобы снять насадку, удерживайте электродвигатель рукой и толкайте втулку насадки в дистальном направлении, одновременно поворачивая насадку в положение разблокировки (Рис. 9-33).
- Отпустите втулку и снимите насадку.

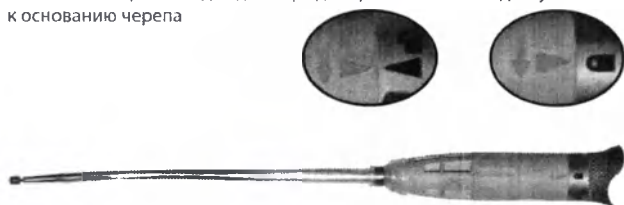
Рис. 9-33. Разборка угловых насадок с двойной фиксацией



### СБОРКА НАСАДКИ ДЛЯ БОРА ДЛЯ ТРАНСНАЗАЛЬНОГО ДОСТУПА К ОСНОВАНИЮ ЧЕРЕПА

1. Надвиньте насадку на зажимной патрон электродвигателя, совмещая треугольные стрелки на насадке и корпусе электродвигателя. Вы услышите и почувствуете щелчок, который подтверждает, что инструмент полностью встал на свое место.
2. Поверните насадку в положение блокировки на корпусе электродвигателя (Рис. 9-34).

Рис. 9-34. Сборка насадки для бора для трансназального доступа к основанию черепа



3. Подсоедините ирригационную трубку (Рис. 9-35).

Рис. 9-35. Сборка насадки для бора для трансназального доступа к основанию черепа



### РАЗБОРКА НАСАДКИ ДЛЯ БОРА ДЛЯ ТРАНСНАЗАЛЬНОГО ДОСТУПА К ОСНОВАНИЮ ЧЕРЕПА

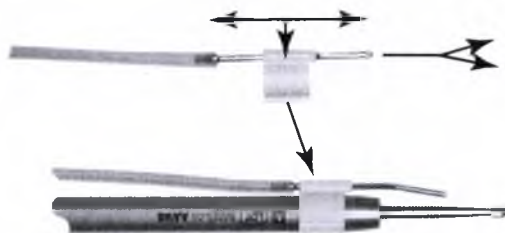
1. Отсоедините ирригационную трубку.
2. Поверните насадку в положение разблокировки на корпусе электродвигателя.
3. Снимите насадку с электродвигателя.

### ЗАКРЕПЛЕНИЕ ИРРИГАЦИОННОЙ ТРУБКИ

**ПРИМЕЧАНИЕ.** Зажим может не держаться на маленькой насадке для бора после использования с насадкой для бора большего диаметра.

1. Наложите пластиковый зажим на ирригационную трубку из нержавеющей стали (Рис. 9-36).
2. Согните ирригационную трубку под нужным углом.
3. Закрепите зажим на рукоятке рядом с инструментом.

Рис. 9-36. Закрепление ирригационной трубки



### ИНСТРУКЦИИ ПО ОЧИСТКЕ И СТЕРИЛИЗАЦИИ LEGEND EHS, LEGEND EHS STYLUS И STYLUS TOUCH

См. документы M000030A234, 68E4132 и M000030A235 в разделе, посвященном очистке и стерилизации.

#### Очистка насадок с переменной длиной выступающей части

Проводите полную очистку насадок. Сначала не изменяя длину трубки, затем полностью выдвинув трубку и затем полностью задвинув трубку.

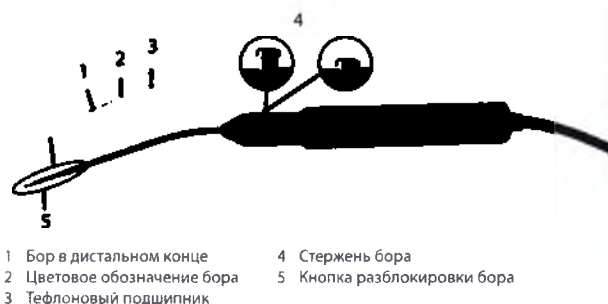
# СВЕРХЛЕГКИЙ ОТОЛОГИЧЕСКИЙ ИНСТРУМЕНТ SKEETER

Приведенные ниже инструкции, касающиеся сверхлегкого отологического инструмента Skeeter, дополняют общие инструкции по сборке, приведенные в разделе «Настройка IPC». Выполните все этапы настройки IPC и перейдите к инструкциям, приведенным ниже. Дополнительную информацию см. в Инструкции по эксплуатации сверхлегкого отологического инструмента Skeeter.

## СБОРКА SKEETER

1. Нажмите кнопку разблокировки бора (Рис. 10-1).
2. Вставьте бор, необходимый для выполнения вмешательства, в дистальный конец рукоятки легким вращательным движением, одновременно нажимая кнопку разблокировки бора.
3. Бор зафиксирован, если вы услышали щелчок. Необходимо проверить блокировку бора до его использования, с усилием потянув его после щелчка.
4. Чтобы проверить надежность посадки бора в рукоятке, потяните его.
5. Чтобы снять бор с рукоятки, нажмите кнопку разблокировки бора на рукоятке и вытяните бор.

Рис. 10-1. Сборка рукоятки Skeeter



## ПОДКЛЮЧЕНИЕ РУКОЯТКИ SKEETER К ПУЛЬТУ УПРАВЛЕНИЯ IPC

На панели разъемов (рис. 10-2) пульта управления IPC найдите порт для подключения Skeeter, совместите отметки на разъеме и пульте управления и затем вставьте разъем.

С рукояткой Skeeter не используется ирригация. По умолчанию задан параметр использования обеих помп **None** (Нет).

Работой Skeeter можно управлять с сенсорного экрана IPC и с помощью multifunction foot pedal (Многофункциональная ножная педаль).

Рис. 10-2. Порт для подключения Skeeter к IPC



## ЭЛЕМЕНТЫ УПРАВЛЕНИЯ SKEETER НА СЕНСОРНОМ ЭКРАНЕ

Чтобы задать или настроить элементы управления Skeeter, выполните следующие действия в поле управления Skeeter на сенсорном экране IPC (Рис. 10-3).

- Для изменения направления вращения в поле управления Mode (Режим) выберите FWD (вперед) или REV (назад).
- Чтобы увеличить или уменьшить скорость, следует нажать в поле управления

Speed (Скорость) соответственно на кнопки «плюс» или «минус».

По умолчанию задана скорость 16 000 об./мин.; возможна настройка в пределах от 1 000 до 16 000 об./мин.

Рис. 10-3. Сенсорный экран Skeeter



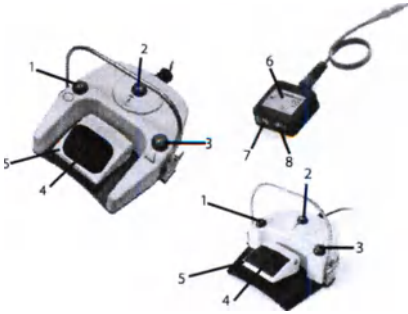
ЭЛЕМЕНТЫ УПРАВЛЕНИЯ SKEETER НА МНОГОФУНКЦИОНАЛЬНОЙ НОЖНОЙ ПЕДАЛИ

**Важная информация!** По умолчанию, для активирования выбранного действия необходимо нажимать каждую кнопку не менее 100 мсек. Изменить это значение по умолчанию можно в экране Settings (Настройки) на сенсорном экране IPC.

Для управления рукояткой с помощью многофункциональной ножной педали (Рис. 10-4) выполните следующие действия.

- Чтобы выбрать режим прямого или обратного вращения, нажмите кнопку режима. 
- Чтобы активировать рукоятку или настроить ее скорость в режиме переменной скорости, нажмите ножную педаль.
- Чтобы переключиться между режимом пуска/остановки и режимом переменной скорости, нажмите кнопку управления. 
- Чтобы сменить рукоятку, нажмите кнопку рукоятки. 

Рис. 10-4. Многофункциональная ножная педаль и У-образный делитель сигнала



- 1

Кнопка переключения режима
- 2

Кнопка рукоятки
- 3

Кнопка управления
- 4

Нескользящая подкладка
- 5

Ножная педаль
- 6

У-образный делитель сигнала
- 7

Порт 1
- 8

Порт 2

ИНСТРУКЦИИ ПО ОЧИСТКЕ И СТЕРИЛИЗАЦИИ SKEETER

См. документы 68E3968 и 68E3969 в разделе, посвященном очистке и стерилизации.

ТЕХНИЧЕСКИЕ ХАРАКТЕРИСТИКИ SKEETER

Skeeter 3055601

|                                                                           |                                                      |
|---------------------------------------------------------------------------|------------------------------------------------------|
| Размер                                                                    | длина — 17,0 см, диаметр — 1,6 см                    |
| Масса                                                                     | 57 г                                                 |
| Скорость                                                                  | 1 000–16 000 об./мин в прямом и обратном направлении |
| Рабочий цикл деталей, находящихся в непосредственном контакте с пациентом | Непрерывная работа                                   |
| Температура хранения                                                      | От -40 °C до +70 °C                                  |
| Влажность                                                                 | Относительная влажность от 10 до 100 %               |
| Атмосферное давление                                                      | От 500 до 1 060 гПа                                  |

# ВЫСОКОСКОРОСТНАЯ ДРЕЛЬ VISAO

## ОПИСАНИЕ УСТРОЙСТВА

При использовании дрели Visao IPC задействует охлаждение через помпу 1, а ирригацию через помпу 2. Картридж охлаждающей помпы Visao оснащен трубками накачки и возврата жидкости в камеру капельницы. Если ирригация не используется, выберите для помпы 2 параметр None (Нет). См. раздел «Установка и наполнение помп». Работой Visao можно управлять с сенсорного экрана IPC и с помощью многофункциональной ножной педали.

**Важная информация!** Во время работы обеспечивайте беспрепятственную ирригацию охлаждающего рукава и бора, пуская тонкую струйку физраствора или деионизированной воды по всей длине охлаждающего рукава.

Приведенные ниже инструкции касаются использования дрели Visao с IPC. Они дополняют общие инструкции по сборке, приведенные в разделе «Настройка IPC».

## НАСТРОЙКА ПОМПЫ VISAO

Заполните прозрачную капельницу охлаждающей жидкостью до заполнения системы охлаждения. См. раздел «Установка и наполнение помп».

## УСТАНОВКА ЗАЩИТЫ БОРА НА ДРЕЛЬ VISAO

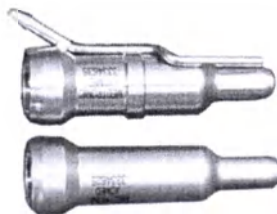
**Важная информация!** При использовании дрели Visao защита (Рис. 11-2) необходима для всех видов боров.

Наденьте защиту бора на передний конец Visao до полной посадки (Рис. 11-1).

Рис. 11-1. Установка защиты бора



Рис. 11-2. Защиты боров для Visao



Многоразовые защиты боров для Visao с ирригацией и без нее.



Одноразовая защита бора для Visao с ирригацией.



Одноразовая защита стимулирующего бора для Visao с ирригацией и без нее. Защита для стимулирующего бора обеспечивает возможность выполнять стимуляцию нервов с помощью стандартных боров в статических и динамических режимах при условии их использования вместе с монитором целостности нервов Medtronic Nerve Integrity Monitor (NIM) и системой IPC.

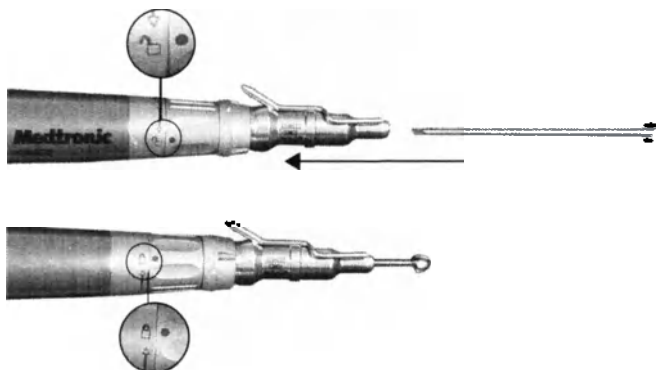


## УСТАНОВКА ПРЯМОГО БОРА НА ДРЕЛЬ VISAO

**Важная информация!** При использовании дрели Visao защита (Рис. 11-2) необходима для всех видов боров.

1. Выровняйте точку совмещения на запорном кольце Visao с символом разблокировки (Рис. 11-3).
2. Вставьте инструмент до полной посадки.
3. Поверните запорное кольцо так, чтобы точка совмещения выровнялась с символом блокировки.
4. Чтобы убедиться в надежном закреплении инструмента, слегка потяните его.

Рис. 11-3. Установка прямого инструмента на дрель Visao

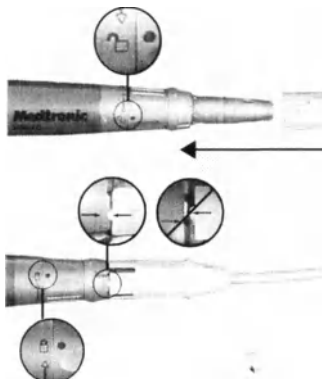


## УСТАНОВКА ИЗОГНУТОГО БОРА НА ДРЕЛЬ VISAO

**Важная информация!** При использовании дрели Visao защита (Рис. 11-2) необходима для всех видов боров.

1. Выровняйте точку совмещения на запорном кольце Visao с символом разблокировки (Рис. 11-4).
2. Совместите выемку на инструменте с выемкой на кольце Visao.
3. Мягко надавите на инструмент до полной посадки.
4. Выровняйте точку совмещения на запорном кольце Visao с символом блокировки.
5. Чтобы убедиться в надежном закреплении инструмента, слегка потяните его.

Рис. 11-4. Установка изогнутого бора на дрель Visao

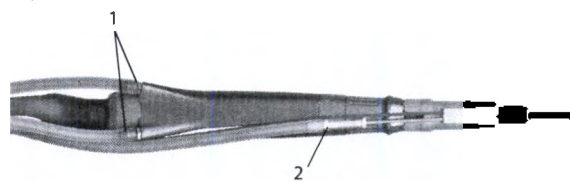


## ЗАКРЕПЛЕНИЕ ТРУБОК ДЛЯ ИРРИГАЦИИ И ОХЛАЖДЕНИЯ НА ДРЕЛИ VISAO

**Внимание!** Не перепутайте трубку для охлаждающей жидкости с ирригационной трубкой.

1. Подсоедините по одной трубке для охлаждающей жидкости к каждому порту для охлаждающей жидкости (Рис. 11-5). Охлаждающую жидкость можно подавать в левый или правый порт, а трубка возврата подсоединяется к противоположному порту.
2. Натяните до упора свободный конец ирригационной трубки на патрубке с бородками для ирригационной системы.
3. Убедитесь в том, что при нажатии педали охлаждения активируется рукоятка и появляется охлаждающая жидкость.  
**Примечание.** После того, как вы отпустите педаль, охлаждающая помпа будет работать еще 1 минуту.
4. Перед первым использованием смочите охлаждающий рукав, погрузив его в емкость с солевым раствором или деионизированной водой.
5. Во время работы поддерживайте обильную ирригацию охлаждающего рукава и бора, пуская тонкую струйку физраствора или деионизированной воды по всей длине охлаждающего рукава.

Рис. 11-5. Закрепление трубок для ирригации и охлаждения на дрели Visao



1 Трубка для охлаждающей жидкости

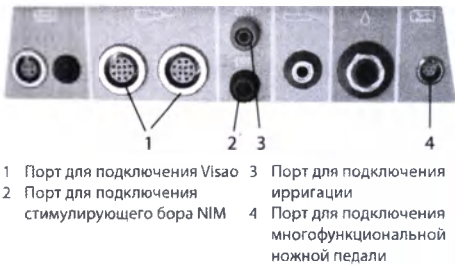
2 Трубка для ирригации

ПОДКЛЮЧЕНИЕ VISAO К ПУЛЬТУ УПРАВЛЕНИЯ IPC

Найдите порт для подключения VISAO на панели разъемов (Рис. 11-6) и вставьте разъем.

**Примечание.** Чтобы вставить многоштырьковые разъемы (такие разъемы обозначены серебряной или красной меткой), совместите метку на разъеме с меткой на пульте управления и вставьте разъем.

Рис. 11-6. Порт для подключения Visao к IPC



ЭЛЕМЕНТЫ УПРАВЛЕНИЯ VISAO НА СЕНСОРНОМ ЭКРАНЕ

Чтобы задать или настроить элементы управления VISAO, выполните следующие действия на сенсорном экране IPC в поле управления VISAO (Рис. 11-7).

- Для изменения направления вращения в поле управления Mode (Режим) выберите FWD (вперед) или REV (назад).
- Чтобы увеличить или уменьшить скорость, следует нажать в поле управления Speed (Скорость) соответственно на кнопки «плюс» или «минус». По умолчанию выставлено значение 80 000 об./мин.; возможна настройка скорости в пределах от 200 до 80 000 об./мин.
- Чтобы увеличить или уменьшить интенсивность ирригации, следует нажать в поле управления Pump (Помпа) соответственно на кнопки «плюс» или «минус». Если в системе есть функция прерывистой ирригации, нажатие кнопки «плюс» или «минус» переключает режим ирригации между прерывистым и постоянным. В режиме прерывистой ирригации система отображает надпись «Intermittent» (Прерывистый). Режим прямого вращения: по умолчанию выставлено значение 30 куб. см. в минуту.

**Примечание.** Для регулирования интенсивности ирригации можно использовать сенсорный экран или пульт дистанционного управления ирригацией Intelliflow.

Рис. 11-7. Сенсорный экран Visao



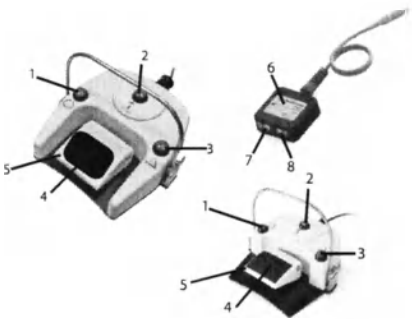
ЭЛЕМЕНТЫ УПРАВЛЕНИЯ VISAO НА МНОГОФУНКЦИОНАЛЬНОЙ НОЖНОЙ ПЕДАЛИ

**Важная информация!** По умолчанию, для активирования выбранного действия необходимо нажимать каждую кнопку не менее 100 мсек. Изменить это значение по умолчанию можно в экране Settings (Настройки) на сенсорном экране IPC.

Для управления рукояткой с помощью многофункциональной ножной педали (Рис. 11-8) выполните следующие действия.

- Чтобы выбрать режим прямого или обратного вращения, нажмите кнопку режима.
  - Чтобы активировать рукоятку или настроить ее скорость в режиме переменной скорости, нажмите ножную педаль.
  - Чтобы переключиться между режимом пуска/остановки и режимом переменной скорости, нажмите кнопку управления.
- Примечание.** В меню рукоятки по умолчанию можно изменить функцию кнопки управления на приостановку ирригации. См. «Изменение настроек системы» в разделе «Действия до начала эксплуатации системы».
- Чтобы сменить рукоятку, нажмите кнопку рукоятки.

Рис. 11-8. Многофункциональная ножная педаль и У-образный делитель сигнала



- |                              |                               |
|------------------------------|-------------------------------|
| 1 Кнопка переключения режима | 5 Ножная педаль               |
| 2 Кнопка рукоятки            | 6 У-образный делитель сигнала |
| 3 Кнопка управления          | 7 Порт 1                      |
| 4 Нескользкая подкладка      | 8 Порт 2                      |

VISAO

ИНСТРУКЦИИ ПО ОЧИСТКЕ И СТЕРИЛИЗАЦИИ VISAO

См. документ 68Е3281 в разделе, посвященном очистке и стерилизации.

ТЕХНИЧЕСКИЕ ХАРАКТЕРИСТИКИ VISAO

Visao 3334800

|                                                                           |                                                                                                                        |
|---------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|
| Размер                                                                    | длина — 16,0 см, диаметр — 2,0 см                                                                                      |
| Масса                                                                     | 148 г                                                                                                                  |
| Скорость                                                                  | 200–80 000 об./мин в прямом и обратном направлении. Высокоскоростная дрель Visao с водяным охлаждением                 |
| Рабочий цикл деталей, находящихся в непосредственном контакте с пациентом | При полной нагрузке высокоскоростная дрель Visao рассчитана на перемежающийся режим работы со следующими показателями. |
|                                                                           | Максимальное время нахождения во включенном состоянии: 60 с                                                            |
|                                                                           | Максимальное время нахождения в выключенном состоянии: 30 с                                                            |

ИСПОЛЬЗОВАНИЕ VISAO С IPC И NIM

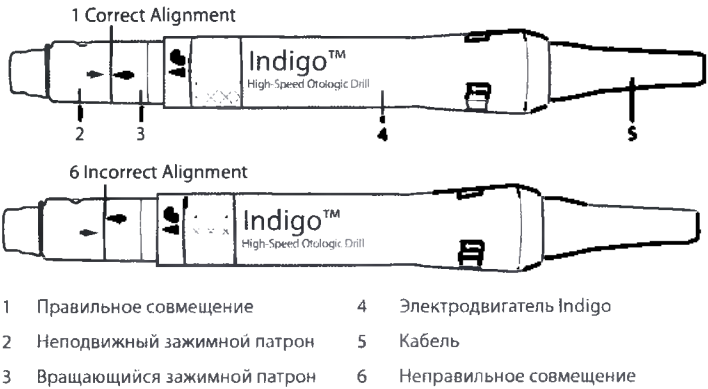
Для использования NIM и IPC необходима защита стимулирующего бора (Рис. 11-2). Защита стимулирующего бора соединяет IPC с NIM через выходной порт стимулирующего сигнала стимулирующего бора (Рис. 11-6). Защита стимулирующего бора обеспечивает проведение стимулирующего тока на кончик инструмента и стимуляцию нерва с помощью стандартных боров в статических и динамических режимах работы. Более подробная информация содержится в Руководстве пользователя NIM и Информации и инструкции по эксплуатации защиты стимулирующего бора.

# ВЫСОКОСКОРОСТНАЯ ОТОЛОГИЧЕСКАЯ ДРЕЛЬ INDIGO

## ОПИСАНИЕ УСТРОЙСТВА

Дрель Indigo — это небольшая компактная высокоскоростная реверсивная электродрель с высоким крутящим моментом, используемая для рассечения кости и биоматериалов с различной скоростью от 200 до 60 000 об./мин. Кабель дрели несъемный. Приведенные ниже инструкции, касающиеся дрели Indigo, дополняют общие инструкции по сборке, приведенные в разделе «Настройка IPC». Выполните все этапы настройки IPC и перейдите к инструкциям, приведенным ниже.

Рис. 12-1. Совмещение меток на компонентах Indigo



## ПОДСОЕДИНЕНИЕ ПРЯМОЙ НАСАДКИ К ДРЕЛИ INDIGO

**Важная информация!** Скоростная отолгическая дрель Indigo предназначена для работы только с борами Medtronic Xomed и насадками Indigo. Использование других боров и насадок может привести к сниженной эффективности работы и приведет к аннулированию заводской гарантии. Не используйте насадки и боры Midas Rex.

1. Убедитесь в том, что метки совмещения на зажимном патроне электродвигателя выровнены (Рис. 12-1).

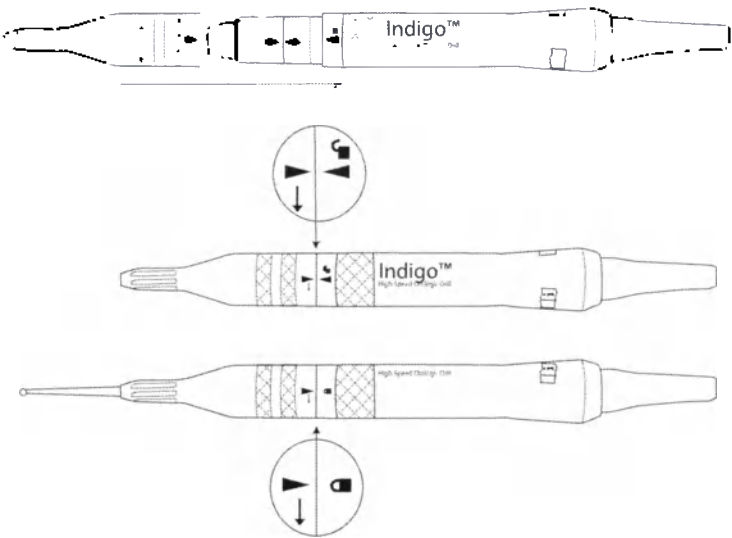
**Примечание.** Если метки не выровнены, поверните зажимной патрон так, чтобы метки совместились.

2. Наденьте насадку на зажимной патрон электродвигателя (Рис. 12-2) так, чтобы метка совмещения на насадке была выровнена с меткой совмещения (символ разблокировки) на зажимном патроне электродвигателя.
3. Вставьте бор, немного вращая его, пока вы не почувствуете, что он стал на место.
4. Поверните насадку так, чтобы метка совмещения выравнивалась с символом блокировки на зажимном патроне электродвигателя. При повороте насадки вы услышите два щелчка.
5. Чтобы убедиться в надежном закреплении инструмента, слегка потяните его.

**Важная информация!** Пока насадка не зафиксирована надлежащим образом, электродвигатель Indigo не будет работать правильно.

**Предупреждение!** Если насадка не заблокирована, возможно появление дыма (W36).

Рис. 12-2. Подсоединение прямой насадки к дрели Indigo



## ПОДСОЕДИНЕНИЕ УГЛОВОЙ НАСАДКИ К ДРЕЛИ INDIGO

**Важная информация!** Скоростная отолгическая дрель Indigo предназначена для работы только с борами Medtronic Xomed и насадками Indigo. Использование других боров и насадок может привести к сниженной эффективности работы и приведет к аннулированию заводской гарантии. Не используйте насадки и боры Midas Rex.

1. Убедитесь в том, что метки совмещения на зажимном патроне электродвигателя выровнены (Рис. 12-1).

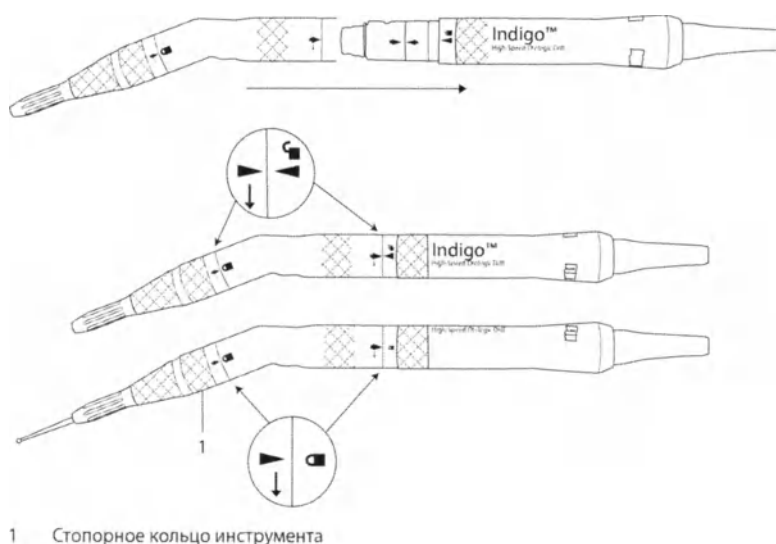
**Примечание.** Если метки не выровнены, поверните зажимной патрон так, чтобы метки совместились.

2. Наденьте насадку на зажимной патрон электродвигателя (Рис. 12-3) так, чтобы метка совмещения на насадке была выровнена с меткой совмещения (символ разблокировки) на зажимном патроне электродвигателя.
3. Поверните насадку так, чтобы метка совмещения выровнялась с символом блокировки на зажимном патроне электродвигателя. При повороте насадки вы услышите два щелчка.
4. Убедитесь в том, что метки совмещения на стопорном кольце инструмента совмещены с символом разблокировки на насадке.
5. Вставьте бор, немного вращая его, пока вы не почувствуете, что он стал на место.
6. Поверните стопорное кольцо так, чтобы метка совмещения выровнялась с символом блокировки на насадке. При повороте насадки вы услышите два щелчка.
7. Чтобы убедиться в надежном закреплении инструмента, слегка потяните его.

**Важная информация!** Пока насадка не зафиксирована надлежащим образом, электродвигатель Indigo не будет работать правильно.

**Предупреждение!** Если насадка не заблокирована, возможно появление дыма (W 36).

Рис. 12-3. Подсоединение угловой насадки к дрели Indigo



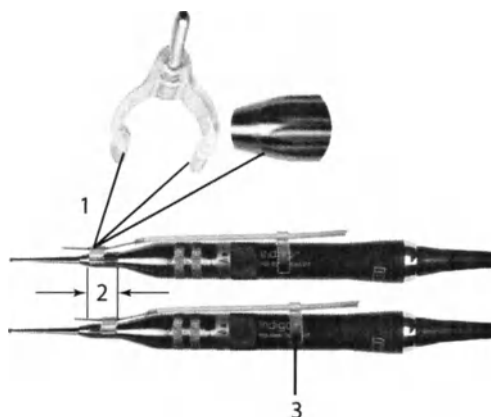
## ИРРИГАЦИЯ ДРЕЛИ INDIGO И ПОДСОЕДИНЕНИЕ ЗАЖИМА ДЛЯ ТРУБКИ

1. Наденьте зажим для ирригационной трубки на насадку (Рис. 12-4).

**Примечание.** Зажим для ирригационной трубки имеет два выступа, которые вставляются в два паза на насадке.

2. Согните ирригационную трубку под нужным углом и расположите зажим ближе к бору или дальше от него, как необходимо.
3. Защелкните держатель трубки на рукоятке или на угловой насадке.

Рис. 12-4. Ирригация и подсоединение зажима для трубки





ПОДСОЕДИНЕНИЕ ДРЕЛИ INDIGO К IPC

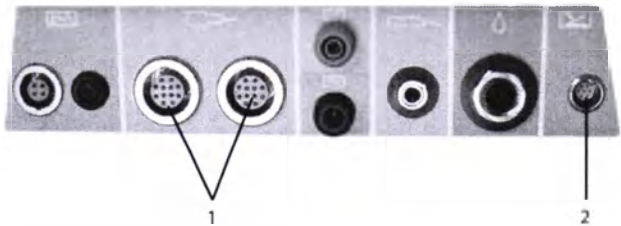
Найдите порт для подключения дрели Indigo на панели разъемов (Рис. 12-5) и вставьте разъем.

**Примечание.** Чтобы вставить многоштырьковые разъемы (такие разъемы обозначены серебряной или красной меткой), совместите метку на разъеме с меткой на пульте управления и вставьте разъем.

При использовании дрели Indigo IPC активирует ирригацию через помпу 2. Если ирригация дрели не используется, выберите для помпы 2 параметр **None** (Нет). Если вы будете использовать аспирационный ирригатор, необходимо вручную выбрать его для помпы 1 или помпы 2.

Работой дрели Indigo можно управлять с сенсорного экрана IPC и с помощью многофункциональной ножной педали.

Рис. 12-5. Порт для подключения Indigo к IPC



- 1 Порт для подключения Indigo
- 2 Порт для подключения многофункциональной ножной педали

ЭЛЕМЕНТЫ УПРАВЛЕНИЯ ДРЕЛЬЮ INDIGO НА СЕНСОРНОМ ЭКРАНЕ

Чтобы задать или настроить элементы управления дрелью Indigo, выполните следующие действия в поле управления (Рис. 12-6).

- Для изменения направления вращения в поле управления Mode (Режим) выберите FWD (вперед) или REV (назад).  
**Важная информация!** Конфигурация системы может отличаться от настроек по умолчанию. Если кнопка REV (назад) кажется отжатой и не имеет селективной кнопки (Рис. 12-7), режим вращения в обратном направлении выбрать нельзя. Если кнопка REV (назад) кажется нажатой (Рис. 12-7) и имеет селективную кнопку, режим вращения в обратном направлении можно выбрать с помощью сенсорного экрана или многофункциональной ножной педали.

- Чтобы увеличить или уменьшить скорость, следует нажимать кнопки «плюс» или «минус» в поле управления Speed (Скорость) соответственно. 

По умолчанию выставлена скорость 52 000 об/мин; возможна настройка скорости в диапазоне от 200 до 60 000 об/мин с шагом 200, 500 и затем с 1000 до 60 000 об/мин.

**Примечание.** При переключении режимов заданная скорость не изменяется.

**Предупреждение.** В зависимости от размера и геометрии инструмента на определенных скоростях может возникать чрезмерная вибрация. В этом случае необходимо увеличить или уменьшить скорость на пульте управления. Во избежание непреднамеренного удаления ткани пациента следует заменить инструмент на новый (W54).

- Чтобы увеличить или уменьшить скорость ирригационного потока, следует нажимать кнопки «плюс» или «минус» в поле управления Pump (Помпа) соответственно. Если в системе есть функция прерывистой ирригации, нажатие кнопки «плюс» или «минус» переключает режим ирригации между прерывистым и постоянным со скоростью потока 5, 10, 15 и 20 куб. см/мин. В режиме прерывистой ирригации система отображает надпись **Intermittent** (Прерывистый).

По умолчанию выставлено значение 30 куб. см в минуту.

**Примечание.** Для регулирования скорости потока можно использовать сенсорный экран или пульт дистанционного управления ирригацией IntelliFlow.

Рис. 12-6. Сенсорный экран Indigo



Рис. 12-7. Режим Indigo



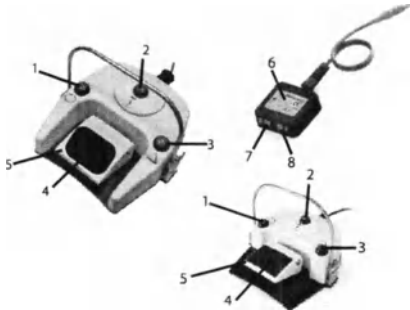
ЭЛЕМЕНТЫ УПРАВЛЕНИЯ ДРЕЛЬЮ INDIGO НА МНОГОФУНКЦИОНАЛЬНОЙ НОЖНОЙ ПЕДАЛИ

**Важная информация!** По умолчанию, для активирования выбранного действия необходимо нажимать каждую кнопку не менее 100 мсек. Изменить это значение по умолчанию можно в экране Settings (Настройки) на сенсорном экране IPC.

Для управления рукояткой с помощью многофункциональной ножной педали (Рис. 12-8) выполните следующие действия.

- Чтобы выбрать режим прямого или обратного вращения, нажмите кнопку режима.
  - Чтобы активировать рукоятку или настроить ее скорость в режиме переменной скорости, нажмите ножную педаль.
  - Чтобы переключиться между режимом пуска/остановки и режимом переменной скорости, нажмите кнопку управления.
- Примечание.** В меню рукоятки по умолчанию можно изменить функцию кнопки управления на приостановку ирригации. См. «Изменение настроек системы» в разделе «Действия до начала эксплуатации системы».
- Чтобы сменить рукоятку, нажмите кнопку рукоятки.

Рис. 12-8. Многофункциональная ножная педаль и U-образный делитель сигнала



- |   |                            |   |                             |
|---|----------------------------|---|-----------------------------|
| 1 | Кнопка переключения режима | 5 | Ножная педаль               |
| 2 | Кнопка рукоятки            | 6 | U-образный делитель сигнала |
| 3 | Кнопка управления          | 7 | Порт 1                      |
| 4 | Нескольльзящая подкладка   | 8 | Порт 2                      |

ИНСТРУКЦИИ ПО ОЧИСТКЕ И СТЕРИЛИЗАЦИИ ДРЕЛИ INDIGO

См. документы 68E4187 и 68E4188 в разделе, посвященном очистке и стерилизации.

ТЕХНИЧЕСКИЕ ХАРАКТЕРИСТИКИ ДРЕЛИ INDIGO

Дрель Indigo 1845000

|                                                                           |                                                                                                                                                                                            |
|---------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Размер                                                                    | Длина — 11,9 см, диаметр — 1,53 см                                                                                                                                                         |
| Масса                                                                     | 102 г                                                                                                                                                                                      |
| Скорость                                                                  | 60 000 об./мин в прямом и обратном направлении                                                                                                                                             |
| Рабочий цикл деталей, находящихся в непосредственном контакте с пациентом | Электродвигатель Indigo рассчитан на постоянную работу в течение 3 минут на скорости 60 000 об./мин при температуре в помещении от комнатной до 40 °C с последующим перерывом на 25 минут. |
|                                                                           | При нормальной комнатной температуре (обычно 20 °C) электродвигатель Indigo рассчитан на постоянную резку в течение неограниченного времени при скорости 60 000 об./мин.                   |

# МИКРОПИЛЫ MIDAS REX

## ОПИСАНИЕ УСТРОЙСТВА

Микропилы Midas Rex предназначены для удаления твердых и костных тканей во время хирургических вмешательств. Пилы как с ножным, так и с пальцевым управлением питаются от ИРС. Активация пил с ножным управлением осуществляется с помощью многофункциональной ножной педали. Активация пил с пальцевым управлением осуществляется с помощью пальцевого рычага.

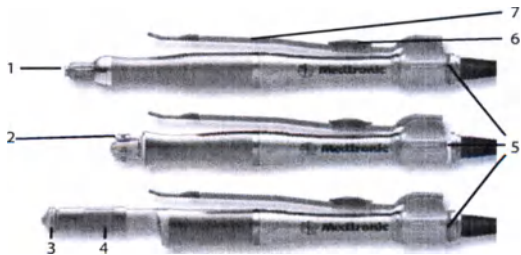
При использовании микропил ИРС задействует ирригацию через помпу 2. Если ирригация не используется, выберите для помпы 2 параметр **None** (Нет). Работой микропил можно управлять с сенсорного экрана ИРС и с помощью многофункциональной ножной педали.

Рис. 13-1. Рукоятки с микропилами с ножным управлением



- 1 Зажимной патрон реципрокной пилы
- 2 Кнопка разблокировки лезвия сагиттальной пилы
- 3 Головка осцилляторной пилы
- 4 Зажимной патрон осцилляторной пилы
- 5 Цветовая полоса

Рис. 13-2. Рукоятки с микропилами (Microsaw Touch (Контактная микропила)) с пальцевым управлением



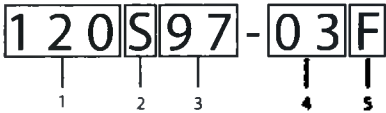
- 1 Зажимной патрон реципрокной пилы
- 2 Кнопка разблокировки лезвия сагиттальной пилы
- 3 Головка осцилляторной пилы
- 4 Зажимной патрон осцилляторной пилы
- 5 Цветовая полоса
- 6 Переключатель безопасного режима пальцевого рычага
- 7 Пальцевой рычаг

## НОМЕНКЛАТУРА ЛЕЗВИЙ И РАСПАТОРОВ

**Важная информация!** С реципрокными пилами можно использовать только реципрокные лезвия и распаторы. Сагиттальные и осцилляторные лезвия взаимозаменяемы.

Номера деталей лезвий для пил составлены по стандартной схеме.

|   |                            |                                                                                                                                                            |
|---|----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Максимальная глубина резки | XX,X мм*                                                                                                                                                   |
| 2 | Тип пилы                   | S Сагиттальная / осцилляторная<br>R Реципрокная                                                                                                            |
| 3 | Ширина или длина разреза   | X,X мм                                                                                                                                                     |
| 4 | Толщина лезвия             | X,X мм                                                                                                                                                     |
| 5 | Другие идентификаторы      | F С мелкими зубьями PT Лезвие с острым концом<br>ARC Закругленное лезвие ST Прямой распатор<br>BAY Штыкообразный резец CC Распатор с перекрестной насечкой |



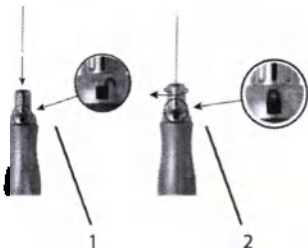
\* Маркировка глубины на лезвиях является приблизительной и должна использоваться только для справки.

## СБОРКА РЕЦИПРОКНОЙ МИКРОПИЛЫ

**Важная информация!** Убедитесь в совпадении цветовой маркировки на упаковках лезвия и рукоятки (Рис. 13-1 и 13-2).

1. Убедитесь в том, что на реципрокной рукоятке (красная полоса) разблокирован зажимной патрон (Рис. 13-3).
2. Вставьте в патрон реципрокное лезвие.
3. Поверните зажимной патрон на 90°, переводя его в зафиксированное положение.
4. Чтобы убедиться в надежном закреплении лезвия, слегка потяните его.

Рис. 13-3. Сборка реципрокной пилы



## СБОРКА САГИТТАЛЬНОЙ МИКРОПИЛЫ

**Важная информация!** Убедитесь в совпадении цветовой маркировки на упаковках лезвия и рукоятки (Рис. 13-1 и 13-2).

1. Нажмите на сагиттальной рукоятке (желтая полоса) кнопку разблокировки лезвия (Рис. 13-4).
2. Вставьте лезвие под нужным углом (Рис. 13-5).
3. Отпустите кнопку разблокировки лезвия.
4. Чтобы убедиться в надежном закреплении лезвия, слегка подвигайте его из стороны в сторону.

Рис. 13-4. Сборка сагиттальной пилы

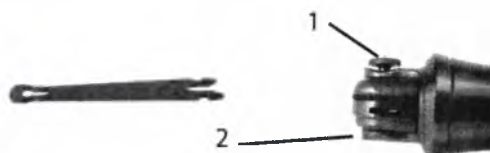


Рис. 13-5. Углы установки реза



## СБОРКА ОСЦИЛЛЯТОРНОЙ МИКРОПИЛЫ

**Важная информация!** Убедитесь в совпадении цветовой маркировки на упаковках лезвия и рукоятки (Рис. 13-1 и 13-2).

1. Убедитесь в том, что на осцилляторной рукоятке (синяя полоса) разблокирован зажимной патрон (Рис. 13-6).
2. Вставьте лезвие в патрон. Лезвие становится на место со щелчком.

**Примечание.** Лезвие можно вставить в любом из 8 положений, с шагом 45° на окружности 360° (Рис. 13-7).

3. Поверните зажимной патрон, переведя его в зафиксированное положение (Рис. 13-6).
4. Чтобы убедиться в надежном закреплении лезвия, слегка подвигайте его из стороны в сторону.

Рис. 13-6. Сборка осцилляторной пилы

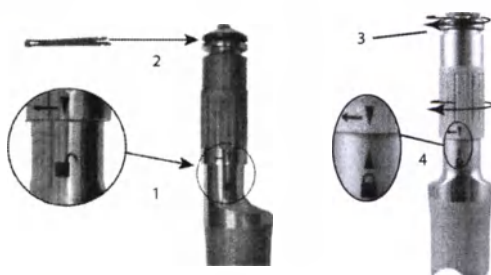
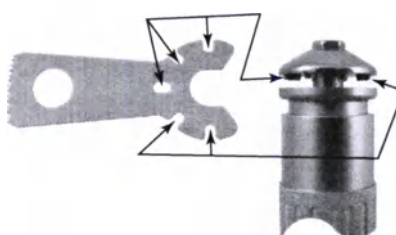


Рис. 13-7. Совмещение выступов осцилляторной пилы



## ИРРИГАЦИЯ МИКРОПИЛ И ПОДСОЕДИНЕНИЕ ЗАЖИМА ДЛЯ ТРУБКИ

**Примечание.** Ирригация пилы необязательна.

1. Наденьте зажим для ирригационной трубки на рукоятку (Рис. 13-8 и 13-9).

**Примечание.** При работе с рукоятками с пальцевым управлением присоедините заднюю часть зажима для ирригационной трубки к вращающемуся основанию пальцевого рычага (Рис. 13-9).

2. Снимите переднюю часть зажима для трубки, если это необходимо для регулирования длины ирригационной трубки.
3. Закрепите зажим для трубки на рукоятке.

Рис. 13-8. Подсоединение трубки для ирригации и держателя трубки к микропиле с ножным управлением



Рис. 13-9. Подсоединение трубки для ирригации и держателя трубки к микропиле с пальцевым управлением

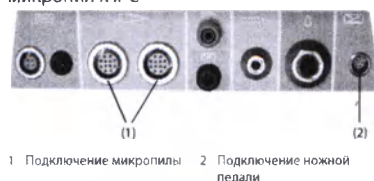




## ПОДСОЕДИНЕНИЕ РУКОЯТКИ С МИКРОПИЛОЙ К IPC

На панели разъемов (Рис. 13-10) пульта управления IPC найдите 12-штырьковый порт, совместите отметки на разъеме и пульте управления и затем вставьте разъем.

Рис. 13-10. Порты для подключения микропил к IPC



## ЭЛЕМЕНТЫ УПРАВЛЕНИЯ МИКРОПИЛАМИ НА СЕНСОРНОМ ЭКРАНЕ

**Важная информация!** IPC распознает подключенную микропилу и отображает на экране соответствующее название и кольцо соответствующего цвета.

- Чтобы увеличить или уменьшить скорость (Рис. 13-11), следует нажать соответственно на кнопки «плюс» или «минус». Регулировать скорость можно в диапазоне от 0 % до 100 %.

**Примечание.** При работе с микропилой с пальцевым управлением в безопасном режиме в поле управления Speed (Скорость) появляется надпись «SAFE» (Безопасный режим) (Рис. 13-12). Дополнительную информацию см. в разделе, посвященном работе с микропилами с пальцевым управлением в безопасном режиме.

- Чтобы увеличить или уменьшить интенсивность ирригации, следует нажать в поле управления Pump (Помпа) соответственно на кнопки «плюс» или «минус». Если в системе есть функция прерывистой ирригации, нажатие кнопки «плюс» или «минус» переключает режим ирригации между прерывистой и постоянной. В режиме прерывистой ирригации система отображает надпись «Intermittent» (Прерывистый). Скорость ирригации по умолчанию составляет 0 куб. см/мин. Максимальная скорость ирригации составляет 50 куб. см в минуту.

**Примечание.** Для регулирования интенсивности ирригации можно использовать сенсорный экран или пульт дистанционного управления ирригацией Intelliflow.

- Чтобы переключиться между ножным и пальцевым управлением или использовать оба варианта, выберите соответствующую опцию в поле управления Control (Управление). Пилами с пальцевым управлением можно управлять с помощью рычага на рукоятке или с помощью ножной педали.

**Примечание.** Эта опция доступна только при использовании рукоятки с пальцевым управлением.

Рис. 13-11. Сенсорный экран управления микропилами



Рис. 13-12. Безопасный режим работы микропилы с ножным управлением



## БЕЗОПАСНЫЙ РЕЖИМ РАБОТЫ МИКРОПИЛЫ С ПАЛЬЦЕВЫМ УПРАВЛЕНИЕМ

Когда рукоятка находится в безопасном режиме, она не поддается управлению до отключения безопасного режима. Когда рукоятка является активной и находится в безопасном режиме, в поле управления Speed (Скорость) в сенсорном экране Microsaws (Микропилы) отображается надпись «SAFE» (Безопасный) (Рис. 13-12).

Всегда переводите устройство в безопасный режим, когда оно подключено к пульта управления, но не используется.

Если к пульта управления подключено несколько рукояток, активируйте аварийный переключатель неактивной рукоятки, чтобы активировать эту рукоятку и подготовить ее к работе.



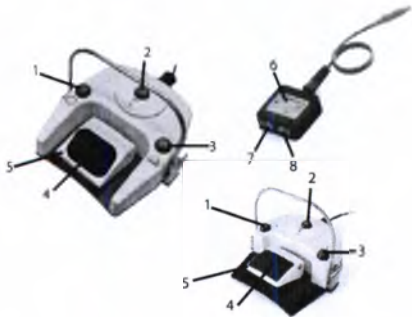
ЭЛЕМЕНТЫ УПРАВЛЕНИЯ МИКРОПИЛОЙ НА МНОГОФУНКЦИОНАЛЬНОЙ НОЖНОЙ ПЕДАЛИ

**Важная информация!** По умолчанию, для активирования выбранного действия необходимо нажимать каждую кнопку не менее 100 мсек. Изменить это значение по умолчанию можно в экране Settings (Настройки) IPC.

Рис. 13-13. Многофункциональная ножная педаль и U-образный делитель сигнала

Для управления рукояткой с помощью многофункциональной ножной педали (Рис. 13-13) выполните следующие действия.

- Чтобы активировать рукоятку или настроить ее скорость в режиме переменной скорости, нажмите педаль.
- Чтобы переключиться между режимом пуска/остановки и режимом переменной скорости, нажмите кнопку управления.  
**Примечание.** В меню рукоятки по умолчанию можно изменить функцию кнопки управления на приостановку ирригации. См. «Изменение настроек системы» в разделе «Действия до начала эксплуатации системы».
- Чтобы сменить активную рукоятку, нажмите кнопку рукоятки.  
**Примечание.** Переключиться между рукоятками с пальцевым управлением можно, нажав пальцевой рычаг на рукоятке.



- |   |                            |   |                             |
|---|----------------------------|---|-----------------------------|
| 1 | Кнопка переключения режима | 5 | Ножная педаль               |
| 2 | Кнопка рукоятки            | 6 | U-образный делитель сигнала |
| 3 | Кнопка управления          | 7 | Порт 1                      |
| 4 | Нескользящая подкладка     | 8 | Порт 2                      |

ИНСТРУКЦИИ ПО ОЧИСТКЕ И СТЕРИЛИЗАЦИИ МИКРОПИЛ

См. документ M000030A231 в разделе, посвященном очистке и стерилизации.

ТЕХНИЧЕСКИЕ ХАРАКТЕРИСТИКИ МИКРОПИЛ

|          |                                                                                                                                                                                                                                                                                                                                                                                  |
|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Размер   | Реципрокная (ES200): Ш 2,3 см, Д 20,3 см<br>Сагиттальная (ES300): Ш 2,3 см, Д 17,3 см<br>Осцилляторная (ES100): Ш 2,3 см, Д 19,8 см<br>Реципрокная с пальцевым управлением (ES210): Ш 2,3 см, В 3,2 см, Д 20,3 см<br>Сагиттальная с пальцевым управлением (ES310): Ш 2,3 см, В 3,2 см, Д 17,8 см<br>Осцилляторная с пальцевым управлением (ES110): Ш 2,3 см, В 3,2 см, Д 21,0 см |
| Масса    | Реципрокная (ES200): 300 г<br>Сагиттальная (ES300): 250 г<br>Осцилляторная (ES100): 300 г<br>Реципрокная с пальцевым управлением (ES210): 320 г<br>Сагиттальная с пальцевым управлением (ES310): 300 г<br>Осцилляторная с пальцевым управлением (ES110): 320 г                                                                                                                   |
| Скорость | Все реципрокные: 1400–14 000 циклов/мин<br>Все сагиттальные: 2000–20 000 циклов/мин<br>Все осцилляторные: 1600–16 000 циклов/мин                                                                                                                                                                                                                                                 |

Рабочий цикл  
Температура воздуха ≤ 20 °C (один период резки = 20 секунд во включенном состоянии / 20 секунд в выключенном состоянии)  
Реципрокная: ≤ 15 периодов резки<sup>1</sup>  
Сагиттальная: ≤ 6 периодов резки<sup>2</sup>  
Осцилляторная: ≤ 4 периодов резки<sup>3</sup>

Температура воздуха > 20 °C (один период резки = 20 секунд во включенном состоянии / 40 секунд в выключенном состоянии)  
Реципрокная: ≤ 5 периодов резки<sup>4</sup>  
Сагиттальная: ≤ 6 периодов резки<sup>5</sup>  
Осцилляторная: ≤ 3 периодов резки<sup>6</sup>

Длительность остывания после максимального количества периодов резки, указанного выше — 25 минут.

<sup>1</sup>5 периодов со слабым осевым усилием (0,8 кгс), 5 периодов со средним осевым усилием (2,1 кгс), 5 периодов с сильным осевым усилием (3,9 кгс)  
<sup>2</sup>2 периода со слабым осевым усилием (0,8 кгс), 2 периода со средним осевым усилием (1,5 кгс), 2 периода с сильным осевым усилием (3,0 кгс)  
<sup>3</sup>1 период со слабым осевым усилием (0,7 кгс), 2 периода со средним осевым усилием (1,5 кгс), 1 период с сильным осевым усилием (2,6 кгс)  
<sup>4</sup>1 период со слабым осевым усилием (0,8 кгс), 2 периода со средним осевым усилием (2,1 кгс), 2 периода с сильным осевым усилием (3,9 кгс)  
<sup>5</sup>2 периода со слабым осевым усилием (0,8 кгс), 2 периода со средним осевым усилием (1,5 кгс), 2 периода с сильным осевым усилием (3,0 кгс)  
<sup>6</sup>1 период со слабым осевым усилием (0,7 кгс), 1 период со средним осевым усилием (1,5 кгс), 1 период с сильным осевым усилием (2,6 кгс)

# ЭЛЕКТРОПРИВОД POWEREASE

## ОПИСАНИЕ УСТРОЙСТВА

Система IPC POWEREASE предназначена для сверления, нарезания резьбы и ввертывания винтов в ходе спинальных хирургических вмешательств.

Система IPC POWEREASE состоит из привода POWEREASE (Рис. 14-1), который питается от IPC, и перечисленных ниже инструментов, которые крепятся на рабочем наконечнике привода POWEREASE и совместимы с ним:

- метчики;
- сверла;
- Привод
- резак для стержней;
- резак для штифтов;
- инструмент для отламывания стопорных винтов (SSBO).

Система POWEREASE и дополнительные принадлежности к ней совместимы со следующими системами имплантатов:

- спинальная система CD HORIZON SOLERA;
- спинальная система TSRH 3Dx.

## ПОДСОЕДИНЕНИЕ СИСТЕМЫ К IPC

**Важная информация!** При использовании привода POWEREASE кнопка ручного запуска и остановки на задней стороне пульта управления IPC (Рис. 1-2) не работает.

Примечание. Привод POWEREASE не использует систему помп IPC. Помпы можно использовать с другими инструментами, требующими ирригации и охлаждения.

1. Убедитесь в том, что все колеса на тележке IPC заблокированы.
2. Проверьте все компоненты на предмет повреждений и определите, готова ли система к работе.
3. Укрепите IPC и пакеты с жидкостью для ирригации и охлаждения на стойке капельницы.

**Важная информация!** Укрепите пакеты с жидкостью для ирригации и охлаждения выше IPC, чтобы обеспечить надлежащий поток.

4. Подключите IPC к источнику электропитания. IPC нужно установить так, чтобы источник электропитания оставался доступным и позволял отключиться от электросети с помощью шнура питания.
5. Найдите порт для подключения POWEREASE на панели разъемов (Рис. 14-2) и вставьте разъем привода POWEREASE.
6. Если вы используете NIM-ECLIPSE с системой IPC POWEREASE, необходимо соединить системы IPC POWEREASE и NIM-ECLIPSE.
7. Включите IPC и выполните следующие действия.
  - Убедитесь в том, система успешно выполнила самодиагностику.
  - Убедитесь в том, что на мониторе IPC появился экран POWEREASE.
8. Убедитесь в функционировании системы IPC POWEREASE.

## ПЕРЕКЛЮЧАТЕЛЬ РЕЖИМА IPC POWEREASE

Переключатель режима используется для изменения направления работы рукоятки между прямым, обратным и колебательным, если рукоятка является активной. Когда рукоятка не активна, используйте переключатель режима для включения рукоятки.

Рис. 14-1. Электропривод POWEREASE



Рис. 14-2. Порты для подключения POWEREASE к IPC



## РАБОТА С СИСТЕМОЙ IPC POWEREASE

1. Поверните переключатель режима на приводе POWEREASE (Рис. 14-3) в положение **F** (вперед).
2. Убедитесь в том, что на сенсорном экране IPC выполняются следующие условия.
  - Поле FWD Speed (Скорость прямого вращения) активно и значение скорости по умолчанию отображается белым цветом.
  - Под надписью Trigger Status (Состояние кнопки-регулятора) написано Ready For Use (Готова к работе).

**Примечание.** Если состояние кнопки-регулятора отображается как Locked (Заблокирована), отпустите и нажмите кнопку-регулятор, чтобы снять блокировку. Если у вас не получается изменить состояние кнопки-регулятора на Ready For Use (Готова к работе), обратитесь в службу технической поддержки.

3. На приводе POWEREASE нажмите кнопку-регулятор (Рис. 14-4) и убедитесь в том, что значение скорости в поле FWD Speed (Скорость прямого вращения) на сенсорном экране отображается зеленым цветом.
4. Нажмите кнопку-регулятор на приводе POWEREASE и убедитесь в выполнении следующих условий.
  - При увеличении силы нажатия на кнопку-регулятор скорость увеличивается.
  - Значение скорости в поле FWD Speed (Скорость прямого вращения) на сенсорном экране отображается желтым цветом.
5. Уберите палец с кнопки-регулятора на приводе POWEREASE и убедитесь в выполнении следующих условий.
  - Вращение привода прекратилось.
  - Значение скорости в поле FWD Speed (Скорость прямого вращения) на сенсорном экране отображается белым цветом.

6. Повторите этапы с 1 по 5 для режимов обратного вращения (R) и колебаний .

Рис. 14-3. Переключатель режима POWEREASE



Рис. 14-4. Сенсорный экран IPC POWEREASE



## ЭЛЕМЕНТЫ УПРАВЛЕНИЯ POWEREASE НА СЕНСОРНОМ ЭКРАНЕ

Чтобы настроить максимальную скорость привода с помощью сенсорного экрана IPC POWEREASE (Рис. 14-4), в соответствующем поле управления скоростью нажимайте кнопки со знаками «плюс» для увеличения максимальной скорости и «минус» для снижения максимальной скорости.

- Изменение скорости:
    - FWD Speed (Скорость прямого вращения) — предусмотрена регулировка в диапазоне от 10 до 250 об./мин с шагом 10 об./мин.
    - REV Speed (Скорость обратного вращения) — предусмотрена регулировка в диапазоне от 10 до 250 об./мин с шагом 10 об./мин.
    - OSC Speed (Скорость колебаний) — предусмотрена регулировка в диапазоне от 10 до 200 об./мин с шагом 10 об./мин.
  - Расшифровка цветовых обозначений данных на сенсорном экране IPC POWEREASE:
    - белый — выбранная скорость не применяется, палец не касается кнопки-регулятора;
    - зеленый — выбранная скорость не применяется, палец касается кнопки-регулятора;
    - желтый — выбранная скорость применяется;
    - серый — неактивно.
  - Trigger Status (Состояние кнопки-регулятора):
    - Ready For Use (Готова к работе) — устройство готово к использованию;
    - Locked (Заблокирована) — в случае, если управление кнопкой-регулятором нарушено, кнопка-регулятор блокируется до устранения нарушения и возможности возобновления работы с POWEREASE.
- Чтобы снять блокировку, отпустите и нажмите кнопку-регулятор. Если устройство не возвращается в состояние Ready For Use (Готова к работе), обратитесь в службу технической поддержки.

## ПОДСОЕДИНЕНИЕ СТАНДАРТНОГО РАБОЧЕГО НАКОНЕЧНИКА И РАБОТА С НИМ

**ПРИМЕЧАНИЕ.** Список совместимых рабочих насадок и дополнительную информацию по их надлежащему использованию см. в руководстве пользователя рабочих насадок системы POWEEASE и в инструкции по применению. Самую новую версию вкладышей к устройствам и руководств можно получить в отделе обслуживания клиентов и у торговых представителей.

1. Чтобы разблокировать зажимной патрон привода POWEEASE, оттяните назад и удерживайте кольцо быстрой разблокировки (Рис. 14-1, 1).
2. Вставьте сердечник стандартного рабочего наконечника (Рис. 14-5, 1) в зажимной патрон до полной посадки. Полная посадка — это значит на или возле запящечика вала привода (Рис. 14-6).

**Примечание.** Если вы используете вал с двумя гранями, совместите плоские грани вала привода с отметками на зажимном патроне (Рис. 14-1, 8).

3. Разблокируйте кольцо быстрой разблокировки, чтобы поместить рабочий наконечник в фиксированное положение (Рис. 14-1, 2).
4. Чтобы задать режим работы привода POWEEASE, поверните переключатель режима (рис. 14-3) в положение Forward (F) (Вперед), Reverse (R) (Назад) или Oscillate (Колебания).
  - Чтобы начать сверление, нарезание резьбы метчиком или ввертывание винта, выберите вращение вперед.
  - Чтобы выкрутить сверло или винт либо прекратить нарезание резьбы, выберите вращение назад.
  - Чтобы заблокировать инструмент в текущем положении, выберите режим колебаний. Дополнительную информацию см. в документе «Электронный храповик электропривода POWEEASE».
5. Чтобы настроить скорость работы привода, увеличивайте давление для увеличения скорости и уменьшайте давление для уменьшения скорости.
6. Чтобы извлечь стандартный рабочий наконечник, выполните процедуру в обратном порядке.

Рис. 14-5. Стандартные рабочие наконечники

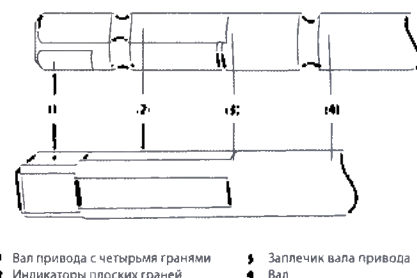
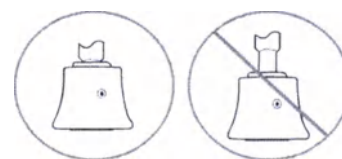


Рис. 14-6. Посадка стандартных рабочих наконечников



## Электронный храповик электропривода POWEEASE

Храповик позволяет поворачивать инструмент вручную только в одном направлении.

- FWD Mode (Режим прямого вращения): При отпущенной кнопке-регуляторе рукоятка работает как храповик, позволяя поворачивать рукоятку по часовой стрелке, а то время как храповик блокирует вращение против часовой стрелки.
- REV Mode (Режим прямого вращения): При отпущенной кнопке-регуляторе рукоятка работает как храповик, позволяя поворачивать рукоятку против часовой стрелки, а то время как храповик блокирует вращение по часовой стрелке.
- OSC Mode (Режим колебаний): При отпущенной кнопке-регуляторе рукоятка блокирует инструмент в текущем положении, а хирург может вручную повернуть рукоятку по часовой стрелке или против нее.

## Проверка работы храповика POWEEASE

1. Установите сверло, метчик или отвертку в зажимной патрон. Подробную информацию см. раздел «Подсоединение стандартного рабочего наконечника и работа с ним».
2. Поверните переключатель режима на приводе POWEEASE (рис. 14-3) в положение Forward (F) (Вперед).
3. Крепко удерживайте вал привода POWEEASE и убедитесь в выполнении следующих условий.
 

**Важная информация! ЗАПРЕЩАЕТСЯ** держаться за инструмент. **НЕ** прикасайтесь к датчику кнопки-регулятора.

  - При вращении вала против часовой стрелки срабатывает храповик.
  - Храповик не срабатывает при вращении вала по часовой стрелке.
4. Поверните переключатель режима в положение Reverse (R) (Назад) и убедитесь в выполнении следующих условий:
  - При вращении вала по часовой стрелке срабатывает храповик.
  - Храповик не срабатывает при вращении вала против часовой стрелки.
5. Поверните переключатель режима в положение колебаний  и убедитесь в том, что храповик не срабатывает при попытке вращении вала в любую сторону.

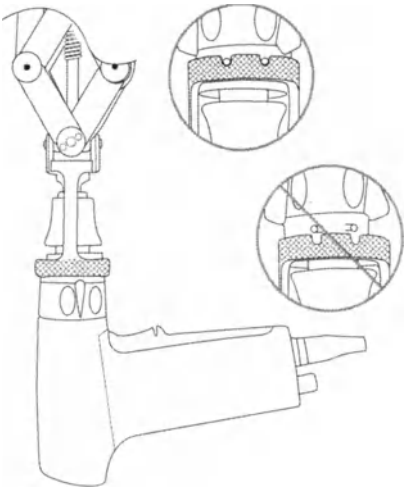


ПОДСОЕДИНЕНИЕ МЕХАНИЗИРОВАННОГО РАБОЧЕГО НАКОНЕЧНИКА И РАБОТА С НИМ

**ПРИМЕЧАНИЕ.** Полный список совместимых рабочих наконечников и полную информацию по их надлежащему использованию см. в документе POWEREASE System Working Ends User’s Manual (Руководство пользователя рабочих наконечников системы POWEREASE) и инструкции по эксплуатации. Самую новую версию вкладышей к устройствам и руководств можно получить в службе технической поддержки и у торговых представителей.

1. Чтобы разблокировать зажимной патрон привода POWEREASE, оттяните назад и удерживайте кольцо быстрой разблокировки (Рис. 14-1, 1).  
**Примечание.** При установке или извлечении инструментов кольцо быстрой разблокировки нужно удерживать в разблокированном положении.
2. Совместите выемки на втулке рабочего наконечника и стопорные штифты на механизированном рабочем наконечнике (Рис. 14-7).
3. Чтобы задать режим работы привода POWEREASE, поверните переключатель режима (рис. 14-3) в положение Forward (F) (Вперед), Reverse (R) (Назад) или Oscillate (Колебания).  
  - Переведите переключатель режима вперед, чтобы срезать или отрезать имплантируемые стержни, отрезать вертикальные штифты и отломать вкрученные винты.
  - Переведите переключатель режима назад для того, чтобы разблокировать инструмент.
  - Режим колебаний предназначен для блокирования вращения стандартных рабочих наконечников и не имеет функций при использовании механизированных рабочих наконечников. Однако при при оттягивании кнопки-регулятора сердечник инструмента будет выполнять колебательные движения на 60° по и против часовой стрелки.
4. Чтобы настроить скорость работы привода, увеличивайте давление для увеличения скорости и уменьшайте давление для уменьшения скорости.  
**ПРИМЕЧАНИЕ.** На сенсорном экране IPC отображается максимальная скорость для выбранного режима.
5. Чтобы извлечь стандартный рабочий наконечник, выполните процедуру в обратном порядке.

Рис. 14-7. Посадка механических рабочих наконечников



ИНСТРУКЦИИ ПО ОЧИСТКЕ И СТЕРИЛИЗАЦИИ POWEREASE

См. документ 68E4189 в разделе, посвященном очистке и стерилизации.

ТЕХНИЧЕСКИЕ ХАРАКТЕРИСТИКИ ПРИВОДА POWEREASE

Электропривод POWEREASE 2300000

|                                                                           |                                                                                                             |
|---------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| Размер                                                                    | 175 мм x 160 мм x 42 мм                                                                                     |
| Масса                                                                     | 900 г (1 200 г вместе с кабелем)                                                                            |
| Скорость                                                                  | от 0 до 250 об./мин (переменная)                                                                            |
| Крутящий момент                                                           | 7 Нм                                                                                                        |
| Длина кабеля (привод)                                                     | 4,5 м                                                                                                       |
| Длина кабеля (от IPC к блоку интерфейса пациента)                         | 4,5 м                                                                                                       |
| Длина кабеля (от привода до IPC)                                          | 4,5 м                                                                                                       |
| Рабочий цикл деталей, находящихся в непосредственном контакте с пациентом | При постоянной температуре в операционной до 33 °C привод POWEREASE рассчитан на постоянную эксплуатацию.   |
|                                                                           | При нормальной температуре в операционной (до 25 °C) привод POWEREASE рассчитан на постоянную эксплуатацию. |



## РАБОТА IPC POWEREASE С СИСТЕМОЙ NIM-ECLIPSE

**Важная информация!** Не используйте комбинацию оборудования IPC POWEREASE - NIM-ECLIPSE с переносными розетками с несколькими гнездами и с удлинителями.

Система POWEREASE снабжена двумя кабелями, соединяющими IPC и систему NIM-ECLIPSE. Провода внутри POWEREASE контактируют с частью инструмента, не имеющей изоляционного покрытия, и проводят стимулирующий ток на кончик инструмента для мониторинга нервных волокон. Для получения более подробной информации обратитесь к региональному представителю NIM-ECLIPSE.

**Важная информация!** Для стимуляции нерва могут применяться только метчики, винты и сверла. Дополнительную информацию о рабочих насадках, пригодных для использования с функцией стимуляции нерва, см. в руководстве пользователя рабочих насадок системы POWEREASE и в инструкции по применению. При использовании привода IPC POWEREASE вместе с NIM-ECLIPSE эта комбинация образует медицинскую электрическую систему. Компоненты системы перечислены ниже.

- IPC
- POWEREASE с инструментами
- NIM-ECLIPSE
- Комплект кабелей NIM

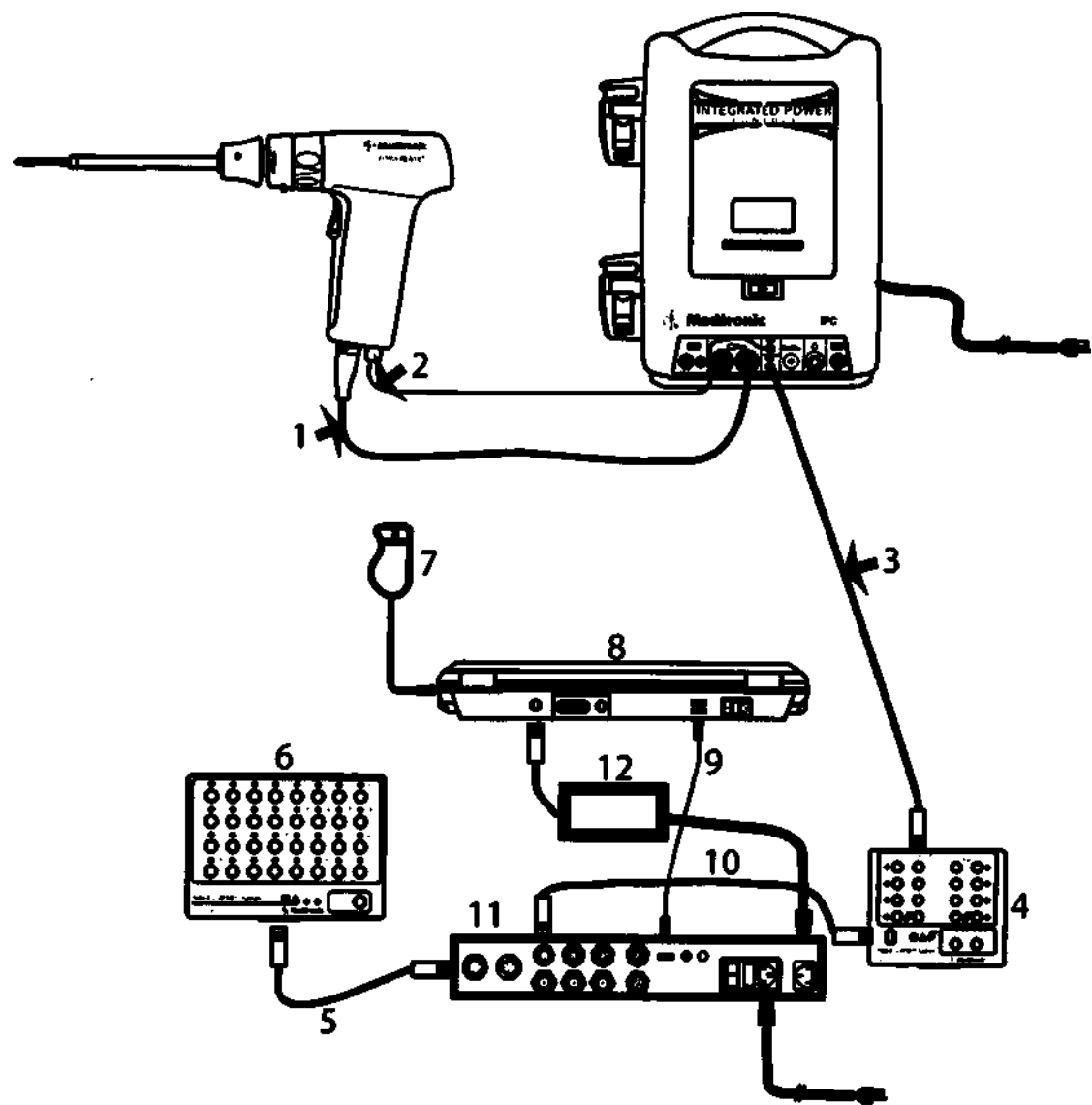
## Соединение систем IPC POWEREASE и NIM-ECLIPSE

**Важная информация!** Инструкции по настройке и эксплуатации системы NIM-ECLIPSE, включая ноутбук, см. в NIM-ECLIPSE Users Guide (Руководстве пользователя NIM-ECLIPSE).

### Предупреждения:

- В среде пациента разрешается применять только рукоятку POWEREASE и принадлежности к ней. NIM-ECLIPSE запрещено использовать вблизи пациента (в радиусе 1,5 м вокруг пациента).
  - Не прикасайтесь к пациенту и корпусу NIM-ECLIPSE одновременно.
  - Утилизируйте одноразовые кабели NIM после каждой процедуры.
  - Все периферийные устройства, подключаемые к системе, должны соответствовать требованиям стандарта IEC60601-1. Проконсультируйтесь со специалистами отдела биомедицинской техники вашей организации, чтобы определить, отвечают ли используемые внешние устройства данному требованию.
1. Подключите IPC и подтвердите функционирование системы IPC POWEREASE.
  2. Соедините компоненты NIM-ECLIPSE в соответствии с инструкциями, приведенными в NIM-ECLIPSE Users Guide (Руководстве пользователя NIM-ECLIPSE). Убедитесь в том, что шнур питания ноутбука подключен к контроллеру NIM-ECLIPSE 945ECLC.
  3. Подсоедините один конец черного кабеля NIM к выходному порту стимулирующего сигнала на удлинителе стимулятора NIM-ECLIPSE (Рис. 14-8).
  4. Подсоедините второй конец черного кабеля NIM к входному порту стимулирующего сигнала на панели разъемов IPC (Рис. 14-8).  
**Важная информация!** Направляйте проволоку так, чтобы она не мешала персоналу операционной.
  5. Подключите один конец синего кабеля NIM к порту выходного стимулирующего сигнала на панели разъемов IPC (Рис. 14-8).
  6. Подключите второй конец синего кабеля NIM к порту входного стимулирующего сигнала NIM на приводе POWEREASE.  
**Важная информация!** Направляйте проволоку так, чтобы она не мешала персоналу операционной.

Рис. 14-8. Соединение POWEREASE, IPC и NIM-ECLIPSE



NIM-ECLIPSE

- |                                             |                                   |
|---------------------------------------------|-----------------------------------|
| 1 Сетевой кабель POWEREASE                  | 7 Мышь                            |
| 2 Кабель 2 NIM (синий)                      | 8 Портативный компьютер (ноутбук) |
| 3 Кабель NIM (черный)                       | 9 USB-кабель                      |
| 4 Удлинитель стимулятора                    | 10 Кабель стимулятора             |
| 5 Кабель интерфейса цифрового предусилителя | 11 Контроллер                     |
| 6 Блок предусилителя                        | 12 Блок питания ноутбука          |

# ПОИСК И УСТРАНЕНИЕ НЕИСПРАВНОСТЕЙ И КОДЫ ОШИБОК

При возникновении любых неполадок, которые не удастся устранить в результате действий, предложенных ниже, обратитесь в службу технической поддержки.

## Поиск и устранение общих неисправностей системы

| Неполадка                                                                                                        | Возможная причина                                                      | Действие                                                                                                                                         |
|------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| Помпа(-ы) не работает(-ют).                                                                                      | Вышли из строя внутренние компоненты.                                  | Обратитесь в службу технической поддержки.                                                                                                       |
| Поток в системе ирригации слабый или отсутствует.                                                                | Комплект трубок неправильно подключен к помпе.                         | Поменяйте местами трубки помпы и убедитесь, что крышка полностью закрыта, а поток движется слева направо.                                        |
|                                                                                                                  | Защемлена или перегнута трубка.                                        | Проверьте трубки сбоку помпы. См. раздел «Помпы для ирригации и охлаждающей жидкости».                                                           |
|                                                                                                                  | Зажимы трубок ограничивают поток.                                      | Проверьте остальную часть трубок на предмет защемления или перегиба. При необходимости замените трубки.                                          |
|                                                                                                                  | Задано низкое значение скорости ирригационного потока.                 | Откройте зажимы трубки.                                                                                                                          |
| Ошибка из-за потери скорости помпы.                                                                              | Задано низкое значение скорости ирригационного потока.                 | Отрегулируйте скорость ирригационного потока.                                                                                                    |
|                                                                                                                  | Засорился ирригатор.                                                   | Замените ирригатор.                                                                                                                              |
|                                                                                                                  | Комплект трубок неправильно подключен к помпе.                         | Поменяйте местами трубки помпы и убедитесь, что крышка полностью закрыта, а поток движется слева направо.                                        |
|                                                                                                                  | Защемлена или перегнута трубка.                                        | Проверьте трубку сбоку помпы на защемление или перегиб (см. раздел «Помпы для ирригации и охлаждающей жидкости»).                                |
| Рукоятка подсоединена, но на пульте управления отображается сообщение «Connect Handpiece» (Подключите рукоятку). | Попадание влаги в кабель мешает распознаванию рукоятки.                | При стерилизации используйте сухой жар.                                                                                                          |
| Рукоятка подсоединена, но на пульте управления отображается другая рукоятка.                                     |                                                                        |                                                                                                                                                  |
| Пульт управления не включается.                                                                                  | Неправильно подсоединен шнур питания.                                  | Подсоедините шнур питания.                                                                                                                       |
|                                                                                                                  | Нет питания.                                                           | Проверьте наличие питания (т. е. разветвитель питания включен, автоматический выключатель замкнут и т. д.).                                      |
|                                                                                                                  | Сгорел предохранитель на входе питания.                                | Вместо сгоревших установите новые замедленные предохранители на 5,00 A, 250 V (номер детали: 11270066 комплект плавких предохранителей 1898125). |
|                                                                                                                  | Вышли из строя внутренние компоненты.                                  | Обратитесь в службу технической поддержки.                                                                                                       |
| Лампочка включения питания горит, но на сенсорном экране нет изображения.                                        | Вышли из строя внутренние компоненты.                                  | Обратитесь в службу технической поддержки.                                                                                                       |
| Пульт управления не выключается.                                                                                 | Вышел из строя выключатель питания.                                    | Отсоедините шнур питания от сети и обратитесь в службу технической поддержки.                                                                    |
| Сенсорный экран не реагирует на касание.                                                                         | Смещение прокладки экрана или выход из строя внутренних компонентов.   | Обратитесь в службу технической поддержки.                                                                                                       |
| Сенсорный экран работает неправильно.                                                                            | Сенсорный экран не откалиброван.                                       | Откалибруйте сенсорный экран.                                                                                                                    |
| На пульте управления отображается неверный тип рукоятки или электродвигателя.                                    | Пульт управления неправильно определяет рукоятку или электродвигатель. | Отсоедините и снова подсоедините кабель электродвигателя. Выключите и снова включите пульт управления.                                           |
|                                                                                                                  | Попадание влаги в кабель мешает распознаванию рукоятки.                | Замените электродвигатель, кабель электродвигателя или пульт управления, чтобы выявить неполадку. При стерилизации используйте сухой жар.        |

ПОИСК И УСТРАНЕНИЕ НЕИСПРАВНОСТЕЙ И КОДЫ ОШИБОК IPC

| Неполадка                                                            | Возможная причина                                                     | Действие                                                                                                                                                                    |
|----------------------------------------------------------------------|-----------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Кнопки или педаль модуля ножного управления не реагируют на нажатие. | Неисправность У-образного делителя сигнала                            | Отсоедините У-образный делитель сигнала и подсоедините МНУ непосредственно к IPC.                                                                                           |
|                                                                      | Неправильное использование модуля.                                    | Нажмите и удерживайте кнопки не менее 1 секунды, подождите пока не раздастся подтверждающий тональный сигнал пульта управления.                                             |
|                                                                      | Не реагирует верхняя кнопка.                                          | Подсоединена одна (1) рукоятка (верхняя кнопка не работает, когда подключена 1 рукоятка).                                                                                   |
|                                                                      | Не полностью вставлен разъем.                                         | Отсоедините и снова подсоедините кабель модуля ножного управления.<br>Попробуйте подключить другой модуль ножного управления или пульт управления, чтобы выявить неполадку. |
|                                                                      | Вышли из строя внутренние компоненты.                                 | Обратитесь в службу технической поддержки.                                                                                                                                  |
| Рукоятка не вращается.                                               | Вышел из строя ножной переключатель.                                  | Отсоедините ножной переключатель и воспользуйтесь тумблером ручного пуска и остановки на задней панели пульта управления.                                                   |
|                                                                      | Вышел из строя электродвигатель рукоятки или привод электродвигателя. | Обратитесь в службу технической поддержки.                                                                                                                                  |
|                                                                      | Неправильно подсоединены кабели.                                      | Убедитесь, что кабель рукоятки подсоединен надлежащим образом.                                                                                                              |
|                                                                      | Повреждены кабели.                                                    | Проверьте, нет ли трещин или разрывов на кабелях и не погнуты ли штырьки разъемов.                                                                                          |
| Рукоятка слишком горячая, чтобы ее можно было касаться или держать.  | Лезвие, бор и/или насадка передает тепло рукоятке.                    | Снимите и переустановите или замените лезвие, бор и/или насадку. Перед возобновлением использования убедитесь, что деталь установлена надлежащим образом.                   |
|                                                                      | Недостаточная ирригация и/или охлаждение.                             | Убедитесь в наличии достаточного потока жидкости для ирригации и/или охлаждения.                                                                                            |

Боры и лезвия XOMED

| Неполадка                                                         | Возможная причина                      | Действие                                                                                                                                                                                                                           |
|-------------------------------------------------------------------|----------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Создается впечатление, что инструмент поврежден или имеет дефект. | Инструмент поврежден или имеет дефект. | Снимите и замените инструмент.                                                                                                                                                                                                     |
| Чрезмерная вибрация инструмента, чрезмерный шум при движении.     | Инструмент вставлен не плотно.         | В случае микродебридеров оттяните назад зажимной патрон и переставьте инструмент.<br>В случае использования дрели Visao разблокируйте запорное кольцо, проверьте и снова установите выступ в выемку, заблокируйте запорное кольцо. |
| Отсутствует аспирация.                                            | Засорилось отверстие лезвия.           | Очистите лезвие с помощью стилета.<br>Чтобы устранить засор, уберите лезвие из операционного поля и погрузите кончик лезвия в стерильную воду, оставив отсос подсоединенным к рукоятке.                                            |
|                                                                   | Засорилась трубка.                     | Снимите и проверьте трубку отсоса. Если она засорена, очистите и снова подсоедините ее.                                                                                                                                            |

| Неполадка                                                     | Возможная причина                                                                           | Действие                                                                                                                                                                                                                                                                                                                                                                     |
|---------------------------------------------------------------|---------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Утечка ирригационной жидкости из инструмента.                 | Инструмент неправильно вставлен в зажимной патрон.<br><br>Аспирация слабая или отсутствует. | Проверьте, правильно ли вставлен инструмент, потянув назад зажимной патрон, и переустановите инструмент.<br><br>См. возможные причины отсутствия аспирации.                                                                                                                                                                                                                  |
| Инструмент неустойчиво ведет себя в рукоятке.                 | Инструмент неустойчиво ведет себя в рукоятке.                                               | Уменьшите рабочую скорость рукоятки.<br><br>Используйте инструменты, номинальная скорость которых соответствует выбранной на пульте управления.<br><br>При необходимости используйте защиту для средних, длинных и сверхдлинных боров.<br><br>Работайте с рукояткой на половине полной скорости для средних, длинных и сверхдлинных боров.<br><br>Выберите новый инструмент. |
| Чрезмерная вибрация инструмента, чрезмерный шум при движении. | Инструмент вставлен неплотно.                                                               | В случае микродебридеров оттяните назад зажимной патрон и переставьте инструмент.<br>У некоторых моделей ход вращения можно проверить, немного повернув дисковый переключатель.<br>В случае дрели Visao разблокируйте запорное кольцо, проверьте и снова установите выступ в выемку, заблокируйте запорное кольцо.                                                           |

### Электродвигатели Legend EHS, Legend EHS Stylus и Indigo

| Неполадка                                                                | Возможная причина                                                                                                                                                                                                                                                            | Действие                                                                                                                                                                                                                                                                                                                                                                                                                         |
|--------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Электродвигатель слишком горячий, и его невозможно касаться или держать. | Электродвигатель недостаточно остыл после стерилизации.<br><br>Электродвигатель нагревается от насадки.<br><br>Большая боковая нагрузка во время рассечения ткани.<br><br>Недостаточная ирригация.                                                                           | После стерилизации паром нужно подождать, пока электродвигатель остынет.<br><br>Смените насадку, чтобы выяснить, что является причиной нагрева, электродвигатель или насадка.<br><br>Прекратите работу и дайте остыть электродвигателю, используя его в прерывистом режиме, или оберните электродвигатель влажным стерильным полотенцем.<br><br>Обеспечьте надлежащую ирригацию операционного поля во время рассечения кости.    |
| Инструмент с трудом извлекается из насадки.                              | Износ насадки.<br><br>Использование инструментов, подвергшихся повторной обработке.<br><br>Использование неразрешенного средства для восстановления свойств инструмента.<br><br>Неправильная очистка.                                                                        | Обратитесь в службу технической поддержки.<br><br><br><br>Тщательно очистите насадку в соответствии с инструкциями, приведенными в данном руководстве.<br><br>Замените инструмент.                                                                                                                                                                                                                                               |
| Насадка неправильно садится на электродвигатель.                         | Не выровнены грани зажимного патрона электродвигателя.                                                                                                                                                                                                                       | С помощью гаечного ключа электродвигателя Legend поворачивайте ближайшую к корпусу электродвигателя грань, пока отметка не совместится с отметкой на самой удаленной от корпуса электродвигателя грани.                                                                                                                                                                                                                          |
| Электродвигатель не работает.                                            | Неправильно подсоединены кабели.<br><br>Задана слишком маленькая скорость.<br><br>На электродвигателе неправильно установлена и заблокирована насадка.<br><br>Внутренний сбой электродвигателя или пульта управления.<br><br>Неправильно работает модуль ножного управления. | Убедитесь в правильности подсоединения кабелей электродвигателя и ножного переключателя.<br><br>Убедитесь в том, что выбрана скорость более 10 000 об./мин (EHS) или 3000 об./мин (Stylus).<br><br>Снимите и правильно переустановите насадку и инструмент для препарирования.<br><br>Замените электродвигатель или пульт управления, чтобы выявить неполадку.<br><br>Проверьте, нет ли посторонних предметов под ножной pedalю. |



| Неполадка                                                       | Возможная причина                                                        | Действие                                                                                     |
|-----------------------------------------------------------------|--------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|
| Электродвигатель с насадкой вращаются, но издают необычный шум. | Повреждены кабели.                                                       | Проверьте, нет ли трещин или разрывов на кабелях, и не погнуты ли штырьки разъемов.          |
|                                                                 | Износились подшипники.                                                   | Замените насадку, чтобы выявить источник неполадки.                                          |
|                                                                 | Неполный электрический контакт.                                          | Проверьте все соединения от источника электропитания до пульта управления.                   |
|                                                                 | Внутренняя неисправность электродвигателя, пульта управления или кабеля. | Убедитесь в правильности подсоединения кабелей электродвигателя и ножного переключателя.     |
|                                                                 | Неправильно установлена насадка.                                         | Замените электродвигатель, пульт управления или кабель, чтобы выявить неисправный компонент. |
|                                                                 |                                                                          | Снимите и правильно переустановите насадку и инструмент для препарирования.                  |

Электродвигатели Stylus Touch

| Неполадка                     | Возможная причина                                                                           | Действие                                                                                               |
|-------------------------------|---------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|
| Электродвигатель не работает. | Пальцевой переключатель не достигает максимальной скорости.                                 | Удостоверьтесь в том, что кольцо рычага управления правильно расположено в одном из четырех положений. |
|                               | Пальцевой переключатель не реагирует. Аварийный переключатель переведен в безопасный режим. | Переставьте переключатель в положение рабочего режима.                                                 |
|                               | Пальцевой переключатель поврежден.                                                          | Обратитесь в службу технической поддержки.                                                             |

Насадки и телескопические трубки Legend EHS, Legend EHS Stylus и Stylus Touch

| Неполадка                                                                                                 | Возможная причина                                                                                                                            | Действие                                                                                                                                                                                 |
|-----------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Невозможно держать насадку или телескопическую трубку или прикасаться к ней из-за высокой температуры.    | Нагрев в результате износа подшипников насадки или трубки.                                                                                   | ЗАПРЕЩАЕТСЯ использовать компонент. Попробуйте использовать другую насадку или трубку.                                                                                                   |
|                                                                                                           | Насадка или трубка загрязнена из-за неправильной очистки.                                                                                    | Телескопические трубки выбрасываются после многократного использования. Если с новой телескопической трубкой неполадка устраняется, выбросьте перегревшуюся трубку.                      |
|                                                                                                           | Большая боковая нагрузка во время рассечения ткани.                                                                                          | Соблюдайте надлежащий порядок очистки.                                                                                                                                                   |
| Насадка или телескопическая трубка погнута, болтается, повреждена или в ней не хватает какой-либо детали. | Неправильное обращение с насадкой, насадка вышла из строя из-за длительного использования или приложения чрезмерного усилия во время работы. | Прекратите работу и дайте остыть насадке, используя ее в прерывистом режиме. Попробуйте другую такую же насадку или оберните насадку влажным стерильным полотенцем.                      |
|                                                                                                           | Неправильный способ очистки или стерилизации.                                                                                                | ЗАПРЕЩАЕТСЯ использовать компонент. Выбросьте телескопическую трубку. Телескопические трубки выбрасываются после многократного использования. Обратитесь в службу технической поддержки. |
|                                                                                                           | Применение коррозионных или содержащих хлор средств.                                                                                         | Подберите соответствующий инструмент для препарирования по номенклатуре или обратитесь в службу технической поддержки.                                                                   |
| Цветная маркировочная полоса на насадке или телескопической трубке выцвела или обесцветилась.             | Износ                                                                                                                                        | Телескопические трубки выбрасываются после многократного использования.                                                                                                                  |
|                                                                                                           | Чрезмерная смазка насадки                                                                                                                    | Нанесение избытка смазки во время очистки.                                                                                                                                               |
| В насадке на ножке отсутствует деталь из области ножки или погнута ножка.                                 | Насадка повреждена инструментом для препарирования, просверлившим часть или всю область ножки.                                               | Осмотрите компонент и протрите лишнюю смазку.                                                                                                                                            |
|                                                                                                           | Насадка погнута из-за неправильного использования.                                                                                           | ЗАПРЕЩАЕТСЯ использовать компонент. Обратитесь в службу технической поддержки.                                                                                                           |

| Неполадка                                 | Возможная причина                                                                                                                                                                                   | Действие                                                                                      |
|-------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|
| Перегрев контругловой насадки 16-MF.      | В контругловой насадке вал привода входит в зацепление с комплектом шестерен. Поэтому область насадки приблизительно в 2 см от дистального конца и правая часть угловой головки обычно нагреваются. | Если температура растет или становится чрезмерной, обратитесь в службу технической поддержки. |
| Из насадки или электродвигателя идет дым. | Насадка не заблокирована.                                                                                                                                                                           | Убедитесь в том, что насадка заблокирована.                                                   |

Инструменты Legend EHS, Legend EHS Stylus и Stylus Touch

| Неполадка                                                                         | Возможная причина                                                                                                         | Действие                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Неустойчивое поведение инструмента.                                               | Вместо инструмента Legend используется другой инструмент.                                                                 | Вставьте инструмент Legend.                                                                                                                                                                                                                                                                                                                              |
|                                                                                   | Износ подшипников насадки или трубки.                                                                                     | Попробуйте другую насадку или трубку, чтобы выявить источник неполадки.<br>Если неисправна насадка, обратитесь в службу технической поддержки.                                                                                                                                                                                                           |
|                                                                                   | Насадка или трубка несовместима с инструментом.                                                                           | Если неисправна трубка, выбросьте ее и воспользуйтесь другой трубкой.                                                                                                                                                                                                                                                                                    |
|                                                                                   | Поврежден электродвигатель.<br>При определенных скоростях размер и геометрия инструмента могут усугублять нестабильность. | Цветовая маркировка на упаковке инструмента и на насадке или трубке должна совпадать.<br>Обратитесь в службу технической поддержки.<br>Отрегулируйте скорость, изменив настройку давления либо с помощью ножного или пальцевого управления. Запрещается использовать инструмент, если его нестабильное поведение не устраняется.<br>Замените инструмент. |
| Чрезмерная вибрация инструмента.                                                  | При определенных скоростях размер и геометрия инструмента могут быть причиной его сильной вибрации.                       | Отрегулируйте скорость.                                                                                                                                                                                                                                                                                                                                  |
|                                                                                   |                                                                                                                           | Замените инструменты.                                                                                                                                                                                                                                                                                                                                    |
| Инструмент затупился.                                                             | Длительное использование инструмента.                                                                                     | Замените инструмент на новый.                                                                                                                                                                                                                                                                                                                            |
|                                                                                   | Использовался инструмент, подвергшийся вторичной обработке.                                                               |                                                                                                                                                                                                                                                                                                                                                          |
|                                                                                   | Неправильная геометрия инструмента.                                                                                       | Обратитесь в службу технической поддержки.                                                                                                                                                                                                                                                                                                               |
| Неправильная посадка инструмента в электродвигателе или зажимном патроне насадки. | Инеродные предметы в зажимном патроне насадки или электродвигателе.                                                       | Тщательно очистите насадку или электродвигатель в соответствии с инструкциями, приведенными в данном руководстве.<br>Если очистка не помогает устранить неполадку, обратитесь в службу технической поддержки.                                                                                                                                            |
|                                                                                   | Вместо инструмента Legend используется другой инструмент.                                                                 | Вставьте инструмент Legend.                                                                                                                                                                                                                                                                                                                              |

КОДЫ ОШИБОК

| № кода | Название                                                                                                                                                                                              | Причина                                    | Описание                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|--------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1      | ПКЭ (плата контроллера электродвигателя) не сообщает о загрузке в течение 5 секунд после получения команды от монтажной платы Active Interlink о запуске, и последующие попытки завершаются неудачно. | Системная ошибка                           | Выключите питание. Подождите 10 секунд. Включите питание. Если ошибка не устраняется, обратитесь в службу технической поддержки.                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 2      | НЕ ИСПОЛЬЗУЕТСЯ                                                                                                                                                                                       | НЕ ИСПОЛЬЗУЕТСЯ                            | НЕ ИСПОЛЬЗУЕТСЯ                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 3      | Сбой связи ПИ-ПКЭ — превышено максимальное число повторных передач                                                                                                                                    | Системная ошибка                           | Выключите питание. Подождите 10 секунд. Включите питание. Если ошибка не устраняется, обратитесь в службу технической поддержки.                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 4      | Сбой связи ПИ-ПКЭ — не удалось получить ответ.                                                                                                                                                        |                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 5      | Сбой связи ПИ-ПКЭ — не получено сообщение о состоянии.                                                                                                                                                |                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 6      | Сбой связи UI-МСВ — ошибка идентификатора сериализации.                                                                                                                                               |                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 7      | Сбой связи ПИ-ПКЭ — прерывание по истечении времени ожидания.                                                                                                                                         |                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 8      | Сбой связи ПИ-ПКЭ — ошибка распознавания переменной.                                                                                                                                                  |                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 9      | Сбой потока помпы 1 (нет переходов на оптическом датчике).                                                                                                                                            | Сбой потока помпы №1                       | Проверьте подсоединение трубок.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 10     | Сбой потока помпы 2 (нет переходов на оптическом датчике).                                                                                                                                            | Сбой потока помпы №2                       | Проверьте подсоединение трубок.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 11     | К порту 1 (первые 12 штырьков) подключена нераспознанная или поврежденная рукоятка.                                                                                                                   | Рукоятка                                   | Отсоедините разъем рукоятки и снова вставьте его. Если ошибка не устраняется, замените рукоятку.                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 12     | К порту 2 (вторые 12 штырьков) подключена нераспознанная или поврежденная рукоятка.                                                                                                                   |                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 13     | К порту 3 (4 штырька) подключена нераспознанная или поврежденная рукоятка.                                                                                                                            |                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 14     | К порту 4 (Skeeter) подключена нераспознанная или поврежденная рукоятка.                                                                                                                              |                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 15     | Рукоятка застопорилась.                                                                                                                                                                               | Рукоятка застопорилась.                    | Проверьте инструмент.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 16     | Обнаружена перегрузка по току электродвигателя ПКЭ                                                                                                                                                    | Перегрузка по току электродвигателя        | Отсоедините разъем рукоятки и снова вставьте его. Если ошибка не устраняется, замените рукоятку.                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 17     | Подключена нераспознанная или поврежденная многофункциональная ножная педаль.                                                                                                                         | Ошибка подключения ножной педали           | <p>При использовании только ножной педали отсоедините ножную педаль и снова подсоедините ее. Если ошибка не будет устранена, замените ножную педаль или перейдите на ручное управление.</p> <p>При использовании Y-Splitter отключите ножную педаль и Y-Splitter, затем подключите ножную педаль напрямую к IPC. Если после повторного подключения ножной педали ошибка исчезла, замените Y-Splitter на другое устройство. Если ошибка не будет устранена, замените ножную педаль и подключите Y-Splitter и ножную педаль повторно или перейдите на ручное управление.</p> |
| 18     | Повреждена рукоятка или основание пальцевого рычага находится в неправильном положении.                                                                                                               | Ошибка управления пальцевого переключателя | Stylus Touch — выявлена ошибка управления пальцевого переключателя. Удостоверьтесь в том, что кольцо рычага управления правильно расположено в одном из четырех положений. При повторном возникновении ошибки обратитесь в отдел обслуживания клиентов. Нажмите ОК, чтобы перейти к альтернативному методу управления.<br>Triton/POWERAISE — убедитесь в том, что переключатель режима переведен в соответствующее положение с помощью механизма вращения и зафиксирован в этом положении. При повторном возникновении ошибки обратитесь в отдел обслуживания клиентов.    |
| 19     | Не удалось выполнить самопроверку ПИ — в реестре нарушена запись региональных настроек (язык).                                                                                                        | Не удалось выполнить самопроверку.         | Выключите питание. Подождите 10 секунд. Включите питание. Если ошибка не устраняется, обратитесь в службу технической поддержки.                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| 20     | Не удалось выполнить самопроверку ПИ — в реестре нарушена запись конфигурации сектора.                                                                                                                |                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 21     | Не удалось выполнить самопроверку ПИ — поврежден файл рабочих характеристик или не удается его создать.                                                                                               |                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| 22     | НЕ ИСПОЛЬЗУЕТСЯ                                                                                                                                                                                       | НЕ ИСПОЛЬЗУЕТСЯ                            | НЕ ИСПОЛЬЗУЕТСЯ                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

# ПОИСК И УСТРАНЕНИЕ НЕИСПРАВНОСТЕЙ И КОДЫ ОШИБОК IRS

| № кода | Название                                                                       | Причина                            | Описание                                                                                                                         |
|--------|--------------------------------------------------------------------------------|------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|
| 23     | Неспецифический сбой самопроверки ПКЭ                                          | Не удалось выполнить самопроверку. | Выключите питание. Подождите 10 секунд. Включите питание. Если ошибка не устраняется, обратитесь в службу технической поддержки. |
| 24     | Не удалось выполнить самопроверку ПКЭ — порт 1                                 |                                    |                                                                                                                                  |
| 25     | Не удалось выполнить самопроверку ПКЭ — порт 2                                 |                                    |                                                                                                                                  |
| 26     | Не удалось выполнить самопроверку ПКЭ — порт 3                                 |                                    |                                                                                                                                  |
| 27     | Не удалось выполнить самопроверку ПКЭ — порт 4                                 |                                    |                                                                                                                                  |
| 28     | Не удалось выполнить самопроверку ПКЭ — закорочен транзистор 1 мостовой схемы. |                                    |                                                                                                                                  |
| 29     | Не удалось выполнить самопроверку ПКЭ — закорочен транзистор 2 мостовой схемы. |                                    |                                                                                                                                  |
| 30     | Не удалось выполнить самопроверку ПКЭ — закорочен транзистор 3 мостовой схемы. |                                    |                                                                                                                                  |
| 31     | Не удалось выполнить самопроверку ПКЭ — закорочен транзистор 4 мостовой схемы. |                                    |                                                                                                                                  |
| 32     | Не удалось выполнить самопроверку ПКЭ — закорочен транзистор 5 мостовой схемы. |                                    |                                                                                                                                  |
| 33     | Не удалось выполнить самопроверку ПКЭ — закорочен транзистор 6 мостовой схемы. |                                    |                                                                                                                                  |
| 34     | Не удалось выполнить самопроверку ПКЭ — аналого-цифровой преобразователь.      |                                    |                                                                                                                                  |
| 35     | Не удалось выполнить самопроверку ПКЭ — ошибка электродвигателя.               |                                    |                                                                                                                                  |
| 36     | Не удалось выполнить самопроверку ПКЭ — питание 3,3 вольт.                     |                                    |                                                                                                                                  |
| 37     | Не удалось выполнить самопроверку ПКЭ — питание 12 вольт.                      |                                    |                                                                                                                                  |
| 38     | Не удалось выполнить самопроверку ПКЭ — питание 48 вольт.                      |                                    |                                                                                                                                  |
| 39     | Не удалось выполнить самопроверку ПКЭ — порт FCU.                              |                                    |                                                                                                                                  |

# ОЧИСТКА И СТЕРИЛИЗАЦИЯ

Инструкции по повторной обработке могут быть изменены. Актуальные инструкции по повторной обработке можно найти на сайте [manuals.medtronic.com](http://manuals.medtronic.com).

## ДЕЙСТВИЯ ПОСЛЕ ОКОНЧАНИЯ РАБОТЫ С СИСТЕМОЙ

### Отсоединение кабеля инструмента от пульта управления

Чтобы отсоединить кабели с несиликоновыми многоштырьковыми разъемами от пульта управления, прижмите разъем к пулту управления и затем вытяните его, удерживая за стопорное кольцо.

**Примечание.** Многоштырьковые и одноштырьковые разъемы с силиконовой изоляцией не имеют стопорного кольца (1). Разъемы такого типа отсоединяются от панели разъемов под прямым углом.

**Предупреждение!** После отсоединения изолированных разъемов (см. W79) от пульта управления разъемы, на которых имеются загрязнения под изоляционным слоем, следует очистить в соответствии с инструкциями по очистке и стерилизации. Если после очистки и стерилизации загрязнения все еще присутствуют, верните разъем на гарантийное обслуживание.



### Очистка многофункциональной ножной педали

**Важная информация!** Если под защитным чехлом кабеля ножной педали есть загрязнения, верните педаль на гарантийное обслуживание.

ЗАПРЕЩАЕТСЯ погружать педаль в жидкость или стерилизовать.

ЗАПРЕЩАЕТСЯ использовать спирт, другие растворители или абразивные чистящие средства.

1. ТОЛЬКО на нескользящую подкладку распылите нейтральное ферментативное моющее средство с pH 6,0–8,0 или дезинфицирующее средство на основе фенола, разведенное в соответствии с инструкциями производителя моющего средства.
2. Оставьте раствор на подкладке приблизительно на 10 минут.
3. Смочите салфетку в нейтральном ферментативном моющем средстве с pH 6,0–8,0 или в дезинфицирующем средстве на основе фенола, разведенном в соответствии с инструкциями производителя моющего средства.
4. Вытрите ножную педаль смоченной салфеткой до устранения видимых загрязнений.
5. Протрите педаль насухо чистой неабразивной тканью.

### Очистка У-образного делителя сигнала

1. ЗАПРЕЩАЕТСЯ погружать У-образный делитель сигнала в жидкость или стерилизовать его.
2. ЗАПРЕЩАЕТСЯ использовать спирт, другие растворители или абразивные чистящие средства.
3. Смочите салфетку в нейтральном ферментативном моющем средстве с pH 6,0–8,0 или в дезинфицирующем средстве на основе фенола, разведенном в соответствии с инструкциями производителя моющего средства.
4. Вытрите У-образный делитель сигнала смоченной салфеткой до устранения видимых загрязнений.
5. Протрите модуль насухо чистой неабразивной тканью.





Medtronic

Инструкции по повторной  
обработке  
Электрорукотка Triton с высоким крутящим моментом

Инструкции по повторной обработке  
Инструкции по очистке и стерилизации могут  
быть изменены. Актуальные инструкции можно  
найти на веб-узле [manuals.medtronic.com](http://manuals.medtronic.com).  
M000030A322 D

|                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                         |                                                                         |                                                                          |                                                                     |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
|---------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|-------------------------------------------------------------------------|--------------------------------------------------------------------------|---------------------------------------------------------------------|--------------------|---------------------------------------------------------|---------------------------------------------------------|-------------------------------------------------------------------------|--------------------------------------------------------------------------|------|--------|--------|--------|--------|-------------|--------|-------|--------|-------|-------|--------|--------|--------|--------|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|--------------------------------|---------------|--|--|--|-------------------------------|---------------|--|--|--|--------------------------------------------|--------------------------------------------------------------------|--|--|--|---------------------------|--|--|--|--|--------------|-------------|----------|--|--|--|-------------------------|------------|--|--|--|---------------------------|---------------|--|--|--|--------------------------------------|--------|--|--|--|---------|--------------------|--|--|
| Предупреждения и меры предосторожности                                    | <ul style="list-style-type: none"><li>Замачивать устройства или погружать их в жидкость запрещается.</li><li>Запрещается выполнять ультразвуковую чистку рукоятки Triton с высоким крутящим моментом.</li><li>Запрещается использовать вызывающие коррозию или содержащие хлор чистящие средства, такие как отбеливатель, щелок, ацетон, гипохлорит натрия, едкий натр, муравьиная кислота или растворы, содержащие глутаральдегид.</li><li>После стерилизации паром необходимо дождаться остывания компонентов.</li><li>Применение мойки-дезинфектора эндоскопов может привести к преждевременному ухудшению рабочих характеристик.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                         |                                                                         |                                                                          |                                                                     |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
| Ограничения                                                               | Перед тем как снова воспользоваться рукояткой, проверьте ее функциональность, подсоединив ее к IPC и нажав спусковую кнопку. Убедитесь в том, что вал привода вращается.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                         |                                                                         |                                                                          |                                                                     |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
| Важные замечания                                                          | Отсоедините устройство от IPC. Снимите и утилизируйте одноразовые компоненты.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                         |                                                                         |                                                                          |                                                                     |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
| Защита от загрязнений и транспортировка                                   | Рекомендуется выполнять обработку инструментов немедленно после их использования.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                         |                                                                         |                                                                          |                                                                     |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
| Подготовка к обеззараживанию                                              | Отсоедините устройство от IPC. Снимите и утилизируйте одноразовые компоненты.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                         |                                                                         |                                                                          |                                                                     |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
| Очистка                                                                   | Рукоятка и насадки                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                         |                                                                         |                                                                          |                                                                     |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
| Автоматизированные методы (НЕ используйте ультразвуковой моечный аппарат) | <ul style="list-style-type: none"><li>Перед закладкой устройств в моечную машину промойте их вручную в водопроводной воде до исчезновения видимых загрязнений.</li><li>Несколько раз переместите подвижные элементы в разные стороны с тем, чтобы вода могла проникнуть в труднодоступные полости корпуса.</li><li>Поместите устройства в моечную машину. Размещать устройства в моечной машине следует таким образом, чтобы обеспечить свободное стекание с них воды.</li><li>Удостоверьтесь в том, что после автоматической очистки на устройствах отсутствуют видимые загрязнения.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                         |                                                                         |                                                                          |                                                                     |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
|                                                                           | Рекомендуемый цикл обработки в моечной машине                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Фаза                                                    | Длительность рециркуляции                                               | Температура воды                                                         | Тип и концентрация моющего средства                                 |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
|                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Замачивание                                             | 2 мин                                                                   | Холодная водопроводная вода                                              | –                                                                   |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
|                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Промывка                                                | 5 мин                                                                   | 66 °C                                                                    | Нейтральное ферментативное моющее средство с показателем pH 6,0–8,0 |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
|                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Ополаскивание                                           | 1 мин                                                                   | Горячая водопроводная вода                                               | –                                                                   |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
| Очистка Ручные методы                                                     | Рукоятка и насадки                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                         |                                                                         |                                                                          |                                                                     |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
|                                                                           | <ol style="list-style-type: none"><li>Тщательно промойте все устройство, включая кабели, в проточной воде.</li><li>Протрите все наружные поверхности устройства и кабель тканью, смоченной в нейтральном ферментативном моющем составе с показателем pH 6,0–8,0 (далее по тексту — «чистящий раствор»).</li><li>Тщательно потрите устройство щеткой с мягкой щетиной, смоченной в чистящем растворе, уделяя особое внимание неровным поверхностям, бороздкам и труднодоступным местам. Приведите в действие имеющиеся подвижные элементы, чтобы обеспечить проникновение воды во все места устройства.</li><li>Очистите центральную канолированную ось рукоятки с помощью щетки для очистки (номер детали 120-028-1 или аналог), смоченной чистящим раствором.</li><li>Введите щетку для очистки в переднее отверстие канолированной оси и сделайте не меньше 6 движений щеткой. Если вы видите загрязнения на щетке, когда вынимаете ее после движения внутри рукоятки, смывайте их в чистящем растворе.</li><li>Повторите описанные выше действия с боковой стороны рукоятки.</li><li>С помощью шприца введите приблизительно 30 мл чистящего раствора в переднее отверстие канолированной оси.</li><li>Введите приблизительно 30 мл чистящего раствора из шприца в триггер и переключатель движения вперед/назад, двигая при этом движущие части устройства.</li><li>Повторите промывание, описанное в действиях 7 и 8, используя воду вместо чистящего раствора.</li><li>Тщательно промойте все устройство в проточной воде. Приведите в действие имеющиеся подвижные элементы, чтобы обеспечить проникновение воды во все места устройства. Пусть вода также тщательно промоет центральную канолированную ось. Промывайте устройство до тех пор, пока на нем не останется видимых следов загрязнений.</li><li>Просушите полностью все устройство салфеткой.</li></ol> |                                                         |                                                                         |                                                                          |                                                                     |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
|                                                                           | Насадки с сагитальной и реципрокной пилой                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                         |                                                                         |                                                                          |                                                                     |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
|                                                                           | <ol style="list-style-type: none"><li>Тщательно промойте все устройство в проточной воде.</li><li>Протрите все наружные поверхности устройства тканью, смоченной в нейтральном ферментативном моющем составе с показателем pH 6,0–8,0 (далее по тексту — «чистящий раствор»).</li><li>Тщательно потрите устройство щеткой с мягкой щетиной, смоченной в чистящем растворе, уделяя особое внимание неровным поверхностям, бороздкам и труднодоступным местам. Обязательно очистите отверстие реза, зазоры и мелкие детали между и вокруг зажимов реза.</li><li>Погрузите дистальный конец полотна пилы (приблизительно на 3 см от дистального конца) в чистящий раствор и помешайте раствор в течение 10–15 секунд.</li><li>С помощью шприца введите приблизительно 30 мл чистящего раствора в отверстие реза и мелкие компоненты между и вокруг двух зажимов. Повторите описанную выше процедуру промывки, используя вместо чистящего раствора воду.</li><li>Повторите предыдущий этап еще раз.</li><li>Промойте все устройство в проточной воде. Вода должна тщательно омыть все зазоры и мелкие компоненты между и вокруг зажимов реза. Промывайте устройство до тех пор, пока на нем не останется видимых следов загрязнений.</li><li>Просушите устройство салфеткой.</li></ol>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                         |                                                                         |                                                                          |                                                                     |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
| Дезинфекция                                                               | Необходимо следовать процедуре, принятой в медицинском учреждении.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                         |                                                                         |                                                                          |                                                                     |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
| Упаковка                                                                  | Для стерилизации поместите устройства в поток для инструментов. Устройства можно стерилизовать без обертывания или завернутыми в два слоя однослойной полипропиленовой обертки.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                         |                                                                         |                                                                          |                                                                     |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
| Стерилизация (указаны минимальные необходимые температура и время)        | <table><tr><td>Стерилизация паром</td><td>Паровая стерилизация с гравитационным удалением воздуха</td><td>Паровая стерилизация с предварительной откачкой воздуха</td><td>Паровая стерилизация с предварительной откачкой воздуха (Франция / ВОЗ)</td><td>Паровая стерилизация с предварительной откачкой воздуха (Великобритания)</td></tr><tr><td>Цикл</td><td>132 °C</td><td>132 °C</td><td>134 °C</td><td>134 °C</td></tr><tr><td>Температура</td><td>25 мин</td><td>4 мин</td><td>18 мин</td><td>3 мин</td></tr><tr><td>Время</td><td>30 мин</td><td>20 мин</td><td>30 мин</td><td>22 мин</td></tr><tr><td>Сушка</td><td colspan="4">И-за ограниченного внутреннего диаметра просвета и длины трубки ЗАПРЕЩАЕТСЯ применять стерилизацию в низкотемпературной газовой плазме перекиси водорода.</td></tr><tr><td>Стерилизация в системе STERRAD</td><td colspan="4">Не применимо.</td></tr><tr><td>Стерилизация в системе STERIS</td><td colspan="4">Не применимо.</td></tr><tr><td>Параметры стерилизации 100 % этиленоксидом</td><td colspan="4">При температуре 51–59 °C, относительной влажности 70 ± 5 %, 30 мин</td></tr><tr><td>Предварительная обработка</td><td colspan="4"></td></tr><tr><td>Стерилизация</td><td>Температура</td><td colspan="3">51–59 °C</td></tr><tr><td></td><td>Относительная влажность</td><td colspan="3">70 +/- 5 %</td></tr><tr><td></td><td>Концентрация этиленоксида</td><td colspan="3">725 ± 25 мг/л</td></tr><tr><td></td><td>Время воздействия газа (полный цикл)</td><td colspan="3">4 часа</td></tr><tr><td></td><td>Аэрация</td><td colspan="3">51–59 °C, 18 часов</td></tr></table>                                                                                                                                                                                                                                       |                                                         |                                                                         |                                                                          |                                                                     | Стерилизация паром | Паровая стерилизация с гравитационным удалением воздуха | Паровая стерилизация с предварительной откачкой воздуха | Паровая стерилизация с предварительной откачкой воздуха (Франция / ВОЗ) | Паровая стерилизация с предварительной откачкой воздуха (Великобритания) | Цикл | 132 °C | 132 °C | 134 °C | 134 °C | Температура | 25 мин | 4 мин | 18 мин | 3 мин | Время | 30 мин | 20 мин | 30 мин | 22 мин | Сушка | И-за ограниченного внутреннего диаметра просвета и длины трубки ЗАПРЕЩАЕТСЯ применять стерилизацию в низкотемпературной газовой плазме перекиси водорода. |  |  |  | Стерилизация в системе STERRAD | Не применимо. |  |  |  | Стерилизация в системе STERIS | Не применимо. |  |  |  | Параметры стерилизации 100 % этиленоксидом | При температуре 51–59 °C, относительной влажности 70 ± 5 %, 30 мин |  |  |  | Предварительная обработка |  |  |  |  | Стерилизация | Температура | 51–59 °C |  |  |  | Относительная влажность | 70 +/- 5 % |  |  |  | Концентрация этиленоксида | 725 ± 25 мг/л |  |  |  | Время воздействия газа (полный цикл) | 4 часа |  |  |  | Аэрация | 51–59 °C, 18 часов |  |  |
| Стерилизация паром                                                        | Паровая стерилизация с гравитационным удалением воздуха                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Паровая стерилизация с предварительной откачкой воздуха | Паровая стерилизация с предварительной откачкой воздуха (Франция / ВОЗ) | Паровая стерилизация с предварительной откачкой воздуха (Великобритания) |                                                                     |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
| Цикл                                                                      | 132 °C                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 132 °C                                                  | 134 °C                                                                  | 134 °C                                                                   |                                                                     |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
| Температура                                                               | 25 мин                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 4 мин                                                   | 18 мин                                                                  | 3 мин                                                                    |                                                                     |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
| Время                                                                     | 30 мин                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 20 мин                                                  | 30 мин                                                                  | 22 мин                                                                   |                                                                     |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
| Сушка                                                                     | И-за ограниченного внутреннего диаметра просвета и длины трубки ЗАПРЕЩАЕТСЯ применять стерилизацию в низкотемпературной газовой плазме перекиси водорода.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                         |                                                                         |                                                                          |                                                                     |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
| Стерилизация в системе STERRAD                                            | Не применимо.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                         |                                                                         |                                                                          |                                                                     |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
| Стерилизация в системе STERIS                                             | Не применимо.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                         |                                                                         |                                                                          |                                                                     |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
| Параметры стерилизации 100 % этиленоксидом                                | При температуре 51–59 °C, относительной влажности 70 ± 5 %, 30 мин                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                         |                                                                         |                                                                          |                                                                     |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
| Предварительная обработка                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                         |                                                                         |                                                                          |                                                                     |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
| Стерилизация                                                              | Температура                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 51–59 °C                                                |                                                                         |                                                                          |                                                                     |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
|                                                                           | Относительная влажность                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 70 +/- 5 %                                              |                                                                         |                                                                          |                                                                     |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
|                                                                           | Концентрация этиленоксида                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 725 ± 25 мг/л                                           |                                                                         |                                                                          |                                                                     |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
|                                                                           | Время воздействия газа (полный цикл)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 4 часа                                                  |                                                                         |                                                                          |                                                                     |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
|                                                                           | Аэрация                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 51–59 °C, 18 часов                                      |                                                                         |                                                                          |                                                                     |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
| Техническое обслуживание, осмотр и проверка                               | <ul style="list-style-type: none"><li>Перед каждым использованием и после него необходимо осматривать компоненты на предмет повреждения. В случае обнаружения повреждения запрещается использовать инструмент, пока он не будет отремонтирован.</li><li>Перед повторным использованием инструмента выполняйте проверку его работоспособности.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                         |                                                                         |                                                                          |                                                                     |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
| Хранение                                                                  | Храните в чистом сухом месте.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                         |                                                                         |                                                                          |                                                                     |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |
| Дополнительная информация                                                 | Отсутствует.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                         |                                                                         |                                                                          |                                                                     |                    |                                                         |                                                         |                                                                         |                                                                          |      |        |        |        |        |             |        |       |        |       |       |        |        |        |        |       |                                                                                                                                                           |  |  |  |                                |               |  |  |  |                               |               |  |  |  |                                            |                                                                    |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |            |  |  |  |                           |               |  |  |  |                                      |        |  |  |  |         |                    |  |  |

**Примечание.** Циклы стерилизации с предварительным вакуумированием (для Франции/рекомендованные ВОЗ и для Великобритании) не считаются Управлением по контролю за пищевыми продуктами и лекарственными средствами США (FDA) стандартными. Пользователям следует применять только стерилизаторы и принадлежности (такие как стерилизационный оберточный материал, стерилизационные пакеты, химические индикаторы, биологические индикаторы и стерилизационные контейнеры), утвержденные в технических условиях FDA для выбранного цикла стерилизации (время и температура).

**Примечание.** Вышеизложенные инструкции прошли валидацию и рекомендованы производителем в качестве процедур. СПОСОБНЫХ подготовить продукт для повторного использования. Ответственность за фактическое осуществление повторной обработки с использованием оборудования, материалов и персонала обрабатывающего предприятия, обеспечивающих требуемый результат, несет обработчик. Обычно для этого необходима валидация процесса и его рутинный контроль.

**Примечание.** Все процессы валидации выполняются согласно требованиям стандарта AAMI TIR12 «Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers» (Разработка, проверка и маркировка повторно используемых устройств медицинского назначения для повторной обработки в учреждениях здравоохранения, рекомендация для производителей устройств медицинского назначения).

Компания Medtronic рекомендует сжигание устройств, которые находились в непосредственном контакте с пациентами, имеющими предполагаемый или подтвержденный диагноз трансмиссивной губчатой энцефалопатии (ТГЭ) или болезни Крейтцфельда-Якоба (БКЯ).



Medtronic

## Инструкции по повторной обработке Пальцевой переключатель Endo-Scrub 2

Инструкции по повторной обработке  
Инструкции по очистке и стерилизации  
могут быть изменены. Актуальные  
инструкции можно найти на веб-узле  
[manuals.medtronic.com](http://manuals.medtronic.com).  
68E4005 D

|                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                |                                                         |                                                                          |
|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|---------------------------------------------------------|--------------------------------------------------------------------------|
| Предупреждения и меры предосторожности                                            | Перед очисткой отсоедините пальцевой переключатель от насоса Endo-Scrub 2.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                |                                                         |                                                                          |
| Ограничения                                                                       | После очистки и стерилизации перед повторным использованием проверьте работоспособность изделия.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                |                                                         |                                                                          |
| Важные замечания                                                                  | <ul style="list-style-type: none"><li>Данный продукт поставляется нестерильным. Перед первым использованием и последующими повторными применениями следует выполнить очистку и стерилизацию изделия.</li><li>После использования извлеките пальцевой переключатель из чехла и отсоедините вилку от насоса.</li><li>После использования устройства тщательно ополосните его водой.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                |                                                         |                                                                          |
| Защита от загрязнений и транспортировка                                           | Рекомендуется выполнять обработку инструментов немедленно после их использования.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                |                                                         |                                                                          |
| Подготовка к обеззараживанию                                                      | После каждого использования немедленно тщательно промывайте инструменты деионизированной водой.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                |                                                         |                                                                          |
| Очистка Автоматизированные методы (НЕ используйте ультразвуковой моечный аппарат) | Валидация не проводилась.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                |                                                         |                                                                          |
| Очистка Ручные методы                                                             | <ul style="list-style-type: none"><li>Погрузите корпус пальцевого переключателя в разбавленный раствор мягкого (pH 7,0–8,5) ферментативного моющего средства. (При разбавлении моющего средства следуйте инструкциям производителя.)</li><li>Тщательно очистите корпус мягкой щеткой для инструментов, чтобы удалить всю кровь и остатки тканей.</li><li>Тщательно ополосните корпус водопроводной водой и вытрите насухо.</li><li>Примечание. Во время протирки шнура нужно держаться за него, а не за корпус, чтобы не сдавливать электрические разъемы, расположенные внутри корпуса, и не сломать их.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                |                                                         |                                                                          |
| Дезинфекция                                                                       | Запрещается стерилизовать инструменты при пониженной температуре в глутаральдегиде, хлоре или аммиачных растворах или методом сухой тепловой стерилизации, поскольку это может вызвать повреждение их поверхности.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                |                                                         |                                                                          |
| Упаковка                                                                          | <ul style="list-style-type: none"><li>Может использоваться стандартный оберточный материал для стерилизации. В США должен использоваться хирургический оберточный материал, соответствующий требованиям FDA. Убедитесь, что упаковка достаточно велика, чтобы вместить инструмент и не оказывать давления на уплотнения.</li><li>Для комплектов инструментов: инструменты можно загружать в специальные инструментальные лотки или лотки для универсальной стерилизации. Убедитесь в том, что режущие края изолированы. Оберните лотки, используя соответствующий метод.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                |                                                         |                                                                          |
| Стерилизация (указаны минимальные необходимые температура и время)                | <ul style="list-style-type: none"><li>Проверьте чистоту и работоспособность инструмента. Еще раз очистите инструменты с сохранившимися инородными веществами, а поврежденные инструменты изымите из употребления. Зажмите инструменты с помощью защелок и штативов в первой выемке. Разместите инструменты в контейнерах для стерилизации с отверстиями внизу и вверху и на подставках, которые используются в микрохирургии. Выполните подходящий цикл обработки, приведенный в следующей таблице.</li><li>Указанные ниже параметры стерилизации должны применяться для стерилизации устройств в полностью разобранном виде, если разборка возможна. После стерилизации применяйте стандартные стерильные способы сборки устройств, чтобы сохранить стерильность инструментов.</li><li>Валидацию прошли все циклы паровой стерилизации инструментария в обертке, при этом инструменты можно стерилизовать как в обертке, так и без нее. Для данных устройств валидация выполнялась только в отношении методов стерилизации паром.</li></ul> |                                                                |                                                         |                                                                          |
|                                                                                   | Стерилизация паром                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                |                                                         |                                                                          |
|                                                                                   | Цикл                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Паровая стерилизация с гравитационным удалением воздуха        | Паровая стерилизация с предварительной откачкой воздуха | Паровая стерилизация с предварительной откачкой воздуха (Великобритания) |
|                                                                                   | Температура                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 132 °C                                                         | 132 °C                                                  | 134 °C                                                                   |
|                                                                                   | Время                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 10 мин                                                         | 4 мин                                                   | 3 мин                                                                    |
|                                                                                   | Сушка                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 15–30 минут или до появления визуальных признаков высушивания. |                                                         |                                                                          |
|                                                                                   | Стерилизация в системе STERRAD                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Валидация не проводилась.                                      |                                                         |                                                                          |
|                                                                                   | Параметры стерилизации 100 % этиленоксидом                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Валидация не проводилась.                                      |                                                         |                                                                          |
| Техническое обслуживание, осмотр и проверка                                       | <ul style="list-style-type: none"><li>Перед каждым использованием и после него необходимо осматривать пальцевой переключатель на предмет повреждения. В случае обнаружения повреждения запрещается использовать вышедший из строя пальцевой переключатель, пока он не будет отремонтирован или заменен.</li><li>После очистки и стерилизации перед повторным использованием проверьте работоспособность изделия.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                |                                                         |                                                                          |
| Хранение                                                                          | Храните в чистом сухом месте.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                |                                                         |                                                                          |
| Дополнительная информация                                                         | Отсутствует.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                |                                                         |                                                                          |

**Примечание.** Вышеизложенные инструкции прошли валидацию и рекомендованы производителем в качестве процедур. СПОСОБНЫХ подготовить продукт для повторного использования. Ответственность за фактическое осуществление повторной обработки с использованием оборудования, материалов и персонала обрабатывающего предприятия, обеспечивающих требуемый результат, несет обработчик. Обычно для этого необходима валидация процесса и его рутинный контроль.

**Примечание.** Все процессы валидации выполняются согласно требованиям стандарта AAMI TIR12 «Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers» (Разработка, проверка и маркировка повторно используемых устройств медицинского назначения для повторной обработки в учреждениях здравоохранения: рекомендация для производителей устройств медицинского назначения).

Компания Medtronic рекомендует сжигание устройств, которые находились в непосредственном контакте с пациентами, имеющими предполагаемый или подтвержденный диагноз трансмиссивной губчатой энцефалопатии (ТГЭ) или болезни Крейтцфельда-Якоба (БКЯ).



Инструкции по повторной  
обработке  
Микродебридеры

Спинальные шейверы StraightShot M5, StraightShot M4, StraightShot  
Magnum II, StraightShot III и Midas Rex

Инструкции по повторной обработке

Инструкции по очистке и стерилизации могут  
быть изменены. Актуальные инструкции можно  
найти на веб-узле [manuals.medtronic.com](http://manuals.medtronic.com).  
68E3282 F

Предупреждения и меры  
предосторожности

- Перед очисткой отсоединяйте шнур питания от сети.
- Не погружайте этот инструмент полностью в жидкость и не выполняйте ультразвуковую чистку.
- Не выполняйте стерилизацию в низкотемпературном растворе глутаральдегида. В противном случае гарантия будет аннулирована.
- Не используйте органические растворители для чистки зажимного устройства бора.
- При очистке рукоятки Microdebrider закройте разъем кабеля рукоятки одним из следующих колпачков для кабелей рукояток:
  - Колпачок для очистки рукоятки, универсальный — номер по каталогу 3318520.
  - Колпачок кабеля рукоятки, малый — номер по каталогу 3318510.
  - Используйте 3318520 для StraightShot M4, спинального шейвера, StraightShot Magnum II и StraightShot III.
  - Использование 3318520 со StraightShot M5 является опциональным.
  - Для других устройств Microdebrider используйте компонент с номером по каталогу 3318510.
- После завершения очистки снимайте колпачок кабеля рукоятки и другие установленные перед очисткой защитные компоненты.

Ограничения

После очистки и стерилизации перед повторным использованием проверьте работоспособность изделия.

Важные замечания

- Данный продукт поставляется нестерильным. Перед первым использованием и последующими повторными применениями следует выполнить очистку и стерилизацию изделия.
- Для удаления случайно попавших на разъем кабеля рукоятки остаточных загрязнений используйте мягкую щетку и изопропиловый спирт.

Защита от загрязнений  
и транспортировка

Рекомендуется выполнять обработку инструментов немедленно после их использования.

Подготовка  
к обеззараживанию

Извлеките бор из рукоятки, другая разборка не требуется.

Очистка  
Автоматизированные  
методы (НЕ используйте  
ультразвуковой  
моечный аппарат)

- Извлеките инструменты и оборудование из лотков для инструментов.
- Используйте щелочные моющие средства (pH ≤ 10,5) или средства с нейтральным pH.
- Не погружайте рукоятку в жидкость.

Инструкции по предварительной очистке перед автоматической мойкой с помощью нейтрального моющего средства

- Вручную ополосните рукоятку, кабель и зажимы для трубок под струей водопроводной воды, чтобы удалить с устройства все видимые загрязнения. С помощью щетки с мягкой щетиной и раствора нейтрального моющего средства осторожно и тщательно прочистите весь просвет устройства. Во время ополаскивания запустите зажимной патрон и поверните дисковый переключатель. При ополаскивании держите рукоятку зажимным патроном вниз. Промойте струей воды аспирационное отверстие.
- Разместите устройства в моечной машине зажимным патроном вниз, чтобы обеспечить свободное стекание с них воды.

| Автоматическая мойка с помощью нейтрального ферментативного моющего средства |                   |                             |                                                                                               |
|------------------------------------------------------------------------------|-------------------|-----------------------------|-----------------------------------------------------------------------------------------------|
| Фаза                                                                         | Минимальное время | Температура                 | Моющее средство                                                                               |
| Замачивание 1                                                                | 02:00             | Холодная водопроводная вода | Неприменимо                                                                                   |
| Мойка ферментативным раствором                                               | 05:00             | < 50° C                     | Ферментативное моющее средство с нейтральным pH в рекомендованной производителем концентрации |
| Ополаскивание 1                                                              | 01:00             | Горячая водопроводная вода  | Неприменимо                                                                                   |
| Термическое ополаскивание                                                    | 01:00             | не менее 82 °C              | Неприменимо                                                                                   |

Визуально проверьте на предмет чистоты.

Инструкции по предварительной очистке перед автоматической мойкой с помощью щелочного моющего средства

- Вручную ополосните рукоятку, кабель и зажимы для трубок под струей водопроводной воды, чтобы удалить с устройства все видимые загрязнения. С помощью щетки с мягкой щетиной и раствора нейтрального моющего средства осторожно и тщательно прочистите весь просвет устройства. Во время ополаскивания запустите зажимной патрон и поверните дисковый переключатель. При ополаскивании держите рукоятку зажимным патроном вниз. Промойте струей воды аспирационное отверстие.
- Разместите устройства в моечной машине зажимным патроном вниз, чтобы обеспечить свободное стекание с них воды.

| Автоматическая мойка с помощью щелочного моющего средства |                   |                             |                                    |
|-----------------------------------------------------------|-------------------|-----------------------------|------------------------------------|
| Фаза                                                      | Минимальное время | Температура                 | Моющее средство                    |
| Замачивание 1                                             | 02:00             | Холодная водопроводная вода | Неприменимо                        |
| Мойка 1                                                   | 05:00             | 66 °C (заданное значение)   | Щелочное моющее средство pH ≤ 10,5 |
| Ополаскивание 1                                           | 01:00             | Горячая водопроводная вода  | Неприменимо                        |
| Термическое ополаскивание                                 | 01:00             | не менее 82 °C              | Неприменимо                        |

Визуально проверьте на предмет чистоты.





Medtronic

## Инструкции по повторной обработке

### Микродебридеры

Спинальные шейверы StraightShot M5, StraightShot M4, StraightShot Magnum II, StraightShot III и Midas Rex

### Инструкции по повторной обработке

Инструкции по очистке и стерилизации могут быть изменены. Актуальные инструкции можно найти на веб-узле [manuals.medtronic.com](http://manuals.medtronic.com).

68E3282 F

| Очистка<br>Ручные методы                                                    | <ul style="list-style-type: none"><li>• Извлеките инструменты и оборудование из лотков для инструментов.</li><li>• Не погружайте рукоятку в жидкость.</li><li>• Протрите рукоятку и кабель чистой мягкой тканью, смоченной нейтральным моющим средством.</li><li>• Вручную ополосните рукоятку, кабель и зажимы для трубок под струей водопроводной воды, чтобы удалить с устройства все видимые загрязнения. При ополаскивании держите рукоятку зажимным патроном вниз. Промойте струей воды аспирационное отверстие.</li><li>• Для разрыхления и удаления из инструмента скопившихся тканей используйте раствор ферментативного моющего средства.</li><li>• Протрите электродвигатель и кабель с помощью мягкой ткани, смоченной в растворе ферментативного моющего средства. Осторожно протрите рукоятку, кабель и зажимы для трубок с помощью щетки с мягкой щетиной, смоченной в ферментативном моющем средстве. С помощью щетки с мягкой щетиной осторожно и тщательно прочистите весь просвет устройства. Во время очистки запустите зажимной патрон и поверните дисковый переключатель. С помощью щетки тщательно очистите зажимы для трубок.</li><li>• Вручную ополосните рукоятку, кабель и зажимы для трубок под струей водопроводной воды, чтобы удалить с устройства все видимые загрязнения.</li><li>• Удерживая рукоятку зажимным патроном вниз, тщательно ополосните просвет.*<ul style="list-style-type: none"><li>* Дополнительные инструкции по очистке микродебридера XPS StraightShot M5/M4/спинального шейвера.</li><li>• Во время обычного цикла очистки пропустите слабый поток теплой воды в зажимной патрон (передний конец) и в запорный рычаг StraightShot M4/спинального шейвера.</li><li>• При попадании теплой воды в зажимной патрон выполните несколько оборотов механизма (вращайте колесо), а при попадании воды в запорный рычаг несколько раз задействуйте его (зажимая и отжимая рычаг).</li><li>• Вытряхните остатки воды из рукоятки.</li><li>• МЕРА ПРЕОСТОРОЖНОСТИ. На этой дополнительной фазе очистки поток теплой воды должен быть очень слабым.</li></ul></li></ul> |                                                           |                                                         |                                                                         |                                                                          |                    |  |  |  |  |  |      |                                                            |                                                           |                                                         |                                                                         |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                             |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |      |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |               |  |  |  |
|-----------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|---------------------------------------------------------|-------------------------------------------------------------------------|--------------------------------------------------------------------------|--------------------|--|--|--|--|--|------|------------------------------------------------------------|-----------------------------------------------------------|---------------------------------------------------------|-------------------------------------------------------------------------|--------------------------------------------------------------------------|-------------|--------|--------|--------|--------|--------|-------|--------|--------|-------|--------|-------|-------|-------------------------------------------------------------|--|--|--|--|----------------------------------------------------------------|--|--|--|--|--|---------------------------|-----------------------------------------------------------|--|--|--|--|--------------|-------------|------|--|--|--|-------------------------|------|--|--|--|---------------------------|----------|--|--|--|--------------------------------------|---------|--|--|--|---------|---------------|--|--|--|
| Сушка и смазка                                                              | <ul style="list-style-type: none"><li>• Протрите насухо наконечник и кабель безворсовым полотенцем. Убедитесь в том, что электрические разъемы на концах кабеля сухие.</li><li>• Распылите небольшое количество силиконового спрея на передний зажимной патрон и наружный конец рукоятки.</li><li>• Сразу же после очистки простерилизуйте рукоятку.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                           |                                                         |                                                                         |                                                                          |                    |  |  |  |  |  |      |                                                            |                                                           |                                                         |                                                                         |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                             |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |      |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |               |  |  |  |
| Дезинфекция                                                                 | Не выдерживайте в низкотемпературном растворе глутаральдегида.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                           |                                                         |                                                                         |                                                                          |                    |  |  |  |  |  |      |                                                            |                                                           |                                                         |                                                                         |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                             |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |      |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |               |  |  |  |
| Упаковка                                                                    | <ul style="list-style-type: none"><li>• Может использоваться стандартный оберточный материал для стерилизации. В США должен использоваться хирургический оберточный материал, соответствующий требованиям FDA. Убедитесь, что упаковка достаточно велика, чтобы вместить инструмент и не оказывать давления на уплотнения.</li><li>• Для комплектов инструментов: инструменты можно загружать в специальные лотки для инструментов. Оберните лотки, используя соответствующий метод.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                           |                                                         |                                                                         |                                                                          |                    |  |  |  |  |  |      |                                                            |                                                           |                                                         |                                                                         |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                             |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |      |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |               |  |  |  |
| Стерилизация<br>(указаны минимальные<br>необходимые<br>температура и время) | <p>Указанные ниже параметры стерилизации должны применяться для стерилизации устройств в полностью разобранном виде, если разборка возможна. После стерилизации применяйте стандартные стерильные способы сборки устройств, чтобы сохранить стерильность инструментов. Валидацию прошли все циклы паровой стерилизации инструментария в обертке, при этом инструменты можно стерилизовать как в обертке, так и без нее.</p> <table><tr><th colspan="6">Стерилизация паром</th></tr><tr><th>Цикл</th><th>Паровая стерилизация с гравитационным вытеснением воздуха*</th><th>Паровая стерилизация с гравитационным вытеснением воздуха</th><th>Паровая стерилизация с предварительной откачкой воздуха</th><th>Паровая стерилизация с предварительной откачкой воздуха (Франция / ВОЗ)</th><th>Паровая стерилизация с предварительной откачкой воздуха (Великобритания)</th></tr><tr><td>Температура</td><td>121 °C</td><td>132 °C</td><td>132 °C</td><td>134 °C</td><td>134 °C</td></tr><tr><td>Время</td><td>40 мин</td><td>15 мин</td><td>4 мин</td><td>18 мин</td><td>3 мин</td></tr><tr><td>Сушка</td><td colspan="5">25 минут или до появления визуальных признаков высушивания.</td></tr><tr><td colspan="6">Параметры стерилизации 100 % этиленоксидом (заданные значения)</td></tr><tr><td>Предварительная обработка</td><td colspan="5">При температуре 54°C, относительной влажности 60%, 60 мин</td></tr><tr><td rowspan="5">Стерилизация</td><td>Температура</td><td colspan="4">54°C</td></tr><tr><td>Относительная влажность</td><td colspan="4">60 %</td></tr><tr><td>Концентрация этиленоксида</td><td colspan="4">725 мг/л</td></tr><tr><td>Время воздействия газа (полный цикл)</td><td colspan="4">120 мин</td></tr><tr><td>Аэрация</td><td colspan="4">54°C, 8 часов</td></tr></table>                                                                                                                                                                                                                                                                                                         |                                                           |                                                         |                                                                         |                                                                          | Стерилизация паром |  |  |  |  |  | Цикл | Паровая стерилизация с гравитационным вытеснением воздуха* | Паровая стерилизация с гравитационным вытеснением воздуха | Паровая стерилизация с предварительной откачкой воздуха | Паровая стерилизация с предварительной откачкой воздуха (Франция / ВОЗ) | Паровая стерилизация с предварительной откачкой воздуха (Великобритания) | Температура | 121 °C | 132 °C | 132 °C | 134 °C | 134 °C | Время | 40 мин | 15 мин | 4 мин | 18 мин | 3 мин | Сушка | 25 минут или до появления визуальных признаков высушивания. |  |  |  |  | Параметры стерилизации 100 % этиленоксидом (заданные значения) |  |  |  |  |  | Предварительная обработка | При температуре 54°C, относительной влажности 60%, 60 мин |  |  |  |  | Стерилизация | Температура | 54°C |  |  |  | Относительная влажность | 60 % |  |  |  | Концентрация этиленоксида | 725 мг/л |  |  |  | Время воздействия газа (полный цикл) | 120 мин |  |  |  | Аэрация | 54°C, 8 часов |  |  |  |
| Стерилизация паром                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                           |                                                         |                                                                         |                                                                          |                    |  |  |  |  |  |      |                                                            |                                                           |                                                         |                                                                         |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                             |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |      |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |               |  |  |  |
| Цикл                                                                        | Паровая стерилизация с гравитационным вытеснением воздуха*                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Паровая стерилизация с гравитационным вытеснением воздуха | Паровая стерилизация с предварительной откачкой воздуха | Паровая стерилизация с предварительной откачкой воздуха (Франция / ВОЗ) | Паровая стерилизация с предварительной откачкой воздуха (Великобритания) |                    |  |  |  |  |  |      |                                                            |                                                           |                                                         |                                                                         |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                             |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |      |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |               |  |  |  |
| Температура                                                                 | 121 °C                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 132 °C                                                    | 132 °C                                                  | 134 °C                                                                  | 134 °C                                                                   |                    |  |  |  |  |  |      |                                                            |                                                           |                                                         |                                                                         |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                             |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |      |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |               |  |  |  |
| Время                                                                       | 40 мин                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 15 мин                                                    | 4 мин                                                   | 18 мин                                                                  | 3 мин                                                                    |                    |  |  |  |  |  |      |                                                            |                                                           |                                                         |                                                                         |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                             |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |      |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |               |  |  |  |
| Сушка                                                                       | 25 минут или до появления визуальных признаков высушивания.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                           |                                                         |                                                                         |                                                                          |                    |  |  |  |  |  |      |                                                            |                                                           |                                                         |                                                                         |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                             |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |      |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |               |  |  |  |
| Параметры стерилизации 100 % этиленоксидом (заданные значения)              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                           |                                                         |                                                                         |                                                                          |                    |  |  |  |  |  |      |                                                            |                                                           |                                                         |                                                                         |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                             |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |      |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |               |  |  |  |
| Предварительная обработка                                                   | При температуре 54°C, относительной влажности 60%, 60 мин                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                           |                                                         |                                                                         |                                                                          |                    |  |  |  |  |  |      |                                                            |                                                           |                                                         |                                                                         |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                             |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |      |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |               |  |  |  |
| Стерилизация                                                                | Температура                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 54°C                                                      |                                                         |                                                                         |                                                                          |                    |  |  |  |  |  |      |                                                            |                                                           |                                                         |                                                                         |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                             |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |      |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |               |  |  |  |
|                                                                             | Относительная влажность                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 60 %                                                      |                                                         |                                                                         |                                                                          |                    |  |  |  |  |  |      |                                                            |                                                           |                                                         |                                                                         |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                             |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |      |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |               |  |  |  |
|                                                                             | Концентрация этиленоксида                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 725 мг/л                                                  |                                                         |                                                                         |                                                                          |                    |  |  |  |  |  |      |                                                            |                                                           |                                                         |                                                                         |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                             |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |      |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |               |  |  |  |
|                                                                             | Время воздействия газа (полный цикл)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 120 мин                                                   |                                                         |                                                                         |                                                                          |                    |  |  |  |  |  |      |                                                            |                                                           |                                                         |                                                                         |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                             |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |      |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |               |  |  |  |
|                                                                             | Аэрация                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 54°C, 8 часов                                             |                                                         |                                                                         |                                                                          |                    |  |  |  |  |  |      |                                                            |                                                           |                                                         |                                                                         |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                             |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |      |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |               |  |  |  |
| Техническое обслуживание, осмотр и проверка                                 | <ul style="list-style-type: none"><li>• Перед каждым использованием и после него необходимо осматривать компоненты на предмет повреждения. При обнаружении повреждений не используйте инструмент, пока он не будет отремонтирован.</li><li>• После очистки и стерилизации перед повторным использованием проверьте работоспособность изделия.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                           |                                                         |                                                                         |                                                                          |                    |  |  |  |  |  |      |                                                            |                                                           |                                                         |                                                                         |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                             |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |      |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |               |  |  |  |
| Хранение                                                                    | Во избежание коррозии и скопления остатков тканей в подшипнике и электродвигателе перед отправкой на хранение крайне важно выполнить быструю и полную вакуумную сушку рукоятки.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                           |                                                         |                                                                         |                                                                          |                    |  |  |  |  |  |      |                                                            |                                                           |                                                         |                                                                         |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                             |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |      |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |               |  |  |  |
| Дополнительная информация                                                   | Применяйте температуру выше указанных значений, если это необходимо для выполнения требований правительственных организаций или внутренних правил медицинского учреждения при условии, что температура не превышает 149 °C. Нагрев рукоятки свыше 145 °C может привести к ее повреждению и вызовет аннулирование гарантии.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                           |                                                         |                                                                         |                                                                          |                    |  |  |  |  |  |      |                                                            |                                                           |                                                         |                                                                         |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                             |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |      |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |               |  |  |  |

\* Данный 40-минутный стерилизационный цикл с гравитационным вытеснением воздуха, проходящий при температуре 121 °C, не считается United States Food and Drug Administration (Управление по контролю за пищевыми продуктами и лекарственными средствами США) (US FDA) стандартным стерилизационным циклом. Пользователям следует применять только стерилизаторы и дополнительные принадлежности (например, оберточный материал для стерилизации, стерилизационные пакеты, химические индикаторы, биологические индикаторы и стерилизационные контейнеры), утвержденные US FDA для технических условий выбранного стерилизационного цикла (40 минут и 121 °C).

**Примечание.** Вышеизложенные инструкции прошли валидацию и рекомендованы производителем в качестве процедур. СПОСОБНЫХ подготовить продукт для повторного использования. Ответственность за фактическое осуществление повторной обработки с использованием оборудования, материалов и персонала обрабатывающего предприятия, обеспечивающих требуемый результат, несет обработчик. Обычно для этого необходима валидация процесса и его рутинный контроль.

**Примечание.** Все процессы валидации выполняются согласно требованиям стандарта AAMI TIR12 «Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers» (Разработка, проверка и маркировка повторно используемых устройств медицинского назначения для повторной обработки в учреждениях здравоохранения: рекомендация для производителей устройств медицинского назначения).

Компания Medtronic рекомендует сжигание устройств, которые находились в непосредственном контакте с пациентами, имеющими предполагаемый или подтвержденный диагноз трансмиссивной губчатой энцефалопатии (ПТЭ) или болезни Крейтцфельда-Якоба (БКЯ).

|                                                                                                   |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                            |                                                                                                                                                                                                                                         |                                                                |                                            |
|---------------------------------------------------------------------------------------------------|--|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|--------------------------------------------|
|  <b>Medtronic</b> |  | <b>Инструкции по повторной обработке</b><br>Legend EHS и Legend EHS Stylus                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                            | <b>Инструкции по повторной обработке</b><br>Инструкции по очистке и стерилизации могут быть изменены. Актуальные инструкции можно найти на веб-узле <a href="http://manuals.medtronic.com">manuals.medtronic.com</a> .<br>M000030A234 C |                                                                |                                            |
| <b>Предупреждения и меры предосторожности</b>                                                     |  | <ul style="list-style-type: none"><li>Замачивать устройства или погружать их в жидкость запрещается.</li><li>Запрещается ультразвуковая очистка устройств.</li><li>Запрещается использовать вызывающие коррозию или содержащие хлор чистящие средства, такие как отбеливатель, щелок, ацетон, гипохлорит натрия, едкий натр, муравьиная кислота или растворы, содержащие глутаральдегид.</li><li>Применение мойки-дезинфектора эндоскопов может привести к ухудшению рабочих характеристик.</li><li>После стерилизации паром необходимо дождаться остывания компонентов.</li></ul>                                                                             |                                                                                                                                                            |                                                                                                                                                                                                                                         |                                                                |                                            |
| <b>Ограничения</b>                                                                                |  | Перед повторным использованием инструмента выполняйте проверку его работоспособности.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                            |                                                                                                                                                                                                                                         |                                                                |                                            |
| <b>Важные замечания</b>                                                                           |  | Необходимо следовать процедуре, принятой в медицинском учреждении.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                            |                                                                                                                                                                                                                                         |                                                                |                                            |
| <b>Защита от загрязнений и транспортировка</b>                                                    |  | Рекомендуется выполнять обработку инструментов немедленно после их использования.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                            |                                                                                                                                                                                                                                         |                                                                |                                            |
| <b>Подготовка к обеззараживанию</b>                                                               |  | Необходимо следовать процедуре, принятой в медицинском учреждении.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                            |                                                                                                                                                                                                                                         |                                                                |                                            |
| <b>Очистка Автоматизированные методы (НЕ используйте ультразвуковой моечный аппарат)</b>          |  | <ul style="list-style-type: none"><li>Перед использованием этого метода очистки просмотрите приведенное выше предупреждение, относящееся к мойке-дезинфектору эндоскопов.</li><li>Устройства необходимо извлечь из лотков для инструментов, прежде чем помещать в корзину моечной машины.</li><li>Устройства следует ориентировать в соответствии с рекомендациями производителя моечной машины или аппарата для дезинфекции.</li></ul>                                                                                                                                                                                                                        |                                                                                                                                                            |                                                                                                                                                                                                                                         |                                                                |                                            |
|                                                                                                   |  | <b>Рекомендуемый цикл обработки в моечной машине</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>Фаза</b>                                                                                                                                                | <b>Длительность рециркуляции</b>                                                                                                                                                                                                        | <b>Температура воды</b>                                        | <b>Тип и концентрация моющего средства</b> |
|                                                                                                   |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>Замачивание</b>                                                                                                                                         | 2 мин                                                                                                                                                                                                                                   | Холодная водопроводная вода                                    | –                                          |
|                                                                                                   |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>Промывка</b>                                                                                                                                            | 5 мин                                                                                                                                                                                                                                   | 66 °C (заданное значение)                                      | –                                          |
|                                                                                                   |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>Окончательное ополаскивание</b>                                                                                                                         | 1 мин                                                                                                                                                                                                                                   | Горячая водопроводная вода                                     | –                                          |
| <b>Очистка Ручные методы</b>                                                                      |  | <ul style="list-style-type: none"><li>Протрите наружную поверхность электродвигателя и кабель тканью, смоченной в нейтральном ферментативном моющем составе с показателем pH 6,0–8,0.</li><li>Очистите корпус и зажимной патрон электродвигателя нейлоновой щеткой, смоченной в нейтральном ферментативном моющем средстве.</li><li>Тщательно ополосните электродвигатель в проточной воде, держа его зажимным патроном вниз. Протрите насухо зажимной патрон и электродвигатель салфеткой.</li><li>Удостоверьтесь в том, что после ручной очистки на устройствах отсутствуют видимые загрязнения.</li><li>Тщательно ополосните водопроводной водой.</li></ul> |                                                                                                                                                            |                                                                                                                                                                                                                                         |                                                                |                                            |
| <b>Дезинфекция</b>                                                                                |  | Необходимо следовать процедуре, принятой в медицинском учреждении.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                            |                                                                                                                                                                                                                                         |                                                                |                                            |
| <b>Упаковка</b>                                                                                   |  | Для стерилизации поместите устройства в лоток для инструментов. Устройства можно стерилизовать без обертывания или завернутыми в два слоя однослойной полипропиленовой обертки.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                            |                                                                                                                                                                                                                                         |                                                                |                                            |
| <b>Стерилизация (указаны минимальные необходимые температура и время)</b>                         |  | <b>Стерилизация паром</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                            |                                                                                                                                                                                                                                         |                                                                |                                            |
|                                                                                                   |  | <b>Цикл</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <b>Паровая стерилизация с гравитационным удалением воздуха</b>                                                                                             | <b>Паровая стерилизация с предварительной откачкой воздуха</b>                                                                                                                                                                          | <b>Паровая стерилизация с предварительной откачкой воздуха</b> |                                            |
|                                                                                                   |  | <b>Температура</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 132 °C                                                                                                                                                     | 132 °C                                                                                                                                                                                                                                  | 134 °C                                                         |                                            |
|                                                                                                   |  | <b>Время</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 25 мин                                                                                                                                                     | 4 мин                                                                                                                                                                                                                                   | 3 мин                                                          |                                            |
|                                                                                                   |  | <b>Сушка</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 15 мин                                                                                                                                                     | 15 мин                                                                                                                                                                                                                                  | 10 мин                                                         |                                            |
|                                                                                                   |  | <b>Стерилизация в системе STERRAD</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Из-за ограниченного внутреннего диаметра просвета и длины трубки ЗАПРЕЩАЕТСЯ применять стерилизацию в низкотемпературной газовой плазме перекиси водорода. |                                                                                                                                                                                                                                         |                                                                |                                            |
|                                                                                                   |  | <b>Стерилизация в системе STERIS</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Запрещается стерилизовать в жидкой перуксусной кислоте, так как эта процедура подразумевает погружение.                                                    |                                                                                                                                                                                                                                         |                                                                |                                            |
|                                                                                                   |  | <b>Параметры стерилизации 100 % этиленоксидом</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                            |                                                                                                                                                                                                                                         |                                                                |                                            |
|                                                                                                   |  | <b>Предварительная обработка</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | При температуре 51–59 °C, относительной влажности 70 ± 5 %, 30 мин                                                                                         |                                                                                                                                                                                                                                         |                                                                |                                            |
|                                                                                                   |  | <b>Стерилизация</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <b>Температура</b>                                                                                                                                         | 51–59 °C                                                                                                                                                                                                                                |                                                                |                                            |
|                                                                                                   |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>Относительная влажность</b>                                                                                                                             | 70 +/- 5 %                                                                                                                                                                                                                              |                                                                |                                            |
|                                                                                                   |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>Концентрация этиленоксида</b>                                                                                                                           | 725 ± 25 мг/л                                                                                                                                                                                                                           |                                                                |                                            |
|                                                                                                   |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>Время воздействия газа (полный цикл)</b>                                                                                                                | 4 часа                                                                                                                                                                                                                                  |                                                                |                                            |
|                                                                                                   |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>Аэрация</b>                                                                                                                                             | 51–59 °C, 18 часов                                                                                                                                                                                                                      |                                                                |                                            |
| <b>Техническое обслуживание, осмотр и проверка</b>                                                |  | <ul style="list-style-type: none"><li>Перед каждым использованием и после него необходимо осматривать компоненты на предмет повреждения. В случае обнаружения повреждения запрещается использовать инструмент, пока он не будет отремонтирован.</li><li>Перед повторным использованием инструмента выполняйте проверку его работоспособности.</li></ul>                                                                                                                                                                                                                                                                                                        |                                                                                                                                                            |                                                                                                                                                                                                                                         |                                                                |                                            |
| <b>Хранение</b>                                                                                   |  | Храните вместе с другими стерильными устройствами.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                            |                                                                                                                                                                                                                                         |                                                                |                                            |
| <b>Дополнительная информация</b>                                                                  |  | Отсутствует.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                            |                                                                                                                                                                                                                                         |                                                                |                                            |

Примечание. Вышеизложенные инструкции прошли валидацию и рекомендованы производителем в качестве процедур. СПОСОБНЫХ подготовить продукт для повторного использования. Ответственность за фактическое осуществление повторной обработки с использованием оборудования, материалов и персонала обрабатывающего предприятия, обеспечивающих требуемый результат, несет обработчик. Обычно для этого необходима валидация процесса и его рутинный контроль.

Примечание. Все процессы валидации выполняются согласно требованиям стандарта AAMI TIR12 «Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers» (Разработка, проверка и маркировка повторно используемых устройств медицинского назначения для повторной обработки в учреждениях здравоохранения: рекомендация для производителей устройств медицинского назначения).

Компания Medtronic рекомендует сжигание устройств, которые находились в непосредственном контакте с пациентами, имеющими предполагаемый или подтвержденный диагноз трансмиссивной губчатой энцефалопатии (ТГЭ) или болезни Крейтцфельда-Якоба (БКЯ).





Medtronic

## Инструкции по повторной обработке Stylus Touch

Инструкции по повторной обработке  
Инструкции по очистке и стерилизации могут быть изменены. Актуальные инструкции можно найти на веб-узле [manuals.medtronic.com](http://manuals.medtronic.com).  
68E4132 D

|                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                       |                                                         |                                                         |                                                                     |                                                                              |
|-----------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|---------------------------------------------------------|---------------------------------------------------------------------|------------------------------------------------------------------------------|
| Предупреждения и меры предосторожности                                            | <ul style="list-style-type: none"><li>• Замачивать устройства или погружать их в жидкость запрещается.</li><li>• Запрещается ультразвуковая очистка устройств.</li><li>• Запрещается использовать вызывающие коррозию или содержащие хлор чистящие средства, такие как отбеливатель, щелок, ацетон, гипохлорит натрия, едкий натр, муравьиная кислота или растворы, содержащие глутаральдегид.</li><li>• Применение мойки-дезинфектора эндоскопов может привести к ухудшению рабочих характеристик.</li><li>• После стерилизации паром необходимо дождаться остывания компонентов.</li></ul> |                                                                                                                                       |                                                         |                                                         |                                                                     |                                                                              |
| Ограничения                                                                       | Перед повторным использованием инструмента выполняйте проверку его работоспособности.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                       |                                                         |                                                         |                                                                     |                                                                              |
| Важные замечания                                                                  | Данный продукт поставляется нестерильным. Перед первым использованием и последующими повторными применениями следует выполнить очистку и стерилизацию изделия.                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                       |                                                         |                                                         |                                                                     |                                                                              |
| Защита от загрязнений и транспортировка                                           | Рекомендуется выполнять обработку инструментов немедленно после их использования.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                       |                                                         |                                                         |                                                                     |                                                                              |
| Подготовка к обеззараживанию                                                      | Необходимо следовать процедуре, принятой в медицинском учреждении.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                       |                                                         |                                                         |                                                                     |                                                                              |
| Очистка Автоматизированные методы (НЕ используйте ультразвуковой моечный аппарат) | Перед использованием этого метода очистки просмотрите приведенное выше предупреждение, относящееся к мойке-дезинфектору эндоскопов. Устройства необходимо извлечь из лотков для инструментов, прежде чем помещать в корзину моечной машины. Устройства следует ориентировать в соответствии с рекомендациями производителя моечной машины или аппарата для дезинфекции. Удостоверьтесь в том, что после автоматической очистки на устройствах отсутствуют видимые загрязнения.                                                                                                               |                                                                                                                                       |                                                         |                                                         |                                                                     |                                                                              |
|                                                                                   | Рекомендуемый цикл обработки в моечной машине                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Фаза                                                                                                                                  | Длительность рециркуляции                               | Температура воды                                        | Тип и концентрация моющего средства                                 |                                                                              |
|                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Замачивание                                                                                                                           | 2 мин                                                   | Холодная водопроводная вода                             | –                                                                   |                                                                              |
|                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Промывка                                                                                                                              | 5 мин                                                   | 66 °C (заданное значение)                               | Нейтральное ферментативное моющее средство с показателем pH 6,0–8,0 |                                                                              |
|                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Ополаскивание                                                                                                                         | 1 мин                                                   | Горячая водопроводная вода                              | –                                                                   |                                                                              |
| Очистка Ручные методы                                                             | <ul style="list-style-type: none"><li>• Протрите все наружные поверхности тканью, смоченной в нейтральном ферментативном моющем составе с показателем pH 6,0–8,0.</li><li>• Очистите корпус и зажимной патрон электродвигателя нейлоновой щеткой, смоченной в нейтральном ферментативном моющем средстве.</li><li>• Тщательно ополосните электродагатель в проточной воде, держа его зажимным патроном вниз.</li><li>• Просушите полотенцем.</li><li>• Удостоверьтесь в том, что после ручной очистки на устройствах отсутствуют видимые загрязнения.</li></ul>                              |                                                                                                                                       |                                                         |                                                         |                                                                     |                                                                              |
| Дезинфекция                                                                       | Необходимо следовать процедуре, принятой в медицинском учреждении.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                       |                                                         |                                                         |                                                                     |                                                                              |
| Упаковка                                                                          | Для стерилизации поместите устройства в лоток для инструментов. Устройства можно стерилизовать без обертыивания или обернутыми двумя слоями однослойной полипропиленовой обертки.                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                       |                                                         |                                                         |                                                                     |                                                                              |
| Стерилизация (указаны минимальные необходимые температура и время)                | Стерилизация паром                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                       |                                                         |                                                         |                                                                     |                                                                              |
|                                                                                   | Цикл                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Паровая стерилизация с предварительной откачкой воздуха                                                                               | Паровая стерилизация с гравитационным удалением воздуха | Паровая стерилизация с предварительной откачкой воздуха | Паровая стерилизация с предварительной откачкой воздуха             | Экспресс-стерилизация (с предварительной откачкой воздуха, без обертыивания) |
|                                                                                   | Температура                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 132 °C                                                                                                                                | 132 °C                                                  | 134 °C                                                  | 134 °C                                                              | 132 °C                                                                       |
|                                                                                   | Время                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 4 мин                                                                                                                                 | 25 мин                                                  | 3 мин                                                   | 18 мин                                                              | 4 мин                                                                        |
|                                                                                   | Сушка                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 15 мин                                                                                                                                | 15 мин                                                  | 10 мин                                                  | 20 мин                                                              |                                                                              |
|                                                                                   | Стерилизация в системе STERRAD                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Валидация не проводилась.                                                                                                             |                                                         |                                                         |                                                                     |                                                                              |
|                                                                                   | Параметры стерилизации 100 % этиленоксидом                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                       |                                                         |                                                         |                                                                     |                                                                              |
|                                                                                   | Предварительная обработка                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | при температуре 55 °C и относительной влажности 70 %, заданное значение вакуума: 1,3 фунта на кв. дюйм (8,96 кПа) абс., время: 30 мин |                                                         |                                                         |                                                                     |                                                                              |
|                                                                                   | Стерилизация                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Температура                                                                                                                           |                                                         | 55 °C ± 4 °C                                            |                                                                     |                                                                              |
|                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Относительная влажность                                                                                                               |                                                         | 70 +/- 5 %                                              |                                                                     |                                                                              |
|                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Концентрация этиленоксида                                                                                                             |                                                         | 725 ± 25 мг/л                                           |                                                                     |                                                                              |
|                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Время воздействия газа (полный цикл)                                                                                                  |                                                         | 4 часа                                                  |                                                                     |                                                                              |
|                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Аэрация                                                                                                                               |                                                         | 55 °C +/- 4 °C, 12 часов                                |                                                                     |                                                                              |
| Техническое обслуживание, осмотр и проверка                                       | <ul style="list-style-type: none"><li>• Перед каждым использованием и после него необходимо осматривать компоненты на предмет повреждения. В случае обнаружения повреждения запрещается использовать инструмент, пока он не будет отремонтирован.</li><li>• После очистки и стерилизации перед повторным использованием проверьте работоспособность изделия.</li></ul>                                                                                                                                                                                                                       |                                                                                                                                       |                                                         |                                                         |                                                                     |                                                                              |
| Хранение                                                                          | Храните вместе с другими стерильными устройствами.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                       |                                                         |                                                         |                                                                     |                                                                              |
| Дополнительная информация                                                         | Отсутствует.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                       |                                                         |                                                         |                                                                     |                                                                              |

Примечание. Вышеизложенные инструкции прошли валидацию и рекомендованы производителем в качестве процедур, СПОСОБНЫХ подготовить продукт для повторного использования. Ответственность за фактическое осуществление повторной обработки с использованием оборудования, материалов и персонала обрабатывающего предприятия, обеспечивающих требуемый результат, несет обработчик. Обычно для этого необходима валидация процесса и его рутинный контроль.

Примечание. Все процессы валидации выполняются согласно требованиям стандарта AAMI TIR12 «Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers» (Разработка, проверка и маркировка повторно используемых устройств медицинского назначения для повторной обработки в учреждениях здравоохранения: рекомендация для производителей устройств медицинского назначения).

Компания Medtronic рекомендует сжигание устройств, которые находились в непосредственном контакте с пациентами, имеющими предполагаемый или подтвержденный диагноз трансмиссивной губчатой энцефалопатии (ТГЭ) или болезни Крейтцфельда-Якоба (БКЯ).

|                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                  |                                                         |                                                                         |                                                                          |  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|-------------------------------------------------------------------------|--------------------------------------------------------------------------|--|
| <div><div></div><div>Инструкции по повторной обработке<br/>Насадки и трубки Legend</div></div>                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Инструкции по повторной обработке<br>Инструкции по очистке и стерилизации могут быть изменены. Актуальные инструкции можно найти на веб-узле <a href="http://manuals.medtronic.com">manuals.medtronic.com</a> .<br>M000030A235 D |                                                         |                                                                         |                                                                          |  |
| Предупреждения и меры предосторожности                                                                                                                                                                                                                                                                                                                  | <ul style="list-style-type: none"><li>Замачивать устройства или погружать их в жидкость запрещается.</li><li>Запрещается ультразвуковая очистка устройств.</li><li>Запрещается использовать вызывающие коррозию или содержащие хлор чистящие средства, такие как отбеливатель, щелок, ацетон, гипохлорит натрия, едкий натр, муравьиная кислота или растворы, содержащие глутаральдегид.</li><li>Применение мойки-дезинфектора эндоскопов может привести к преждевременному ухудшению рабочих характеристик.</li><li>После стерилизации паром необходимо дождаться остывания компонентов.</li><li>Используйте ТОЛЬКО нейлоновые чистящие щетки. Чистящие щетки из другого материала оставляют следы, которые препятствуют надежной фиксации инструмента в наконечнике.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                  |                                                         |                                                                         |                                                                          |  |
| Ограничения                                                                                                                                                                                                                                                                                                                                             | Перед повторным использованием инструмента выполняйте проверку его работоспособности.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                  |                                                         |                                                                         |                                                                          |  |
| Важные замечания                                                                                                                                                                                                                                                                                                                                        | Необходимо следовать процедуре, принятой в медицинском учреждении.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                  |                                                         |                                                                         |                                                                          |  |
| Защита от загрязнений и транспортировка                                                                                                                                                                                                                                                                                                                 | Рекомендуется выполнять обработку инструментов немедленно после их использования.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                  |                                                         |                                                                         |                                                                          |  |
| Подготовка к обеззараживанию                                                                                                                                                                                                                                                                                                                            | Необходимо следовать процедуре, принятой в медицинском учреждении.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                  |                                                         |                                                                         |                                                                          |  |
| Очистка<br>Автоматизированные методы (НЕ используйте ультразвуковой моечный аппарат)                                                                                                                                                                                                                                                                    | <ul style="list-style-type: none"><li>Перед использованием этого метода очистки просмотрите приведенное выше предупреждение, относящееся к мойке-дезинфектору эндоскопов.</li><li>Перед загрузкой в автоматическую моечную машину насадки/трубки следует промыть вручную водопроводной водой, пока не будут удалены видимые следы загрязнений.</li><li>Устройства необходимо извлечь из лотков для инструментов, прежде чем помещать в корзину моечной машины.</li><li>Устройства следует ориентировать в соответствии с рекомендациями производителя моечной машины или аппарата для дезинфекции.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                  |                                                         |                                                                         |                                                                          |  |
|                                                                                                                                                                                                                                                                                                                                                         | Рекомендуемый цикл обработки в моечной машине                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | База                                                                                                                                                                                                                             | Длительность рециркуляции                               | Температура воды                                                        | Тип и концентрация моющего средства                                      |  |
|                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Замачивание                                                                                                                                                                                                                      | 2 мин                                                   | Холодная водопроводная вода                                             | -                                                                        |  |
|                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Промывка                                                                                                                                                                                                                         | 5 мин                                                   | 66 °C (заданное значение)                                               | Нейтральное ферментативное моющее средство с показателем pH 6,0–8,0      |  |
|                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Ополаскивание                                                                                                                                                                                                                    | 1 мин                                                   | Горячая водопроводная вода                                              | -                                                                        |  |
| Очистка<br>Ручные методы                                                                                                                                                                                                                                                                                                                                | <ol style="list-style-type: none"><li>1. Протрите все насадки и телескопические трубки тканью, смоченной раствором для чистки хирургических инструментов.</li><li>2. Погрузите головку контрольной насадки в раствор для чистки хирургических инструментов и включите электродвигатель на одну минуту.</li><li>3. Остальные насадки и трубки можно механически поболтать в чистящем растворе, но не замачивать и не погружать их полностью.</li><li>4. Наружные поверхности насадок и трубок и внутренние соединительные поверхности можно почистить нейлоновой щеткой, смоченной в растворе для чистки хирургических инструментов.</li><li>5. Для прямых насадок, насадок на ножках и телескопических прямых трубок имеются чистящие щетки, размер которых соответствует внутреннему диаметру насадок и телескопических трубок. Протолкните щетку, смоченную раствором для чистки хирургических инструментов, через насадку или телескопическую трубку с задней стороны вперед, чтобы разрыхлить и удалить остатки тканей внутри.</li><li>6. Подвигайте все движущиеся детали взад и вперед, чтобы тщательно очистить раствором всю насадку, например втулку на насадке с ножкой, насадку перфоратора.</li><li>7. Тщательно ополосните водопроводной водой.</li></ol> |                                                                                                                                                                                                                                  |                                                         |                                                                         |                                                                          |  |
| Сушка и смазка                                                                                                                                                                                                                                                                                                                                          | <ol style="list-style-type: none"><li>1. Тщательно просушите насадки. Можно продуть влагу с задней части насадки вперед с помощью сжатого воздуха.</li></ol> <p><b>Примечание.</b> Medtronic больше не рекомендует применение чистящего сопла для насадок Legend (PA120), т.к. это может привести к перегреву некоторых насадок.</p> <ol style="list-style-type: none"><li>2. С помощью смазки в аэрозольной упаковке (напр., спрей Pana) проделайте следующую процедуру для смазки насадок.<ul style="list-style-type: none"><li>• Держа аэрозольный баллончик на расстоянии 10–15 см от насадки, нанесите смазку на все движущиеся, вращающиеся или скользящие детали, делая по три коротких нажатия для смазки каждой детали.</li><li>• Подвигайте движущиеся части для надлежащей смазки.</li><li>• Удалите излишки смазки чистой тканью.</li></ul></li></ol>                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                  |                                                         |                                                                         |                                                                          |  |
| Дезинфекция                                                                                                                                                                                                                                                                                                                                             | Необходимо следовать процедуре, принятой в медицинском учреждении.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                  |                                                         |                                                                         |                                                                          |  |
| Упаковка                                                                                                                                                                                                                                                                                                                                                | Для стерилизации поместите устройства в лоток для инструментов. Устройства можно стерилизовать без обертывания или обернутыми двумя слоями однослойной полипропиленовой обертки.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                  |                                                         |                                                                         |                                                                          |  |
| Стерилизация<br>(указаны минимальные необходимые температура и время)                                                                                                                                                                                                                                                                                   | Стерилизация паром                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                  |                                                         |                                                                         |                                                                          |  |
|                                                                                                                                                                                                                                                                                                                                                         | Цикл                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Паровая стерилизация с гравитационным удалением воздуха                                                                                                                                                                          | Паровая стерилизация с предварительной откачкой воздуха | Паровая стерилизация с предварительной откачкой воздуха (Франция / ВОЗ) | Паровая стерилизация с предварительной откачкой воздуха (Великобритания) |  |
|                                                                                                                                                                                                                                                                                                                                                         | Температура                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 132 °C                                                                                                                                                                                                                           | 132 °C                                                  | 134 °C                                                                  | 134 °C                                                                   |  |
|                                                                                                                                                                                                                                                                                                                                                         | Время                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 15 мин                                                                                                                                                                                                                           | 1 мин                                                   | 15 мин                                                                  | 1 мин                                                                    |  |
|                                                                                                                                                                                                                                                                                                                                                         | Сушка                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 15 мин                                                                                                                                                                                                                           | 15 мин                                                  | 20 мин                                                                  | 10 мин                                                                   |  |
|                                                                                                                                                                                                                                                                                                                                                         | Стерилизация в системе STERRAD                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Из-за ограниченного внутреннего диаметра просвета и длины трубки ЗАПРЕЩАЕТСЯ применять стерилизацию в низкотемпературной газовой плазме перекиси водорода.                                                                       |                                                         |                                                                         |                                                                          |  |
|                                                                                                                                                                                                                                                                                                                                                         | Стерилизация в системе STERIS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Запрещается стерилизовать в жидкой перуксусной кислоте, так как эта процедура подразумевает погружение.                                                                                                                          |                                                         |                                                                         |                                                                          |  |
|                                                                                                                                                                                                                                                                                                                                                         | Параметры стерилизации 100 % этиленоксидом                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                  |                                                         |                                                                         |                                                                          |  |
|                                                                                                                                                                                                                                                                                                                                                         | Предварительная обработка                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | При температуре 51–59 °C, относительной влажности 70 ± 5 %, 30 мин                                                                                                                                                               |                                                         |                                                                         |                                                                          |  |
|                                                                                                                                                                                                                                                                                                                                                         | Стерилизация                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Температура                                                                                                                                                                                                                      | 51–59 °C                                                |                                                                         |                                                                          |  |
|                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Относительная влажность                                                                                                                                                                                                          | 70 ± 5%                                                 |                                                                         |                                                                          |  |
|                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Концентрация этиленоксида                                                                                                                                                                                                        | 725 ± 25 мг/л                                           |                                                                         |                                                                          |  |
|                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Время воздействия газа (полный цикл)                                                                                                                                                                                             | 4 часа                                                  |                                                                         |                                                                          |  |
|                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Аэрация                                                                                                                                                                                                                          | 51–59 °C, 18 часов                                      |                                                                         |                                                                          |  |
| <ul style="list-style-type: none"><li>Перед каждым использованием и после него необходимо осматривать компоненты на предмет повреждения. В случае обнаружения повреждения запрещается использовать инструмент, пока он не будет отремонтирован.</li><li>Перед повторным использованием инструмента выполняйте проверку его работоспособности.</li></ul> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                  |                                                         |                                                                         |                                                                          |  |
| Хранение                                                                                                                                                                                                                                                                                                                                                | Храните вместе с другими стерильными устройствами.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                  |                                                         |                                                                         |                                                                          |  |
| Дополнительная информация                                                                                                                                                                                                                                                                                                                               | Отсутствует.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                  |                                                         |                                                                         |                                                                          |  |

**Примечание.** Вышеизложенные инструкции прошли валидацию и рекомендованы производителем в качестве процедур, СПОСОБНЫХ подготовить продукт для повторного использования. Ответственность за фактическое осуществление повторной обработки с использованием оборудования, материалов и персонала обрабатывающего предприятия, обеспечивающих требуемый результат, несет обработчик. Обычно для этого необходимы валидация процесса и его рутинный контроль.

**Примечание.** Все процессы валидации выполняются согласно требованиям стандарта AAMI TIR12 «Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers» (Разработка, проверка и маркировка повторно используемых устройств медицинского назначения для повторной обработки в учреждениях здравоохранения: рекомендация для производителей устройств медицинского назначения).

Компания Medtronic рекомендует сжигание устройств, которые находились в непосредственном контакте с пациентами, имеющими предполагаемый или подтвержденный диагноз трансмиссивной губчатой энцефалопатии (ТГЭ) или болезни Крейтцфельда-Якоба (БКЯ).



Medtronic

## Инструкции по повторной обработке инструментов многоразового использования Боры Skeeter Oto-Flex

Инструкции по повторной обработке  
Инструкции по очистке и стерилизации  
могут быть изменены. Актуальные  
инструкции можно найти на веб-узле  
[manuals.medtronic.com](http://manuals.medtronic.com).  
68E3968 F

|                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                              |                                                           |                                                         |                                                                       |                                                                          |
|--------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------|-----------------------------------------------------------|---------------------------------------------------------|-----------------------------------------------------------------------|--------------------------------------------------------------------------|
| Предупреждения и меры предосторожности                             | <ul style="list-style-type: none"><li>• Перед повторной обработкой боры и/или рукоятки снимите бор с рукоятки.</li><li>• Перед стерилизацией внимательно осмотрите кончики боров.</li><li>• Боры подлежат замене при наличии следующих признаков:<ul style="list-style-type: none"><li>• зазубрины на режущих поверхностях;</li><li>• заметный износ политетрафторэтиленовых (ПТФЭ) подшипников;</li><li>• выраженные изгибы или вмятины на сердечнике бора.</li></ul></li><li>• Замачивание устройств в холодных растворах, содержащих глутаральдегид, хлор или аммиак, а также сухожаровая стерилизация не рекомендуются, поскольку эти процедуры могут повредить бор.</li><li>• Храните боры в чистом сухом месте.</li></ul>                                                                                                                                       |                                                                                              |                                                           |                                                         |                                                                       |                                                                          |
| Ограничения                                                        | Утилизируйте боры с признаками повреждения или износа.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                              |                                                           |                                                         |                                                                       |                                                                          |
| Важные замечания                                                   | <ul style="list-style-type: none"><li>• Перед чисткой и стерилизацией снимите боры с рукоятки.</li><li>• После каждого использования немедленно тщательно промывайте инструменты деионизированной водой.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                              |                                                           |                                                         |                                                                       |                                                                          |
| Защита от загрязнений и транспортировка                            | Рекомендуется повторно обрабатывать инструменты как можно скорее после использования.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                              |                                                           |                                                         |                                                                       |                                                                          |
| Подготовка к обеззараживанию                                       | После каждого использования немедленно тщательно промывайте инструменты деионизированной водой.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                              |                                                           |                                                         |                                                                       |                                                                          |
| Чистка: автоматизированная                                         | <ul style="list-style-type: none"><li>• Перед укладкой в корзины моечной машины извлекайте боры из лотков для инструментов.</li><li>• Располагайте боры в соответствии с рекомендациями производителей моечного или дезинфицирующего оборудования.</li><li>• Используйте щелочные моющие средства или средства с нейтральным pH, рекомендованные производителями моечного или дезинфицирующего оборудования или производителями моющих средств.</li><li>• После очистки нанесите тонкий слой силиконового спрея или спрея Rapra следующим образом: удерживая бор за подшипник из PTFE, вращайте бор так, чтобы спрей попал внутрь подшипника.</li></ul>                                                                                                                                                                                                               |                                                                                              |                                                           |                                                         |                                                                       |                                                                          |
|                                                                    | Фаза                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Длительность рециркуляции                                                                    | Температура воды                                          | Тип моющего средства                                    |                                                                       |                                                                          |
|                                                                    | Замачивание 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 3 мин                                                                                        | Холодная водопроводная вода                               | Не применимо                                            |                                                                       |                                                                          |
|                                                                    | Мойка с ферментами                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 5 мин                                                                                        | Горячая водопроводная вода                                | Ферментативное моющее средство с нейтральным pH         |                                                                       |                                                                          |
|                                                                    | Мойка 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 5 мин                                                                                        | Заданное значение 66 °C                                   | Моющее средство с нейтральным pH                        |                                                                       |                                                                          |
| Ополаскивание 1                                                    | 3 мин                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Горячая водопроводная вода                                                                   | Не применимо                                              |                                                         |                                                                       |                                                                          |
| Чистка: ручная                                                     | <ul style="list-style-type: none"><li>• Замочите в теплом (менее 43 °C) мягком (pH 7,0–8,5) растворе ферментативного моющего средства и деионизированной воды и выдержите не менее 2 минут.</li><li>• Затем выполните ультразвуковую чистку в теплом растворе мягкого моющего средства (менее 43 °C; pH 7,0–8,5) и деионизированной воды в течение не менее 10 минут.</li><li>• Тщательно ополосните деионизированной водой и вытрите насухо.</li><li>• После очистки нанесите тонкий слой силиконового спрея или спрея Rapra следующим образом: удерживая бор за подшипник из PTFE, вращайте бор так, чтобы спрей попал внутрь подшипника.</li></ul> <p><b>Примечание.</b> При использовании ультразвукового очистителя или струйной моечной машины следуйте рекомендациям производителя, особенно в отношении шарнирных инструментов и ориентации инструментов.</p> |                                                                                              |                                                           |                                                         |                                                                       |                                                                          |
| Дезинфекция                                                        | Не замачивайте в холодном растворе глутаральдегида.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                              |                                                           |                                                         |                                                                       |                                                                          |
| Упаковка                                                           | <ul style="list-style-type: none"><li>• Может использоваться стандартный оберточный материал для стерилизации. В США должен использоваться хирургический оберточный материал, утвержденный FDA. Убедитесь, что упаковка достаточно велика, чтобы вместить инструмент и не оказывать давления на уплотнения.</li><li>• В комплектах: Инструменты можно загружать в специальные лотки для инструментов компании Medtronic Xomed. Убедитесь, что режущие края изолированы. Оберните лотки, используя соответствующий метод.</li></ul>                                                                                                                                                                                                                                                                                                                                    |                                                                                              |                                                           |                                                         |                                                                       |                                                                          |
| Стерилизация (указаны минимальные необходимые температура и время) | <ul style="list-style-type: none"><li>• Указанные ниже параметры стерилизации должны применяться для стерилизации устройств в полностью разобранном состоянии, если разборка возможна. После стерилизации применяйте стандартные асептические способы сборки устройств, чтобы сохранить стерильность инструментов.</li><li>• Валидация всех циклов стерилизации паром выполнялась с обертыванием. Инструменты можно стерилизовать как в обертке, так и без обертки</li></ul>                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                              |                                                           |                                                         |                                                                       |                                                                          |
|                                                                    | Цикл                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Паровая стерилизация с гравитационным вытеснением воздуха                                    | Паровая стерилизация с гравитационным вытеснением воздуха | Паровая стерилизация с предварительной откачкой воздуха | Паровая стерилизация с предварительной откачкой воздуха (Франция/ВОЗ) | Паровая стерилизация с предварительной откачкой воздуха (Великобритания) |
|                                                                    | Температура                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 121 °C                                                                                       | 132 °C                                                    | 132 °C                                                  | 134 °C                                                                | 134 °C                                                                   |
|                                                                    | Время                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 30 мин                                                                                       | 10 мин                                                    | 4 мин                                                   | 18 мин                                                                | 3 мин                                                                    |
|                                                                    | Сушка                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 15 минут или до появления визуальных признаков высушивания                                   |                                                           |                                                         |                                                                       |                                                                          |
|                                                                    | Стерилизация в системе STERRAD                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Валидация не проводилась.                                                                    |                                                           |                                                         |                                                                       |                                                                          |
|                                                                    | Параметры стерилизации 100 % этиленоксидом                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                              |                                                           |                                                         |                                                                       |                                                                          |
|                                                                    | Обработка в камере                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                              |                                                           | Стерилизация                                            |                                                                       |                                                                          |
|                                                                    | Температура                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 54 ± 2 °C                                                                                    | Температура                                               |                                                         |                                                                       | 54 ± 2 °C                                                                |
|                                                                    | Относительная влажность                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 60 ± 5 %                                                                                     | Относительная влажность                                   |                                                         |                                                                       | 60 ± 5 %                                                                 |
|                                                                    | Заданное значение отрицательного давления                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 8,9 кПа                                                                                      | Концентрация этиленоксида                                 |                                                         |                                                                       | 600 ± 25 мг/л                                                            |
|                                                                    | Продолжительность предварительной обработки                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 30 мин                                                                                       | Время обработки газом (полный цикл)                       |                                                         |                                                                       | 120 мин                                                                  |
|                                                                    | Аэрация                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 8 ч аэрации с нагреванием до температуры 48–52 °C или 24 ч аэрации при комнатной температуре |                                                           |                                                         |                                                                       |                                                                          |
| Техническое обслуживание, осмотр и проверка                        | Утилизируйте боры с признаками повреждения или износа.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                              |                                                           |                                                         |                                                                       |                                                                          |
| Хранение                                                           | Храните боры в чистом сухом месте.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                              |                                                           |                                                         |                                                                       |                                                                          |
| Дополнительная информация                                          | Отсутствует                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                              |                                                           |                                                         |                                                                       |                                                                          |

**Примечание.** Вышеизложенные инструкции валидированы производителем в качестве процедур, СПОСОБНЫХ подготовить продукт для повторного использования. Обработчик несет ответственность за то, чтобы повторная обработка выполнялась с помощью валидированного оборудования для достижения требуемого результата. Обычно для этого требуется валидация и плановый контроль процесса. Некоторые устройства укомплектованы особыми инструкциями по сборке. В этом случае см. дополнительные инструкции на вкладыше по сборке, поставляемому с устройством.

Все процессы валидации выполняются согласно требованиям стандарта AAMI TIR12 «Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers» (Разработка, проверка и маркировка повторно используемых устройств медицинского назначения для повторной обработки в учреждениях здравоохранения: рекомендация для производителей устройств медицинского назначения).

Компания Medtronic рекомендует сжигание устройств, которые находились в непосредственном контакте с пациентами, имеющими предполагаемый или подтвержденный диагноз трансмиссивной губчатой энцефалопатии (ПГЭ) или болезни Крейтцфельда-Якоба (БКЯ).



|                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                |                                                                  |                                                                  |                                                                                     |                                                                                   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|------------------------------------------------------------------|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|
| <div> <b>Medtronic</b></div> <div><div>Инструкции по повторной<br/>обработке</div><div>Наконечник Skeeter</div></div> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Инструкции по повторной обработке<br>Инструкции по очистке и стерилизации могут быть<br>изменены. Актуальные инструкции можно найти на<br>веб-узле <b>manuals.medtronic.com</b> .<br>68E3969 G |                                                                  |                                                                  |                                                                                     |                                                                                   |
| Предупреждения и меры<br>предосторожности                                                                                                                                                             | <ul style="list-style-type: none"><li>• Перед очисткой отсоединяйте шнур питания от сети.</li><li>• Не погружайте этот инструмент полностью в жидкость и не выполняйте ультразвуковую чистку.</li><li>• Не вводите инструменты для очистки в канюлированную ось рукоятки.</li><li>• Не выполняйте стерилизацию в низкотемпературном растворе глутаральдегида. В противном случае гарантия будет аннулирована.</li><li>• Не используйте органические растворители для чистки зажимного устройства бора.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                |                                                                  |                                                                  |                                                                                     |                                                                                   |
| Ограничения                                                                                                                                                                                           | После очистки и стерилизации перед повторным использованием проверьте работоспособность изделия.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                |                                                                  |                                                                  |                                                                                     |                                                                                   |
| Важные замечания                                                                                                                                                                                      | <ul style="list-style-type: none"><li>• Данный продукт поставляется нестерильным. Перед первым использованием и последующими повторными применениями следует выполнить очистку и стерилизацию изделия.</li><li>• Для удаления случайно попавших на разъем кабеля рукоятки остаточных загрязнений используйте мягкую щетку и изопропиловый спирт.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                |                                                                  |                                                                  |                                                                                     |                                                                                   |
| Защита от загрязнений и<br>транспортировка                                                                                                                                                            | Рекомендуется выполнять обработку инструментов немедленно после их использования.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                |                                                                  |                                                                  |                                                                                     |                                                                                   |
| Подготовка<br>к обеззараживанию                                                                                                                                                                       | Разборка не требуется. Достаточно извлечь бор.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                |                                                                  |                                                                  |                                                                                     |                                                                                   |
| Очистка<br>Автоматизированные<br>методы (НЕ используйте<br>ультразвуковой моечный<br>аппарат)                                                                                                         | <ul style="list-style-type: none"><li>• Перед укладкой в корзину моечной машины извлекайте инструменты и оборудование из всех лотков для стерилизации.</li><li>• Располагайте устройства в соответствии с рекомендациями производителей моечного или дезинфицирующего оборудования.</li><li>• Используйте щелочные моющие средства или средства с нейтральным pH, рекомендованные производителями моечного или дезинфицирующего оборудования или производителями моющих средств.</li><li>• Проведенная валидация методов очистки продемонстрировала, что эффективная очистка данных изделий достигается при автоматическом цикле моюще-дезинфицирующего оборудования общей продолжительностью не менее 44 минут, включая предварительную мойку, основную мойку, ополаскивание и промывку горячим раствором. Промывка горячим раствором должна выполняться не менее 10 минут при температуре не ниже 60 °C.</li></ul> |                                                                                                                                                                                                |                                                                  |                                                                  |                                                                                     |                                                                                   |
| Очистка Ручные методы                                                                                                                                                                                 | <ul style="list-style-type: none"><li>• Выполните тщательную чистку ферментативным моющим средством. Не погружайте этот инструмент полностью в жидкость.</li><li>• Чистка канюлированной игловидной носовой части выполняется погружением в раствор моющего средства до уровня кнопки высвобождения бора. Не вводите инструменты для чистки в канюлированную ось рукоятки.</li><li>• Промойте погружением дистального конца рукоятки (до уровня кнопки высвобождения бора) в дистиллированную воду. Осторожным вращательным движением удалите остатки чистящего раствора. Избегайте накопления воды под кожухом электродвигателя. Стряхивайте избыток воды движением сверху вниз.</li></ul>                                                                                                                                                                                                                          |                                                                                                                                                                                                |                                                                  |                                                                  |                                                                                     |                                                                                   |
| Сушка и смазка                                                                                                                                                                                        | <ul style="list-style-type: none"><li>• Избегайте накопления воды под кожухом электродвигателя. Стряхивайте избыток воды движением сверху вниз.</li><li>• Перед стерилизацией распылите в канюлированной оси рукоятки силиконовую смазку или спрей Rapa. Наносите силиконовую смазку или спрей Rapa до тех пор, пока смазка не выступит над кнопкой высвобождения бора. Удалите избыток смазки с рукоятки. Перед продолжением процедуры удостоверьтесь, что механизм высвобождения бора смазан достаточно для надлежащего функционирования.</li><li>• Сразу же после очистки простерилизуйте рукоятку.</li></ul>                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                |                                                                  |                                                                  |                                                                                     |                                                                                   |
| Дезинфекция                                                                                                                                                                                           | Не выдерживайте в низкотемпературном растворе глутаральдегида.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                |                                                                  |                                                                  |                                                                                     |                                                                                   |
| Упаковка                                                                                                                                                                                              | <ul style="list-style-type: none"><li>• Может использоваться стандартный оберточный материал для стерилизации. В США должен использоваться хирургический оберточный материал, соответствующий требованиям FDA. Убедитесь, что упаковка достаточно велика, чтобы вместить инструмент и не оказывать давления на уплотнения.</li><li>• Для комплектов инструментов: инструменты можно загружать в специальные инструментальные лотки или универсальные лотки для стерилизации. Оберните лотки, используя соответствующий метод.</li></ul>                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                |                                                                  |                                                                  |                                                                                     |                                                                                   |
| Стерилизация (указаны<br>минимальные<br>необходимые<br>температура и время)                                                                                                                           | <ul style="list-style-type: none"><li>• Указанные ниже параметры стерилизации должны применяться для стерилизации устройств в полностью разобранном виде, если разборка возможна. После стерилизации применяйте стандартные стерильные способы сборки устройств, чтобы сохранить стерильность инструментов.</li><li>• Валидацию прошли все циклы паровой стерилизации инструментария в обертке, при этом инструменты можно стерилизовать как в обертке, так и без нее.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                |                                                                  |                                                                  |                                                                                     |                                                                                   |
|                                                                                                                                                                                                       | Стерилизация паром                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                |                                                                  |                                                                  |                                                                                     |                                                                                   |
|                                                                                                                                                                                                       | Цикл                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Паровая<br>стерилизация<br>с гравитационным<br>удалением воздуха                                                                                                                               | Паровая<br>стерилизация<br>с гравитационным<br>удалением воздуха | Паровая<br>стерилизация<br>с предварительной<br>откачкой воздуха | Паровая<br>стерилизация с<br>предварительной<br>откачкой воздуха<br>(Франция / ВОЗ) | Паровая стерилизация<br>с предварительной<br>откачкой воздуха<br>(Великобритания) |
|                                                                                                                                                                                                       | Температура                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 121 °C                                                                                                                                                                                         | 132 °C                                                           | 132 °C                                                           | 134 °C                                                                              | 134 °C                                                                            |
|                                                                                                                                                                                                       | Время                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 10 мин                                                                                                                                                                                         | 10 мин                                                           | 4 мин                                                            | 10 мин                                                                              | 3 мин                                                                             |
|                                                                                                                                                                                                       | Сушка                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 15 минут или до появления визуальных признаков высушивания.                                                                                                                                    |                                                                  |                                                                  |                                                                                     |                                                                                   |
|                                                                                                                                                                                                       | Стерилизация в<br>системе STERRAD                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Совместимо с моделью 100S                                                                                                                                                                      |                                                                  |                                                                  |                                                                                     |                                                                                   |
|                                                                                                                                                                                                       | Параметры стерилизации 100 % этиленоксидом                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                |                                                                  |                                                                  |                                                                                     |                                                                                   |
|                                                                                                                                                                                                       | Обработка в камере                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                |                                                                  | Стерилизация                                                     |                                                                                     |                                                                                   |
|                                                                                                                                                                                                       | Температура                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                | 54 ± 2 °C                                                        | Температура                                                      |                                                                                     | 54 ± 2 °C                                                                         |
| Относительная влажность                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 60 ± 5 %                                                                                                                                                                                       | Относительная влажность                                          |                                                                  | 60 ± 5 %                                                                            |                                                                                   |
| Заданное значение отрицательного<br>давления                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 8,9 кПа                                                                                                                                                                                        | Концентрация этиленоксида                                        |                                                                  | 600 ± 25 мг/л                                                                       |                                                                                   |
| Продолжительность предварительной<br>обработки                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 30 мин                                                                                                                                                                                         | Время обработки газом (полный цикл)                              |                                                                  | 120 мин                                                                             |                                                                                   |
| Аэрация                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 8 ч аэрации с нагреванием до температуры 48-52 °C или 24 ч аэрации при комнатной температуре                                                                                                   |                                                                  |                                                                  |                                                                                     |                                                                                   |
| Техническое<br>обслуживание, осмотр и<br>проверка                                                                                                                                                     | <ul style="list-style-type: none"><li>• Перед каждым использованием и после него необходимо осматривать компоненты на предмет повреждения. При обнаружении повреждений не используйте инструмент, пока он не будет отремонтирован.</li><li>• После очистки и стерилизации перед повторным использованием проверьте работоспособность изделия.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                |                                                                  |                                                                  |                                                                                     |                                                                                   |
| Хранение                                                                                                                                                                                              | Во избежание коррозии и скопления остатков тканей в подшипнике и электродвигателе перед отправкой на хранение крайне важно выполнить быструю и полную вакуумную сушку рукоятки.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                |                                                                  |                                                                  |                                                                                     |                                                                                   |
| Дополнительная<br>информация                                                                                                                                                                          | Отсутствует.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                |                                                                  |                                                                  |                                                                                     |                                                                                   |

**Примечание.** Вышеизложенные инструкции прошли валидацию и рекомендованы производителем в качестве процедур, СПОСОБНЫХ подготовить продукт для повторного использования. Ответственность за фактическое осуществление повторной обработки с использованием оборудования, материалов и персонала обрабатывающего предприятия, обеспечивающих требуемый результат, несет обработчик. Обычно для этого необходима валидация процесса и его рутинный контроль.

**Примечание.** Все процессы валидации выполняются согласно требованиям стандарта AAMI TIR12 «Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers» (Разработка, проверка и маркировка повторно используемых устройств медицинского назначения для повторной обработки в учреждениях здравоохранения: рекомендация для производителей устройств медицинского назначения).

Компания Medtronic рекомендует сжигание устройств, которые находились в непосредственном контакте с пациентами, имеющими предполагаемый или подтвержденный диагноз трансмиссивной губчатой энцефалопатии (ТГЭ) или болезни Крейтцфельда-Якоба (БКЯ).



Medtronic

## Инструкции по повторной обработке Visao

### Инструкции по повторной обработке

Инструкции по очистке и стерилизации могут быть изменены. Актуальные инструкции можно найти на веб-узле [manuals.medtronic.com](http://manuals.medtronic.com).  
68E3281 F

|                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                         |                                                                         |                                                                          |  |      |                                                         |                                                         |                                                                         |                                                                          |             |        |        |        |        |       |        |       |        |       |       |                                                            |  |  |  |                                |                                             |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |          |  |  |  |                           |               |  |  |  |                                      |         |  |  |  |         |                   |  |  |
|--------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|-------------------------------------------------------------------------|--------------------------------------------------------------------------|--|------|---------------------------------------------------------|---------------------------------------------------------|-------------------------------------------------------------------------|--------------------------------------------------------------------------|-------------|--------|--------|--------|--------|-------|--------|-------|--------|-------|-------|------------------------------------------------------------|--|--|--|--------------------------------|---------------------------------------------|--|--|--|---------------------------|--|--|--|--|--------------|-------------|----------|--|--|--|-------------------------|----------|--|--|--|---------------------------|---------------|--|--|--|--------------------------------------|---------|--|--|--|---------|-------------------|--|--|
| Предупреждения и меры предосторожности                             | <ul style="list-style-type: none"><li>Перед очисткой отсоединяйте шнур питания от сети.</li><li>Не погружайте этот инструмент полностью в жидкость и не выполняйте ультразвуковую чистку.</li><li>Не выполняйте стерилизацию в низкотемпературном растворе глутаральдегида. В противном случае гарантия будет аннулирована.</li><li>Не используйте органические растворители для чистки зажимного устройства бора.</li><li>Перед очисткой рукоятки Visao (а также высокоскоростной рукоятки Xcalibur с изогнутым кабелем) закройте разъем кабеля рукоятки универсальным колпачком для очистки рукоятки, номер по каталогу 3318520.</li><li>После завершения очистки снимайте колпачок кабеля рукоятки и другие установленные перед очисткой защитные компоненты.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                         |                                                                         |                                                                          |  |      |                                                         |                                                         |                                                                         |                                                                          |             |        |        |        |        |       |        |       |        |       |       |                                                            |  |  |  |                                |                                             |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |          |  |  |  |                           |               |  |  |  |                                      |         |  |  |  |         |                   |  |  |
| Ограничения                                                        | После очистки и стерилизации перед повторным использованием проверьте работоспособность изделия.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                         |                                                                         |                                                                          |  |      |                                                         |                                                         |                                                                         |                                                                          |             |        |        |        |        |       |        |       |        |       |       |                                                            |  |  |  |                                |                                             |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |          |  |  |  |                           |               |  |  |  |                                      |         |  |  |  |         |                   |  |  |
| Важные замечания                                                   | <ul style="list-style-type: none"><li>Данный продукт поставляется нестерильным. Перед первым использованием и последующими повторными применениями следует выполнить очистку и стерилизацию изделия.</li><li>Для удаления случайно попавших на разъем кабеля рукоятки остаточных загрязнений используйте мягкую щетку и изопропиловый спирт.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                         |                                                                         |                                                                          |  |      |                                                         |                                                         |                                                                         |                                                                          |             |        |        |        |        |       |        |       |        |       |       |                                                            |  |  |  |                                |                                             |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |          |  |  |  |                           |               |  |  |  |                                      |         |  |  |  |         |                   |  |  |
| Защита от загрязнений и транспортировка                            | Рекомендуется выполнять обработку инструментов немедленно после их использования.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                         |                                                                         |                                                                          |  |      |                                                         |                                                         |                                                                         |                                                                          |             |        |        |        |        |       |        |       |        |       |       |                                                            |  |  |  |                                |                                             |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |          |  |  |  |                           |               |  |  |  |                                      |         |  |  |  |         |                   |  |  |
| Подготовка к обеззараживанию                                       | Извлеките бор из рукоятки, другая разборка не требуется.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                         |                                                                         |                                                                          |  |      |                                                         |                                                         |                                                                         |                                                                          |             |        |        |        |        |       |        |       |        |       |       |                                                            |  |  |  |                                |                                             |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |          |  |  |  |                           |               |  |  |  |                                      |         |  |  |  |         |                   |  |  |
| Очистка<br>Автоматизированные методы                               | <ul style="list-style-type: none"><li>Перед укладкой в корзину моечной машины извлекайте инструменты и оборудование из всех лотков для стерилизации. Располагайте устройства в соответствии с рекомендациями производителей моечного или дезинфицирующего оборудования.</li><li>Используйте щелочные моющие средства или средства с нейтральным pH, рекомендованные производителями моечного или дезинфицирующего оборудования или производителями моющих средств.</li><li>Проведенная валидация методов очистки продемонстрировала, что эффективная очистка данных изделий достигается при автоматическом цикле моечного или дезинфицирующего оборудования общей продолжительностью не менее 44 минут, включая предварительную мойку, основную мойку, ополаскивание и промывку горячим раствором. Промывка горячим раствором должна выполняться не менее 10 минут при температуре не ниже 60 °C.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                         |                                                                         |                                                                          |  |      |                                                         |                                                         |                                                                         |                                                                          |             |        |        |        |        |       |        |       |        |       |       |                                                            |  |  |  |                                |                                             |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |          |  |  |  |                           |               |  |  |  |                                      |         |  |  |  |         |                   |  |  |
| Очистка<br>Ручные методы                                           | <ul style="list-style-type: none"><li>После операции выполните чистку промывочных муфт и защитных устройств бора ферментативным моющим раствором. Протрите рукоятку и кабель с остатками применяемого при очистке дезинфицирующего вещества чистой неабразивной тканевой салфеткой.</li><li>Чтобы облегчить удаление жидкостей, остатков тканей или фрагментов костей и надежно очистить все каналы рукоятки Visao, промывочных муфт и защитных устройств боров, можно ввести щетку для очистки зажимного устройства (REF 3112500) или небольшую щетку для канала (с пластиковыми щетинками) соответствующего размера в дистальный конец этих устройств. Для разрыхления и удаления из инструмента скопившихся тканей используйте раствор ферментативного моющего средства.</li><li>Промойте дистальный конец рукоятки. Вытряхните остатки воды из рукоятки.</li><li>Убедитесь, что вся вода вытекла из кожуха охлаждения. Если во время операции для охлаждения использовался солевой раствор, то для промывки кожуха перед его осушением используйте дистиллированную воду.</li><li>Смойте дистиллированной водой остатки солевого раствора в промывочных насадках. Слейте из насадок всю воду.</li><li>Сразу же после очистки простерилизуйте рукоятку.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                         |                                                                         |                                                                          |  |      |                                                         |                                                         |                                                                         |                                                                          |             |        |        |        |        |       |        |       |        |       |       |                                                            |  |  |  |                                |                                             |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |          |  |  |  |                           |               |  |  |  |                                      |         |  |  |  |         |                   |  |  |
| Дезинфекция                                                        | Не выдерживайте в низкотемпературном растворе глутаральдегида.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                         |                                                                         |                                                                          |  |      |                                                         |                                                         |                                                                         |                                                                          |             |        |        |        |        |       |        |       |        |       |       |                                                            |  |  |  |                                |                                             |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |          |  |  |  |                           |               |  |  |  |                                      |         |  |  |  |         |                   |  |  |
| Упаковка                                                           | <ul style="list-style-type: none"><li>Может использоваться стандартный оберточный материал для стерилизации. В США должен использоваться хирургический оберточный материал, соответствующий требованиям FDA. Убедитесь, что упаковка достаточно велика, чтобы вместить инструмент и не оказывать давления на уплотнения.</li><li>Для комплектов инструментов: инструменты можно загружать в специальные инструментальные лотки или универсальные лотки для стерилизации. Оберните лотки надлежащим способом.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                         |                                                                         |                                                                          |  |      |                                                         |                                                         |                                                                         |                                                                          |             |        |        |        |        |       |        |       |        |       |       |                                                            |  |  |  |                                |                                             |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |          |  |  |  |                           |               |  |  |  |                                      |         |  |  |  |         |                   |  |  |
| Стерилизация (указаны минимальные необходимые температура и время) | <p>Указанные ниже параметры стерилизации должны применяться для стерилизации устройств в полностью разобранном виде, если разборка возможна. После стерилизации применяйте стандартные стерильные способы сборки устройств, чтобы сохранить стерильность инструментов. Валидацию прошли все циклы паровой стерилизации инструментария в обертке, при этом инструменты можно стерилизовать как в обертке, так и без нее.</p> <p><b>Стерилизация паром</b></p> <table><tr><td>Цикл</td><td>Паровая стерилизация с гравитационным удалением воздуха</td><td>Паровая стерилизация с предварительной откачкой воздуха</td><td>Паровая стерилизация с предварительной откачкой воздуха (Франция / ВОЗ)</td><td>Паровая стерилизация с предварительной откачкой воздуха (Великобритания)</td></tr><tr><td>Температура</td><td>121 °C</td><td>132 °C</td><td>134 °C</td><td>134 °C</td></tr><tr><td>Время</td><td>40 мин</td><td>4 мин</td><td>18 мин</td><td>3 мин</td></tr><tr><td>Сушка</td><td colspan="4">8 минут или до появления визуальных признаков высушивания.</td></tr><tr><td>Стерилизация в системе STERRAD</td><td colspan="4">совместимо с моделью 100S (только рукоятка)</td></tr></table> <p><b>Параметры стерилизации 100 % этиленоксидом</b></p> <table><tr><td>Предварительная обработка</td><td colspan="4"></td></tr><tr><td>Стерилизация</td><td>Температура</td><td colspan="3">54–55 °C</td></tr><tr><td></td><td>Относительная влажность</td><td colspan="3">60 ± 5 %</td></tr><tr><td></td><td>Концентрация этиленоксида</td><td colspan="3">600 ± 25 мг/л</td></tr><tr><td></td><td>Время воздействия газа (полный цикл)</td><td colspan="3">120 мин</td></tr><tr><td></td><td>Аэрация</td><td colspan="3">48–52 °C, 8 часов</td></tr></table> |                                                         |                                                                         |                                                                          |  | Цикл | Паровая стерилизация с гравитационным удалением воздуха | Паровая стерилизация с предварительной откачкой воздуха | Паровая стерилизация с предварительной откачкой воздуха (Франция / ВОЗ) | Паровая стерилизация с предварительной откачкой воздуха (Великобритания) | Температура | 121 °C | 132 °C | 134 °C | 134 °C | Время | 40 мин | 4 мин | 18 мин | 3 мин | Сушка | 8 минут или до появления визуальных признаков высушивания. |  |  |  | Стерилизация в системе STERRAD | совместимо с моделью 100S (только рукоятка) |  |  |  | Предварительная обработка |  |  |  |  | Стерилизация | Температура | 54–55 °C |  |  |  | Относительная влажность | 60 ± 5 % |  |  |  | Концентрация этиленоксида | 600 ± 25 мг/л |  |  |  | Время воздействия газа (полный цикл) | 120 мин |  |  |  | Аэрация | 48–52 °C, 8 часов |  |  |
| Цикл                                                               | Паровая стерилизация с гравитационным удалением воздуха                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Паровая стерилизация с предварительной откачкой воздуха | Паровая стерилизация с предварительной откачкой воздуха (Франция / ВОЗ) | Паровая стерилизация с предварительной откачкой воздуха (Великобритания) |  |      |                                                         |                                                         |                                                                         |                                                                          |             |        |        |        |        |       |        |       |        |       |       |                                                            |  |  |  |                                |                                             |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |          |  |  |  |                           |               |  |  |  |                                      |         |  |  |  |         |                   |  |  |
| Температура                                                        | 121 °C                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 132 °C                                                  | 134 °C                                                                  | 134 °C                                                                   |  |      |                                                         |                                                         |                                                                         |                                                                          |             |        |        |        |        |       |        |       |        |       |       |                                                            |  |  |  |                                |                                             |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |          |  |  |  |                           |               |  |  |  |                                      |         |  |  |  |         |                   |  |  |
| Время                                                              | 40 мин                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 4 мин                                                   | 18 мин                                                                  | 3 мин                                                                    |  |      |                                                         |                                                         |                                                                         |                                                                          |             |        |        |        |        |       |        |       |        |       |       |                                                            |  |  |  |                                |                                             |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |          |  |  |  |                           |               |  |  |  |                                      |         |  |  |  |         |                   |  |  |
| Сушка                                                              | 8 минут или до появления визуальных признаков высушивания.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                         |                                                                         |                                                                          |  |      |                                                         |                                                         |                                                                         |                                                                          |             |        |        |        |        |       |        |       |        |       |       |                                                            |  |  |  |                                |                                             |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |          |  |  |  |                           |               |  |  |  |                                      |         |  |  |  |         |                   |  |  |
| Стерилизация в системе STERRAD                                     | совместимо с моделью 100S (только рукоятка)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                         |                                                                         |                                                                          |  |      |                                                         |                                                         |                                                                         |                                                                          |             |        |        |        |        |       |        |       |        |       |       |                                                            |  |  |  |                                |                                             |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |          |  |  |  |                           |               |  |  |  |                                      |         |  |  |  |         |                   |  |  |
| Предварительная обработка                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                         |                                                                         |                                                                          |  |      |                                                         |                                                         |                                                                         |                                                                          |             |        |        |        |        |       |        |       |        |       |       |                                                            |  |  |  |                                |                                             |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |          |  |  |  |                           |               |  |  |  |                                      |         |  |  |  |         |                   |  |  |
| Стерилизация                                                       | Температура                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 54–55 °C                                                |                                                                         |                                                                          |  |      |                                                         |                                                         |                                                                         |                                                                          |             |        |        |        |        |       |        |       |        |       |       |                                                            |  |  |  |                                |                                             |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |          |  |  |  |                           |               |  |  |  |                                      |         |  |  |  |         |                   |  |  |
|                                                                    | Относительная влажность                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 60 ± 5 %                                                |                                                                         |                                                                          |  |      |                                                         |                                                         |                                                                         |                                                                          |             |        |        |        |        |       |        |       |        |       |       |                                                            |  |  |  |                                |                                             |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |          |  |  |  |                           |               |  |  |  |                                      |         |  |  |  |         |                   |  |  |
|                                                                    | Концентрация этиленоксида                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 600 ± 25 мг/л                                           |                                                                         |                                                                          |  |      |                                                         |                                                         |                                                                         |                                                                          |             |        |        |        |        |       |        |       |        |       |       |                                                            |  |  |  |                                |                                             |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |          |  |  |  |                           |               |  |  |  |                                      |         |  |  |  |         |                   |  |  |
|                                                                    | Время воздействия газа (полный цикл)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 120 мин                                                 |                                                                         |                                                                          |  |      |                                                         |                                                         |                                                                         |                                                                          |             |        |        |        |        |       |        |       |        |       |       |                                                            |  |  |  |                                |                                             |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |          |  |  |  |                           |               |  |  |  |                                      |         |  |  |  |         |                   |  |  |
|                                                                    | Аэрация                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 48–52 °C, 8 часов                                       |                                                                         |                                                                          |  |      |                                                         |                                                         |                                                                         |                                                                          |             |        |        |        |        |       |        |       |        |       |       |                                                            |  |  |  |                                |                                             |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |          |  |  |  |                           |               |  |  |  |                                      |         |  |  |  |         |                   |  |  |
| Техническое обслуживание, осмотр и проверка                        | <ul style="list-style-type: none"><li>Перед каждым использованием и после него необходимо осматривать компоненты на предмет повреждения. При обнаружении повреждений не используйте инструмент, пока он не будет отремонтирован.</li><li>После очистки и стерилизации перед повторным использованием проверьте работоспособность изделия.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                         |                                                                         |                                                                          |  |      |                                                         |                                                         |                                                                         |                                                                          |             |        |        |        |        |       |        |       |        |       |       |                                                            |  |  |  |                                |                                             |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |          |  |  |  |                           |               |  |  |  |                                      |         |  |  |  |         |                   |  |  |
| Хранение                                                           | Во избежание коррозии и скопления остатков тканей подшпильники и электродвигатели перед отправкой на хранение крайне важно выполнить быструю и полную вакуумную сушку рукоятки.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                         |                                                                         |                                                                          |  |      |                                                         |                                                         |                                                                         |                                                                          |             |        |        |        |        |       |        |       |        |       |       |                                                            |  |  |  |                                |                                             |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |          |  |  |  |                           |               |  |  |  |                                      |         |  |  |  |         |                   |  |  |
| Дополнительная информация                                          | Применяйте температуру выше указанных значений, если это необходимо для выполнения требований правительственных организаций или внутренних правил медицинского учреждения при условии, что температура не превышает 149 °C. Нагрев рукоятки свыше 149 °C может привести к ее повреждению и вызовет аннулирование гарантии.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                         |                                                                         |                                                                          |  |      |                                                         |                                                         |                                                                         |                                                                          |             |        |        |        |        |       |        |       |        |       |       |                                                            |  |  |  |                                |                                             |  |  |  |                           |  |  |  |  |              |             |          |  |  |  |                         |          |  |  |  |                           |               |  |  |  |                                      |         |  |  |  |         |                   |  |  |

**Примечание.** Вышеизложенные инструкции прошли валидацию и рекомендованы производителем в качестве процедур. СПОСОБНЫХ подготовить продукт для повторного использования. Ответственность за фактическое осуществление повторной обработки с использованием оборудования, материалов и персонала обрабатывающего предприятия, обеспечивающих требуемый результат, несет обработчик. Обычно для этого необходима валидация процесса и его рутинный контроль.

**Примечание.** Все процессы валидации выполняются согласно требованиям стандарта AAMI TIR12 «Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers» (Разработка, проверка и маркировка повторно используемых устройств медицинского назначения для повторной обработки в учреждениях здравоохранения: рекомендация для производителей устройств медицинского назначения).

Компания Medtronic рекомендует сжигание устройств, которые находились в непосредственном контакте с пациентами, имеющими предполагаемый или подтвержденный диагноз трансмиссивной губчатой энцефалопатии (ТГЭ) или болезни Крейтцфельда-Якоба (БКЯ).





# Инструкции по повторной обработке Высокоскоростная отолгическая дрель Indigo

Инструкции по повторной обработке  
Инструкции по очистке и стерилизации могут  
быть изменены. Актуальные инструкции  
можно найти на веб-узле **manuals.medtronic.com**.  
68E4187 D

|                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                            |                                                         |                                                                         |                                                                                 |
|-----------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|---------------------------------------------------------|-------------------------------------------------------------------------|---------------------------------------------------------------------------------|
| Предупреждения и меры предосторожности                                            | <ul style="list-style-type: none"><li>Замачивать устройства или погружать их в жидкость запрещается.</li><li>Запрещается ультразвуковая очистка устройств.</li><li>Запрещается использовать вызывающие коррозию или содержащие хлор чистящие средства, такие как отбеливатель, щелок, ацетон, гипохлорит натрия, едкий натр, муравьиная кислота или растворы, содержащие глутаральдегид.</li><li>Применение мойки-дезинфектора эндоскопов может привести к преждевременному ухудшению рабочих характеристик.</li><li>После стерилизации паром необходимо дождаться остывания компонентов.</li></ul>                                                                                                                                                                                                                                                                                               |                                                            |                                                         |                                                                         |                                                                                 |
| Ограничения                                                                       | Перед повторным использованием инструмента выполняйте проверку его работоспособности.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                            |                                                         |                                                                         |                                                                                 |
| Важные замечания                                                                  | Данный продукт поставляется нестерильным. Перед первым использованием и последующими повторными применениями следует выполнить очистку и стерилизацию изделия.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                            |                                                         |                                                                         |                                                                                 |
| Защита от загрязнений и транспортировка                                           | Рекомендуется выполнять обработку инструментов немедленно после их использования                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                            |                                                         |                                                                         |                                                                                 |
| Подготовка к обеззараживанию                                                      | Необходимо следовать процедуре, принятой в медицинском учреждении.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                            |                                                         |                                                                         |                                                                                 |
| Очистка: с применением моющего средства                                           | Используйте моющее вещество, подходящее для применения на алюминиевых поверхностях. Предпочтительно применение веществ от нейтральных ферментных до умеренно-щелочных (с pH от 6,0 до 10,5). Если используется мойка-дезинфектор, см. рекомендуемые средства для очистки в инструкции к нему.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                            |                                                         |                                                                         |                                                                                 |
| Очистка Автоматизированные методы (НЕ используйте ультразвуковой моечный аппарат) | <ul style="list-style-type: none"><li>Устройства необходимо извлечь из лотков для инструментов, прежде чем помещать в корзину моечной машины.</li><li>Перед очисткой закройте конец разъема кабеля дрели колпачком для очистки рукоятки, номер по каталогу 3318520.</li><li>Устройства следует ориентировать в соответствии с рекомендациями производителя моечной машины или аппарата для дезинфекции.</li><li><b>После завершения очистки снимайте колпачок для очистки рукоятки и другие установленные перед стерилизацией защитные компоненты.</b></li></ul>                                                                                                                                                                                                                                                                                                                                  |                                                            |                                                         |                                                                         |                                                                                 |
|                                                                                   | Рекомендуемый цикл обработки в моечной машине                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Фаза                                                       | Длительность рециркуляции                               | Температура воды                                                        | Тип и концентрация моющего средства                                             |
|                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Замачивание                                                | 2 мин                                                   | Холодная водопроводная вода                                             | -                                                                               |
|                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Промывка                                                   | 5 мин                                                   | 66 °C (заданное значение)                                               | Моющее средство от нейтрального ферментного до умеренно-щелочного, pH 6,0–10,5. |
|                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Ополаскивание                                              | 1 мин                                                   | Горячая водопроводная вода                                              | -                                                                               |
| Очистка Ручные методы                                                             | <ul style="list-style-type: none"><li>Перед очисткой закройте конец разъема кабеля дрели колпачком для очистки рукоятки, номер по каталогу 3318520.</li><li>Протрите все наружные поверхности электродвигателя и кабель тканью, смоченной в моющем средстве, разведенном в теплой водопроводной воде.</li><li>Очистите корпус и зажимной патрон электродвигателя нейлоновой щеткой, смоченной в нейтральном ферментативном моющем средстве.</li><li>Тщательно ополосните электродвигатель в проточной воде, держа его зажимным патроном вниз.</li><li>Протрите насухо зажимной патрон и электродвигатель салфеткой из безворсовой ткани.</li><li>После завершения очистки снимайте колпачок для очистки рукоятки и другие установленные перед стерилизацией защитные компоненты.</li><li>Удостоверьтесь в том, что после ручной очистки на устройствах отсутствуют видимые загрязнения.</li></ul> |                                                            |                                                         |                                                                         |                                                                                 |
| Дезинфекция                                                                       | Необходимо следовать процедуре, принятой в медицинском учреждении.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                            |                                                         |                                                                         |                                                                                 |
| Упаковка                                                                          | Поместите устройства в лоток для инструментов и дважды оберните футляр для инструментов однослойной пропиленовой оберткой. В США должен использоваться хирургический оберточный материал, соответствующий требованиям FDA.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                            |                                                         |                                                                         |                                                                                 |
| Стерилизация (указаны минимальные необходимые температура и время)                | Стерилизация паром                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                            |                                                         |                                                                         |                                                                                 |
|                                                                                   | Цикл                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Паровая стерилизация с гравитационным удалением воздуха    | Паровая стерилизация с предварительной откачкой воздуха | Паровая стерилизация с предварительной откачкой воздуха (Франция / ВОЗ) | Паровая стерилизация с предварительной откачкой воздуха (Великобритания)        |
|                                                                                   | Температура                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 132 °C                                                     | 132 °C                                                  | 134 °C                                                                  | 134 °C                                                                          |
|                                                                                   | Время                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 25 мин                                                     | 4 мин                                                   | 18 мин                                                                  | 3 мин                                                                           |
|                                                                                   | Сушка                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 20 мин                                                     |                                                         |                                                                         |                                                                                 |
|                                                                                   | Стерилизация в системе STERRAD                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Валидация не проводилась.                                  |                                                         |                                                                         |                                                                                 |
|                                                                                   | Параметры стерилизации 100 % этиленоксидом                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                            |                                                         |                                                                         |                                                                                 |
|                                                                                   | Предварительная обработка                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | при 55 °C, относительной влажности 70 % в течение 30 минут |                                                         |                                                                         |                                                                                 |
|                                                                                   | Стерилизация                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Температура                                                | 55 °C                                                   |                                                                         |                                                                                 |
|                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Относительная влажность                                    | 70 %                                                    |                                                                         |                                                                                 |
|                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Концентрация этиленоксида                                  | 725 мг/л                                                |                                                                         |                                                                                 |
|                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Время воздействия газа (полный цикл)                       | 240 мин                                                 |                                                                         |                                                                                 |
|                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Аэрация                                                    | 53–57 °C, 18 часов                                      |                                                                         |                                                                                 |
| Техническое обслуживание, осмотр и проверка                                       | <ul style="list-style-type: none"><li>Перед каждым использованием и после него необходимо осматривать компоненты на предмет повреждения. При обнаружении повреждений не используйте инструмент, пока он не будет отремонтирован.</li><li>После очистки и стерилизации перед повторным использованием проверьте работоспособность изделия.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                            |                                                         |                                                                         |                                                                                 |
| Хранение                                                                          | Храните вместе с другими стерильными устройствами.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                            |                                                         |                                                                         |                                                                                 |
| Дополнительная информация                                                         | Отсутствует.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                            |                                                         |                                                                         |                                                                                 |

**Примечание.** Вышеизложенные инструкции прошли валидацию и рекомендованы производителем в качестве процедур, СПОСОБНЫХ подготовить продукт для повторного использования. Ответственность за фактическое осуществление повторной обработки с использованием оборудования, материалов и персонала обрабатывающего предприятия, обеспечивающих требуемый результат, несет обработчик. Обычно для этого необходима валидация процесса и его рутинный контроль.

**Примечание.** Все процессы валидации выполняются согласно требованиям стандарта AAMI TR12 «Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers» (Разработка, проверка и маркировка повторно используемых устройств медицинского назначения для повторной обработки в учреждениях здравоохранения; рекомендация для производителей устройств медицинского назначения).

Компания Medtronic рекомендует сжигание устройств, которые находились в непосредственном контакте с пациентами, имеющими предполагаемый или подтвержденный диагноз трансмиссивной / убачтой энцефалопатии (ТЭЗ) или болезни Крейтцфельда-Якоба (БКЯ).



Medtronic

Инструкции по повторной  
обработке  
Насадки для высокоскоростной отоларингологической  
дрели Indigo

Инструкции по повторной обработке  
Инструкции по очистке и стерилизации могут  
быть изменены. Актуальные инструкции  
можно найти на веб-узле [manuals.medtronic.com](http://manuals.medtronic.com).  
68E4188 D

|                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                            |                                                         |                                                                                 |                                                                          |                                               |      |                                                         |                                                         |                                                                         |                                                                          |             |        |                             |                                                                                 |        |          |        |                           |        |               |       |                            |  |  |  |                                |                           |  |  |  |                                           |  |  |  |  |                           |                                                            |  |  |  |              |             |       |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |  |                    |  |  |
|-----------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|---------------------------------------------------------|---------------------------------------------------------------------------------|--------------------------------------------------------------------------|-----------------------------------------------|------|---------------------------------------------------------|---------------------------------------------------------|-------------------------------------------------------------------------|--------------------------------------------------------------------------|-------------|--------|-----------------------------|---------------------------------------------------------------------------------|--------|----------|--------|---------------------------|--------|---------------|-------|----------------------------|--|--|--|--------------------------------|---------------------------|--|--|--|-------------------------------------------|--|--|--|--|---------------------------|------------------------------------------------------------|--|--|--|--------------|-------------|-------|--|--|--|-------------------------|------|--|--|--|---------------------------|----------|--|--|--|--------------------------------------|---------|--|--|--|---------|--|--------------------|--|--|
| Предупреждения и меры предосторожности                                            | <ul style="list-style-type: none"><li>• Замачивать устройства или погружать их в жидкость запрещается.</li><li>• Запрещается ультразвуковая очистка устройств.</li><li>• Запрещается использовать вызывающие коррозию или содержащие хлор чистящие средства, такие как отбеливатель, щелок, уксетон, гипохлорит натрия, едкий натр, муравьиная кислота или растворы, содержащие глутаральдегид.</li><li>• Применение мойки-дезинфектора эндоскопов может привести к преждевременному ухудшению рабочих характеристик.</li><li>• После стерилизации паром необходимо дождаться остывания компонентов.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                            |                                                         |                                                                                 |                                                                          |                                               |      |                                                         |                                                         |                                                                         |                                                                          |             |        |                             |                                                                                 |        |          |        |                           |        |               |       |                            |  |  |  |                                |                           |  |  |  |                                           |  |  |  |  |                           |                                                            |  |  |  |              |             |       |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |  |                    |  |  |
| Ограничения                                                                       | Перед повторным использованием инструмента выполняйте проверку его работоспособности.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                            |                                                         |                                                                                 |                                                                          |                                               |      |                                                         |                                                         |                                                                         |                                                                          |             |        |                             |                                                                                 |        |          |        |                           |        |               |       |                            |  |  |  |                                |                           |  |  |  |                                           |  |  |  |  |                           |                                                            |  |  |  |              |             |       |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |  |                    |  |  |
| Важные замечания                                                                  | Данный продукт поставляется нестерильным. Перед первым использованием и последующими повторными применениями следует выполнить очистку и стерилизацию изделия.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                            |                                                         |                                                                                 |                                                                          |                                               |      |                                                         |                                                         |                                                                         |                                                                          |             |        |                             |                                                                                 |        |          |        |                           |        |               |       |                            |  |  |  |                                |                           |  |  |  |                                           |  |  |  |  |                           |                                                            |  |  |  |              |             |       |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |  |                    |  |  |
| Защита от загрязнений и транспортировка                                           | Рекомендуется выполнять обработку инструментов немедленно после их использования.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                            |                                                         |                                                                                 |                                                                          |                                               |      |                                                         |                                                         |                                                                         |                                                                          |             |        |                             |                                                                                 |        |          |        |                           |        |               |       |                            |  |  |  |                                |                           |  |  |  |                                           |  |  |  |  |                           |                                                            |  |  |  |              |             |       |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |  |                    |  |  |
| Подготовка к обеззараживанию                                                      | Необходимо следовать процедуре, принятой в медицинском учреждении.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                            |                                                         |                                                                                 |                                                                          |                                               |      |                                                         |                                                         |                                                                         |                                                                          |             |        |                             |                                                                                 |        |          |        |                           |        |               |       |                            |  |  |  |                                |                           |  |  |  |                                           |  |  |  |  |                           |                                                            |  |  |  |              |             |       |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |  |                    |  |  |
| Очистка: с применением моющего средства                                           | Используйте моющее вещество, подходящее для применения на алюминиевых поверхностях. Предпочтительно применение веществ от нейтральных ферментных до умеренно-щелочных (с pH от 6,0 до 10,5). Если используется мойка-дезинфектор, см. рекомендуемые средства для очистки в инструкции к нему.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                            |                                                         |                                                                                 |                                                                          |                                               |      |                                                         |                                                         |                                                                         |                                                                          |             |        |                             |                                                                                 |        |          |        |                           |        |               |       |                            |  |  |  |                                |                           |  |  |  |                                           |  |  |  |  |                           |                                                            |  |  |  |              |             |       |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |  |                    |  |  |
| Очистка Автоматизированные методы (НЕ используйте ультразвуковой моечный аппарат) | <ul style="list-style-type: none"><li>• Перед загрузкой в автоматическую моечную машину для обработки все насадки надлежит тщательно промывать вручную водопроводной водой, обеспечивая проникновение воды во все труднодоступные полости.</li><li>• Устройства необходимо извлечь из лотков для инструментов, прежде чем помещать в корзину моечной машины.</li><li>• <b>Устройства не следует обрабатывать в автоматическом режиме при повторной обработке моющих машин или аппаратов для дезинфекции.</b></li></ul> <table><tr><td>Рекомендуемый цикл обработки в моечной машине</td><td>Фаза</td><td>Длительность рециркуляции</td><td>Температура воды</td><td>Тип и концентрация моющего средства</td></tr><tr><td></td><td>Замачивание</td><td>2 мин</td><td>Холодная водопроводная вода</td><td rowspan="3">Моющее средство от нейтрального ферментного до умеренно-щелочного, pH 6,0–10,5.</td></tr><tr><td></td><td>Промывка</td><td>5 мин</td><td>66 °C (заданное значение)</td></tr><tr><td></td><td>Ополаскивание</td><td>1 мин</td><td>Горячая водопроводная вода</td></tr></table>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                            |                                                         |                                                                                 |                                                                          | Рекомендуемый цикл обработки в моечной машине | Фаза | Длительность рециркуляции                               | Температура воды                                        | Тип и концентрация моющего средства                                     |                                                                          | Замачивание | 2 мин  | Холодная водопроводная вода | Моющее средство от нейтрального ферментного до умеренно-щелочного, pH 6,0–10,5. |        | Промывка | 5 мин  | 66 °C (заданное значение) |        | Ополаскивание | 1 мин | Горячая водопроводная вода |  |  |  |                                |                           |  |  |  |                                           |  |  |  |  |                           |                                                            |  |  |  |              |             |       |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |  |                    |  |  |
| Рекомендуемый цикл обработки в моечной машине                                     | Фаза                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Длительность рециркуляции                                  | Температура воды                                        | Тип и концентрация моющего средства                                             |                                                                          |                                               |      |                                                         |                                                         |                                                                         |                                                                          |             |        |                             |                                                                                 |        |          |        |                           |        |               |       |                            |  |  |  |                                |                           |  |  |  |                                           |  |  |  |  |                           |                                                            |  |  |  |              |             |       |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |  |                    |  |  |
|                                                                                   | Замачивание                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 2 мин                                                      | Холодная водопроводная вода                             | Моющее средство от нейтрального ферментного до умеренно-щелочного, pH 6,0–10,5. |                                                                          |                                               |      |                                                         |                                                         |                                                                         |                                                                          |             |        |                             |                                                                                 |        |          |        |                           |        |               |       |                            |  |  |  |                                |                           |  |  |  |                                           |  |  |  |  |                           |                                                            |  |  |  |              |             |       |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |  |                    |  |  |
|                                                                                   | Промывка                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 5 мин                                                      | 66 °C (заданное значение)                               |                                                                                 |                                                                          |                                               |      |                                                         |                                                         |                                                                         |                                                                          |             |        |                             |                                                                                 |        |          |        |                           |        |               |       |                            |  |  |  |                                |                           |  |  |  |                                           |  |  |  |  |                           |                                                            |  |  |  |              |             |       |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |  |                    |  |  |
|                                                                                   | Ополаскивание                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 1 мин                                                      | Горячая водопроводная вода                              |                                                                                 |                                                                          |                                               |      |                                                         |                                                         |                                                                         |                                                                          |             |        |                             |                                                                                 |        |          |        |                           |        |               |       |                            |  |  |  |                                |                           |  |  |  |                                           |  |  |  |  |                           |                                                            |  |  |  |              |             |       |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |  |                    |  |  |
| Очистка Ручные методы                                                             | <ul style="list-style-type: none"><li>• Для очистки следует использовать моющее средство, разведенное в теплой водопроводной воде</li><li>• Тщательно протрите прямые и угловые насадки тканью, смоченной в моющем средстве.</li><li>• Протрите полностью всю насадку, пока не будут удалены все основные загрязнения.</li><li>• Обработайте насадки щеткой, смоченной в моющем средстве, очистив внешние поверхности и внутренние поверхности в местах соединения.</li><li>• В случае угловых насадок: смочите щетку подходящего размера (Ø 2,4 мм) в моющем средстве. Вставьте щетку в канал насадки через отверстие на переднем конце. Прочистите канал щеткой, чтобы отделить от стенок скопившиеся внутри насадки остатки тканей. Промойте канал, чтобы удалить из него остатки тканей.</li><li>• В случае прямых насадок: смочите щетку подходящего размера (Ø 2,4 мм) в моющем средстве. Протолкните щетку сквозь прямую насадку от заднего до переднего конца, чтобы отделить от стенок и вычистить скопившиеся внутри остатки тканей. Промойте канал, чтобы удалить из него остатки тканей.</li><li>• Погрузите прямую или угловую насадку на половину длины в раствор моющего средства. Не погружайте в жидкость всю насадку целиком. Осторожно промойте насадки в моющем средстве взбалтывающим движением и подвигайте подвижные элементы.</li><li>• Погрузите насадку в моющее средство другим концом и повторите описанную выше процедуру. Не погружайте в жидкость всю насадку целиком.</li><li>• Тщательно промойте насадку водопроводной водой. Промывать насадку следует с обоих концов, чтобы удалить из нее остатки моющего средства.</li></ul> |                                                            |                                                         |                                                                                 |                                                                          |                                               |      |                                                         |                                                         |                                                                         |                                                                          |             |        |                             |                                                                                 |        |          |        |                           |        |               |       |                            |  |  |  |                                |                           |  |  |  |                                           |  |  |  |  |                           |                                                            |  |  |  |              |             |       |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |  |                    |  |  |
| Дезинфекция                                                                       | <ul style="list-style-type: none"><li>• Тщательно просушите насадки. В случае прямой насадки допускается использовать сжатый воздух для ее продувки со стороны заднего конца с целью удаления влаги.</li><li>• С помощью смазки в аэрозольной упаковке (напр., спрей Pana) проделайте следующую процедуру для смазки насадок.<ul style="list-style-type: none"><li>• Держа аэрозольный баллончик на расстоянии 10–15 см от насадки, нанесите смазку на все движущиеся, вращающиеся или скользящие детали, делая по три коротких нажатия для смазки каждой детали.</li><li>• Подвигайте движущиеся части для надлежащей смазки.</li><li>• Удалите излишки смазки чистой тканью.</li></ul></li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                            |                                                         |                                                                                 |                                                                          |                                               |      |                                                         |                                                         |                                                                         |                                                                          |             |        |                             |                                                                                 |        |          |        |                           |        |               |       |                            |  |  |  |                                |                           |  |  |  |                                           |  |  |  |  |                           |                                                            |  |  |  |              |             |       |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |  |                    |  |  |
| Дезинфекция Упаковка                                                              | Необходимо следовать процедуре, принятой в медицинском учреждении.<br>Поместите устройства в лоток для инструментов и дважды оберните футляр для инструментов односторонней пропиленовой оберткой. В США должен использоваться хирургический оберточный материал, соответствующий требованиям FDA.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                            |                                                         |                                                                                 |                                                                          |                                               |      |                                                         |                                                         |                                                                         |                                                                          |             |        |                             |                                                                                 |        |          |        |                           |        |               |       |                            |  |  |  |                                |                           |  |  |  |                                           |  |  |  |  |                           |                                                            |  |  |  |              |             |       |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |  |                    |  |  |
| Стерилизация (указаны минимальные необходимые температура и время)                | <table><tr><td rowspan="10">Стерилизация паром</td><td>Цикл</td><td>Паровая стерилизация с гравитационным удалением воздуха</td><td>Паровая стерилизация с предварительной откачкой воздуха</td><td>Паровая стерилизация с предварительной откачкой воздуха (Франция / ВОЗ)</td><td>Паровая стерилизация с предварительной откачкой воздуха (Великобритания)</td></tr><tr><td>Температура</td><td>132 °C</td><td>132 °C</td><td>134 °C</td><td>134 °C</td></tr><tr><td>Время</td><td>25 мин</td><td>4 мин</td><td>1A мин</td><td>3 мин</td></tr><tr><td>Сушка</td><td>20 мин</td><td></td><td></td><td></td></tr><tr><td>Стерилизация в системе STERRAD</td><td colspan="4">Валидация не проводилась.</td></tr><tr><td>Параметры стерилизации 100 % этиленоксида</td><td colspan="4"></td></tr><tr><td>Предварительная обработка</td><td colspan="4">при 55 °C, относительной влажности 70 % в течение 30 минут</td></tr><tr><td>Стерилизация</td><td>Температура</td><td>55 °C</td><td></td><td></td></tr><tr><td></td><td>Относительная влажность</td><td>70 %</td><td></td><td></td></tr><tr><td></td><td>Концентрация этиленоксида</td><td>725 мг/л</td><td></td><td></td></tr><tr><td></td><td>Время воздействия газа (полный цикл)</td><td>240 мин</td><td></td><td></td></tr><tr><td></td><td>Аэрация</td><td></td><td>53–57 °C, 18 часов</td><td></td><td></td></tr></table>                                                                                                                                                                                                                                                                               |                                                            |                                                         |                                                                                 |                                                                          | Стерилизация паром                            | Цикл | Паровая стерилизация с гравитационным удалением воздуха | Паровая стерилизация с предварительной откачкой воздуха | Паровая стерилизация с предварительной откачкой воздуха (Франция / ВОЗ) | Паровая стерилизация с предварительной откачкой воздуха (Великобритания) | Температура | 132 °C | 132 °C                      | 134 °C                                                                          | 134 °C | Время    | 25 мин | 4 мин                     | 1A мин | 3 мин         | Сушка | 20 мин                     |  |  |  | Стерилизация в системе STERRAD | Валидация не проводилась. |  |  |  | Параметры стерилизации 100 % этиленоксида |  |  |  |  | Предварительная обработка | при 55 °C, относительной влажности 70 % в течение 30 минут |  |  |  | Стерилизация | Температура | 55 °C |  |  |  | Относительная влажность | 70 % |  |  |  | Концентрация этиленоксида | 725 мг/л |  |  |  | Время воздействия газа (полный цикл) | 240 мин |  |  |  | Аэрация |  | 53–57 °C, 18 часов |  |  |
| Стерилизация паром                                                                | Цикл                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Паровая стерилизация с гравитационным удалением воздуха    | Паровая стерилизация с предварительной откачкой воздуха | Паровая стерилизация с предварительной откачкой воздуха (Франция / ВОЗ)         | Паровая стерилизация с предварительной откачкой воздуха (Великобритания) |                                               |      |                                                         |                                                         |                                                                         |                                                                          |             |        |                             |                                                                                 |        |          |        |                           |        |               |       |                            |  |  |  |                                |                           |  |  |  |                                           |  |  |  |  |                           |                                                            |  |  |  |              |             |       |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |  |                    |  |  |
|                                                                                   | Температура                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 132 °C                                                     | 132 °C                                                  | 134 °C                                                                          | 134 °C                                                                   |                                               |      |                                                         |                                                         |                                                                         |                                                                          |             |        |                             |                                                                                 |        |          |        |                           |        |               |       |                            |  |  |  |                                |                           |  |  |  |                                           |  |  |  |  |                           |                                                            |  |  |  |              |             |       |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |  |                    |  |  |
|                                                                                   | Время                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 25 мин                                                     | 4 мин                                                   | 1A мин                                                                          | 3 мин                                                                    |                                               |      |                                                         |                                                         |                                                                         |                                                                          |             |        |                             |                                                                                 |        |          |        |                           |        |               |       |                            |  |  |  |                                |                           |  |  |  |                                           |  |  |  |  |                           |                                                            |  |  |  |              |             |       |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |  |                    |  |  |
|                                                                                   | Сушка                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 20 мин                                                     |                                                         |                                                                                 |                                                                          |                                               |      |                                                         |                                                         |                                                                         |                                                                          |             |        |                             |                                                                                 |        |          |        |                           |        |               |       |                            |  |  |  |                                |                           |  |  |  |                                           |  |  |  |  |                           |                                                            |  |  |  |              |             |       |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |  |                    |  |  |
|                                                                                   | Стерилизация в системе STERRAD                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Валидация не проводилась.                                  |                                                         |                                                                                 |                                                                          |                                               |      |                                                         |                                                         |                                                                         |                                                                          |             |        |                             |                                                                                 |        |          |        |                           |        |               |       |                            |  |  |  |                                |                           |  |  |  |                                           |  |  |  |  |                           |                                                            |  |  |  |              |             |       |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |  |                    |  |  |
|                                                                                   | Параметры стерилизации 100 % этиленоксида                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                            |                                                         |                                                                                 |                                                                          |                                               |      |                                                         |                                                         |                                                                         |                                                                          |             |        |                             |                                                                                 |        |          |        |                           |        |               |       |                            |  |  |  |                                |                           |  |  |  |                                           |  |  |  |  |                           |                                                            |  |  |  |              |             |       |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |  |                    |  |  |
|                                                                                   | Предварительная обработка                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | при 55 °C, относительной влажности 70 % в течение 30 минут |                                                         |                                                                                 |                                                                          |                                               |      |                                                         |                                                         |                                                                         |                                                                          |             |        |                             |                                                                                 |        |          |        |                           |        |               |       |                            |  |  |  |                                |                           |  |  |  |                                           |  |  |  |  |                           |                                                            |  |  |  |              |             |       |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |  |                    |  |  |
|                                                                                   | Стерилизация                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Температура                                                | 55 °C                                                   |                                                                                 |                                                                          |                                               |      |                                                         |                                                         |                                                                         |                                                                          |             |        |                             |                                                                                 |        |          |        |                           |        |               |       |                            |  |  |  |                                |                           |  |  |  |                                           |  |  |  |  |                           |                                                            |  |  |  |              |             |       |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |  |                    |  |  |
|                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Относительная влажность                                    | 70 %                                                    |                                                                                 |                                                                          |                                               |      |                                                         |                                                         |                                                                         |                                                                          |             |        |                             |                                                                                 |        |          |        |                           |        |               |       |                            |  |  |  |                                |                           |  |  |  |                                           |  |  |  |  |                           |                                                            |  |  |  |              |             |       |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |  |                    |  |  |
|                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Концентрация этиленоксида                                  | 725 мг/л                                                |                                                                                 |                                                                          |                                               |      |                                                         |                                                         |                                                                         |                                                                          |             |        |                             |                                                                                 |        |          |        |                           |        |               |       |                            |  |  |  |                                |                           |  |  |  |                                           |  |  |  |  |                           |                                                            |  |  |  |              |             |       |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |  |                    |  |  |
|                                                                                   | Время воздействия газа (полный цикл)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 240 мин                                                    |                                                         |                                                                                 |                                                                          |                                               |      |                                                         |                                                         |                                                                         |                                                                          |             |        |                             |                                                                                 |        |          |        |                           |        |               |       |                            |  |  |  |                                |                           |  |  |  |                                           |  |  |  |  |                           |                                                            |  |  |  |              |             |       |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |  |                    |  |  |
|                                                                                   | Аэрация                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                            | 53–57 °C, 18 часов                                      |                                                                                 |                                                                          |                                               |      |                                                         |                                                         |                                                                         |                                                                          |             |        |                             |                                                                                 |        |          |        |                           |        |               |       |                            |  |  |  |                                |                           |  |  |  |                                           |  |  |  |  |                           |                                                            |  |  |  |              |             |       |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |  |                    |  |  |
| Техническое обслуживание, осмотр и проверка                                       | <ul style="list-style-type: none"><li>• Перед каждым использованием и после него необходимо осматривать компоненты на предмет повреждения. При обнаружении повреждений не используйте инструмент, пока он не будет отремонтирован.</li><li>• После очистки и стерилизации перед повторным использованием проверьте работоспособность изделия.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                            |                                                         |                                                                                 |                                                                          |                                               |      |                                                         |                                                         |                                                                         |                                                                          |             |        |                             |                                                                                 |        |          |        |                           |        |               |       |                            |  |  |  |                                |                           |  |  |  |                                           |  |  |  |  |                           |                                                            |  |  |  |              |             |       |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |  |                    |  |  |
| Хранение                                                                          | Храните вместе с другими стерильными устройствами.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                            |                                                         |                                                                                 |                                                                          |                                               |      |                                                         |                                                         |                                                                         |                                                                          |             |        |                             |                                                                                 |        |          |        |                           |        |               |       |                            |  |  |  |                                |                           |  |  |  |                                           |  |  |  |  |                           |                                                            |  |  |  |              |             |       |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |  |                    |  |  |
| Дополнительная информация                                                         | Отсутствует.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                            |                                                         |                                                                                 |                                                                          |                                               |      |                                                         |                                                         |                                                                         |                                                                          |             |        |                             |                                                                                 |        |          |        |                           |        |               |       |                            |  |  |  |                                |                           |  |  |  |                                           |  |  |  |  |                           |                                                            |  |  |  |              |             |       |  |  |  |                         |      |  |  |  |                           |          |  |  |  |                                      |         |  |  |  |         |  |                    |  |  |

**Примечание.** Вышеизложенные инструкции прошли валидацию и рекомендованы производителем в качестве процедур, СПОСОБНЫХ подготовить продукт для повторного использования. Ответственность за фактическое осуществление повторной обработки с использованием оборудования, материалов и персонала обрабатывающего предприятия, обеспечивающих требуемый результат, несет обработчик. Обычно для этого необходима валидация процесса и его рутинный контроль.

**Примечание.** Все процессы валидации выполняются согласно требованиям стандарта AAMI TIR12 «Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers» (Разработка, проверка и маркировка повторно используемых устройств медицинского назначения для повторной обработки в учреждениях здравоохранения: рекомендация для производителей устройств медицинского назначения).

Компания Medtronic рекомендует сжигание устройств, которые находились в непосредственном контакте с пациентами, имеющими предполагаемый или подтвержденный диагноз трансмиссивной губчатой энцефалопатии (ТГЭ) или болезни Крейтцфельда-Якоба (БКЯ).



Инструкции по повторной  
обработке  
Микропилы

Инструкции по повторной обработке  
Инструкции по очистке и стерилизации могут  
быть изменены. Актуальные инструкции  
можно найти на веб-узле [manuals.medtronic.com](http://manuals.medtronic.com).  
M000030A231 D

| Предупреждения и меры предосторожности                                    | <ul style="list-style-type: none"><li>Замачивать устройства или погружать их в жидкость запрещается.</li><li>Запрещается ультразвуковая очистка микропилы Midas Rex.</li><li>Запрещается использовать вызывающие коррозию или содержащие хлор чистящие средства, такие как отбеливатель, щелок, ацетон, гипохлорит натрия, едкий натр, муравьиная кислота или растворы, содержащие глутаральдегид.</li><li>После стерилизации паром необходимо дождаться остывания компонентов.</li><li>Применение мойки-дезинфектора эндоскопов может привести к преждевременному ухудшению рабочих характеристик.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                         |                                                                          |                                                                     |  |                                               |                                                         |                                                                         |                                                                          |                                     |             |             |        |                             |   |       |          |        |                           |                                                                     |       |               |        |                            |   |                                |                                                                                                                                                            |  |  |  |                               |                                                                                                         |  |  |  |
|---------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|--------------------------------------------------------------------------|---------------------------------------------------------------------|--|-----------------------------------------------|---------------------------------------------------------|-------------------------------------------------------------------------|--------------------------------------------------------------------------|-------------------------------------|-------------|-------------|--------|-----------------------------|---|-------|----------|--------|---------------------------|---------------------------------------------------------------------|-------|---------------|--------|----------------------------|---|--------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|-------------------------------|---------------------------------------------------------------------------------------------------------|--|--|--|
| Ограничения                                                               | Перед повторным использованием инструмента выполняйте проверку его работоспособности.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                         |                                                                          |                                                                     |  |                                               |                                                         |                                                                         |                                                                          |                                     |             |             |        |                             |   |       |          |        |                           |                                                                     |       |               |        |                            |   |                                |                                                                                                                                                            |  |  |  |                               |                                                                                                         |  |  |  |
| Важные замечания                                                          | Необходимо следовать процедуре, принятой в медицинском учреждении.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                         |                                                                          |                                                                     |  |                                               |                                                         |                                                                         |                                                                          |                                     |             |             |        |                             |   |       |          |        |                           |                                                                     |       |               |        |                            |   |                                |                                                                                                                                                            |  |  |  |                               |                                                                                                         |  |  |  |
| Защита от загрязнений и транспортировка                                   | Рекомендуется выполнять обработку инструментов немедленно после их использования.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                         |                                                                          |                                                                     |  |                                               |                                                         |                                                                         |                                                                          |                                     |             |             |        |                             |   |       |          |        |                           |                                                                     |       |               |        |                            |   |                                |                                                                                                                                                            |  |  |  |                               |                                                                                                         |  |  |  |
| Подготовка к обеззараживанию                                              | <ul style="list-style-type: none"><li>Отсоедините рукоятку от пульта управления.</li><li>Отсоедините трубки для ирригации/держатели, лезвие пилы и зажимы для укладки кабеля.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                         |                                                                          |                                                                     |  |                                               |                                                         |                                                                         |                                                                          |                                     |             |             |        |                             |   |       |          |        |                           |                                                                     |       |               |        |                            |   |                                |                                                                                                                                                            |  |  |  |                               |                                                                                                         |  |  |  |
| Очистка                                                                   | <ul style="list-style-type: none"><li>Перед тем как загрузить пилы в автоматическую моечную машину, промойте корпус пилы, размещенной дальним концом вниз, вручную под струей водопроводной воды, пока на ней не останется видимых следов загрязнений.</li><li>Несколько раз переместите подвижные элементы в разные стороны с тем, чтобы вода могла проникнуть в труднодоступные полости корпуса.</li><li>Загрузите устройства в моечную машину для обработки, удостоверившись в том, что зажимной патрон осцилляторной пилы находится в открытом положении. Размещать устройства в моечной машине следует таким образом, чтобы обеспечить свободное стекание с них воды.</li><li>Удостоверьтесь в том, что после автоматической очистки на устройствах отсутствуют видимые загрязнения.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                         |                                                                          |                                                                     |  |                                               |                                                         |                                                                         |                                                                          |                                     |             |             |        |                             |   |       |          |        |                           |                                                                     |       |               |        |                            |   |                                |                                                                                                                                                            |  |  |  |                               |                                                                                                         |  |  |  |
| Автоматизированные методы (НЕ используйте ультразвуковой моечный аппарат) | <table><tr><th>Рекомендуемый цикл обработки в моечной машине</th><th>Фаза</th><th>Длительность рециркуляции</th><th>Температура воды</th><th>Тип и концентрация моющего средства</th></tr><tr><td></td><td>Замачивание</td><td>2 мин</td><td>Холодная водопроводная вода</td><td>—</td></tr><tr><td></td><td>Промывка</td><td>5 мин</td><td>66 °C (заданное значение)</td><td>Нейтральное ферментативное моющее средство с показателем pH 6,0–8,0</td></tr><tr><td></td><td>Ополаскивание</td><td>1 мин</td><td>Горячая водопроводная вода</td><td>—</td></tr></table>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                         |                                                                          |                                                                     |  | Рекомендуемый цикл обработки в моечной машине | Фаза                                                    | Длительность рециркуляции                                               | Температура воды                                                         | Тип и концентрация моющего средства |             | Замачивание | 2 мин  | Холодная водопроводная вода | — |       | Промывка | 5 мин  | 66 °C (заданное значение) | Нейтральное ферментативное моющее средство с показателем pH 6,0–8,0 |       | Ополаскивание | 1 мин  | Горячая водопроводная вода | — |                                |                                                                                                                                                            |  |  |  |                               |                                                                                                         |  |  |  |
| Рекомендуемый цикл обработки в моечной машине                             | Фаза                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Длительность рециркуляции                                               | Температура воды                                                         | Тип и концентрация моющего средства                                 |  |                                               |                                                         |                                                                         |                                                                          |                                     |             |             |        |                             |   |       |          |        |                           |                                                                     |       |               |        |                            |   |                                |                                                                                                                                                            |  |  |  |                               |                                                                                                         |  |  |  |
|                                                                           | Замачивание                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 2 мин                                                                   | Холодная водопроводная вода                                              | —                                                                   |  |                                               |                                                         |                                                                         |                                                                          |                                     |             |             |        |                             |   |       |          |        |                           |                                                                     |       |               |        |                            |   |                                |                                                                                                                                                            |  |  |  |                               |                                                                                                         |  |  |  |
|                                                                           | Промывка                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 5 мин                                                                   | 66 °C (заданное значение)                                                | Нейтральное ферментативное моющее средство с показателем pH 6,0–8,0 |  |                                               |                                                         |                                                                         |                                                                          |                                     |             |             |        |                             |   |       |          |        |                           |                                                                     |       |               |        |                            |   |                                |                                                                                                                                                            |  |  |  |                               |                                                                                                         |  |  |  |
|                                                                           | Ополаскивание                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 1 мин                                                                   | Горячая водопроводная вода                                               | —                                                                   |  |                                               |                                                         |                                                                         |                                                                          |                                     |             |             |        |                             |   |       |          |        |                           |                                                                     |       |               |        |                            |   |                                |                                                                                                                                                            |  |  |  |                               |                                                                                                         |  |  |  |
| Очистка                                                                   | <ul style="list-style-type: none"><li>Тщательно промойте устройство в проточной воде, держа его зажимным патроном вниз.</li><li>Протрите корпус пилы и кабель тканью, смоченной в нейтральном ферментативном моющем средстве с показателем pH 6,0–8,0 (далее по тексту — «чистящий раствор»).</li><li>Расположив устройство патроном вниз, очистите корпус и кнопку разблокировки лезвия нейлоновой щеткой, смоченной в чистящем растворе.</li><li>Только для сагиттальных пил:<ol style="list-style-type: none"><li>Погрузите дистальный конец пилы в чистящий раствор и поболтайте пилу в течение 10–15 секунд.</li><li>Нажмите и удерживайте кнопку разблокировки лезвия и повторите этап 1.</li><li>Нажав и удерживая кнопку разблокировки лезвия, шприцем впрысните приблизительно 15 мл чистящего раствора в отверстие лезвия.</li><li>Промойте все порты 15 мл чистящего раствора.</li><li>Повторите этапы 1–4, используя вместо чистящего раствора воду.</li></ol></li><li>Только для реципрокных пил:<ol style="list-style-type: none"><li>Расположив устройство дистальным концом вверх, впрысните 30 мл чистящего раствора с помощью шприца в дистальный конец пилы так, чтобы раствор попал внутрь патрона.</li><li>Удерживая устройство в вертикальном положении, поверните корпус патрона в разные стороны три раза.</li><li>Затем дайте раствору стечь из устройства.</li><li>Повторите этапы 1–3 второй раз, используя чистящий раствор.</li><li>Повторите этапы 1–3 третий раз, используя воду.</li></ol></li><li>Промойте устройство в проточной воде, убедившись в том, что вода попадает во все порты и отверстия. Приведите в действие имеющиеся подвижные элементы, чтобы обеспечить проникновение воды во все места устройства. Промывайте устройство до тех пор, пока на нем не останется видимых следов загрязнений.</li></ul> |                                                                         |                                                                          |                                                                     |  |                                               |                                                         |                                                                         |                                                                          |                                     |             |             |        |                             |   |       |          |        |                           |                                                                     |       |               |        |                            |   |                                |                                                                                                                                                            |  |  |  |                               |                                                                                                         |  |  |  |
| Сушка и смазка                                                            | <ul style="list-style-type: none"><li>Просушите все устройство безворсовой салфеткой.</li><li>Только для реципрокных и осцилляторных пил: Если необходимо, выполните следующие действия по смазке патрона пилы с помощью спрея Rapa.<ol style="list-style-type: none"><li>Держа аэрозольный баллончик на расстоянии 10–15 см от патрона пилы, распылите смазку в отверстие сердечника (реципрокная пила) или на проксимальную/нижнюю часть патрона возле индикаторов блокировки/разблокировки (осцилляторная пила), делая по три коротких нажатия для смазки каждой детали.</li><li>Подвигайте патрон для надлежащей смазки.</li><li>Удалите излишки смазки чистой тканью.</li></ol></li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                         |                                                                          |                                                                     |  |                                               |                                                         |                                                                         |                                                                          |                                     |             |             |        |                             |   |       |          |        |                           |                                                                     |       |               |        |                            |   |                                |                                                                                                                                                            |  |  |  |                               |                                                                                                         |  |  |  |
| Дезинфекция                                                               | Необходимо следовать процедуре, принятой в медицинском учреждении.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                         |                                                                          |                                                                     |  |                                               |                                                         |                                                                         |                                                                          |                                     |             |             |        |                             |   |       |          |        |                           |                                                                     |       |               |        |                            |   |                                |                                                                                                                                                            |  |  |  |                               |                                                                                                         |  |  |  |
| Упаковка                                                                  | Для стерилизации поместите устройства в лоток для инструментов. Устройства можно стерилизовать без обертыивания или обернутыми двумя слоями однослойной полипропиленовой обертки.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                         |                                                                          |                                                                     |  |                                               |                                                         |                                                                         |                                                                          |                                     |             |             |        |                             |   |       |          |        |                           |                                                                     |       |               |        |                            |   |                                |                                                                                                                                                            |  |  |  |                               |                                                                                                         |  |  |  |
| Стерилизация (указаны минимальные необходимые температура и время)        | <table><tr><th>Цикл</th><th>Паровая стерилизация с предварительной откачкой воздуха</th><th>Паровая стерилизация с предварительной откачкой воздуха (Франция / ВОЗ)</th><th>Паровая стерилизация с предварительной откачкой воздуха (Великобритания)</th><th></th></tr><tr><td>Температура</td><td>132 °C</td><td>134 °C</td><td>134 °C</td><td></td></tr><tr><td>Время</td><td>4 мин</td><td>18 мин</td><td>3 мин</td><td></td></tr><tr><td>Сушка</td><td>20 мин</td><td>30 мин</td><td>22 мин</td><td></td></tr><tr><td>Стерилизация в системе STERRAD</td><td colspan="4">Из-за ограниченного внутреннего диаметра просвета и длины трубки ЗАПРЕЩАЕТСЯ применять стерилизацию в низкотемпературной газовой плазме перекиси водорода.</td></tr><tr><td>Стерилизация в системе STERIS</td><td colspan="4">Запрещается стерилизовать в жидкой перуксусной кислоте, так как эта процедура подразумевает погружение.</td></tr></table>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                         |                                                                          |                                                                     |  | Цикл                                          | Паровая стерилизация с предварительной откачкой воздуха | Паровая стерилизация с предварительной откачкой воздуха (Франция / ВОЗ) | Паровая стерилизация с предварительной откачкой воздуха (Великобритания) |                                     | Температура | 132 °C      | 134 °C | 134 °C                      |   | Время | 4 мин    | 18 мин | 3 мин                     |                                                                     | Сушка | 20 мин        | 30 мин | 22 мин                     |   | Стерилизация в системе STERRAD | Из-за ограниченного внутреннего диаметра просвета и длины трубки ЗАПРЕЩАЕТСЯ применять стерилизацию в низкотемпературной газовой плазме перекиси водорода. |  |  |  | Стерилизация в системе STERIS | Запрещается стерилизовать в жидкой перуксусной кислоте, так как эта процедура подразумевает погружение. |  |  |  |
| Цикл                                                                      | Паровая стерилизация с предварительной откачкой воздуха                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Паровая стерилизация с предварительной откачкой воздуха (Франция / ВОЗ) | Паровая стерилизация с предварительной откачкой воздуха (Великобритания) |                                                                     |  |                                               |                                                         |                                                                         |                                                                          |                                     |             |             |        |                             |   |       |          |        |                           |                                                                     |       |               |        |                            |   |                                |                                                                                                                                                            |  |  |  |                               |                                                                                                         |  |  |  |
| Температура                                                               | 132 °C                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 134 °C                                                                  | 134 °C                                                                   |                                                                     |  |                                               |                                                         |                                                                         |                                                                          |                                     |             |             |        |                             |   |       |          |        |                           |                                                                     |       |               |        |                            |   |                                |                                                                                                                                                            |  |  |  |                               |                                                                                                         |  |  |  |
| Время                                                                     | 4 мин                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 18 мин                                                                  | 3 мин                                                                    |                                                                     |  |                                               |                                                         |                                                                         |                                                                          |                                     |             |             |        |                             |   |       |          |        |                           |                                                                     |       |               |        |                            |   |                                |                                                                                                                                                            |  |  |  |                               |                                                                                                         |  |  |  |
| Сушка                                                                     | 20 мин                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 30 мин                                                                  | 22 мин                                                                   |                                                                     |  |                                               |                                                         |                                                                         |                                                                          |                                     |             |             |        |                             |   |       |          |        |                           |                                                                     |       |               |        |                            |   |                                |                                                                                                                                                            |  |  |  |                               |                                                                                                         |  |  |  |
| Стерилизация в системе STERRAD                                            | Из-за ограниченного внутреннего диаметра просвета и длины трубки ЗАПРЕЩАЕТСЯ применять стерилизацию в низкотемпературной газовой плазме перекиси водорода.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                         |                                                                          |                                                                     |  |                                               |                                                         |                                                                         |                                                                          |                                     |             |             |        |                             |   |       |          |        |                           |                                                                     |       |               |        |                            |   |                                |                                                                                                                                                            |  |  |  |                               |                                                                                                         |  |  |  |
| Стерилизация в системе STERIS                                             | Запрещается стерилизовать в жидкой перуксусной кислоте, так как эта процедура подразумевает погружение.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                         |                                                                          |                                                                     |  |                                               |                                                         |                                                                         |                                                                          |                                     |             |             |        |                             |   |       |          |        |                           |                                                                     |       |               |        |                            |   |                                |                                                                                                                                                            |  |  |  |                               |                                                                                                         |  |  |  |
| Техническое обслуживание, осмотр и проверка                               | <ul style="list-style-type: none"><li>Перед каждым использованием и после него необходимо осматривать компоненты на предмет повреждения. При обнаружении повреждений не используйте инструмент, пока он не будет отремонтирован.</li><li>После очистки и стерилизации перед повторным использованием проверьте работоспособность изделия.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                         |                                                                          |                                                                     |  |                                               |                                                         |                                                                         |                                                                          |                                     |             |             |        |                             |   |       |          |        |                           |                                                                     |       |               |        |                            |   |                                |                                                                                                                                                            |  |  |  |                               |                                                                                                         |  |  |  |
| Хранение                                                                  | Храните вместе с другими стерильными устройствами.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                         |                                                                          |                                                                     |  |                                               |                                                         |                                                                         |                                                                          |                                     |             |             |        |                             |   |       |          |        |                           |                                                                     |       |               |        |                            |   |                                |                                                                                                                                                            |  |  |  |                               |                                                                                                         |  |  |  |
| Дополнительная информация                                                 | Отсутствует.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                         |                                                                          |                                                                     |  |                                               |                                                         |                                                                         |                                                                          |                                     |             |             |        |                             |   |       |          |        |                           |                                                                     |       |               |        |                            |   |                                |                                                                                                                                                            |  |  |  |                               |                                                                                                         |  |  |  |

**Примечание.** Вышеизложенные инструкции прошли валидацию и рекомендованы производителем в качестве процедур, СПОСОБНЫХ подготовить продукт для повторного использования. Ответственность за фактическое осуществление повторной обработки с использованием оборудования, материалов и персонала обрабатывающего предприятия, обеспечивающих требуемый результат, несет обработчик. Обычно для этого необходима валидация процесса и его рутинный контроль

**Примечание.** Все процессы валидации выполняются согласно требованиям стандарта AAMI TIR12 «Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers» (Разработка, проверка и маркировка повторно используемых устройств медицинского назначения для повторной обработки в учреждениях здравоохранения: рекомендация для производителей устройств медицинского назначения).

Компания Medtronic рекомендует сжигание устройств, которые находились в непосредственном контакте с пациентами, имеющими предполагаемый или подтвержденный диагноз трансмиссивной губчатой энцефалопатии (ТГЭ) или болезни Крейтцфельда-Якоба (БКЯ).



|                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                    |                                                                                  |                                                                                   |                                                                        |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|------------------------------------------------------------------------|
| <div><div></div><div>Инструкции по повторной<br/>обработке<br/>Электропривод POWEREASE</div></div> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Инструкции по повторной обработке<br>Инструкции по очистке и стерилизации могут быть<br>изменены. Актуальные инструкции можно найти на<br>веб-узле <a href="http://manuals.medtronic.com">manuals.medtronic.com</a> .<br>68E4189 C |                                                                                  |                                                                                   |                                                                        |
| Предупреждения<br>и меры<br>предосторожности                                                                                                                                        | <ul style="list-style-type: none"><li>Замачивать устройства или погружать их в жидкость запрещается.</li><li>Запрещается ультразвуковая очистка устройств.</li><li>Запрещается использовать вызывающие коррозию или содержащие хлор чистящие средства, такие как отбеливатель, щелок, ацетон, гипохлорит натрия, едкий натр, муравьиная кислота или растворы, содержащие глутаральдегид.</li><li>Применение мойки-дезинфектора эндоскопов может привести к преждевременному ухудшению рабочих характеристик.</li><li>После стерилизации паром необходимо дождаться остывания компонентов.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                    |                                                                                  |                                                                                   |                                                                        |
| Ограничения                                                                                                                                                                         | Перед повторным использованием инструмента выполняйте проверку его работоспособности.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                    |                                                                                  |                                                                                   |                                                                        |
| Важные замечания                                                                                                                                                                    | Особые требования отсутствуют.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                    |                                                                                  |                                                                                   |                                                                        |
| Защита от<br>загрязнений<br>и транспортировка                                                                                                                                       | Рекомендуется выполнять обработку инструментов немедленно после их использования.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                    |                                                                                  |                                                                                   |                                                                        |
| Подготовка<br>к обеззараживанию                                                                                                                                                     | Отсоедините рукоятку от пульта управления.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                    |                                                                                  |                                                                                   |                                                                        |
| Очистка<br>Ручные методы                                                                                                                                                            | <ul style="list-style-type: none"><li>Струей водопроводной воды промойте внутренний просвет рукоятки, расположенной зажимным патроном вниз, пока из нее не будут удалены все видимые загрязнения и остатки тканей. Приводя в действие зажимной патрон, промойте его.</li><li>Протрите наружную поверхность электродвигателя и кабель тканью, смоченной в нейтральном ферментативном моющем составе с показателем pH 6,0–8,0.</li><li>Тщательно очистите корпус и зажимной патрон электродвигателя, а также область кнопки-регулятора нейлоновой щеткой, смоченной в нейтральном ферментативном моющем средстве с показателем pH 6,0–8,0. В процессе очистки щеткой зажимной патрон и кнопку-регулятор следует приводить в действие.</li><li>С помощью щетки для просвета прочистите просвет по всей длине.</li><li>Промойте полностью все устройство под струей водопроводной воды, расположив его зажимным патроном вниз.</li><li>Погрузите ту часть устройства, где расположен патрон, в нейтральное ферментативное моющее средство с pH 6,0–8,0 минимум на 2 минуты. Пока зажимной патрон будет находиться в жидкости, приводите его в действие и тщательно очистите с помощью щетки. Для промывки труднодоступных мест следует использовать шприц.</li><li>Промойте полностью все устройство под струей водопроводной воды, расположив его зажимным патроном вниз. Для промывки труднодоступных мест следует использовать шприц.</li><li>Протрите насухо безворсовой тканью.</li><li>Удостоверьтесь в том, что на устройстве отсутствуют визуальные признаки загрязнения.</li></ul>                                                                                                                                                 |                                                                                                                                                                                                                                    |                                                                                  |                                                                                   |                                                                        |
| Очистка<br>Автоматизированные<br>методы<br>(НЕ используйте<br>ультразвуковой<br>моечный аппарат)                                                                                    | <p>Перед дальнейшей обработкой в моечной машине или аппарате для дезинфекции привод POWEREASE <u>должен</u> быть подвергнут процедуре очистки вручную.</p> <ol style="list-style-type: none"><li>Струей водопроводной воды промойте внутренний просвет рукоятки, расположенной зажимным патроном вниз, пока из нее не будут удалены все видимые загрязнения и остатки тканей. Приводя в действие зажимной патрон, промойте его.</li><li>Протрите наружную поверхность электродвигателя и кабель тканью, смоченной в нейтральном ферментативном моющем составе.</li><li>Очистите корпус и зажимной патрон электродвигателя, а также область кнопки-регулятора нейлоновой щеткой, смоченной в нейтральном ферментативном моющем средстве. В процессе очистки щеткой зажимной патрон и кнопку-регулятор следует приводить в действие.</li><li>С помощью щетки для просвета прочистите просвет по всей длине.</li><li>Промойте полностью все устройство под струей водопроводной воды, расположив его зажимным патроном вниз.</li><li>Погрузите ту часть устройства, где расположен патрон, в нейтральное ферментативное моющее средство минимум на 2 минуты. Пока зажимной патрон будет находиться в жидкости, приводите его в действие и выполните его очистку с помощью щетки. Для промывки труднодоступных мест следует использовать шприц.</li><li>Промойте полностью все устройство под струей водопроводной воды, расположив его зажимным патроном вниз. Для промывки труднодоступных мест следует использовать шприц.</li><li>Поместите привод POWEREASE в подходящую корзину для моечной машины или аппарата для дезинфекции и подвергните его следующему циклу обработки в моечной машине или аппарате для дезинфекции.</li></ol> |                                                                                                                                                                                                                                    |                                                                                  |                                                                                   |                                                                        |
| Рекомендуемый цикл обработки<br>в моечной машине                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Фаза                                                                                                                                                                                                                               | Длительность<br>рециркуляции                                                     | Температура воды                                                                  | Тип и концентрация моющего средства                                    |
|                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Замачивание                                                                                                                                                                                                                        | 2 мин                                                                            | Холодная<br>водопроводная вода                                                    | Нейтральное ферментативное моющее средство<br>с показателем pH 6,0–8,0 |
|                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Промывка                                                                                                                                                                                                                           | 5 мин                                                                            | 66 °C (заданное<br>значение)                                                      |                                                                        |
|                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Ополаскивание                                                                                                                                                                                                                      | 1 мин                                                                            | Горячая<br>водопроводная вода                                                     |                                                                        |
| Дезинфекция                                                                                                                                                                         | Необходимо следовать процедуре, принятой в медицинском учреждении.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                    |                                                                                  |                                                                                   |                                                                        |
| Упаковка                                                                                                                                                                            | Стерилизация паром может выполняться как в обернутом виде, так и без обертывания. В случае стерилизации в завернутом виде в США должен использоваться хирургический оберточный материал, соответствующий требованиям FDA.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                    |                                                                                  |                                                                                   |                                                                        |
| Стерилизация<br>(указаны<br>минимальные<br>необходимые<br>температура и время)                                                                                                      | Стерилизация паром                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                    |                                                                                  |                                                                                   |                                                                        |
| Цикл                                                                                                                                                                                | Паровая<br>стерилизация<br>с гравитационным<br>удалением воздуха                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Паровая<br>стерилизация<br>с предварительной<br>откачкой воздуха                                                                                                                                                                   | Паровая стерилизация<br>с предварительной<br>откачкой воздуха<br>(Франция / ВОЗ) | Паровая стерилизация<br>с предварительной<br>откачкой воздуха<br>(Великобритания) |                                                                        |
| Температура                                                                                                                                                                         | 132 °C                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 132 °C                                                                                                                                                                                                                             | 134 °C                                                                           | 134 °C                                                                            |                                                                        |
| Время                                                                                                                                                                               | 25 мин                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 4 мин                                                                                                                                                                                                                              | 18 мин                                                                           | 3 мин                                                                             |                                                                        |
| Сушка                                                                                                                                                                               | 40 мин                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                    |                                                                                  |                                                                                   |                                                                        |
| Стерилизация<br>в системе STERRAD                                                                                                                                                   | Валидация не проводилась.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                    |                                                                                  |                                                                                   |                                                                        |
| Стерилизация<br>в системе STERIS                                                                                                                                                    | Валидация не проводилась.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                    |                                                                                  |                                                                                   |                                                                        |
| Параметры<br>стерилизации 100 %<br>этиленоксидом                                                                                                                                    | Валидация не проводилась.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                    |                                                                                  |                                                                                   |                                                                        |
| Техническое<br>обслуживание,<br>осмотр и проверка                                                                                                                                   | <ul style="list-style-type: none"><li>Перед каждым использованием и после него необходимо осматривать компоненты на предмет повреждения. В случае обнаружения повреждения запрещается использовать инструмент, пока он не будет отремонтирован.</li><li>После очистки и стерилизации перед повторным использованием проверьте работоспособность изделия.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                    |                                                                                  |                                                                                   |                                                                        |
| Хранение                                                                                                                                                                            | Храните вместе с другими стерильными устройствами.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                    |                                                                                  |                                                                                   |                                                                        |
| Дополнительная<br>информация                                                                                                                                                        | Отсутствует.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                    |                                                                                  |                                                                                   |                                                                        |

**Примечание.** Вышеизложенные инструкции прошли валидацию и рекомендованы производителем в качестве процедур, СПОСОБНЫХ подготовить продукт для повторного использования. Ответственность за фактическое осуществление повторной обработки с использованием оборудования, материалов и персонала обрабатывающего предприятия, обеспечивающих требуемый результат, несет обработчик. Обычно для этого необходима валидация процесса и его рутинный контроль.

**Примечание.** Все процессы валидации выполняются согласно требованиям стандарта AAMI TIR12 «Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers» (Разработка, проверка и маркировка повторно используемых устройств медицинского назначения для повторной обработки в учреждениях здравоохранения: рекомендация для производителей устройств медицинского назначения).

Компания Medtronic рекомендует сжигание устройств, которые находились в непосредственном контакте с пациентами, имеющими предполагаемый или подтвержденный диагноз трансмиссивной губчатой энцефалопатии (ТГЭ) или болезни Крейтцфельда-Якоба (БКЯ).

СИМВОЛЫ

На данном устройстве и его упаковке могут встречаться следующие символы.

|  |                                             |  |                                                                                               |  |                                                                    |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|--|---------------------------------------------|--|-----------------------------------------------------------------------------------------------|--|--------------------------------------------------------------------|--|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | Кнопка включения и выключения               |  | Содержимое упаковки                                                                           |  | См. инструкцию по эксплуатации                                     |  | Соответствует требованиям ANSI/AAMI ES60601-1, Сертифицировано по CAN/CSA-C22.2 № 60601-1, IEC/EN 60601-1                                                                                                                                                                                                                                                                                                                                                                                     |
|  | Знак соответствия требованиям стандарта ЭМС |  | Не смазывать жирами                                                                           |  | Не погружать в жидкости                                            |  | ВНИМАНИЕ! Согласно Федеральному законодательству США, это устройство может быть продано только врачу или по заказу врача.                                                                                                                                                                                                                                                                                                                                                                     |
|  | Плавкий предохранитель                      |  | Защищено от вертикально падающих капель воды                                                  |  | Колесование                                                        |  | Официальный представитель в ЕС                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|  | Срок годности                               |  | Защищено от воздействия временного погружения в воду                                          |  | Вперед                                                             |  | Мера предосторожности: опасность защемления. Не допускайте попадания пальцев в ролики.                                                                                                                                                                                                                                                                                                                                                                                                        |
|  | Инструмент                                  |  | Контактная деталь типа BF                                                                     |  | Назад                                                              |  | Содержит ДЭГФ (ди-2-этилгексил фталат)                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|  | Питание от сети переменного тока            |  | Пуск/Стоп                                                                                     |  | Разъем для педали                                                  |  | Защитное заземление                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|  | Выход                                       |  | РЧ-передатчик (могут возникать помехи)                                                        |  | Тонкая регулировка иригации                                        |  | Разъем для эквипотенциального заземления                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|  | Приблизительно равно                        |  | См. инструкцию по эксплуатации                                                                |  | Левая кнопка модуля ножного управления/ кнопка переключения режима |  | Использовать с                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|  | Нестерильно                                 |  | Разъем для стимулирующего бора                                                                |  | Правая кнопка модуля ножного управления/ кнопка управления         |  | Требования стандартов RoHS — благоприятный для окружающей среды период эксплуатации — Китай (SJ/T11364-2006)                                                                                                                                                                                                                                                                                                                                                                                  |
|  | Нестерильно                                 |  | Разъем для пульты NIM                                                                         |  | Верхняя кнопка модуля ножного управления/ кнопка рукоятки          |  | Не выбрасывайте это устройство вместе с неотсортированным бытовым мусором. Утилизируйте устройство в соответствии с действующим законодательством. Для получения инструкций по правильной утилизации этого продукта посетите веб-сайт <b>Recycling.Medtronic.Com</b> .                                                                                                                                                                                                                        |
|  | Количество                                  |  | Разъем для электрической высокоскоростной рукоятки                                            |  | Заблокировано                                                      |  | Если на этикетке устройства есть символ, обозначающий однократное применение, это устройство предназначено для использования только для одного пациента. Не использовать повторно, не обрабатывать повторно и не подвергать изделие повторной стерилизации. Повторное использование, обработка или повторная стерилизация может нарушить структурную целостность устройства и/или нести риск микробного загрязнения устройства, что может привести к травме, заболеванию или смерти пациента. |
|  | Не более 120 В переменного тока             |  | Всемирный стандарт для диаметра медицинских трубок                                            |  | Разблокировано                                                     |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|  | Предостережение                             |  |                                                                                               |  |                                                                    |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|  | Рабочий цикл контактной детали              |  | Дата изготовления                                                                             |  | Рукоятка                                                           |  | Дополнительная принадлежность / Адаптер / Насадка / Костная мельница / Щетка / Блок управления / Инструмент для препарирования / Корпус инструмента / Любрикант/диффузор / Электродвигатель / Многоцелевая одноразовая насадка / Регулятор                                                                                                                                                                                                                                                    |
|  | Номер по каталогу                           |  | Производитель                                                                                 |  | Skeeter                                                            |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|  | Номер партии                                |  | Стерилизовано облучением                                                                      |  | Головка помпы 1                                                    |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|  | Серийный номер                              |  | Температурные ограничения Внешние пределы — транспортировка Внутренние пределы — эксплуатация |  | Головка помпы 2                                                    |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|  | Соединенные Штаты Америки только            |  | Эргономичная конструкция                                                                      |  | Обновленный                                                        |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |

Информация, содержащаяся в данном документе, является достоверной на момент его публикации. Корпорация Medtronic оставляет за собой право вносить изменения в изделие, описанное в руководстве. Актуальные редакции см. на [manuals.medtronic.com](http://manuals.medtronic.com).





68M0005 L

2016-06

© 2016 Medtronic, Inc.



# Medtronic

[medtronic.com](http://medtronic.com)

[manuals.medtronic.com](http://manuals.medtronic.com)



Medtronic Xomed, Inc.  
6743 Southpoint Drive North  
Jacksonville, Florida США 32216  
800 874 5797



Medtronic B.V.  
Earl Bakkenstraat 10  
6422 PJ Heerlen  
Нидерланды  
+31 45 566 8000

## Instrument Tray

Plateau à instruments

Vassoio per strumenti

Instrumentenschale

Bandeja de instrumentos

Instrumententray

Instrumentbakke

Instrumentttitarjottimet

Instrumentbricka

Tabuleiro de instrumentos

Δίσκος εργαλείων

Taca na narzędzia

Podnos na nástroje

Műszertálca

Alet Tepsisi

Instrumentbrett

Лоток для инструментов

Posuda za instrumente

Podložak za instrumente

Bandeja para instrumental

### Product Information and Instructions

**FR** Instructions et Informations sur le Produit **IT** Informazioni

sul prodotto e istruzioni per l'uso **DE** Produktinformationen

und Gebrauchsanweisung **ES** Instrucciones e informacón

sobre el producto **NL** Productinformatie en instructies **DA**

Produktinformation og -vejledning **FI** Tuotetiedot ja käyttöohjeet

**SV** Produktinformation och instruktioner **PT-PT** Informações

do produto e instruções **EL** Πληροφορίες προϊόντος και

οδηγίες **PL** Informacja o produkcie i instrukcje **CS** Informace o

výrobku a návod k použití **HU** Termékinformáció és utasítások

**TR** Ürün Bilgileri ve Talimatlar **NO** Produktinformasjon og

instruksjoner **RU** Информация о продукте и инструкция по его

эксплуатации **SR** Informacije o proizvodu i uputstvo **HR** Podaci

o proizvodu i upute **PT-BR** Informações e instruções sobre o

produto



Indications for use

Instrument trays are intended to provide a general configuration to organize, store, protect and transport medical devices for use in surgical procedures.

Precautions

If you choose to use the instrument tray as part of a sterilization system for reprocessing devices:

- Ensure that you validate the tray within your internal processes and systems.
- Follow all instructions for sterilization of the device(s) you are reprocessing.
- Gravity Steam sterilization must not be used for instrument trays as cycle times would be exceedingly long.
- STERRAD processing must not be used for Medtronic Xomed instrument trays.
- Instrument Trays are not intended to provide a sterile barrier to prevent re-contamination of sterilized instruments; and must be double wrapped in hospital CSR wrap for this process to maintain the sterility of the instruments contained inside the tray.
- Remove instruments, loose internal tray components and lid prior to cleaning instruments and/or tray.
- Medtronic recommends incineration of devices that have directly contacted patients suspected or confirmed with Transmissible Spongiform Encephalopathy (TSE)/ CJD diagnosis. NHS Estates HTM 2010 Parts 4 & 6: Appendix 2, Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies refers to a TSE decontamination cycle using a steam autoclave at a temperature of 134-137°C for a single cycle of 18 minutes or repeated for a total of six 3-minute cycles.
- When applying dry times to Medtronic instrument trays and their accessories, dry times outside the standard healthcare prevacuum parameters may be required. The current recommended dry times may range from a standard 15 minutes to an extended time of 40 minutes. This is especially important for polymer-based (plastic) instrument trays. The user should have adequate means to verify drying time, such as visual inspection.

Cleaning

**Note:** To minimize water spotting, using deionized water for the final rinse is recommended. If practical, deionized water may be used for the entire cleaning process.

Automated cleaning

All trays shall be thoroughly rinsed with water prior to placement in the automatic washer.

Remove instruments and equipment from any instrument trays before placing into washer baskets. Orient devices following recommendations of washer/disinfector manufacturers.

Use neutral pH detergent recommended by washer/disinfector or detergent manufacturers.

| Phase       | Recirculation Time | Water Temperature | Detergent Type                 |
|-------------|--------------------|-------------------|--------------------------------|
| Pre-wash 1  | 3 minutes          | cold water        | N/A                            |
| Enzyme Wash | 5 minutes          | hot water         | neutral pH enzymatic detergent |
| Wash 1      | 5 minutes          | 66°C set point    | neutral pH detergent           |
| Rinse 1     | 3 minutes          | hot water         | N/A                            |

Manual cleaning

Soak in lukewarm (less than 43°C), mild (pH 7.0 - 8.5), enzymatic detergent and water for a minimum of 2 minutes. Use a soft instrument brush to scrub instrument trays while submerged in cleaning solution to remove organic matter. Rinse with water, then clean ultrasonically in a lukewarm (less than 43°C), mild (pH 7.0 - 8.5), detergent and water for 10 minutes.

Rinse thoroughly with water. Clean in this manner until no visible soil remains on the instrument tray.

Dry with compressed air, or wipe dry with a lint-free cloth. Examine instrument trays for any staining or deterioration; remove from use as appropriate.

**Note:** When using an ultrasonic cleaner or a spray washing machine, follow the manufacturer's recommendations for positioning of instrument trays.

Following cleaning, lightly lubricate instrument trays with movable parts. Use a lubricant intended for sterilizable instruments such as a water-soluble instrument milk. Do not use silicone spray.

## FR

### Limited warranty

- A. This LIMITED WARRANTY provides assurance for the customer who purchases a Medtronic Xomed Product (hereinafter the "Product") that should the Product fail to function to Medtronic Xomed's published specifications during the term of this LIMITED WARRANTY (one year from the date of shipment for new Product, 90 days from date of shipment for refurbished or used Product), Medtronic Xomed will either replace, repair, or issue a credit (adjusted to reflect the age of the Product) for the Product or any portion thereof. This LIMITED WARRANTY is extended only to the buyer purchasing the Product directly from Medtronic Xomed or from its affiliate or its authorized distributor or representative.
- B. To qualify for this LIMITED WARRANTY, the following conditions must be met:
1. The Product must be used on or before its "Use By" or "Use Before" date, if applicable.
  2. The Product must be used in accordance with its labeling and may not be altered or subjected to misuse, abuse, accident or improper handling.
  3. Medtronic Xomed must be notified in writing within thirty (30) days following discovery of a defect.
  4. The Product must be returned to Medtronic Xomed within thirty (30) days of Medtronic Xomed receiving notice as provided for in (3) above.
  5. Upon examination of the Product by Medtronic Xomed, Medtronic Xomed shall have determined that: (i) the Product was not repaired or altered by anyone other than Medtronic Xomed or its authorized representative, (ii) the Product was not operated under conditions other than normal use, and (iii) the prescribed periodic maintenance and services have been performed on the Product.
- C. This LIMITED WARRANTY is limited to its express terms. THIS LIMITED WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED WHETHER STATUTORY OR OTHERWISE, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. In no event shall Medtronic Xomed be liable for any consequential, incidental, prospective or other similar damage resulting from a defect, failure, or malfunction of the Product, whether a claim for such damage is based upon the warranty, contract, negligence or otherwise.
- D. The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. Users may benefit from statutory warranty rights under legislation governing the sale of consumer goods. If any part or term of this LIMITED WARRANTY is held by any court of competent jurisdiction to be illegal, unenforceable, or in conflict with applicable law, the validity of the remaining portion of the LIMITED WARRANTY shall not be affected, and all rights and obligations shall be construed and enforced as if this LIMITED WARRANTY did not contain the particular part or term held to be invalid.

## FR

### Indications d'utilisation

Les plateaux à instruments sont prévus pour permettre l'organisation, le rangement, la protection et le transport des instruments dans le cadre des procédures chirurgicales.

### Précautions d'utilisation

Si vous choisissez d'utiliser le plateau à instruments avec un système de stérilisation pour le retraitement des instruments :

- Assurez-vous de valider le plateau dans vos processus et systèmes internes.
- Suivez toutes les instructions de stérilisation du ou des instruments à retraiter.
- La stérilisation à la vapeur par gravité est contre-indiquée pour les plateaux à instruments en plastique de polymère car les cycles sont beaucoup trop longs.
- Le traitement STERRAD ne doit pas être utilisé pour les plateaux à instruments Medtronic Xomed.
- Les plateaux à instruments ne sont pas conçus pour fournir une barrière stérile en vue d'empêcher la recontamination des instruments stérilisés. Ils doivent être placés dans un double emballage CSR hospitalier pour conserver la stérilité des instruments contenus dans les plateaux.
- Retirer les instruments, les composants amovibles du plateau interne et le couvercle avant de nettoyer les instruments et/ou le plateau.
- Medtronic recommande d'incinérer tous les dispositifs rentres en contact direct avec les patients chez qui un diagnostic d'encéphalopathie spongiforme transmissible/de maladie de Creutzfeldt-Jakob (EST/MCJ) est suspecté ou confirmé. Le document NHS Estates HTM 2010 Parties 4 & 6 : annexe 2, Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies (Éléments contaminés par les agents EST et le guide de contrôle des infections des encéphalopathies spongiformes transmissibles (EST) établi par l'OMS) fait référence à un cycle de décontamination EST par stérilisation à la vapeur (autoclave) à une température comprise entre 134 et 137 °C durant un seul cycle de 18 minutes ou durant six cycles de 3 minutes.
- Lors de la définition des temps de séchage pour les plateaux à instruments Medtronic et leurs accessoires, il peut être nécessaire d'appliquer des durées différentes des paramètres de prévide standard. Les temps de séchage actuellement recommandés peuvent aller de 15 minutes (durée standard) à 40 minutes (durée prolongée). Ce point est particulièrement important pour les plateaux à instruments en polymère (plastique). L'utilisateur doit pouvoir vérifier le temps de séchage, par exemple en procédant à une inspection visuelle.



Nettoyage

**Remarque :** Pour minimiser les taches d'eau, il est recommandé d'utiliser de l'eau déionisée pour le rinçage final. Si possible, utiliser de l'eau déionisée pour tout le processus de nettoyage.

Nettoyage automatisé

Tous les plateaux doivent être soigneusement rincés sous l'eau avant d'être placés dans l'appareil de lavage automatique.  
Retirer les instruments et accessoires des plateaux à instruments avant de les placer dans les paniers de l'appareil de lavage. Orienter les instruments selon les recommandations du fabricant de l'appareil de lavage/désinfection.  
Utiliser le détergent a pH neutre recommandé par les fabricants du désinfectant ou de l'appareil de lavage/désinfection.

| Phase              | Temps de recyclage | Température de l'eau    | Type de détergent                 |
|--------------------|--------------------|-------------------------|-----------------------------------|
| Prélavage 1        | 3 minutes          | Eau froide              | S/O                               |
| Lavage enzymatique | 5 minutes          | Eau chaude              | Détergent enzymatique à pH neutre |
| Lavage 1           | 5 minutes          | Point de consigne 66 °C | Détergent a pH neutre             |
| Rinçage 1          | 3 minutes          | Eau chaude              | S/O                               |

Nettoyage manuel

Tremper dans une solution tiède (moins de 43 °C) d'eau et de détergent enzymatique doux (pH 7,0 - 8,5) pendant au moins 2 minutes. Utiliser une brosse à instruments douce pour frotter les plateaux à instruments pendant l'immersion dans la solution nettoyante et éliminer les résidus organiques. Rincer avec de l'eau, puis nettoyer dans un bain ultrasonique d'eau tiède (moins de 43 °C) additionnée d'un détergent doux (pH 7,0-8,5) pendant 10 minutes.  
Rincer abondamment à l'eau. Nettoyer ainsi jusqu'à la disparition complète des résidus sur le plateau à instruments.  
Sécher à l'air comprimé ou essuyer à l'aide d'un tissu dépourvu de peluches. Examiner les plateaux à instruments à la recherche de taches ou de signes de détérioration et les mettre au rebut si nécessaire.  
**Remarque :** En cas d'utilisation d'un nettoyeur à ultrasons ou d'un appareil de lavage a aspersion, suivre les recommandations du fabricant pour positionner les plateaux a instruments.  
Après le nettoyage, lubrifier légèrement les plateaux à instruments dotés de parties mobiles. Utiliser un lubrifiant prévu pour les instruments stérilisables tel qu'un lait à instruments soluble à l'eau. Ne pas utiliser de silicone en aérosol.

Limitation de garantie

manuals.medtronic.com

IT

Indicazioni per l'uso

I vassoi per strumenti hanno lo scopo di fornire una configurazione generale per organizzare, conservare, proteggere, trasportare dispositivi medici per l'uso in procedure chirurgiche.

Precauzioni

- Se si sceglie di utilizzare il vassoio per strumenti come parte di un sistema di sterilizzazione per dispositivi di ritrattamento:
- Assicurarsi di convalidare il vassoio ai sensi dei processi e dei sistemi interni.
  - Seguire tutte le istruzioni per la sterilizzazione del dispositivo in caso di ritrattamento.
  - La sterilizzazione a vapore mediante gravita non deve essere utilizzata per i vassoi per strumenti, in quanto i tempi di ciclo sarebbero estremamente lunghi.
  - La procedura STERRAD non deve essere utilizzata per vassoi per strumenti Medtronic Xomed.
  - I vassoi per strumenti non sono destinati a fornire una barriera sterile per impedire la ricontaminazione di strumenti sterilizzati e devono essere avvolti in un doppio involucro sterile (CSR) per ospedale idoneo a questo processo per mantenere la sterilità degli strumenti contenuti all'interno del vassoio.
  - Rimuovere gli strumenti, i componenti sciolti del vassoio interno e il coperchio prima di pulire gli strumenti e/o il vassoio.

DE

- Medtronic consiglia di ricorrere all'incenerimento di quei dispositivi che siano stati a diretto contatto con pazienti con diagnosi sospetta o confermata di TSE (Encefalopatia Spongiforme Trasmissibile) o CJD. Le NHS Estates HTM 2010 Parti 4 & 6: Appendice 2, Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies (Elementi contaminati con agenti TSE e le Linee guida della WHO per il controllo dell'infezione da encefalopatie spongiformi trasmissibili) indicano un ciclo di decontaminazione da TSE mediante autoclave a vapore a una temperatura di 134-137 °C per un ciclo singolo di 18 minuti oppure per cicli ripetuti per un totale di 6 cicli da 3 minuti.
- In sede di applicazione dei tempi di asciugatura per i vassoi per strumenti Medtronic e dei loro accessori, possono essere necessari tempi di asciugatura di fuori dei parametri standard sanitari di prevuoto. Gli attuali tempi di asciugatura consigliati potrebbero variare da uno standard di 15 minuti fino ad un tempo prolungato di 40 minuti. Ciò è particolarmente importante per vassoi per strumenti a base polimerica (plastica). L'utente deve disporre di mezzi adeguati per verificare i tempi di asciugatura, come ad esempio l'ispezione visiva.

Pulizia

**Nota:** per ridurre al minimo le macchie d'acqua, si consiglia di utilizzare acqua deionizzata per il risciacquo finale. Se possibile, l'acqua deionizzata può essere utilizzata per l'intero processo di pulizia.

Pulizia automatizzata

Tutti i vassoi devono essere accuratamente risciacquati con acqua prima del posizionamento nella lavatrice automatica. Rimuovere gli strumenti e le apparecchiature dai vassoi prima di collocarli nei cestelli della lavatrice. Sistemare i dispositivi in base alle raccomandazioni fornite dai produttori della lavatrice/del dispositivo di disinfezione. Utilizzare un detergente con pH neutro raccomandato dai produttori della lavatrice/ del dispositivo di disinfezione o del detergente.

| Fase                | Tempo di ricircolo | Temperatura acqua | Tipo di detergente                |
|---------------------|--------------------|-------------------|-----------------------------------|
| Prelavaggio 1       | 3 minuti           | acqua fredda      | N/D                               |
| Lavaggio enzimatico | 5 minuti           | acqua calda       | Detergente enzimatico a pH neutro |
| Lavaggio 1          | 5 minuti           | Livello 66 °C     | Detergente a pH neutro            |
| Risciacquo 1        | 3 minuti           | acqua calda       | N/D                               |

Pulizia manuale

Immergere in una soluzione composta da detergente enzimatico tiepido (meno di 43 °C) con pH neutro (7,0-8,5) e acqua per almeno 2 minuti. Strofinare i vassoi per strumenti mentre sono immersi nella soluzione detergente utilizzando una spazzola morbida per rimuovere eventuali tracce organiche. Risciacquare con acqua, quindi eseguire la pulizia ad ultrasuoni in una soluzione tiepida (meno di 43 °C), neutra (pH 7,0-8,5), composta da detergente e acqua deionizzata per 10 minuti. Sciacquare accuratamente con acqua. Pulire in questo modo fino ad eliminare tutti i residui di sporco visibili sul vassoio per strumenti. Asciugare con aria compressa o con un panno che non lasci pelucchi. Verificare che i vassoi per strumenti non presentino macchie o segni di deterioramento; se necessario, smaltirli.

**Nota:** se viene utilizzato un sistema di pulizia ad ultrasuoni o una lavatrice a spruzzo, attenersi alle raccomandazioni del produttore, per il posizionamento dei vassoi per strumenti. Dopo la pulizia, lubrificare leggermente i vassoi per strumenti dotati di parti mobili. Utilizzare un lubrificante indicato per gli strumenti sterilizzabili quale, ad esempio, latte chirurgico idrosolubile. Non utilizzare spray al silicone.

Garanzia limitata

manuals.medtronic.com

DE

Indikationen

Instrumentenschalen dienen als allgemeines Konfigurationszubehör bei der Organisation, Lagerung, Protektion und dem Transport von Instrumenten für chirurgische Eingriffe.

Vorsichtsmaßnahmen

Bei Verwendung der Instrumentenschale als Teil eines Sterilisationssystems für die Wiederaufbereitung von Geräten:

- Die Validierung der Schale innerhalb der internen Verfahren und Systeme sicherstellen.
- Alle Anweisungen in Bezug auf die Sterilisation von wiederaufzubereitenden Geräten befolgen.

- Die Schwerkraft-Dampfsterilisation darf für Instrumentenschalen nicht eingesetzt werden, da die Zykluszeiten extrem lang waren.
- Die STERRAD-Wiederaufbereitung darf für Medtronic Xomed-Instrumentenschalen nicht eingesetzt werden.
- Die Instrumentenschalen dienen nicht als sterile Barriere, um die Rekontaminierung von sterilisierten Instrumenten zu verhindern; sie müssen für diesen Prozess mit Umhüllungen der zentralen Sterilgutversorgung des Krankenhauses doppelt verpackt werden, um die Sterilität der Instrumente in der Schale zu gewährleisten.
- Instrumente, lockere interne Komponenten der Schale und den Deckel vor der Reinigung der Instrumente und/oder der Schale entfernen.
- Medtronic empfiehlt die Verbrennung von Geräten, die in direkten Kontakt mit Patienten gekommen sind oder bei denen TSE (Transmissible Spongiforme Enzephalopathie) oder CJD (Creutzfeldt-Jakob-Krankheit) vermutet oder diagnostiziert wurde. Die Vorschriften des staatlichen Gesundheitssystems in Großbritannien NHS Estates, HTM 2010, Teile 4 & 6: Anhang 2, Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies (Mit TSE-Erregern kontaminierte Komponenten und die Richtlinien der Weltgesundheitsorganisation (WHO) für übertragbare spongiforme Enzephalopathien) sehen ein TSE-Dekontaminationsprogramm vor, das eine Dampfsterilisation bei einer Temperatur von 134–137 °C beinhaltet, die entweder in einem einzelnen Programmzyklus über 18 Minuten oder in sechs 3-minütigen Programmzyklen durchzuführen ist.
- Die Trockenzeiten für Medtronic-Instrumentenschalen und deren Zubehör könnten die sonst üblichen Zeiträume der Vorvakuum-Sterilisierung im Gesundheitsbereich überschreiten. Die momentan empfohlenen Trockenzeiten reichen von den üblichen 15 Minuten bis hin zu 40 Minuten. Dies ist besonders für polymerbasierte (Kunststoff-)Instrumentenschalen von Bedeutung. Der Anwender sollte in der Lage sein, die Trockenzeit angemessen z. B. durch Sichtkontrolle zu verifizieren.

### Reinigung

**Hinweis:** Zur Vermeidung von Wasserflecken wird die Verwendung von deionisiertem Wasser für die abschließende Spülung empfohlen. Deionisiertes Wasser ggf. für den gesamten Reinigungsprozess verwenden.

### Automatisierte Reinigung

Alle Schalen sollten vor der Platzierung in einem automatischen Reinigungsgerät gründlich mit Wasser gespült werden.

Sterilisierungsschalen erst in die Reinigungskörbe legen, wenn alle Instrumente und Zubehör aus den Sterilisierungsschalen entfernt wurden. Die Instrumente gemäß den Herstellerempfehlungen des Reinigungs-/Sterilisierungsgeräts ausrichten.

Ein pH-neutrales Reinigungsmittel verwenden, das vom Hersteller des Reinigungs-/Desinfektionsgeräts oder des Reinigungsmittels empfohlen wird.

| Phase       | Umwälzzeit | Wassertemperatur | Art des Reinigungsmittels          |
|-------------|------------|------------------|------------------------------------|
| Vorwasche 1 | 3 Minuten  | Kaltes Wasser    | –                                  |
| Enzymwasche | 5 Minuten  | Heißes Wasser    | pH-neutrales Enzymreinigungsmittel |
| Wäsche 1    | 5 Minuten  | 66 °C (Sollwert) | pH-neutrales Reinigungsmittel      |
| Spülung 1   | 3 Minuten  | Heißes Wasser    | –                                  |

### Manuelle Reinigung

Die Instrumente mindestens zwei Minuten lang in einer lauwarmen (maximal 43 °C) Lösung aus einem milden (pH-Wert 7,0–8,5), enzymatischen Reinigungsmittel und Wasser einweichen lassen. Die in Reinigungslösung eingelegten Instrumentenschalen mit einer weichen Instrumentenbürste von organischem Material säubern. Die Instrumentenschale mit Wasser abspülen und anschließend mindestens 10 Minuten lang mit Ultraschall in einer lauwarmen (maximal 43 °C) Lösung aus mildem (pH-Wert 7,0–8,5) Reinigungsmittel und Wasser reinigen.

Gründlich mit Wasser spülen. Die Reinigung auf diese Weise weiterführen, bis keine Schmutzreste an der Instrumentenschale mehr sichtbar sind.

Mit Druckluft trocknen oder mit einem fusselfreien Tuch trocken wischen. Die Instrumentenschalen auf Flecken oder Verschleiß überprüfen und gegebenenfalls außer Gebrauch nehmen.

**Hinweis:** Bei Verwendung einer Ultraschallreinigungsanlage oder Spruhwaschmaschine den Empfehlungen des Herstellers folgen, besonders im Hinblick auf die Positionierung von Instrumentenschalen. Instrumentenschalen mit beweglichen Teilen nach dem Reinigen leicht abschmieren. Ein für sterilisierbare Instrumente geeignetes Schmiermittel wie z. B. wasserlösliche Instrumentenmilch verwenden. Kein Silikon Spray verwenden.

### Eingeschränkte Garantie

manuals.medtronic.com

ES  
ES

### Indicaciones de uso

Las bandejas de instrumentos están indicadas para ofrecer una configuración general de organización, almacenamiento, protección y transporte de los dispositivos médicos con el fin de utilizarlos en procedimientos quirúrgicos.

### Precauciones

Si opta por utilizar la bandeja de instrumentos como parte de un sistema de esterilización para el reprocesamiento de dispositivos:

- Asegurese de validar la bandeja de acuerdo con sus procesos y sistemas internos.
- Siga todas las instrucciones para la esterilización del dispositivo o dispositivos que esté reprocesando.
- No se debe usar la esterilización al vapor por gravedad en las bandejas de instrumentos, ya que los periodos de los ciclos serían excesivamente largos.
- No se debe usar el procesamiento STERRAD en las bandejas de instrumentos de Medtronic Xomed.
- Las bandejas de instrumentos no están indicadas para ofrecer una barrera estéril con la que evitar la recontaminación de instrumentos esterilizados; además, deberán tener una doble envoltura de CSR en este proceso para mantener la esterilidad de los instrumentos contenidos dentro de la bandeja.
- Retire los instrumentos, los componentes internos sueltos de la bandeja y la tapa antes de proceder a la limpieza de los instrumentos y/o la bandeja.
- Medtronic recomienda la incineración de los dispositivos que hayan estado en contacto directo con pacientes con un diagnóstico sospechado o confirmado de encefalopatía espongiforme transmisible/enfermedad de Creutzfeldt Jakob (EET/ECJ). En NHS Estates HTM 2010 partes 4 y 6. Apéndice 2: Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies (Elementos contaminados con agentes de EET y directrices de control de infecciones para encefalopatías espongiformes transmisibles de la Organización Mundial de la Salud) se hace referencia al ciclo de descontaminación de las EET mediante la esterilización en autoclave a una temperatura de 134-137 °C en un único ciclo de 18 minutos o repitiendo seis ciclos de 3 minutos cada uno.
- Al aplicar tiempos de secado a las bandejas de instrumentos y sus accesorios de Medtronic, pueden ser necesarios tiempos de secado fuera de los parámetros de prevación sanitario estándar. Los tiempos de secado que se recomiendan en la actualidad oscilan entre un tiempo estándar 15 minutos hasta un tiempo ampliado de 40 minutos. Esto es especialmente importante en el caso de bandejas de instrumentos basadas en polímero (plástico). El usuario debe disponer de los medios adecuados para verificar el tiempo de secado, como la inspección visual.

### Limpieza

**Nota:** Se recomienda utilizar agua desionizada en el enjuague final para minimizar las manchas provocadas por el agua. Si resulta práctico, puede usarse agua desionizada para todo el proceso de limpieza.

### Limpieza automática

Todas las bandejas deben enjuagarse bien con agua antes de su colocación en el equipo de lavado automático.

Retire el instrumental y el equipo de las bandejas de instrumentos antes de colocarlos en los contenedores del equipo de lavado. Oriente los dispositivos conforme a las recomendaciones del fabricante del equipo de lavado/desinfección.

Utilice un detergente con pH neutro recomendado por los fabricantes del equipo de lavado/desinfección o del detergente.

| Fase              | Tiempo de recirculación | Temperatura del agua  | Tipo de detergente                  |
|-------------------|-------------------------|-----------------------|-------------------------------------|
| Prelavado 1       | 3 minutos               | Agua fría             | N/D                                 |
| Lavado enzimático | 5 minutos               | Agua caliente         | Detergente enzimático con pH neutro |
| Lavado 1          | 5 minutos               | 66 °C punto de ajuste | Detergente con pH neutro            |
| Aclarado 1        | 3 minutos               | Agua caliente         | N/D                                 |

### Limpieza manual

Sumerja el instrumental en una solución tibia (temperatura inferior a 43 °C) de detergente enzimático suave (pH de 7,0-8,5) y agua durante 2 minutos como mínimo. Utilice un cepillo de cerdas blandas para cepillar las bandejas de instrumentos mientras se encuentran sumergidas en la solución de limpieza para eliminar la materia orgánica. Aclárelas con agua, límpielas mediante ultrasonidos en una solución templada (menos de 43 °C) de detergente suave (pH 7,0-8,5) y agua durante 10 minutos como mínimo.

Enjuague exhaustivamente con agua. Proceda a limpiar de este modo hasta que no queden restos de suciedad visible en la bandeja de instrumentos.

Seque con aire comprimido o con un paño que no desprenda pelusa. Examine las bandejas de instrumentos con el fin de detectar posibles manchas o signos de deterioro; retirelo del servicio si fuese necesario.

**Nota:** Cuando utilice un aparato de limpieza por ultrasonidos o una lavadora por pulverización, siga las recomendaciones del fabricante para la colocación de las bandejas de instrumentos.

Después de la limpieza, lubrique ligeramente las bandejas de instrumentos con piezas móviles. Utilice un lubricante válido para instrumental esterilizable, como lubricante vegetal hidrosoluble para instrumental. No utilice un pulverizador de silicona.

#### Garantía limitada

manuals.medtronic.com

## NL

### Indicaties voor gebruik

Instrumententrays zijn bedoeld als algemene configuratie om medische hulpmiddelen te ordenen, te bewaren, te beschermen en te transporteren voor gebruik tijdens chirurgische procedures.

### Voorzorgsmaatregelen

Het volgende is van toepassing als u ervoor kiest de instrumententray te gebruiken in een sterilisatiesysteem voor het opnieuw steriliseren van hulpmiddelen:

- Zorg ervoor dat de tray wordt gevalideerd binnen de interne processen en systemen van uw instelling.
- Volg alle sterilisatie-instructies voor de hulpmiddelen die u opnieuw steriliseert.
- Stoomsterilisatie met zwaartekracht mag niet gebruikt worden voor instrumententrays omdat de cyclustijden buitensporig lang zijn.
- STERRAD-verwerking mag niet gebruikt worden voor Medtronic Xomed-instrumententrays.
- Instrumententrays zijn niet bedoeld als steriele barrière om te voorkomen dat steriele instrumenten opnieuw worden besmet. Trays moeten voor de sterilisatie worden verpakt in een dubbele laag CSR-wikkel om de steriliteit van de instrumenten in de tray te behouden.
- Verwijder instrumenten, losse interne componenten van de tray en het deksel vóór het reinigen van de instrumenten en/of de tray.
- Medtronic adviseert om de producten te verbranden die direct in contact zijn geweest met patienten bij wie de diagnose TSE/CJD wordt vermoed of is bevestigd. NHS Estates HTM 2010 Deel 4 & 6: Bijlage 2, Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies (Met TSE-agentia besmette items en WHO-richtlijnen voor infectiebestrijding voor overdraagbare spongiforme encefalopathieën) verwijst naar een TSE-ontsmettingscyclus met behulp van een stoomautoclaf bij een temperatuur van 134 tot 137 °C gedurende één cyclus van 18 minuten of herhaald gedurende in totaal zes cycli van 3 minuten.
- Bij het toepassen van droogtijden op instrumententrays en bijbehorende accessoires van Medtronic, kunnen andere droogtijden nodig zijn dan de standaardparameters voor prevacuüm in de gezondheidszorg. De huidige aanbevolen droogtijden kunnen variëren van een standaardperiode van 15 minuten tot een langere periode van 40 minuten. Dit is vooral belangrijk voor instrumententrays van polymeer (plastic). De gebruiker dient voldoende mogelijkheden te hebben om de droogtijd te controleren, zoals visuele inspectie.

### Reiniging

**Opmerking:** om watervlekken tot een minimum te beperken wordt het gebruik van gedeïoniseerd water bij de laatste keer afspoelen aanbevolen. Indien het handiger is, mag er voor de hele reinigingsprocedure gedeïoniseerd water gebruikt worden.

### Automatische reiniging

Alle trays dienen grondig te worden afgespoeld met water voordat u ze in de wasmachine plaatst.

Haal instrumenten en apparatuur uit de instrumentenbakjes voordat u ze in afwasmachinemandjes plaatst. Houd u bij het plaatsen van de apparaten aan de aanbevelingen van de fabrikant van de afwasmachine/desinfector.

Gebruik een pH-neutraal reinigingsmiddel dat wordt aanbevolen door de fabrikant van de afwasmachine/desinfector of het reinigingsmiddel.

| Fase             | Hercirculatietijd | Watertemperatuur | Type reinigingsmiddel                    |
|------------------|-------------------|------------------|------------------------------------------|
| Voorwas 1        | 3 minuten         | Koud water       | N.v.t.                                   |
| Enzymatische was | 5 minuten         | Warm water       | pH-neutraal enzymatisch reinigingsmiddel |
| Was 1            | 5 minuten         | instelpunt 66 °C | pH-neutraal reinigingsmiddel             |
| Spoeling 1       | 3 minuten         | Warm water       | N.v.t.                                   |



## DA

### Handmatige reiniging

Dompel het instrument ten minste 2 minuten onder in een lauwarme (minder dan 43 °C), milde (pH 7,0 tot 8,5) oplossing van een enzymatisch reinigingsmiddel en water weken. Was instrumententrays met een zachte instrumentenborstel terwijl ze in de reinigungsoplossing ondergedompeld blijven, om organisch materiaal te verwijderen. Spoel de instrumenten grondig met water en reinig ze vervolgens gedurende 10 minuten ultrasoon in een lauwarme (minder dan 43 °C), milde (pH 7,0 -tot 8,5) oplossing van reinigingsmiddel en water.

Spoel grondig met water. Reinig op deze manier totdat er geen vuil op de instrumententrays meer zichtbaar is.

Drogen met perslucht of een schone, pluisvrije doek. Inspecteer de instrumententrays op vlekken of slijtage; neem ze zo nodig uit gebruik.

**Opmerking:** volg bij gebruik van ultrasone reinigungsapparatuur of een sproeiwasmachine de aanbevelingen van de fabrikant op met betrekking tot het positioneren van de instrumententrays.

Instrumententrays met beweegbare onderdelen moeten na het reinigen licht worden gesmeerd. Gebruik een smeermiddel dat bedoeld is voor steriliseerbare instrumenten, zoals een in water oplosbare instrumentenmelk. Gebruik geen siliconenspray.

### Beperkte garantie

manuals.medtronic.com

## DA

### Indikationer

Instrumentbakker er beregnet til at give en generel konfiguration med henblik på organisering, opbevaring, beskyttelse og transport af medicinske anordninger til brug ved kirurgiske procedurer.

### Forholdsregler

Hvis du vælger at bruge instrumentbakken som en del af sterilisationssystemet til genklargøring af anordninger:

- Sørg for at validere bakken i dine interne processer og systemer.
- Følg alle anvisninger til sterilisation af anordningen/anordningerne, der genklargøres.
- Dampsterilisering ved normaltryk må ikke bruges til instrumentbakker, da cyklustiderne vil blive for lange.
- STERRAD-behandling må ikke bruges til Medtronic Xomed instrumentbakker.
- Instrumentbakker er ikke beregnet til at yde en steril barriere til forhindring af genkontaminering af steriliserede instrumenter. De skal dobbeltindpakkes i CSR-indpakning af hospitalskvalitet til denne proces for at opretholde steriliteten af de instrumenter, der befinder sig i bakken.
- Udtag instrumenter, løse interne bakkekomponenter og låg, før instrumenter og/eller bakke rengøres.
- Medtronic anbefaler, at enheder bortskaffes ved forbrænding, hvis de har været i direkte kontakt med patienter, som er mistænkt for at have eller har fået bekræftet transmissible spongiforme encefalopatii (TSE)/ Creutzfeldt-Jakob-diagnose (CJD). NHS Estates HTM 2010 stykke 4 & 6: Appendix 2 Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies (Genstande kontamineret med TSE-midler og WHO's retningslinjer for infektionskontrol ved smitsom spongiform encefalopati) henviser til en TSE-dekontamineringscyklus ved brug af dampautoklavering ved en temperatur på 134-137 °C i en enkelt cyklus på 18 minutter eller gentaget i alt seks cyklusser af 3 minutter.
- Når der anvendes tørretider for Medtronic instrumentbakker og deres tilbehør, kan der være behov for tørretider ud over de standardmæssige parametre for sundheds-forvakuum. De aktuelt anbefalede tørtider kan ligge fra som standard 15 minutter til en udvidet tid på 40 minutter. Dette er særligt vigtigt for polymerbaserede (plast) instrumentbakker. Brugeren skal have tilstrækkelige midler til at kontrollere tørretiderne, så som visuelt eftersyn.

### Rengøring

**Bemærk:** For at minimere vandpletter anbefales det, at der bruges deioniseret vand til den sidste skylning. I praksis kan deioniseret vand bruges under hele rengøringsprocessen.

### Automatisk rengøring

Alle bakker skal skylles omhyggeligt med vand, før de placeres i den automatiske opvaskemaskine.

Tag instrumenter og udstyr op af eventuelle instrumentbakker, inden de anbringes i maskinens kurve. Vend udstyret i henhold til kravene fra opvaske-/desinfektionsmaskinens fabrikant.

Brug et rensmiddel med neutral pH-værdi som anbefalet af opvaske-/desinfektionsmaskinens eller rensmidlets fabrikant.

| Fase       | Recirkuleringstid | Vandtemperatur          | Rengøringsmiddeltype                               |
|------------|-------------------|-------------------------|----------------------------------------------------|
| Forvask 1  | 3 minutter        | koldt vand              | I/R                                                |
| Enzymvask  | 5 minutter        | varmt vand              | enzymholdigt rengøringsmiddel med neutral pH-værdi |
| Vask 1     | 5 minutter        | 66 °C<br>referencepunkt | en renseopløsning med neutral pH                   |
| Skylning 1 | 3 minutter        | varmt vand              | I/R                                                |

### Manuel rengøring

Læg i blød i lunken (mindre end 43 °C), mild (pH 7,0-8,5) enzymholdigt rengøringsmiddel og vand i min. 2 minutter. Brug en blød instrumentbørste til at skrubbe instrumentbakkerne, mens de er nedsænket i rengøringsvæsken, for at fjerne organisk materiale. Skyl med vand, og rengør derefter med ultralyd i lunkent (mindre end 43 °C), mildt (pH 7,0-8,5) vand med rengøringsmiddel i 10 minutter. Skyl grundigt med vand. Rengør på denne måde, indtil der ikke længere er synligt snavs på instrumentbakken.

Tør med trykluft, eller tør af med en fnugfri klud. Undersøg instrumentbakker for pletter eller nedbrydning; kassér dem om nødvendigt.

**Bemærk:** Ved anvendelse af en ultralydsrenser eller opvaskemaskine følges fabrikantens anbefalinger for placering af instrumentbakker.

Efter rengøring smøres et tyndt lag smøremiddel på instrumentbakker med bevægelige dele. Brug et smøremiddel, der er beregnet til steriliserbare instrumenter, såsom vandopløseligt instrumentsmøremiddel. Der må ikke bruges silikonespray.

### Begrænset garanti

manuals.medtronic.com

## FI

### Käyttöaiheet

Instrumenttitarjottimet on tarkoitettu yleiseksi kokoonpanoksi leikkauksissa käytettävien laakinnallisten laitteiden järjestämiseen, säilytykseen, suojaamiseen ja kuljettamiseen.

### Varotoimet

Jos instrumenttitarjotinta käytetään sterilointijärjestelman osana laitteiden uudelleenkasittelyssä:

- Validoi tarjotin voimassa olevilla sisäisillä prosesseilla ja järjestelmillä.
- Noudata uudelleenkasiteltävien laitteiden kaikkia sterilointiohjeita.
- Painovoimahöyrysterilointia ei saa käyttää polymeerimuovista valmistetuille instrumenttitarjottimille, sillä jaksoajat olisivat liian pitkiä.
- STERRAD-kasittelyä ei saa käyttää Medtronic Xomed -instrumenttitarjottimille.
- Instrumenttitarjottimia ei ole tarkoitettu steriiliksi suluksi steriloitujen instrumenttien uudelleenkontaminaation ehkäisyyn. Ne on kaarittava tata varten kaksinkertaiseen CSR-sairaalaakaareeseen tarjottimen sisällä olevien instrumenttien pitämiseksi steriileinä.
- Poista instrumentit, tarjottimen sisäiset irralliset osat ja kansi ennen instrumenttien ja/tai tarjottimen puhdistamista.
- Medtronic suosittelee laitteen polttamista, jos se on ollut suorassa kosketuksessa potilaaseen, jolla epäillään olevan tai jolla on todettu tarttuva sienimainen enkefalopatia (TSE) tai Creutzfeldt-Jakobin tauti (CJD). NHS Estates HTM 2010, osat 4 ja 6: liite 2, Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies (TSE:n taudinaiheuttajilla kontaminoituneet valineet ja WHO:n infektioiden valvontaohjeet koskien tarttuvia spongiformisia enkefalopatioita), viittaa TSE-dekontaminaatiojaksoon, jossa käytetään höyryautoklaavia 134–137 °C:n lampötilassa yhden 18 minuutin jakson ajan tai toistaen yhteensä kuuden 3 minuutin jakson ajan.
- Sovellettaessa kuivumisaikoja Medtronicin instrumenttitarjottimiin ja niiden lisävarusteisiin on mahdollisesti käytettävä kuivumisaikoja, jotka ovat tavanomaisten terveydenhuollossa käytettävien esityhjiöparametrien ulkopuolella. Nykyään suositeltavat kuivumisaikat voivat ulottua normaalista 15 minuutista pidennettyyn 40 minuutin kuivumisaikaan. Tämä on erityisen tärkeää polymeeripohjaisten (muovisten) instrumenttitarjottimien yhteydessä. Käyttäjällä on oltava riittävät mahdollisuudet varmistaa kuivumisaika, esimerkiksi mahdollisuus silmämääräiseen tarkastukseen.

### Puhdistus

**Huomautus:** Vesitahrojen muodostumisen minimoimiseksi loppuhuuhTELussa on suositeltavaa käyttää deionisoitua vettä. Jos tämä on käytännöllistä, deionisoitua vettä voidaan käyttää koko puhdistuksen ajan.

### Automaattinen puhdistus

Kaikki tarjottimet on huuhdeltava huolellisesti vedellä ennen niiden asettamista automaattipesuriin.

## SV

Poista instrumentit ja laitteet instrumenttitarjottimilta ennen niiden asettamista pesukoreihin. Noudata laitteiden asettelussa pesurin/desinfointilaitteen valmistajan antamia suosituksia.

Käytä pesurin/desinfointilaitteen tai puhdistusaineen valmistajan suosittelemaa pH-neutraalia puhdistusainetta.

| Vaihe        | Kiertoaika  | Veden lämpötila    | Puhdistusainetyyppi                       |
|--------------|-------------|--------------------|-------------------------------------------|
| Esipesu 1    | 3 minuuttia | kylmä vesi         | –                                         |
| Entsyymipesu | 5 minuuttia | kuuma vesi         | pH-neutraali entsymaattinen puhdistusaine |
| Pesu 1       | 5 minuuttia | 66 °C (asetusarvo) | pH-neutraali puhdistusaine                |
| Huuhtelu 1   | 3 minuuttia | kuuma vesi         | –                                         |

### Manuaalinen puhdistus

Liota haaleassa (alle 43 °C) miedon (pH 7,0–8,5) puhdistusaineen ja veden seoksessa 2 minuutin ajan. Poista orgaaninen aines instrumenttitarjottimista pehmeällä instrumenttiharjalla niiden ollessa upotettuina puhdistusliuokseen. Huuhtele vedellä ja puhdista sen jälkeen ultraäänellä haaleassa (alle 43 °C) miedon (pH 7,0–8,5) puhdistusaineen ja veden seoksessa 10 minuutin ajan.

Huuhtele huolellisesti vedellä. Jatka puhdistusta niin, kunnes instrumenttitarjottimessa ei ole näkyvää likaa.

Kuivaa paineilmalla tai pyyhi kuivaksi nukkaamattomalla liinalla. Tarkasta, etteivät instrumenttitarjottimet ole syöpyneet eivätkä kuluneet. Poista ne tarvittaessa käytöstä.

**Huomautus:** Käytettäessä ultraääni- tai suihkupesuria noudata pesurin valmistajan suosituksia, jotka koskevat instrumenttitarjottimien asettamista.

Instrumenttitarjottimet, joissa on liikkuvia osia, on voideltava kevyesti puhdistuksen jälkeen. Käytä steriloitaville instrumenteille tarkoitettua voiteluainetta, kuten vesiliukoista instrumenttivoitetta. Älä käytä silikonisuihkettä.

### Rajoitettu takuu

manuals.medtronic.com

## SV

### Indikationer för användning

Instrumentbrickor är avsedda för att tillhandahålla en generell konfiguration för att organisera, förvara, skydda och transportera medicinska instrument för användning vid kirurgiska ingrepp.

### Försiktighetsåtgärder

Tänk på följande om du väljer att använda instrumentbrickan som en del av ett steriliseringssystem för återanvändning av instrument:

- Sakerställ att brickan utvärderas inom de interna processerna och systemen.
- Följ alla instruktioner för sterilisering av instrumentet som ska återanvändas.
- Sterilisering med normaltryck får inte användas för instrumentbrickor eftersom cykeltiderna blir alltför långa.
- Behandling med STERRAD får inte användas för Medtronic Xomed instrumentbrickor.
- Instrumentbrickor är inte avsedda att tillhandahålla en steril barriär för att förhindra rekontaminering av steriliserade instrument och måste slås in i dubbla CSR-omslag för sjukhus vid denna process för att bibehålla steriliteten på de instrument som finns inuti brickan.
- Avlagsna instrument, losa interna brickkomponenter och lock innan instrument och/eller bricka rengörs.
- Medtronic rekommenderar förbränning av enheter som har varit i direkt kontakt med patienter med misstänkt eller bekräftad diagnos av transmissibel spongiform encefalopati (TSE)/CJD. NHS Estates HTM 2010 del 4 och 6. Bilaga 2, Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies (Produkter kontaminerade med TSE-agens och WHO:s riktlinjer för infektionskontroll för överförbar spongiform encefalopati), avser TSE-dekontamineringscykeln med en ångautoklav vid en temperatur på 134–137 °C under en enstaka cykel på 18 minuter eller under sammanlagt sex upprepade cykler på 3 minuter.
- Vid tillämpning av torktider för Medtronic instrumentbrickor och deras tillbehör, kan torktider utöver de som finns i standardparametrarna för förvakuum kravas. De nuvarande rekommenderade torktiderna kan sträcka sig från normala 15 minuter till en förlängd tid på 40 minuter. Detta är särskilt viktigt för instrumentbrickor som är polymerbaserade (plast). Användaren ska ha lämpliga sätt att verifiera torktiden, såsom visuell inspektion.

### Rengöring

**Obs!** För att minimera förekomsten av vattenfläckar rekommenderas att avjoniserat vatten används för den sista sköljningen. Om möjlighet finns kan avjoniserat vatten användas för hela rengöringsprocessen.

### Automatisk rengöring

Alla brickor ska sköljas grundligt med vatten innan de placeras i den automatiska diskmaskinen.

Avlägsna instrument och utrustning från eventuella instrumentbrickor innan de placeras i diskmaskinens korgar. Placera enheterna enligt rekommendationer från diskmaskinens/desinfektionsapparatus tillverkare.

Använd ett rengöringsmedel med neutralt pH-värde som rekommenderas av diskmaskinens/desinfektionsapparatus eller rengöringsmedlets tillverkare.

| Fas       | Återcirkulationstid | Vattentemperatur | Typ av rengöringsmedel               |
|-----------|---------------------|------------------|--------------------------------------|
| Fördisk 1 | 3 minuter           | kallt vatten     | Anvands ej                           |
| Enzymdisk | 5 minuter           | varmt vatten     | Enzymrengöringsmedel med neutralt pH |
| Disk 1    | 5 minuter           | Börvarde 66 °C   | Rengöringsmedel med neutralt pH      |
| Skölj 1   | 3 minuter           | varmt vatten     | Anvands ej                           |

### Manuell rengöring

Blotlagg i ljummet (under 43 °C), milt (pH 7,0–8,5), enzymatiskt rengöringsmedel och vatten i minst 2 minuter. Använd en mjuk instrumentborste och skrubba instrumentbrickorna nedsänkta i rengöringslösning så att organiska partiklar avlägsnas. Skölj med vatten och rengör sedan med ultraljud i ljummet (under 43 °C), vatten med ett milt (pH 7,0–8,5) enzymrengöringsmedel i 10 minuter.

Skölj grundligt med vatten. Rengör på detta sätt tills inga synliga föroreningar finns kvar på instrumentbrickan.

Torka med tryckluft eller torka torrt med en luddfri duk. Undersök instrumentbrickorna så att det inte finns missfärgningar eller försämringar. Avbryt användning när så krävs.

**Obs!** Vid användning av ultraljudsrengöring eller diskmaskin ska tillverkarens rekommendationer om placering av instrumentbrickor följas.

Smörj instrument med rörliga delar lätt efter rengöring. Använd ett smörjmedel som är avsett för steriliseringsbara instrument, till exempel vattenlöslig instrumentolja.

Silikonsprej får inte användas.

### Begränsad garanti

manuals.medtronic.com

### PT-PT

#### Indicações de utilização

Os tabuleiros de instrumentos destinam-se a fornecer uma configuração geral para organizar, armazenar, proteger e transportar dispositivos médicos destinados à utilização em procedimentos cirúrgicos.

#### Precauções

Se optar por utilizar o tabuleiro de instrumentos como parte de um sistema de esterilização para reprocessar dispositivos:

- Certifique-se de que valida o tabuleiro de acordo com os seus processos e sistemas internos.
- Siga todas as instruções para a esterilização do(s) dispositivo(s) que está a reprocessar.
- A esterilização a vapor por gravidade não deve ser utilizada para os tabuleiros de instrumentos, uma vez que os tempos dos ciclos serão demasiados longos.
- O processamento STERRAD não deve ser utilizado para os tabuleiros de instrumentos Medtronic Xomed.
- Os tabuleiros de instrumentos não foram concebidos para funcionarem como barreira estéril para prevenir nova contaminação de instrumentos esterilizados; além disso, devem ser duplamente envolvidos num invólucro CSR de grau hospitalar para este procedimento, por forma a manter a esterilidade dos instrumentos no seu interior.
- Remova os instrumentos, desapele os componentes internos e a tampa do tabuleiro antes de limpar os instrumentos e/ou o tabuleiro.
- A Medtronic recomenda a incineração de dispositivos que tenham estado em contacto directo com doentes suspeitos ou com diagnóstico confirmado de encefalopatia espongiforme transmissível (EET)/DCJ. Tanto as indicações NHS Estates HTM 2010 Partes 4 & 6: Anexo 2, Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies (Itens contaminados com agentes de EET e as Directivas da OMS para o controlo de infecções relativas a encefalopatias espongiformes transmissíveis) indicam um ciclo de descontaminação de EET através de autoclave a vapor a uma temperatura de 134-137 °C para um único ciclo de 18 minutos ou repetido durante um total de seis ciclos de 3 minutos cada.

EL

- Aquando da aplicação dos tempos de secagem em tabuleiros de instrumentos Medtronic e respectivos acessórios, poderão ser necessários tempos de secagem fora dos parâmetros de pré-vácuo de cuidados de saúde padrão. Os tempos de secagem actualmente recomendados podem variar de um período de tempo padrão de 15 minutos até um período de tempo prolongado de 40 minutos. Isto é especialmente importante para tabuleiros de instrumentos à base de polímeros (plástico). O utilizador deve dispor de meios adequados para verificar o tempo de secagem, como por ex., inspecção visual.

Limpeza

**Nota:** para minimizar a formação de manchas devido à água, recomenda-se a utilização de água desionizada para efectuar o enxaguamento final. Se for prático, pode utilizar-se água desionizada em todo o processo de limpeza.

Limpeza automática

Todos os tabuleiros devem ser cuidadosamente enxaguados com água antes de serem colocados no aparelho de lavagem automática.

Retire os instrumentos e o equipamento dos tabuleiros de instrumentos antes de os colocar nos cestos de lavagem. Oriente os dispositivos segundo as recomendações do fabricante dos aparelhos de lavagem/desinfecção.

Utilize um detergente com pH neutro recomendado pelo fabricante do aparelho de lavagem/desinfecção ou do detergente.

| Fase               | Tempo de recirculação | Temperatura da água          | Tipo de detergente                 |
|--------------------|-----------------------|------------------------------|------------------------------------|
| Pré-lavagem 1      | 3 minutos             | água fria                    | N/A                                |
| Lavagem enzimática | 5 minutos             | água quente                  | detergente enzimático de pH neutro |
| Lavagem 1          | 5 minutos             | ponto de referência de 66 °C | detergente de pH neutro            |
| Enxaguamento 1     | 3 minutos             | água quente                  | N/A                                |

Limpeza manual

Mergulhe numa solução tépida (menos de 43 °C) de água e detergente enzimático suave (pH 7,0 - 8,5) durante um mínimo de 2 minutos. Utilize uma escova macia para instrumentos para esfregar os tabuleiros de instrumentos enquanto estiverem submersos na solução de limpeza, de modo a retirar a matéria orgânica. Enxague com água e, em seguida, limpe por meio de ultra-sons numa solução tépida (menos de 43 °C) de água e detergente suave (pH 7,0 - 8,5) durante 10 minutos.

Enxague abundantemente com água. Limpe desta forma até não restar sujidade visível no tabuleiro de instrumentos.

Seque com ar comprimido ou enxugue com um pano que não largue pêlos. Examine os tabuleiros de instrumentos, verificando se apresentam manchas ou qualquer deterioração; retire-os do circuito de utilização se necessário.

**Nota:** ao utilizar um dispositivo de limpeza de ultra-sons ou uma máquina de lavagem com aspersão, siga as recomendações do fabricante quanto ao posicionamento dos tabuleiros de instrumentos.

Após a limpeza, lubrifique ligeiramente os tabuleiros de instrumentos com peças móveis. Utilize um lubrificante destinado a instrumentos esterilizáveis, como leite para instrumentos solúvel em água. Não utilize spray de silicone.

Garantia limitada

manuals.medtronic.com

EL

Ενδείξεις χρήσης

Οι δίσκοι εργαλείων προορίζονται ως μια γενική διάταξη για την οργάνωση, την αποθήκευση, την προστασία και τη μεταφορά ιατρικών συσκευών που χρησιμοποιούνται σε χειρουργικές επεμβάσεις.

Προφυλάξεις

Αν επιλέξετε να χρησιμοποιήσετε το δίσκο εργαλείων ως μέρος ενός συστήματος αποστείρωσης για την επανεπεξεργασία συσκευών:

- Μην παραλείψετε να επικυρώσετε την καταλληλότητα του δίσκου για τις εσωτερικές σας διαδικασίες και συστήματα.
- Ακολουθείτε όλες τις οδηγίες αποστείρωσης των συσκευών που πρόκειται να υποβάλετε σε επανεπεξεργασία.
- Η αποστείρωση ατμού με βαρύτητα δεν πρέπει να χρησιμοποιείται για τους δίσκους εργαλείων, καθώς κάτι τέτοιο θα οδηγούσε σε υπερβολικά παρατεταμένη διάρκεια των κύκλων αποστείρωσης.
- Η επεξεργασία στο σύστημα STERRAD δεν πρέπει να χρησιμοποιείται για τους δίσκους εργαλείων Medtronic Xomed.



- Οι δίσκοι εργαλείων δεν προορίζονται για την παροχή στείρου φραγμού προς αποτροπή της επιμόλυνσης αποστειρωμένων εργαλείων και θα πρέπει να φέρουν διπλή περιτύλιξη με περιτύλιγμα CSR νοσοκομειακού τύπου για τη διατήρηση της στειρότητας των εργαλείων που περιέχονται εντός του δίσκου.
- Αφαιρέστε τα εργαλεία, τα μη στερεωμένα εσωτερικά εξαρτήματα του δίσκου και το καπάκι προτού καθαρίσετε τα εργαλεία ή/και το δίσκο.
- Η Medtronic συνιστά την καύση των συσκευών που έχουν έρθει σε απευθείας επαφή με ασθενείς για τους οποίους υπάρχει υπονοια ή έχει επιβεβαιωθεί η διάγνωση μεταδοτικής σπογγώδους εγκεφαλοπάθειας/νόσου Creutzfeldt-Jakob (ΜΣΕ/СJD). Τα έγγραφα NHS Estates HTM 2010 Μερή 4 & 6: Παράρτημα 2, Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies (Εξαρτήματα που έχουν μολυνθεί με παράγοντες μεταδοτικής σπογγώδους εγκεφαλοπάθειας και Κατευθυντήριες οδηγίες ελέγχου λοιμώξεων για τις μεταδοτικές σπογγώδεις εγκεφαλοπάθειες του Παγκόσμιου Οργανισμού Υγείας) αναφέρονται σε κύκλο απολύμανσης ΜΣΕ με τη χρήση αυτόκαυστου ατμού σε θερμοκρασία 134-137 °C για ένα μόνο κύκλο 18 λεπτών ή επαναλαμβανόμενα για συνολικά έξι κύκλους 3 λεπτών.
- Κατά την εφαρμογή των χρόνων στεγνώματος στους δίσκους εργαλείων Medtronic και στα βοηθητικά εξαρτήματά τους, ενδέχεται να απαιτούνται χρόνοι στεγνώματος εκτός των τυπικών παραμέτρων προκατεργασίας κενού της υγειονομικής περίθαλψης. Οι τρέχοντες συνιστώμενοι χρόνοι στεγνώματος μπορεί να κυμαίνονται από τα τυπικά 15 λεπτά έως και ένα εκτεταμένο διάστημα διάρκειας 40 λεπτών. Αυτό είναι ιδιαίτερα σημαντικό για τους δίσκους εργαλείων με βάση το πολυμερές (πλαστικό). Ο χρήστης θα πρέπει να διαθέτει επαρκή μέσα για την επαλήθευση του χρόνου στεγνώματος, όπως π.χ. οπτική επιθεώρηση.

### Καθαρισμός

**Σημείωση:** Για την ελαχιστοποίηση των στιγμάτων νερού, συνιστάται η χρήση απιονισμένου νερού για την τελική εκπλύση. Εάν είναι πρακτικά δυνατό, μπορεί να χρησιμοποιήσετε απιονισμένο νερό για ολοκληρή τη διαδικασία καθαρισμού.

### Αυτόματος καθαρισμός

Όλοι οι δίσκοι πρέπει να εκπλένονται σχολαστικά με νερό πριν από την τοποθέτησή τους στη συσκευή αυτόματης πλύσης.

Αφαιρέστε τα εργαλεία και τον εξοπλισμό από τους δίσκους εργαλείων προτού τους τοποθετήσετε στους κλωβούς της συσκευής καθαρισμού. Προσανατολίστε τα προϊόντα σύμφωνα με τις συστάσεις των κατασκευαστών των συσκευών πλύσης/απολύμανσης.

Χρησιμοποιείτε απορρυπαντικό με ουδέτερο pH, όπως συνιστάται από τον κατασκευαστή της συσκευής πλύσης/απολύμανσης ή τον παρασκευαστή του απορρυπαντικού.

| Φάση           | Χρόνος ανακυκλοφορίας | Θερμοκρασία νερού     | Τύπος απορρυπαντικού                  |
|----------------|-----------------------|-----------------------|---------------------------------------|
| Πρόπλυση 1     | 3 λεπτά               | κρύο νερό             | Δ/Ε                                   |
| Ενζυμική πλύση | 5 λεπτά               | ζεστό νερό            | ενζυματικό απορρυπαντικό ουδέτερου pH |
| Πλύση 1        | 5 λεπτά               | σημείο ρύθμισης 66 °C | απορρυπαντικό ουδέτερου pH            |
| Έκπλυση 1      | 3 λεπτά               | ζεστό νερό            | Δ/Ε                                   |

### Μη αυτόματος καθαρισμός

Εμβυθίστε σε χλιαρό (κάτω από 43 °C), ήπιο (pH 7,0 - 8,5) ενζυματικό απορρυπαντικό και νερό για τουλάχιστον 2 λεπτά. Χρησιμοποιήστε μαλακή βουρτσα, ειδική για εργαλεία, για να τρίψετε τους δίσκους εργαλείων ενώ είναι εμβυθισμένοι στο διάλυμα καθαρισμού, ώστε να απομακρυνθεί η οργανική υλη. Ξεπλύνετε με νερό και, στη συνέχεια, καθαρίστε με υπερήχους σε χλιαρό (κάτω από 43 °C), ήπιο (pH 7,0 - 8,5) απορρυπαντικό και νερό για 10 λεπτά.

Εκπλύνετε σχολαστικά με νερό. Καθαρίστε με αυτό τον τρόπο, έως ότου να μην υπάρχουν πλέον ορατά υπολείμματα ρυπων στο δίσκο εργαλείων.

Στεγνώστε με πεπιεσμένο αέρα ή σκουπίστε με πανί που δεν αφήνει χνούδι. Πρέπει να εξετάζετε τους δίσκους εργαλείων για τυχόν κηλίδωση ή φθορές. Διακοψτε τη χρήση τους ανάλογα με την περίπτωση.

**Σημείωση:** Κατά τη χρήση συσκευής καθαρισμού με υπερήχους ή συσκευής πλύσης με ψεκασμό, ακολουθείτε τις συστάσεις του κατασκευαστή όσον αφορά την τοποθέτηση των δίσκων εργαλείων.

Μετά τον καθαρισμό, να λιπαίνετε ελαφρά τους δίσκους εργαλείων με κινητά μέρη.

Χρησιμοποιείτε λιπαντικά που προορίζονται για χρήση με εργαλεία επιδεχόμενα αποστείρωση, όπως υδατοδιαλυτό γαλάκτωμα κατάλληλο για εργαλεία. Μη χρησιμοποιείτε σπρέι σιλικόνης.

### Περιορισμένη εγγύηση

manuals.medtronic.com

PL  
PL

### Wskazania do użycia

Tace na narzędzia służą do porządkowania, przechowywania, ochrony i przenoszenia narzędzi stosowanych podczas zabiegów chirurgicznych.

### Środki ostrożności

Jeśli tace na narzędzia mają zostać użyte w ramach sterylizacji instrumentów ponownego użytku:

- Zatwierdzić tacę względem wewnętrznych procesów i systemów kontroli.
- Postępować zgodnie z odpowiednią instrukcją sterylizacji każdego z instrumentów wielokrotnego użytku.
- Sterylizacji grawitacyjno-parowej nie wolno stosować przypadku tac na narzędzia, ponieważ czas trwania cyklu takiej sterylizacji jest zbyt długi.
- W przypadku tac na narzędzia Medtronic Xomed nie wolno stosować procesu STERRAD.
- Tace na narzędzia nie chronią wysterylizowanych narzędzi przed utratą sterylności w wyniku powtórnego zanieczyszczenia. Tace należy owinać podwójną warstwą szpitalnego materiału CSR, aby utrzymać sterylność narzędzi w nich umieszczonych.
- Przed rozpoczęciem czyszczenia narzędzi i/lub tacy należy wyjąć z tacy narzędzia i luźne elementy wewnętrzne oraz zdjąć pokrywę tacy.
- Firma Medtronic zaleca spalenie wyrobów, które miały bezpośredni kontakt z pacjentami, u których podejrzewa się lub u których potwierdzono występowanie zakaźnej encefalopatii gąbczastej/choroby Creutzfeldta-Jakoba. Dokumenty NHS Estates HTM 2010 części 4 i 6: załącznik 2, Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies (Przedmioty skażone czynnikami zakaźnej encefalopatii gąbczastej oraz Wytyczne Światowej Organizacji Zdrowia dotyczące kontroli zakażeń zakaźną encefalopatią gąbczastą) dotyczą cyklu odkazania w przypadku wystąpienia zakaźnej encefalopatii gąbczastej w autoklawie parowym w temperaturze 134–137°C przez jeden cykl trwający 18 minut lub w powtarzanych sześciu cyklach 3-minutowych.
- W przypadku tac firmy Medtronic i ich akcesoriów może być konieczne stosowanie czasów suszenia wykraczających poza standardowe parametry próżni wstępnej stosowane w placówkach służby zdrowia. Obecnie zalecane czasy suszenia mogą wynosić od standardowych 15 minut do wydłużonego czasu 40 minut. Jest to szczególnie ważne w przypadku polimerowych (plastikowych) tac na narzędzia. Użytkownik powinien mieć możliwość weryfikacji czasu suszenia, np. za pomocą kontroli wzrokowej.

### Czyszczenie

**Uwaga:** aby zminimalizować plamy od wody, do końcowego płukania zaleca się użycie wody dejonizowanej. Jeśli jest to praktyczne, wodę dejonizowaną można zastosować w całym cyklu czyszczenia.

### Czyszczenie automatyczne

Wszystkie tace należy dokładnie opłukać wodą przed ich umieszczeniem w myjni automatycznej.

Przyrządy i wyposażenie zdjąć z tac narzędziowych przed umieszczeniem ich w koszykach myjni. Ułożyć przyrządy zgodnie z zaleceniami producentów myjni/dezynfektora.

Stosować detergenty o obojętnym odczynie pH zgodnie z zaleceniami producentów myjni/urządzenia dezynfekującego lub detergentu.

| Faza               | Czas recyrkulacji | Temperatura wody      | Rodzaj detergentu                              |
|--------------------|-------------------|-----------------------|------------------------------------------------|
| Mycie wstępne 1    | 3 min             | zimna woda            | N/D                                            |
| Mycie enzymatyczne | 5 min             | gorąca woda           | detergent enzymatyczny o obojętnym odczynie pH |
| Mycie 1            | 5 min             | 66°C (wartość zadana) | detergent o obojętnym odczynie pH              |
| Płukanie 1         | 3 min             | gorąca woda           | N/D                                            |

### Czyszczenie ręczne

Moczyć w letnim (o temperaturze niższej niż 43°C), łagodnym (pH 7,0–8,5) roztworze detergentu enzymatycznego w wodzie dejonizowanej przez co najmniej 2 minuty. W celu usunięcia substancji organicznych należy szorować tace na narzędzia zanurzone w roztworze czyszczącym miękką szczotką do narzędzi chirurgicznych. Przepłukać wodą, a następnie przez 10 minut czyścić za pomocą metody wykorzystującej ultradźwięki w letnim (o temperaturze niższej niż 43°C), łagodnym (pH 7,0–8,5) roztworze detergentu w wodzie.

Dokładnie opłukać wodą. Kontynuować czyszczenie opisaną metodą aż do usunięcia z tacy na narzędzia wszelkich widocznych zanieczyszczeń.

Osuszyć sprężonym powietrzem lub wytrzeć do sucha ściereczką niepozostawiającą włókien. Sprawdzić, czy na tacach na narzędzia nie ma plam ani widocznych śladów zużycia; w razie konieczności wycofać z użytku.

**Uwaga:** podczas korzystania z myjni ultradźwiękowej lub natryskowej należy przestrzegać zaleceń producenta dotyczących układania tac na narzędzia.

Tace z ruchomymi częściami należy po oczyszczeniu lekko nasmarować. Używać smaru przeznaczonego do narzędzi przystosowanych do sterylizacji, takiego jak rozpuszczalne w wodzie mleczko do narzędzi chirurgicznych. Nie należy używać silikonu w aerozolu.

### Ograniczona gwarancja

manuals.medtronic.com

## CS

### Indikace k použití

Podnosy na nástroje jsou navrženy tak, aby poskytovaly všeobecnou konfiguraci pro rozkládání, ukládání, ochranu a přenášení lékařských zařízení určených k použití při chirurgických zákrocích.

### Bezpečnostní opatření

Pokud se rozhodnete použít podnos na nástroje jako součást sterilizačního systému pro čištění zařízení, je nutné dodržet následující pravidla:

- Zajistěte validaci podnosu v rámci interních postupů a systémů.
- Dodržujte všechny pokyny pro sterilizaci čištěných zařízení.
- Podnosy na nástroje nelze sterilizovat pomocí parní sterilizace s gravitačním odvzdušněním, protože doby sterilizačních cyklů jsou velmi dlouhé.
- Podnosy na nástroje Medtronic Xomed nelze sterilizovat pomocí systému STERRAD.
- Podnosy na nástroje nejsou určeny k tomu, aby tvořily sterilní bariéru na ochranu před rekontaminací sterilizovaných nástrojů, a za tímto účelem musí být obaleny dvěma nemocničními obaly CSR, aby se zachovala sterilita nástrojů na podnosu.
- Před čištěním nástrojů a nebo podnosu odstraňte nástroje, vnitřní volné komponenty podnosu a uzávěr.
- Společnost Medtronic doporučuje spálit zařízení, která přišla do přímého kontaktu s pacienty, u kterých existuje podezření nebo byla potvrzena diagnóza transmisivní spongiformní encefalopatie (TSE)/CJD. NHS Estates HTM 2010, část 4 a 6; Příloha 2, Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies (Součásti kontaminované TSE a Pokyny Světové zdravotnické organizace k zamezení šíření infekce způsobené transmisivní spongiformní encefalopatií) pojednávají o cyklu dekontaminace TSE sterilizací v parním autoklávu při teplotě 134–137 °C v jednom cyklu po dobu 18 minut nebo opakovaně v šesti cyklech po 3 minutách.
- Při použití dob trvání sušení pro podnosy na nástroje Medtronic a jejich příslušenství může být nutné použít doby trvání sušení mimo rozsah standardní prevakuové sterilizace ve zdravotnických zařízeních. V současné době se doporučované doby trvání sušení mohou pohybovat v rozmezí od standardních 15 minut až po prodlouženou dobu trvání 40 minut. To je zejména důležité u polymerových (plastových) podnosů na nástroje. Uživatel by měl mít k dispozici dostatečné prostředky pro ověření doby sušení, jako je např. vizuální kontrola.

### Čištění

**Poznámka:** Aby se minimalizovala tvorba vodních usazenin, doporučuje se provádět oplachování deionizovanou vodou. Pokud je to praktické, lze deionizovanou vodu použít pro celý postup.

### Automatické čištění

Všechny podnosy je nutné před vložením do automatické myčky důkladně opláchnout vodou.

Před uložením do košu v myčce odeberte z podnosů veškeré nástroje a zařízení.

Zařízení uložte podle pokynů výrobce myčky nebo dezinfekčního zařízení.

Použijte detergent s neutrálním pH doporučený výrobcem myčky/dezinfektoru nebo výrobcem detergentů.

| Fáze             | Doba recirkulace | Teplota vody              | Typ detergentu                        |
|------------------|------------------|---------------------------|---------------------------------------|
| Předmytí 1       | 3 minut          | studená voda              | Není k dispozici                      |
| Enzymatické mytí | 5 minut          | horká voda                | enzymatický detergent s neutrálním pH |
| Mytí 1           | 5 minut          | 66 °C (nastavená hodnota) | detergent s neutrálním pH             |
| Opláchnutí 1     | 3 minut          | horká voda                | Není k dispozici                      |

HU

Ruční čištění

Nejméně 2 minuty namáčejte ve vlažném (s teplotou nižší než 43 °C) roztoku jemného (pH 7,0–8,5) enzymatického čistícího prostředku ve vodě. K odstranění organického materiálu z podnosů na nástroje ponořených do čistícího roztoku použijte měkký kartáček na nástroje. Opláchněte podnos na nástroje ve vodě a poté jej vyčistěte v ultrazvukové lázni ve vlažném (s teplotou nižší než 43 °C) roztoku jemného (pH 7,0–8,5) čistícího prostředku a vody po dobu 10 minut.

Důkladně opláchněte vodou. Čištění tímto způsobem provádějte tak dlouho, dokud nebudou na podnosu na nástroje patrné žádné zbytky nečistot.

Vysušte nástroj stlačeným vzduchem nebo otřete do sucha látkou nepouštějící vlákna. Prohlédněte podnosy na nástroje, zda na nich nejsou skvrny nebo známky opotřebení, a podle potřeby je vyřadte z provozu.

**Poznámka:** Při použití ultrazvukové lázně nebo oštríkovací myčky postupujte podle doporučení výrobce pro umístění podnosů na nástroje.

Podnosy na nástroje s pohyblivými součástmi po čištění lehce namažte. Použijte mazivo určené pro sterilizovatelné nástroje, jako je vodní suspenze „mléka“ na mazání nástrojů. Nepoužívejte silikonový sprej.

Omezená záruka

manuals.medtronic.com

HU

Alkalmazási terület

A műszertálcák a sebészeti beavatkozások során használt orvosi műszerek összeállításához, tárolásához, megővzéséhez és szállításához nyújtanak általános segítséget az eszközök elrendezésével.

Óvintézkedések

Ha a műszertálcát az eszközök regenerálására szolgáló sterilizáló rendszer részeként használja:

- A tálcát a belső eljárásoknak és rendszereknek megfelelően validálni kell.
- Tartsa be a regenerált eszköz(ök) sterilizálására vonatkozó összes utasítást.
- A műszertálcák esetében ellenjavallt a gravitációs gőzsterilizálás, mivel túlságosan hosszú ciklusidőkre lenne szükség.
- A Medtronic Xomed műszertálcákat nem szabad STERRAD berendezéssel sterilizálni.
- A műszertálcák a sterilizált műszereket nem védik meg steril védőborításként az újbóli szennyeződéstől; a tálcákat a bennük lévő műszerek sterilizálásának fenntartásához az eljárás során duplán be kell csomagolni kórházi steril csomagolásba.
- A műszerek elő/vagy a tálca tisztítása előtt vegye ki a műszereket, a tálca belső, nem rögzített elemeit, és vegye le a fedelet.
- A Medtronic azt javasolja, hogy égetéssel semmisítsék meg azokat az eszközöket, amelyek közvetlen kapcsolatba kerültek – gyaníthatóan vagy igazoltan – fertőző szivacsos agysorvadásban / Creutzfeldt–Jakob-kórban szenvedő betegekkel. Az NHS Estates HTM 2010 4. és 6. rész 2. függelék: Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies (TSE-kórokozók szennyezett eszközök, valamint a WHO szivacsos agyvelőgyulladásról szóló infekciókontroll-ajánlása) értelmében a TSE-szennyeződésmentesítési ciklus autoklavozással végezhető, 134–137 °C-on, egy 18 perces vagy összesen hat 3 perces ciklussal.
- A Medtronic műszertálcák és tartozékaik szárításakor előfordulhat, hogy a szabványos egészségügyi elővákuumos paraméterektől eltérő szárítási időket kell alkalmazni. Az aktuálisan ajánlott szárítási idő a szabványos 15 perc és a hosszabb 40 perc közötti tartományban mozoghat. Ez különösen a polimeralapú (műanyag) műszertálcák esetében fontos. A felhasználónak megfelelő módszerekkel, például szemrevételezéssel kell ellenőriznie, hogy elegendes-e a szárítási idő.

Tisztítás

**Megjegyzés:** Az utolsó öblítéshez ionmentes víz használata ajánlott, hogy a megszáradó vízcseppek minimális nyomot hagyjanak. Ha kivitelezhető, a teljes tisztítási eljáráshoz erdemes ionmentes vizet használni.

Tisztítás automatában

Az automata mosóberendezésbe helyezés előtt minden talcat alaposan le kell öblíteni vízzel.

A műszereket és a hozzájuk tartozó elemeket a mosókosárba helyezés előtt ki kell venni az eszköztálcából. Az eszközöket a mosó-/fertőtlenítőberendezés gyártójának ajánlásait követve kell elhelyezni.

A mosó-/fertőtlenítőberendezés, illetve a mosószer gyártója által ajánlott semleges kémhatású mosószert használgon.

| Fázis         | Recirkulációs idő | Vfzhőmérséklet | Tisztítószert típusa                    |
|---------------|-------------------|----------------|-----------------------------------------|
| 1. előmosás   | 3 perc            | hideg víz      | n.a.                                    |
| Enzimes mosás | 5 perc            | meleg víz      | semleges kémhatású enzimátikus mosószer |



| Fázis      | Recirkulációs idő | Víz hőmérséklet    | Tisztítószer típusa         |
|------------|-------------------|--------------------|-----------------------------|
| 1. mosás   | 5 perc            | 66 °C-os alapérték | semleges kémhatású mosószer |
| 1. öblítés | 3 perc            | meleg víz          | n.a.                        |

### Tisztítás kézzel

Áztassa a műszertálcákat legalább 2 percig enyhe (7,0–8,5 pH-jú) enzimes tisztítószer és víz langyos (43 °C alatti hőmérsékletű) keverékében. A szerves anyagok eltávolításához puha sörtéjű kefével súrolja le a tisztítóoldatba merített műszertálcákat. Öblítse le vízzel, majd 10 percen keresztül tisztítsa őket ultrahanggal enyhe (7,0–8,5 közötti pH-jú) tisztítószer és víz langyos (43 °C alatti hőmérsékletű) keverékében.

Öblítse le őket alaposan vízzel. Addig tisztítsa így a műszertálcákat, amíg az összes látható szennyeződést el nem távolítja rólok.

Szárítsa meg szűrített levegővel, vagy törölje őket szárazra szálmentes törölkendővel.

Vizsgálja meg a műszertálcákat, hogy nem látható-e rajtuk folt vagy károsodás, és vonja ki őket a használatból, ha szükséges.

**Megjegyzés:** Ultrahangos tisztítóberendezés vagy permetezőfejes mosóberendezés használata esetén kövesse a gyártó által a műszertálcák elhelyezésére megadott ajánlásokat.

Tisztítás után a mozgó alkatrészekkel ellátott műszertálcákat enyhén síkosítsa.

Szterilizálható műszerekhez való síkosítót alkalmazzon, például vízalapú kenőtejet. Ne használjon szilikonsprayt.

### Korlátozott szavatosság

manuals.medtronic.com

### TR

#### Kullanım endikasyonları

Alet tepsileri; cerrahi prosedürlerde kullanılan tıbbi cihazların düzenlenmesine, saklanması, korunmasına ve taşınmasına yönelik genel bir konfigürasyon sağlamayı amaçlar.

#### Önlemler

Alet tepsisini, cihazların yeniden işlemiden geçirilmesine yönelik sterilizasyon sisteminin bir parçası olarak kullanmayı seçerseniz:

- Tepsiyi dahili proses ve sistemlerinizde onayladığınızdan emin olun.
- Yeniden işlemiden geçirdiğiniz cihazların sterilizasyonuna ilişkin tüm talimatlara uyun.
- Dongü süreleri aşırı uzun olacağı için Yer Çekimi Esaslı Buhar sterilizasyonu alet tepsileri için kullanılmamalıdır.
- Medtronic Xomed alet tepsileri için STERRAD işlemi kullanılmamalıdır.
- Alet Tepsileri sterilize edilmiş aletlerin tekrar kontaminasyonunu önlemek üzere bir steril bariyer sağlamak amaçlı üretilmiştir ve bu işlem için hastane CSR sargısı ile çift katlı sarılarak tepsi içindeki aletlerin sterilitesi korunmalıdır.
- Aletleri ve/veya tepsiyi temizlemeden önce aletleri çıkarın, dahili tepsi bileşenlerini ve kapağı gevşetin.
- Medtronic, Bulaşıcı Süngerimsi Ensefalopati (TSE)/CJD teşhisi konmuş ya da bu hastalığı geçirdiğinden şüphelenilen hastalar ile doğrudan temas eden cihazların insinerasyon (yakma) işlemine tabi tutulmasını önermektedir. NHS Estates HTM 2010 4. ve 6. Bölümlerinde bulunan, Ek 2, Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies (TSE Ajanları bulaşmış Maddeler ve Bulaşıcı Süngerimsi Ensefalopatiler için WHO Enfeksiyon Kılavuzu), 18 dakikalık tek dongü için 134-137°C sıcaklıkta buharlı otoklav kullanarak TSE dekontaminasyon dongüsü uygulamasını veya toplam 3 dakikalık dongülerde bu uygulamanın altı kere tekrarlanmasını önermektedir.
- Medtronic aletlerine ve aksesuarlarına kurutma süresi uygularken, standart sağlık hizmeti on vakum parametreleri gerekebilir. Önerilen mevcut kurutma süreleri, standart 15 dakikadan 40 dakikaya kadar uzun bir süre arasında değişebilir. Bu, özellikle polimer esaslı (plastik) alet tepsileri için önemlidir. Kullanıcı, görsel inceleme gibi kurutma sürelerini doğrulamak için yeterli olanaklara sahip olmalıdır.

#### Temizlik

**Not:** Su lekelerini minimum seviyeye indirmek için son durulamada deiyonize su kullanılması önerilir. Uygulaması mümkünse deiyonize su temizlik işleminin tamamında kullanılabilir.

#### Otomatik temizlik

Tüm tepsiler, otomatik yıkayıcıya yerleştirilmeden önce suyla iyice durulanmalıdır. Aletleri ve ekipmanı yıkayıcının bölmelerine yerleştirmeden önce alet tepsilerinden çıkarın. Aletlere, yıkayıcı/dezenfeksiyon cihazı üreticilerinin tavsiyelerine göre yön verin.

Yıkayıcı/mikrop öldürücü imalatçılarının veya deterjan imalatçılarının önerdiği nötr pH deterjan kullanın.



## NO

| Aşama        | Devridaim Süresi | Su Sıcaklığı      | Deterjan Tipi                 |
|--------------|------------------|-------------------|-------------------------------|
| On yıkama 1  | 3 dakika         | soğuk su          | Yok                           |
| Enzim Yıkama | 5 dakika         | sıcak su          | notr pH'lı enzimatik deterjan |
| Yıkama 1     | 5 dakika         | 66°C ayar noktası | notr pH'lı deterjan           |
| Durulama 1   | 3 dakika         | sıcak su          | Yok                           |

### Manuel temizleme

En az 2 dakika boyunca ılık (43°C'den düşük) sıcaklıktaki, yumuşak (pH 7,0 - 8,5), enzimatik deterjan ve su karışımına daldırın. Alet tepsilerini temizleme solüsyonuna daldırdığınızda organik maddeleri çıkarmak üzere ovalamak için yumuşak bir alet fırçası kullanın. Suyla durulayın, ardından ılık (43°C'den düşük), yumuşak (pH 7,0 - 8,5) deterjan ve suyla 10 dakika ultrasonik temizleme yapın.

Suyla iyice durulayın. Alet tepsisi üzerinde görünür kalıntı kalmayana dek bu şekilde temizleyin.

Sıkıştırılmış hava ile kurutun veya lif bırakmayan bir bezle silerek kurutun. Alet tepsilerini lekelenme veya bozulma açısından inceleyin, gerekirse kullanımdan kaldırın.

**Not:** Ultrasonik temizleyici veya püskürtmeli yıkama makinesi kullanırken, alet tepsilerini yerleştirme konusunda üretici tavsiyelerine uyun.

Temizliğin ardından, hareketli parçalara sahip alet tepsilerini hafifçe yağlayın. Suda çözünebilir alet sütü gibi sterilize edilebilir aletler için tasarlanmış bir yağ kullanın. Silikon sprej kullanmayın.

### Sınırlı garanti

manuals.medtronic.com

## NO

### Indikasjoner for bruk

Instrumentbrett er beregnet på å gi en generell konfigurasjon for a organisere, oppbevare, beskytte og transportere medisinsk utstyr til bruk i kirurgiske prosedyrer.

### Forholdsregler

Hvis du velger å bruke instrumentbrettene som en del av steriliseringssystemet for repossessing av utstyr:

- Sørg for at du validerer brettet med egne interne prosesser og systemer.
- Følg alle instruksjonene for sterilisering av utstyr du repossesserer.
- Gravitasjonsdampsterilisering skal ikke brukes for instrumentbrett, ettersom syklustidene ville bli svært lange.
- STERRAD-prosessering må ikke brukes for Medtronic Xomed instrumentbrett.
- Instrumentbrett er ikke ment å utgjøre noen steril barriere for å hindre ny kontaminering av steriliserte instrumenter, og må pakkes dobbelt inn i sykehusets CSR-innpakning for denne prosessen for å opprettholde sterilitet for instrumentene som befinner på innsiden av brettet.
- Ta bort instrumentene, løsne interne brettkomponenter og lokk før rengjøring av instrumenter og/eller brett.
- Medtronic anbefaler brenning av instrumenter som har vært i direkte kontakt med pasienter som har en antatt eller bekreftet diagnose med smitteførende spongiform encefalopati (TSE) / Creutzfeldt-Jakobs sykdom (CJD). NHS Estates HTM 2010 del 4 og 6: vedlegg 2, Items contaminated with TSE Agents (Elementer kontaminert med TSE-agens) og WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies (WHO's retningslinjer for infeksjonskontroll for overførbare spongiforme encefalopatier) refererer til en dekontamineringscyklus for TSE der det brukes dampautoklaving med en temperatur på 134–137 °C i en syklus på 18 minutter eller 6 sykluser på 3 minutter hver.
- Ved bruk av tørketider på Medtronic-instrumentbrett og tilbehør kan det hende at man må bruke tørketider som ligger utenfor standard forvakuumparametere som benyttes i helsesektoren. Anbefalte tørketider varierer for tiden fra en standardtid på 15 minutter, til hele 40 minutter. Dette er spesielt viktig for polymerbaserte (plast) instrumentbrett. Brukeren må blant annet kunne kontrollere tørketiden med visuell kontroll.

### Rengjøring

**Merk:** Bruk av avionisert vann til den avsluttende skyllingen anbefales for å redusere flekker etter vann. Hvis det er praktisk, kan avionisert vann brukes i hele rengjøringsprosessen.

### Automatisk rengjøring

Alle brett skal skylles grundig med vann før de settes inn i vaskemaskinen.

Fjern instrumenter og utstyr fra instrumentbrett før de plasseres i rengjøringskurvene. Plasser utstyret i henhold til anbefalingene fra produsenten av vaskemaskinen/desinfiseringsmaskinen.

Bruk et rengjøringsmiddel med nøytral pH som er anbefalt av produsenten av vaskemaskinen/desinfiseringsmaskinen eller rengjøringsmiddelet.

| Fase       | Resirkuleringstid | Vanntemperatur    | Type rengjøringsmiddel                      |
|------------|-------------------|-------------------|---------------------------------------------|
| Forvask 1  | 3 minutter        | kaldt vann        | I/R                                         |
| Enzymvask  | 5 minutter        | varmt vann        | enzymatisk rengjøringsmiddel med nøytral pH |
| Vask 1     | 5 minutter        | 66 °C (settpunkt) | rengjøringsmiddel med nøytral pH            |
| Skylling 1 | 3 minutter        | varmt vann        | I/R                                         |

### Manuell rengjøring

La ligge i lunkent (kaldere enn 43 °C), mildt (pH 7,0–8,5), enzymatisk rengjøringsmiddel og vann i minst 2 minutter. Bruk en myk instrumentbørste til å rengjøre instrumentbrettene mens de ligger i rengjøringsvæsken, for å fjerne organiske stoffer. Skyll med vann, og rengjør med ultralyd i lunkent (kaldere enn 43 °C), mildt (pH 7,0–8,5) rengjøringsmiddel og vann i 10 minutter. Skyll grundig med vann. Fortsett med dette til det ikke er igjen noen skittrester på instrumentbrettet.

Tørk med trykkluft, eller tørk det tørt med en lufri klut. Undersøk instrumentbrettene og se til at de ikke har flekker eller svakheter. Ta dem eventuelt ut av bruk.

**Merk:** Ved rengjøring med ultralyd eller vaskemaskin med sprayfunksjon er det viktig å følge produsentens anbefalinger for plassering av instrumentbrettene.

Etter rengjøringen bør bevegelige deler på instrumentbrettene smøres lett. Bruk et smøremiddel som er laget for steriliserbare instrumenter, for eksempel vannoppløselig instrumentmelk. Bruk aldri silikonspray.

### Begrenset garanti

manuals.medtronic.com

### RU

#### Показания к применению

Лотки для инструментов предназначены для создания общей конфигурации при организации, хранении, защите от внешних факторов и транспортировке медицинских устройств, предназначенных для применения в хирургических вмешательствах.

#### Меры предосторожности

При использовании лотка для инструментов в качестве компонента стерилизационной системы для устройств, подлежащих повторной обработке, выполняйте следующие указания:

- Убедитесь в том, что лоток прошел валидацию в рамках утвержденных к применению в вашем учреждении процессов и систем.
- При повторной обработке устройств(а) выполняйте все инструкции по стерилизации.
- Паровая стерилизация с гравитационным вытеснением воздуха запрещена для лотков для инструментов из-за слишком большой продолжительности такого цикла.
- Стерилизация лотков для инструментов Medtronic Xomed в системе STERRAD запрещена.
- Лотки для инструментов не предназначены для создания стерильного барьера, препятствующего повторной контаминации стерилизованных инструментов. Для сохранения стерильности инструментов внутри лотка их необходимо обернуть двумя слоями оберточного материала для стерилизации.
- Перед очисткой инструментов и/или лотка достаньте инструменты, ослабьте крепление внутренних компонентов лотка и крышки.
- Компания Medtronic рекомендует сжигание устройств, которые находились в непосредственном контакте с пациентами, имеющими предполагаемый или подтвержденный диагноз трансмиссивной губчатой энцефалопатии (ТГЭ) или болезни Крейтцфельда-Якоба (БКЯ). Согласно Техническому меморандуму Национальной системы здравоохранения 2010 г., части 4 и 6: приложение 2 Items contaminated with TSE Agents («Предметы, зараженные возбудителями ТГЭ») и WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies («Рекомендации ВОЗ по борьбе с распространением трансмиссивной губчатой энцефалопатии»), цикл обеззараживания ТГЭ следует выполнять с помощью парового автоклава при температуре 134–137 °C, используя однократный цикл продолжительностью 18 минут или шесть последовательных 3-минутных циклов.

SR

- При настройке времени сушки лотков для инструментов и дополнительных принадлежностей к ним компании Medtronic может потребоваться время сушки, выходящее за стандартные параметры предварительного вакуумирования, применяемые в медицине. Согласно действующим рекомендациям, время сушки может находиться в диапазоне от стандартных 15 минут до увеличенной продолжительности 40 минут. Это особенно важно для полимерных (пластиковых) лотков для инструментов. Пользователь должен соответствующим образом контролировать время сушки, например прибегать к визуальной проверке.

Очистка

**Примечание.** Чтобы минимизировать следы высыхания воды, при окончательном ополаскивании рекомендуется использовать деионизированную воду. Деионизированную воду можно использовать на всем протяжении процесса очистки, если это представляется разумным.

Автоматическая очистка

Перед помещением в автоматическую моечную машину все лотки необходимо тщательно промыть водой. Перед укладкой в корзину моечной машины извлекайте инструменты и оборудование из лотков для инструментов. Располагайте устройства в соответствии с рекомендациями производителя моеюще-дезинфицирующего оборудования. Используйте моющие средства с нейтральным pH, рекомендованные производителями моечного или дезинфицирующего оборудования или производителями моющих средств.

| Фаза                           | Длительность рециркуляции | Температура воды               | Тип моющего средства                            |
|--------------------------------|---------------------------|--------------------------------|-------------------------------------------------|
| Замачивание 1                  | 3 мин                     | Холодная вода                  | Н/п                                             |
| Мойка ферментативным раствором | 5 мин                     | Горячая вода                   | Ферментативное моющее средство с нейтральным pH |
| Мойка 1                        | 5 мин                     | 66 °C (установленное значение) | Моющее средство с нейтральным pH                |
| Ополаскивание 1                | 3 мин                     | Горячая вода                   | Н/п                                             |

Очистка вручную

Замочите в теплом (менее 43 °C) растворе мягкого (pH 7,0–8,5) ферментативного моющего средства и воды и выдержите не менее 2 минут. Чтобы удалить органические вещества, почистите лотки для инструментов, погруженные в моющий раствор, мягкой щеткой для инструментов. Прополощите водой, а затем проведите ультразвуковую очистку в теплом (менее 43 °C) растворе мягкого (pH 7,0–8,5) моющего средства и воды в течение 10 минут. Тщательно ополосните водой. Очищайте указанным способом, пока с лотка для инструментов не будут удалены видимые загрязнения. Высушите сжатым воздухом и/или протрите насухо безворсовой тканью. Осмотрите лотки для инструментов на предмет появления пятен или признаков износа и при необходимости изымите из эксплуатации.

**Примечание.** При использовании ультразвукового очистителя или струйной моечной машины следуйте рекомендациям производителя в отношении ориентации лотков для инструментов. После очистки слегка смажьте лотки для инструментов с подвижными частями. Используйте смазку, предназначенную для стерилизуемых инструментов, например растворимое в воде инструментальное молочко. Запрещается использовать аэрозольный силикон.

Ограниченная гарантия

manuals.medtronic.com

SR

Indikacije za upotrebu

Posude za instrumente su namenjene da pruže opštu konfiguraciju za organizovanje, smeštanje, zaštitu i transport medicinskih uređaja koji se koriste u hirurškim procedurama.

Mere predostrožnosti

- Ako odaberete da koristite posudu za instrumente kao deo sistema za sterilizaciju uređaja za ponovnu obradu:
- Obavezno potvrdite valjanost posude putem internih procesa i sistema.
  - Pratite sva uputstva za sterilizaciju uređaja koje ponovno obrađujete.
  - Parna sterilizacija gravitacionim ciklusom ne sme se koristiti za posude za instrumente jer bi vreme trajanja ciklusa bilo predugačko.

- STERRAD obrada se ne sme koristiti za Medtronic Xomed posude za instrumente.
- Nije predviđeno da posude za instrumente pružaju sterilnu barijeru kako bi se sprečila ponovna kontaminacija sterilizovanih instrumenata; u tu svrhu posude moraju biti dvostruko omotane u bolnicki CSR omot kako bi se očuvala sterilnost instrumenata u posudi.
- Pre čišćenja instrumenata i/ili posude izvadite instrumente i odvojte unutrašnje delove posude i poklopac.
- Kompanija Medtronic preporučuje spaljivanje uređaja koji su bili u direktnom kontaktu sa pacijentima za koje se sumnja na dijagnozu prenosive spongiformne encefalopatije (TSE)/CJD ili je ona potvrđena. NHS Estates HTM 2010 delovi 4 i 6: Dodatak 2, Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies (Artikli kontaminirani TSE agensima i Smernice Svetske zdravstvene organizacije za kontrolu infekcija za prenosive spongiformne encefalopatije) nalaže ciklus dekontaminacije TSE korišćenjem parnog autoklava pri temperaturi od 134–137 °C u jednom ciklusu u trajanju od 18 minuta ili u šest ciklusa od po 3 minuta.
- Prilikom određivanja vremena sušenja za Medtronic posude za instrumente i njihov pribor može biti neophodno da se primene vremena sušenja koja odstupaju od standardnih medicinskih parametara za predvakuumsku obradu. Trenutno važeća preporučena vremena sušenja mogu se kretati od standardnih 15 minuta do produženog vremena od 40 minuta. To je posebno važno za posude za instrumente koje su izrađene na bazi polimera (plastike). Korisnik mora imati odgovarajući način za proveru vremena sušenja, npr. vizuelna provera.

### Čišćenje

**Napomena:** Da bi se pojava mrlja od vode svela na minimum, preporučuje se da se poslednje ispiranje vrši dejonizovanom vodom. Ako je izvodljivo, dejonizovana voda se može koristiti za čitav proces čišćenja.

### Automatizovano čišćenje

Sve posude se moraju temeljno isprati vodom pre postavljanja u automatsku mašinu za pranje.

Izvadite instrumente i opremu iz posuda za instrumente pre nego što ih stavite u korpe mašine za pranje. Uređaje postavite u skladu sa preporukama proizvođača mašine za pranje/dezinfekciju.

Koristite deterdžent sa neutralnom pH vrednošću koji preporučuje proizvođač mašine za pranje/dezinfekciju ili proizvođač deterdženta.

| Faza            | Trajanje recirkulacije | Temperatura vode        | Tip deterdženta                            |
|-----------------|------------------------|-------------------------|--------------------------------------------|
| 1. pretpranje   | 3 minuta               | hladna voda             | nije primenljivo                           |
| Enzimsko pranje | 5 minuta               | topla voda              | enzimski deterdžent neutralne pH vrednosti |
| 1. pranje       | 5 minuta               | podešena vrednost 66 °C | deterdžent neutralne pH vrednosti          |
| 1. ispiranje    | 3 minuta               | topla voda              | nije primenljivo                           |

### Ručno čišćenje

Potopite u mlak (temperature niže od 43 °C), blag (pH 7,0–8,5) rastvor enzimskog deterdženta i vode na najmanje 2 minuta. Pomoću meke četke za instrumente oribajte posude za instrumente dok su potopljeni u rastvor za čišćenje kako biste uklonili organske materije. Isperite vodom, a zatim očistite ultrazvukom u mlakom (temperature niže od 43 °C), blagom (pH 7,0–8,5) rastvoru deterdženta i vode u trajanju od 10 minuta.

Temeljno isperite vodom. Čistite na ovaj način sve dok na posudi za instrumente više ne bude vidljive prljavštine.

Osušite kompresovanim vazduhom ili brisanjem krpom koja ne ostavlja trunice. Proverite da na posudama za instrumente nema mrlja niti znakova propadanja; po potrebi ih povucite iz upotrebe.

**Napomena:** Prilikom korišćenja uređaja za ultrazvučno čišćenje ili mašine za pranje prskanjem, sledite preporuke proizvođača koje se odnose na postavljanje posuda za instrumente.

Nakon čišćenja blago podmažite posude za instrumente sa pokretnim delovima. Koristite sredstvo za podmazivanje koje je namenjeno za instrumente koji se mogu sterilisati, kao što je mleko za instrumente koje se rastvara u vodi. Nemojte koristiti silikonski sprej.

### Ograničena garancija

manuals.medtronic.com

Indikacije za upotrebu

Podlošci za instrumente služe za općenito organiziranje, čuvanje, zaštitu i prijenos medicinskih instrumenata koji se koriste tijekom kirurških zahvata.

Mjere opreza

Ako podložak za instrumente koristite u sklopu sterilizacijskog sustava za ponovnu obradu instrumenata:

- Obavezno provjerite valjanost podloška u internim procesima i sustavima.
- Pridržavajte se svih uputa za sterilizaciju uređaja koje ponovno obrađujete.
- Parna gravitacijska sterilizacija ne smije se koristiti za podloške za instrumente jer bi ciklusi predugo trajali.
- Podlošci za instrumente Medtronic Xomed ne smiju se obrađivati pomoću sustava STERRAD.
- Podlošci za instrumente nisu namijenjeni za pružanje sterilne barijere radi sprječavanja ponovne kontaminacije steriliziranih instrumenata; oni u tu svrhu moraju biti dvostruko umotani u omote bolničkog odjela središnje sterilizacije da bi se održala sterilnost instrumenata koji se nalaze unutar podloška.
- Prije čišćenja instrumenata i/ili podloška izvadite instrumente, pomične interne komponente podloška i poklopac.
- Medtronic preporučuje spaljivanje uređaja koji su došli u neposredni dodir s bolesnicima za koje se sumnja da boluju od transmisivne spongiformne encefalopatije (TSE-a) / CJD-a ili im je ta dijagnoza potvrđena. Tehnički memorandum o zdravstvu za 2010. ustanova u sklopu NHS-a, dijelovi 4 i 6: dodatak 2, Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies (Predmeti kontaminirani uzročnicima TSE-a i smjernice Svjetske zdravstvene organizacije o kontroli širenja infekcije transmisivne spongiformne encefalopatije) određuje ciklus dekontaminacije od uzročnika TSE-a pomoću parnog autoklaviranja pri temperaturi od 134 do 137 °C u jednom ciklusu u trajanju od 18 minuta ili ponavljanjem ukupno šest trominutnih ciklusa.
- Potrebno vrijeme sušenja podložaka za instrumente tvrtke Medtronic i njihovih dodataka može biti dulje od standardnih parametara za predvakuumsku sterilizaciju u zdravstvu. Trenutne preporuke za vrijeme sušenja u rasponu su od standardnih 15 minuta do produljenog sušenja u trajanju od 40 minuta. To je osobito važno za polimerne (plastične) podloške za instrumente. Korisnik mora na raspolaganju imati odgovarajuće mogućnosti provjere vremena sušenja, kao što je vizualna provjera.

Čišćenje

**Napomena:** da bi se minimiziralo stvaranje mrlja od vode, prilikom posljednjeg ispiranja preporučuje se korištenje deionizirane vode. Ako je praktično, deionizirana voda može se koristiti tijekom cijelog postupka čišćenja.

Automatsko čišćenje

Prije stavljanja u automatsku perilicu sve podloške prethodno dobro isperite vodom. Prije stavljanja u košaru perilice instrumente i opremu izvadite iz podložaka za instrumente. Instrumente u perilici usmjerite u skladu s preporukama proizvođača uređaja za pranje/dezinfekciju.

Koristite pH neutralne deterdžente koje preporučuju proizvođač uređaja za pranje/dezinfekciju i proizvođači deterdženata.

| Faza            | Vrijeme kružnog protoka | Temperatura vode         | Vrsta deterdženta                |
|-----------------|-------------------------|--------------------------|----------------------------------|
| Pretpranje 1    | 3 minute                | hladna voda              | nije primjenjivo                 |
| Enzimsko pranje | 5 minuta                | vruća voda               | pH neutralni enzimski deterdžent |
| Pranje 1        | 5 minuta                | 66 °C, zadana vrijednost | pH neutralni deterdžent          |
| Ispiranje 1     | 3 minute                | vruća voda               | nije primjenjivo                 |

Ručno čišćenje

Namačite u mlakoj otopini (temperature manje od 43 °C) blagog enzimskog deterdženta (pH 7,0 – 8,5) i vode najmanje dvije minute. Podloške za instrumente uronjene u otopinu za čišćenje čistite mekom četkom za instrumente da biste odstranili organske tvari. Isperite ih vodom, a zatim ih 10 minuta ultrazvučno čistite u mlakoj otopini (temperature manje od 43 °C) blagog deterdženta (pH 7,0 – 8,5) i vode. Dobro isperite vodom. Nastavite s čišćenjem na taj način dok ne uklonite sva vidljiva onečišćenja s podložaka za instrumente.

Osušite komprimiranim zrakom ili obrišite suhom krpom koja ne ostavlja dlačice. Provjerite nema li na podlošcima za instrumente mrlja ili znakova habanja. Ako je potrebno, povucite ih iz uporabe.



**Napomena:** kada koristite ultrazvučni uređaj za čišćenje ili perilicu sa štrcaljkama, slijedite preporuke proizvođača koje se odnose na postavljanje podložaka za instrumente.  
Nakon čišćenja pomične dijelove podložaka za instrumente malo podmažite. Koristite sredstvo za podmazivanje predviđeno za instrumente koji se mogu sterilizirati, npr. mlijeko za instrumente topivo u vodi. Nemojte koristiti silikonski sprej.

**Ograničeno jamstvo**  
manuals.medtronic.com

PT-BR

Indicações de uso

As bandejas para instrumental são desenvolvidas para proporcionar uma composição geral para organizar, armazenar, proteger e transportar dispositivos médicos para uso em procedimentos cirúrgicos.

Precauções

- Se você optar por usar a bandeja para instrumental como parte de um sistema de esterilização para reprocessamento de dispositivos:
- Certifique-se de validar a bandeja em seus sistemas e processos internos.
  - Siga todas as instruções para esterilização do(s) dispositivo(s) que você está reprocessando.
  - A esterilização com vapor por gravidade não deve ser usada para bandejas para instrumental pois os tempos dos ciclos seriam excessivamente longos.
  - O processo de esterilização STERRAD não deve ser usado com as bandejas para instrumental Medtronic Xomed.
  - As Bandejas para Instrumental não foram desenvolvidas para proporcionar uma barreira estéril para impedir a recontaminação dos instrumentos esterilizados; e deve ser acondicionada em envoltório duplo em embalagem hospitalar tipo CSR para esse processo, para manter a esterilidade dos instrumentos contidos na bandeja.
  - Remova os instrumentos, solte os componentes internos da bandeja e a tampa antes de limpar os instrumentos e/ou a bandeja.
  - Medtronic recomenda a incineração dos dispositivos que estiveram em contato direto com pacientes suspeitos ou confirmados com o diagnóstico de encefalopatia espongiforme transmissível (EET)/DCJ. A norma NHS Estates HTM 2010 Partes 4 e 6: Anexo 2, Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies [Itens contaminados com agentes de TSE e Diretrizes de controle de infecções da OMS para encefalopatias espongiformes transmissíveis] mencionam um ciclo de descontaminação para TSE usando autoclave a vapor a uma temperatura de 134-137 °C para um único ciclo de 18 minutos, ou repetição por um total de seis ciclos de 3 minutos.
  - Ao aplicar ciclos secos às bandejas para instrumental Medtronic e seus acessórios, os ciclos secos fora dos parâmetros pré-vácuo de cuidados de saúde padrão podem ser necessários. Os ciclos secos recomendados atualmente podem variar de 15 minutos padrão até um tempo estendido de 40 minutos. Isso é especialmente importante para as bandejas para instrumental a base de polímeros (plásticas). O usuário deve ter meios adequados para verificar o tempo de secagem, como por exemplo a inspeção visual.

Limpeza

**Nota:** Para minimizar a formação de manchas de água, recomenda-se a utilização de água deionizada para o enxague final. Se exequível, a água deionizada pode ser usada em todo o processo de limpeza.

Limpeza automática

Todas as bandejas devem ser completamente enxaguadas com água antes da colocação na lavadora automática.  
Remova os instrumentos e equipamentos das bandejas de instrumental antes de coloca-las nos cestos da lavadora. Oriente os dispositivos de acordo com as recomendações dos fabricantes do equipamento de limpeza/desinfecção.  
Use um detergente de pH neutro recomendado pelos fabricantes do equipamento de limpeza/desinfecção ou do detergente.

| Fase               | Tempo de recirculação | Temperatura da água   | Tipo de detergente                 |
|--------------------|-----------------------|-----------------------|------------------------------------|
| Pré-lavagem 1      | 3 minutos             | agua fria             | N/A                                |
| Lavagem enzimática | 5 minutos             | agua quente           | detergente enzimatico de pH neutro |
| Lavagem 1          | 5 minutos             | ponto de ajuste 66 °C | detergente de pH neutro            |
| Enxágue 1          | 3 minutos             | agua quente           | N/A                                |

## PT-BR

### Limpeza manual

Mergulhe em detergente enzimático e água morna (abaixo de 43 °C), suave (pH 7,0-8,5) por pelo menos 2 minutos. Use uma escova macia para instrumental para escovar as bandejas de instrumento enquanto submersas na solução limpadora, para remover a matéria orgânica. Enxágue com água, então limpe com ultrassom e detergente enzimático e água morna (abaixo de 43 °C), suave (pH 7,0-8,5) por pelo menos 10 minutos.

Enxágue completamente com água. Limpe desse modo até que não haja mais resíduos visíveis sobre a bandeja para instrumental.

Seque com ar comprimido ou com um pano seco que não solte fiapos. Examine as bandejas para instrumental procurando detectar manchas ou deterioração; retire-as de uso, caso indicado.

**Nota:** Quando utilizar um limpador ultrassônico ou uma máquina lavadora com spray, siga as recomendações do fabricante sobre o posicionamento das bandejas para instrumental.

Apos a limpeza, aplique uma fina camada de lubrificante sobre as bandejas para instrumental com peças móveis. Use um lubrificante indicado para instrumentos esterilizáveis como por exemplo a emulsão hidrossolúvel para instrumentos. Não use spray de silicone.

### Garantia limitada

manuals.medtronic.com

**EN** Symbols **FR** Symboles **IT** Simboli **DE** Symbole **ES** Simbolos **NL** Symbolen **DA** Symboler **FI** Symboler **SV** Symboler **PT-PT** Simbolos **EL** σύμβολα **PL** Symboler **CS** Symboly **HU** Jelölések **TR** Semboller **NO** Symboler **RU** Символы **SR** Simboli **HR** Simboli **PT-BR** Símbolos

### PREVACUUM ONLY

**EN** Use prevacuum cycles only for steam sterilization **FR** Utiliser les cycles de vide préalable uniquement pour la stérilisation à la vapeur **IT** Utilizzare i cicli di prevuoto solo per la sterilizzazione a vapore. **DE** Verwenden Sie Vorvakuumzyklen nur bei der Dampfsterilisation. **ES** Utilice ciclos de prevacio solamente para la esterilización con vapor. **NL** Uitsluitend voorvacuümcycli voor stoomsterilisatie gebruiken **DA** Brug kun cyklusser med forvakuum til dampsterilisation **FI** Käytä höyrysteriloinnissa vain esityhjiöjaksoja **SV** Använd forvakuumscykler endast för ångsterilisering **PT-PT** Utilizar ciclos de pré-vácuo apenas para a esterilização a vapor **EL** Χρησιμοποιείτε κυκλούς με προκατεργασία κενού μόνο για την αποστείρωση με ατμό **PL** W przypadku sterylizacji parowej nalezy stosować tylko cykle z próżnią wstępna. **CS** Prevakuové cykly používejte pouze za účelem sterilizace párou **HU** Gőzsterilizálás esetén csakis elővákuumos ciklusokat szabad használni. **TR** On vakum döngülerini sadece buharlı sterilizasyon için kullanın. **NO** Bruk forvakuumscykler kun til dampsterilisering. **RU** При паровой стерилизации применяйте только циклы с предварительным вакуумированием. **SR** Prevakuumske cikluse koristite samo za sterilizaciju parom **HR** Za sterilizaciju parom koristite samo prevakuumske cikluse **PT-BR** Use ciclos pré-vácuo apenas para esterilização a vapor

**EN** The information contained in this document is accurate at time of publication. Medtronic reserves the right to make changes to the product described in this manual. Refer to **manuals.medtronic.com** for the current version. **FR** Les informations contenues dans ce document sont exactes au moment de la publication. Medtronic se réserve le droit d'effectuer d'apporter des modifications au produit décrit dans ce document. Consultez le site **manuals.medtronic.com** pour obtenir la version actuelle. **IT** Le informazioni contenute nel presente documento sono accurate al momento della pubblicazione. Medtronic si riserva il diritto di apportare modifiche al prodotto descritto nel presente manuale. Consultare **manuals.medtronic.com** per la versione più aggiornata. **DE** Die in dieser Publikation enthaltenen Informationen waren zum Zeitpunkt der Veröffentlichung exakt. Medtronic behält sich das Recht vor, Änderungen an dem in dieser Gebrauchsanweisung beschriebenen Produkt vorzunehmen. Informationen zur aktuellen Version finden Sie unter **manuals.medtronic.com**. **ES** La información contenida en este documento era exacta en el momento de su publicación. Medtronic se reserva el derecho de realizar cambios en el producto descrito en este manual. Consulte la versión actual en **manuals.medtronic.com**. **NL** De informatie in dit document was nauwkeurig op het moment van publicatie. Medtronic behoudt zich het recht om wijzigingen door te voeren aan het product dat in deze handleiding vermeld wordt. Raadpleeg **manuals.medtronic.com** voor de huidige versie. **DA** Oplysningerne i dette dokument er korrekte på udgivelsestidspunktet. Medtronic forbeholder sig retten til at ændre produktet, der er beskrevet i denne brugerhåndbog. Se **manuals.medtronic.com** for vejledninger om den aktuelle version. **FI** Tämä asiakirjan sisältämät tiedot ovat paikkansapitäviä julkaisuhetkellä. Medtronic varaa oikeuden tehdä muutoksia tässä käyttöoppaassa kuvattuun tuotteeseen. Uusin versio on osoitteessa **manuals.medtronic.com**. **SV** Informationen i detta dokument är korrekt vid tidpunkten för publicering. Medtronic förbehåller sig rätten att förändra den produkt som beskrivs i den här handboken. Se **manuals.medtronic.com** för den aktuella versionen. **PT-PT** As informações contidas neste documento eram exactas à data da publicação. A Medtronic reserva-se o direito de fazer alterações no produto descrito neste manual. Consulte **manuals.medtronic.com** para obter a versão actual. **EL** Οι πληροφορίες που περιέχονται στο παρόν έγγραφο ήταν ακριβείς κατά την έκδοσή τους. Η Medtronic διατηρεί το δικαίωμα να πραγματοποιεί αλλαγές στο προϊόν που περιγράφεται στο παρόν εγχειρίδιο. Για την τρέχουσα έκδοση, ανατρέξτε στη διεύθυνση **manuals.medtronic.com**. **PL** Informacje przedstawione w niniejszym dokumencie są aktualne w momencie publikacji. Firma Medtronic zastrzega sobie prawo do wprowadzenia zmian w produkcie opisanym w niniejszej instrukcji. Aktualna instrukcja dostępna jest w witrynie **manuals.medtronic.com**. **CS** Informace obsažené v tomto dokumentu byly přesně v době vydání dokumentu. Společnost Medtronic si vyhrazuje právo provádet změny produktu popsaného v této příručce. Aktuální verzi příručky naleznete na webových stránkách na adrese **manuals.medtronic.com**. **HU** A jelen dokumentumban foglalt információk a dokumentum kiadásának idején pontosak voltak. A Medtronic fenntartja a jelen kézikönyvben leírt termékek módosításának jogát. Az aktuális verzió a **manuals.medtronic.com** webhelyen érhető el. **TR** Bu belgedeki bilgiler, yayımlanma zamanı için dogrudur. Medtronic, bu kılavuzda açıklanan ürün üzerinde değışiklik yapma hakkını saklı tutar. Geçerli versiyon için bkz. **manuals.medtronic.com**. **NO** Informasjonen i dette dokumentet var riktig på utgivelsestidspunktet. Medtronic forbeholder seg retten til å gjøre endringer i produktet som er beskrevet i denne bruksanvisningen. Du finner mer informasjon om gjeldende versjon på **manuals.medtronic.com**. **RU** Информация, содержащаяся в данном документе, является достоверной на момент его публикации. Корпорация Medtronic оставляет за собой право вносить изменения в изделие, описанное в руководстве. Актуальные редакции см. на **manuals.medtronic.com**. **SR** Informacije sadržane u ovom dokumentu su verodostojne u trenutku njegovog objavljivanja. Medtronic zadržava pravo da izvrši promene proizvoda opisanog u ovom priručniku. Aktuelnu verziju potražite na **manuals.medtronic.com**. **HR** Informacije sadržane u ovom dokumentu bile su točne u vrijeme objave dokumenta. Medtronic zadržava pravo na promjene proizvoda opisanog u ovom priručniku. Najnoviju verziju potražite na adresi **manuals.medtronic.com**. **PT-BR** As informações contidas neste documento são as mais precisas no momento da publicação. A Medtronic reserva-se o direito de fazer alterações no produto descrito neste manual. Consulte **manuals.medtronic.com** para obter a versão mais atual.



M726750B683 B

2015-08

© 2015 Medtronic Xomed, Inc.



# Medtronic

[medtronic.com](http://medtronic.com)

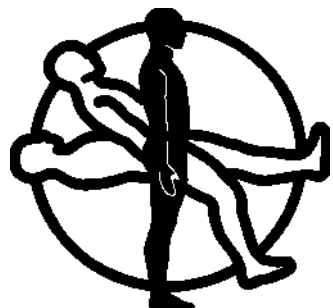
[manuals.medtronic.com](http://manuals.medtronic.com)



Medtronic Xomed, Inc.  
6743 Southpoint Drive North  
Jacksonville, FL 32216-0980 USA  
800 874 5797 / 904 296 9600



Medtronic B.V.  
Earl Bakkenstraat 10  
6422 PJ Heerlen  
The Netherlands  
Phone: 011 31 45 566 8000  
Fax: 011 31 45 566 8668



# Medtronic

## Accessories

**FR** Accessoires **IT** Accessori **DE** Zubehör **ES** Accesorios **NL** Toebehoren **DA** Tilbehør **FI** Lisävarusteet **SV** Tillbehör **PT-PT** Acessórios **EL** Παρελκόμενα **PL** Tilbehør **CS** Akcesoria **HU** Príslušenství **TR** Aksesuarlar **NO** Tartožékok **RU** Принадлежности **SR** Dodatna oprema **HR** Dodatni pribor **PT-BR** Acessórios

**This device is a system component / accessory to the following systems. Detailed instructions for use are in the User's Guide.**

**FR** Le présent appareil est une composante/un accessoire des systèmes suivants. Les instructions détaillées pour l'utilisation figurent dans le Guide de l'utilisateur. **IT** Questo dispositivo è un componente/accessorio dei seguenti sistemi. Istruzioni dettagliate per l'uso, sono reperibili nel Manuale dell'utente. **DE** Dieses Gerät ist eine Systemkomponente/ein Zubehörteil für folgende Systeme. Detaillierte Hinweise zum Gebrauch sind in der Gebrauchsanweisung enthalten. **ES** Este dispositivo es un componente/accesorio de los sistemas siguientes. En la guía de usuario encontrará completas instrucciones. **NL** Dit instrument is een systeemonderdeel/hulpmiddel voor de volgende systemen. Uitgebreide gebruiksaanwijzingen staan in de gebruikershandleiding. **DA** Denne enhed er komponent/tilbehør til følgende systemer. Detaljerede brugsanvisninger findes i brugervejledningen. **FI** Tämä laite on järjestelmän osa/lisävaruste, joka liittyy seuraaviin järjestelmiin. Täydelliset ohjeet ovat Käyttäjän oppaassa. **SV** Denna enhet är en systemkomponent eller ett tillbehör till följande system. Detaljerade instruktioner för användning återfinns i bruksanvisningen. **PT-PT** Este equipamento é um componente de sistema/acessório dos sistemas seguintes. O Guia do Utilizador contém instruções detalhadas sobre a sua utilização. **EL** Αυτή η συσκευή αποτελεί εξάρτημα/αξεσουάρ των παρακάτω συστημάτων. Λεπτομερείς οδηγίες χρήσης βρίσκονται στον Οδηγό Χρήστη. **PL** To urządzenie jest podzespołem lub elementem wyposażenia następujących systemów. Szczegółowe instrukcje dotyczące użytkowania zamieszczono w Instrukcji użytkownika. **CS** Toto zařízení je systémová komponenta nebo příslušenství k následujícím systémům. Podrobné pokyny k použití jsou uvedeny v uživatelské příručce. **HU** Ez az eszköz a következő berendezések alkatrésze/tartozéka. A használatához részletes utasítások találhatók a Kezelési Útmutatóban. **TR** Bu cihaz, aşağıdaki sistemler için bir sistem bileşeni / aksesuarıdır. Kullanımla ilgili ayrıntılı talimatlar Kullanıcı Kılavuzunda yer almaktadır. **NO** Dette utstyret er en del eller tilbehør til følgende systemer. Du finner mer informasjon om bruk i bruksanvisningen. **RU** Данное устройство является компонентом/принадлежностью перечисленных ниже систем. Подробные инструкции по применению приводятся в Руководстве пользователя. **SR** Ovaj uređaj predstavlja komponentu/dodatnu opremu sistema navedenih u nastavku. Detaljna uputstva za upotrebu navedena su u korisničkom vodiču. **HR** Ovaj uređaj je komponenta sustava / dodatni pribor za uporabu sa sljedećim sustavima: Detaljne upute za uporabu nalaze se u Priručniku za korisnike. **PT-BR** Este dispositivo é um componente/acessório para os sistemas a seguir. Instruções detalhadas de uso se encontram no Guia do usuário.



|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>System Name</b><br><b>FR</b> Nom du système <b>IT</b> Nome del sistema <b>DE</b> Systembezeichnung <b>ES</b> Nombre de sistema <b>NL</b> Systeemnaam <b>DA</b> Systemnavn <b>FI</b> Järjestelmän nimi <b>SV</b> Systembeteckning <b>PT-PT</b> Nome do Sistema <b>EL</b> Όνομα συστήματος <b>PL</b> Nazwa systemu <b>CS</b> Název systému <b>HU</b> Berendezés neve <b>TR</b> Sistem Adı <b>NO</b> Navn <b>RU</b> Название системы <b>SR</b> Naziv sistema <b>HR</b> Naziv sustava <b>PT-BR</b> Nome do sistema | <b>User's Guide</b><br><b>FR</b> Manuel d'utilisation <b>IT</b> Manuale dell'utente <b>DE</b> Gebrauchsanweisung <b>ES</b> Guía del usuario <b>NL</b> Gebruiksaanwijzing <b>DA</b> Brugerhåndbog <b>FI</b> Käyttöopas <b>SV</b> Bruksanvisning <b>PT-PT</b> Guia do Usuário <b>EL</b> Οδηγός Χρήστη <b>PL</b> Przewodnik użytkownika <b>CS</b> Felhasználói kézikönyv <b>HU</b> Návod k obsluze <b>TR</b> Kullanıcı Kılavuzu <b>NO</b> Bruksanvisning <b>RU</b> Руководство пользователя <b>SR</b> Korisnički vodič <b>HR</b> Priručnik za korisnike <b>PT-BR</b> Guia do usuário |
| <b>Integrated Power Console (IPC®)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 1898851 (EN)<br>1898851A (EN, FR, ES, PT-PT, EL, PT-BR)<br>1898851B (EN, FR, IT, DE, NL)<br>1898851C (EN, DA, FI, SV, NO)<br>1898851D (EN, PL, CS, HU, TR)<br>1898851E / 68M0005 (EN, RU, SR, HR)<br>M726750B246 (EN)<br>175027EN (EN)<br>175027ML53 (EN, FR, ES, PT-PT, EL, PT-BR)<br>175027ML36 (EN, FR, IT, DE, NL)<br>175027ML51 (EN, DA, FI, SV, NO)<br>175027ML4V (EN, PL, CS, HU, TR)<br>175027MLLH / 68M0004 (EN, RU, SR, HR)                                                                                                                                             |

Medtronic Powered Surgical Solutions  
4620 North Beach Street  
Fort Worth, TX 76137 U.S.A.  
817 788 6400  
800 468 9710  
medtronic.com  
manuals.medtronic.com

Medtronic Xomed, Inc.  
6743 Southpoint Drive North  
Jacksonville, FL 32216-0980 U.S.A.  
904 296 9600  
800 874 5797  
medtronic.com  
manuals.medtronic.com



68E4055 E 2016-02



## Waste Electrical and Electronic Equipment: Compliance information

**FR** Déchets d'équipements électriques et électroniques(DEEE): Informations sur la conformité

**IT** Smaltimento di apparecchiature elettriche ed elettroniche: informazioni sulla conformità

**DE** Richtlinie zur Entsorgung von Elektro- und Elektronik-Altgeräten: Informationen zur Einhaltung

**ES** Residuos de Equipos Eléctricos y Electrónicos (RAEE): Información de conformidad

**NL** Afgedankte elektrische en elektronische apparatuur (AEEA): Informatie over conformiteit

**DA** Kasseret elektrisk og elektronisk udstyr: Overensstemmelsesinformation

**FI** Sähkö- ja elektroniikkalajäte: tietoja määräysten noudattamisesta

**SV** Avfall som utgörs av eller innehåller elektriska och elektroniska produkter (WEEE): Information om överensstämmelse

**PT-PT** Resíduos de equipamentos eléctricos e electrónicos: Informação sobre conformidade

**EL** Απορρίματα ηλεκτρικών και ηλεκτρονικών συσκευών: Πληροφορίες συμμόρφωσης

**PL** Zużyty sprzęt elektrotechniczny i elektroniczny: informacje o zgodności

**CS** Elektrický a elektronický odpad: informace o kompatibilitě

**HU** Elektromos és elektronikai hulladék: Információk a kezelési szabályokról

**TR** Atık Elektrikli ve Elektronik Ekipman: Uyum bilgisi

**NO** Avfall fra elektrisk og elektronisk utstyr: Samsvarsinformasjon

**RU** Отходы электрического и электронного оборудования: сведения о соответствии

**SR** Otpadna električna i elektronska oprema: Informacije o usaglašenosti

**HR** Otpadna električna i elektronička oprema: informacije o sukladnosti

**PT-BR** Resíduos de equipamentos elétricos e eletrônicos: Informações de conformidade



### Explanation of symbol on the device

**FR** Explication des symboles sur l'appareil **IT** Spiegazione dei simboli presenti sul dispositivo

**DE** Erläuterung der Symbole auf dem Gerät **ES** Explicación de los símbolos en el dispositivo

**NL** Verklaring van de symbolen op het apparaat **DA** Forklaring af symboler på enheden **FI**

Laitteen merkintöjen selitykset **SV** Förklaring av symboler på enheten **PT-PT** Explicação dos

símbolos no dispositivo **EL** Επεξήγηση των συμβόλων στη συσκευή **PL** objaśnienie symboli

znajdujących się na urządzeniu **CS** Vysvětlení symbolů na přístroji **HU** Jelmagyarázat a

készülékhez **TR** Cihaz üzerindeki sembolün açıklaması **NO** Forklaring av symboler på utstyret

**RU** Расшифровка символа на устройстве **SR** objašnjenje simbola na uređaju **HR** objašnjenje

simbola na uređaju **PT-BR** Explicação do símbolo no dispositivo



**Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See [recycling.medtronic.com](https://recycling.medtronic.com) for instructions on proper disposal of this product.**

**FR** Ne pas jeter ce produit dans une décharge municipale avec des déchets non triés. Éliminer ce produit conformément à la réglementation locale en vigueur. Consulter le site [Recycling.Medtronic.Com](https://recycling.Medtronic.Com) pour plus d'informations sur la mise au rebut appropriée de ce produit.

**IT** Non smaltire questo prodotto insieme agli altri rifiuti solidi urbani. Smaltirlo secondo le normative locali. Per le istruzioni relative al corretto smaltimento di questo prodotto, visitare [Recycling.Medtronic.Com](https://Recycling.Medtronic.Com).

**DE** Dieses Produkt darf nicht mit dem Restmüll/Hausmüll entsorgt werden. Bei der Entsorgung dieses Produkts sind die einschlägigen Bestimmungen zu beachten. Anweisungen (in englischer Sprache) zur ordnungsgemäßen Entsorgung dieses Produkts finden Sie unter [recycling.medtronic.com](https://recycling.medtronic.com).

**ES** No desechar este producto como residuo urbano sin clasificar. Desechar conforme a la normativa local. Consultar las instrucciones sobre la eliminación adecuada de este producto en [recycling.Medtronic.com](https://recycling.Medtronic.com).

**NL** Dit product niet met het gewone huisvuil weggooien. Verwerk het product volgens de plaatselijk geldende voorschriften. Zie [Recycling.Medtronic.Com](https://Recycling.Medtronic.Com) voor afvalverwerkingsinstructies voor dit product.

**DA** Dette produkt må ikke bortskaffes som almindeligt husholdningsaffald. Dette produkt skal bortskaffes i overensstemmelse med lokale bestemmelser. Se [Recycling.Medtronic.Com](https://Recycling.Medtronic.Com) for vejledning vedrørende korrekt bortskaffelse af dette produkt.

**FI** Älä hävitä laitetta lajittelemattoman yhdyskuntajätteen mukana. Hävitä laite paikallisten määräysten mukaisesti. Katso osoitteesta [Recycling.Medtronic.Com](https://Recycling.Medtronic.Com), miten laite hävitetään oikein.

**SV** Kassera inte denna produkt bland osorterade hushållssopor. Kassera produkten enligt lokala bestämmelser. På [recycling.Medtronic.com](https://recycling.Medtronic.com) finns anvisningar om hur man på lämpligt sätt kasserar denna produkt.

**PT-PT** Não elimine este produto através da rede municipal de tratamento de resíduos indiferenciados. Elimine este produto de acordo com a regulamentação local. Consulte [recycling.medtronic.com](https://recycling.medtronic.com) para obter instruções sobre a eliminação adequada deste produto.

**EL** Μην απορρίπτετε το παρόν προϊόν στο δημοτικό σύστημα μη διαχωρισμένων αποβλήτων. Απορρίπτετε το παρόν προϊόν σύμφωνα με τους τοπικούς κανονισμούς. Για οδηγίες σχετικά με τη σωστή απόρριψη του παρόντος προϊόντος, ανατρέξτε στη διεύθυνση [Recycling.Medtronic.Com](https://Recycling.Medtronic.Com).

**PL** Nie należy wyrzucać tego produktu razem z niesortowanymi odpadami komunalnymi. Produkt należy utylizować zgodnie z lokalnymi przepisami. Instrukcje dotyczące prawidłowej utylizacji tego produktu można znaleźć pod adresem [recycling.medtronic.com](https://recycling.medtronic.com).

**CS** Tento výrobek neodstraňujte v netříděném komunálním odpadu. Výrobek zlikvidujte v souladu s místními předpisy. Návod ke správné likvidaci tohoto výrobku viz [Recycling.Medtronic.Com](https://Recycling.Medtronic.Com).

**HU** Ezt a terméket tilos szelektálatlan kommunális hulladékként ártalmatlanítani. A termék ártalmatlanítását a helyi előírásoknak megfelelően kell végezni. A termék megfelelő ártalmatlanítására vonatkozó utasítások a [recycling.medtronic.com](https://recycling.medtronic.com) webhelyen található.

**TR** Bu Ürünü Sınıflandırılmamış Belediye Atık Sistemine Atmayın. Bu Ürünü Yerel Düzenlemelere Göre Atın. Bu Ürünün Doğru Biçimde Atılmasıyla İlgili Talimatlar için [Recycling.Medtronic.Com](https://Recycling.Medtronic.Com) adresine bakın.

**NO** Dette produktet skal ikke kastes i usortert kommunalt avfall. Produktet skal kastes i samsvar med lokale forskrifter. På [recycling.medtronic.com](https://recycling.medtronic.com) finner du instruksjoner om riktig deponering av dette produktet.

**RU** Не выбрасывайте это устройство вместе с неотсортированным бытовым мусором. Утилизируйте устройство в соответствии с действующим законодательством. Для получения инструкций по правильной утилизации этого продукта посетите веб-сайт [Recycling.Medtronic.Com](https://Recycling.Medtronic.Com).

**SR** Ovaj proizvod nemojte odlagati u nerazvrstani komunalni otpad. Ovaj proizvod odložite na otpad u skladu sa lokalnim propisima. Uputstva za propisno odlaganje ovog proizvoda na otpad potražite na Internet adresi [Recycling.Medtronic.Com](https://Recycling.Medtronic.Com).

**HR** Ovaj proizvod nemojte odlagati u mjesni otpad koji se ne razvrstava. Proizvod kao otpad odložite u skladu s lokalnim propisima. Upute o ispravnom načinu odlaganja ovog proizvoda potražite na adresi [Recycling.Medtronic.Com](https://Recycling.Medtronic.Com).

**PT-BR** Não descarte este produto no lixo comum municipal sem coleta seletiva. Descarte este produto de acordo com as normas locais. Ver **[Recycling.Medtronic.com](https://Recycling.Medtronic.com)** para obter instruções sobre o descarte correto deste produto.











[На бланке компании «Медтроник Ксомед, Инк.»]

«Медтроник» (Medtronic)  
«Медтроник Ксомед, Инк.» (Medtronic Xomed Inc.)  
6743 Саутпойнт Драйв Норт  
Джексонвилл, Флорида 32216 США  
(6743 Southpoint Drive North  
Jacksonville, Florida, 32216 USA)  
www.medtronic.com  
тел. 800 874 5797

Хранитель документов:

/подпись/

Александра Оливер

Помощник специалиста по нормативно-правовому регулированию  
компании «Медтроник Ксомед, Инк.»

Дата: 16 августа 2017 г.

Инструкции по применению «Система интегрированной силовой консоли (IPC)» и «Лоток для инструментов»

Микродебридер StraightShot M5 с принадлежностями

УДОСТОВЕРЕНИЕ

ШТАТ ФЛОРИДА  
ОКРУГ ДУВАЛ

Сегодня, 16 августа 2017 г., я удостоверяю, что прилагаемые или предшествующие документы являются верными, точными, полными и неизменными фотокопиями, сделанными мною с документов «Инструкции по применению “Система интегрированной силовой консоли (IPC)” и “Лоток для инструментов”», выпущенных компанией «Медтроник Ксомед, Инк.» и представленных мне хранителем документов, Александрой Оливер, а также, что, исходя из имеющейся у меня информации, оригиналы документов, с которых сделаны фотокопии, не носят публичного характера, не подлежат регистрации в публичных реестрах и не относятся к документам, копии которых могут быть заверены определенными официальными органами, а не нотариусом.

Нотариус:

/подпись/

Официальная подпись нотариуса

Подписано под присягой в моем присутствии сегодня, 16 августа 2017 г.

[Штамп:

«Медтроник Ксомед, Инк.»  
6743 Саутпойнт Драйв Норт  
Джексонвилл, Флорида 32216-0980 США  
www.medtronic.com  
Тел.: 817-788-6400]

[Штамп:

Мишель Г Хьюз

Нотариус – штат Флорида

Моя лицензия действительна до 09 сентября 2017 г.

Лицензия № FF 41831

Профессиональная ответственность застрахована Национальной ассоциацией нотариусов]

2017 г.



[Далее следует текст документа «Руководство пользователя. Система объединенного пульта управления электроприводами (IPC)», представленного на английском и русском языках.]

CE 0123  
68M0005 L  
июнь 2016 г.

© 2016 «Медтроник, Инк.»

«Медтроник»  
medtronic.com  
manuals.medtronic.com

«Медтроник Ксомед, Инк.»  
6743 Саутпойнт Драйв Норт  
Джексонвилл, Флорида, С.А.Д. 32216  
800 874 5797

«Медтроник Б.В.»  
Эрл Баккенстраат 10  
6422 PJ Херлен  
Нидерланды  
+ 31 45 566 8000



[Далее следует текст документа «Информация о продукте и инструкция по его эксплуатации. Лоток для инструментов», представленного на английском, французском, итальянском, немецком, испанском, нидерландском, датском, финском, шведском, португальском (Португалия), греческом, польском, чешском, венгерском, турецком, норвежском, русском, сербском, хорватском и португальском (Бразилия) языках.]

СЕ  
M726750B683 В  
август 2015 г.

© 2015 «Медтроник Ксомед, Инк.»

«Медтроник»  
medtronic.com  
manuals.medtronic.com

«Медтроник Ксомед, Инк.»  
6743 Саутпойнт Драйв Норт  
Джексонвилл, Флорида 32216-0980 США  
800 874 5797 / 904 296 9600

«Медтроник Б.В.»  
Эрл Баккенстраат 10  
6422 РЈ Херлен  
Нидерланды  
Тел.: 011 31 45 566 8000  
Факс: 011 31 45 566 8668





[Далее следует текст документа «Принадлежности», представленного на английском, французском, итальянском, немецком, испанском, нидерландском, датском, финском, шведском, португальском (Португалия), греческом, польском, чешском, венгерском, турецком, норвежском, русском, сербском, хорватском и португальском (Бразилия) языках.]

CE 0123

«Медтроник Пауэд Серджикал Солюшнз»

4620 Норт Бич Стрит

Форт-Уорт, Техас 76137 США

817 788 6400

800 468 9710

medtronic.com

manuals.medtronic.com

«Медтроник Ксомед, Инк.»

6743 Саутпойнт Драйв Норт

Джексонвилл, Флорида 32216-0980 США

904 296 9600

800 874 5797

medtronic.com

manuals.medtronic.com



[Далее следует текст документа «Отходы электрического и электронного оборудования: сведения о соответствии», представленного на английском, французском, итальянском, немецком, испанском, нидерландском, датском, финском, шведском, португальском (Португалия), греческом, польском, чешском, венгерском, турецком, норвежском, русском, сербском, хорватском и португальском (Бразилия) языках.]

Перевод данного текста сделан мной, переводчиком Клепневым Виктором Игоревичем

**ПОДПИСЬ**

Российская Федерация

Город Москва

Двадцать девятого августа две тысячи семнадцатого года

Я, Акимов Глеб Борисович, нотариус города Москвы, свидетельствую подлинность подписи переводчика Клепнева Виктора Игоревича.

Подпись сделана в моем присутствии.

Личность подписавшего документ установлена.

Зарегистрировано в реестре: № 9-38729

Взыскано государственной пошлины (по тарифу): 100 руб.

Уплачено за оказание услуг правового и технического характера: ---- руб.

**ПОДПИСЬ**

Гербовая печать  
нотариуса г.Москвы  
Акимов Г.Б

Всего прошнуровано, пронумеровано  
и скреплено печатью 125 лист(а)(ов)

Нотариус

**ПОДПИСЬ**

Российская Федерация  
Город Москва

Двадцать девятого августа две тысячи семнадцатого года.

Я, Акимов Глеб Борисович, нотариус города Москвы, свидетельствую  
верность копии с представленного мне документа.

Зарегистрировано в реестре: № 9-38730

Взыскано государственной пошлины (по тарифу): 2430 руб. 00 коп.

Уплачено за оказание услуг правового и технического характера: —  
руб. 00 коп.

Г.Б. Акимов



Всего прошито, пронумеровано, скреплено  
печатью 124 лист(а) (о в)

Нотариус

Г.Б. Акимов





# Medtronic

## Medtronic

Medtronic Xomed, Inc.  
6743 Southpoint Drive North  
Jacksonville, Florida 32216  
USA  
www.medtronic.ru

tel 800 874 5797

Medtronic Xomed, Inc.  
6743 South point Drive North  
Jacksonville FL 32216-0980 USA  
www.medtronic.com  
Tel: 817-788-6400

Custodian:

*Alexandra Oliver*

Alexandra Oliver  
Assoc. Regulatory Affairs Specialist  
Medtronic Xomed Inc.

08/11/2017

Date

### Appendix to IFUs

StraightShot M5 Microdebrider with accessories

### ATTESTATION

STATE OF FLORIDA  
DUVAL COUNTY

On this 16th day of August, 2017, I attest that the preceding or attached documents are true, exact, complete, and unaltered photocopies made by me of the following, Appendix to IFUs, issued by Medtronic Xomed, Inc., presented to me by the document's custodian, Alexandra Oliver, and, to the best of my knowledge, that the photocopied document is neither a public record nor a publicly recordable document, certified copies of which are available from an official source other than a notary public.

Notary:

*Michelle G. Hughes*  
Official Notary Signature

Subscribed and sworn to before me  
This 16th day of August, 2017.





# Medtronic

**Medtronic**  
Medtronic Xomed, Inc.  
6743 Southpoint Drive North  
Jacksonville, Florida 32216  
USA  
[www.medtronic.ru](http://www.medtronic.ru)

## Appendix to the Instruction for use

|                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|--------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. Name of the medical device                                                                    | <b>StraightShot M5 Microdebrider with accessories</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 2.1 With regards to the manufacturer of the medical device                                       | <p><b>Developer:</b><br/>Medtronic Xomed, Inc.,<br/>6743 Southpoint Drive North, Jacksonville, FL, 32216-0980, USA<br/>Тел. / Tel: 817-788-6400, Факс / Fax: 817-788 6401<br/><a href="http://www.medtronic.com">www.medtronic.com</a></p> <p><b>Manufacturer:</b><br/>Medtronic Xomed, Inc.,<br/>6743 Southpoint Drive North, Jacksonville, FL, 32216-0980, USA<br/>Тел. / Tel: 817-788-6400, Факс / Fax: 817-788 6401<br/><a href="http://www.medtronic.com">www.medtronic.com</a></p> <p><b>Addresses of Manufacturing Sites for medical device:</b><br/>Medtronic Xomed, Inc., 6743 Southpoint Drive North, Jacksonville, FL, 32216-0980, USA</p> |
| 2.2 With respect to authorized representative of the manufacturer of the medical device          | <p><b>Authorized Representative of Manufacturer:</b><br/><b>Medtronic, LLC,</b><br/>123317, Moscow, Presnenskaya Naberezhnaya., 10<br/>Tel.: (495) 580-73-77, Fax: (495) 580-73-78,<br/><a href="http://www.medtronic.ru">www.medtronic.ru</a></p> <p><b>Holder of Registration Certificate in Russia:</b><br/><b>Medtronic, LLC,</b><br/>123317, Moscow, Presnenskaya Naberezhnaya., 10<br/>Tel.: (495) 580-73-77, Fax: (495) 580-73-78,<br/><a href="http://www.medtronic.ru">www.medtronic.ru</a></p>                                                                                                                                              |
| 3. Indication of the medical device with potential customer (for example, a health professional) | <p>It is used for endonasal endoscopic operations on the nasal sinuses and the base of the skull</p> <p>The medical device is intended for use in medical-preventive and medical institutions by specially trained, qualified specialists.</p>                                                                                                                                                                                                                                                                                                                                                                                                        |
| 4. Functional characteristics and indication of the medical device                               | <p>The electric systems are centered around the Integrated Power Console (IPC), which provides power to the StraightShot M5 Microdebrider.</p> <p>The principle of work is based on attachment instruments to connection port on the connector panel of IPC Console. This is the active medical device – it works by electric current.</p> <p>The system consists of a power control console, footpedal, connection cables and assorted handpieces to drive various burs, blades, drills, rasps, cannulas and saws. It</p>                                                                                                                            |

Available upon request

|                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                             | <p>includes integrated irrigation pumps for irrigation of blades, burs and for motor coolant.</p> <p>The StraightShot M5 Microdebrider is a handpiece with the ability to perform a 360 ° circular cut that can be used for endonasal endoscopic operations on the nasal sinuses and the base of the skull. StraightShot M5 is the first and only microdebrider capable of 30,000 rpm. The cable cannot be removed from the microdebrider.</p> <p>The StraightShot M5 Microdebrider is designed to work only with Medtronic burs and blades.</p> <p><b>Indications:</b></p> <p>It is used for endonasal endoscopic operations on the nasal sinuses and the base of the skull</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <p>5. Risks of using the medical device, contraindications, expected adverse effects associated with the use of the medical device for intended purpose</p> | <p><b>Contraindications:</b></p> <p>There are no known contraindications for using Microdebrider StraightShot M5.</p> <p><b>Adverse events (Potential complications)</b></p> <p>There are no known potential complications if the medical device is used in accordance with User's Guide.</p> <p><b>Risks Analysis</b></p> <p>The current search of literature indicates that contemporary rates of adverse events after any type of surgery using powered systems are low. The literature review did not identify any new risks that are not addressed in the products' risk assessment.</p> <p>The clinical benefits outweigh the risks of using drill systems and associated attachments for the identified uses. The literature review and low complaint and adverse event rates support the use of Medtronic's powered systems and associated attachments and tools as viable, effective surgical options for the treatment of a wide range of medical conditions.</p> <p><b>Potential hazards and risk management:</b></p> <p><b>Acoustic Damage</b></p> <p>The authors compared the results of their study with the Belgian regulations for occupational noise exposure, which state that noise exposure should not exceed 87 dBA and a peak level of 140 dBC. For noise exposure higher than 85 dBA, hearing protection is required. They concluded that the sound levels fell below those mandated in international occupational noise level regulations, but due to the discomfort experienced by care providers, negative effects may still occur.</p> <p><b>Thermal Damage</b></p> <p>The studies by Lyson et al and Yamamoto et al both found that the high-speed drills generate enough heat to potentially result in serious adverse events. They determined that this risk can be mitigated by drilling intermittently and by frequently flushing the</p> |

Available upon request

operative area with saline. In their study, Takenaka et al determined that lowering the temperature of the saline used to cool and clear the operative area results in significantly lower rates of certain postoperative complications. These studies demonstrate that while there are serious risks involved with the use of a high-speed drill, effective measures can be taken to reduce those risks.

***Collateral Tissue Damage***

Patel and Govindaraj review the literature about and present recommendations for preventing and managing complications of ethmoid sinus surgery.<sup>35</sup> One such complication is damage to the lamina papyracea, especially following powered instrumentation use (such as a surgical drill). The authors suggest that powered instruments should not be angled directly at the lamina and that “traditional instruments” may be a better option for skeletonizing the medial wall of the orbit.

***Infection***

In their prospective review, Minamide et al documented the clinical outcomes of microendoscopic laminotomy in patients with lumbar spinal stenosis (LSS).<sup>48</sup> There was 1 reported case (0.3%) of infection in the study. The authors did not consider this complication to be significant.

***Microdebrider-Assisted Surgery Risks***

The authors noted the seriousness of the reported complications and speculated that such complications may be underreported, but they recognized the possibility of bias in their study. Furthermore, they recognized that the study was not a true case series, but rather should be considered to be expert opinion. A prospectively-designed study is necessary to accurately determine incidence of complications associated with the use of a laryngologic microdebrider. In the meantime, in order to minimize risk, great care should be taken in selecting the appropriate type of microdebrider for the patient and the surgery and in using the microdebrider appropriately during surgery

***Bleeding***

Excessive bleeding is a common surgical complication, and as such it frequently occurs throughout the course of procedures that employ powered systems. None of the researchers that reported incidents of hemorrhage identified an association between significantly elevated risk of bleeding and the use of powered systems in surgery. Furthermore, no specific brand of powered system was found to be associated with an elevated risk of hemorrhage.

***Risk Assessment Conclusion***

The current search of literature indicates that contemporary rates of adverse events after any type of surgery using powered systems are low. The literature review did not identify any new risks that are not addressed in the products’ risk assessment.

Available upon request



**6. Technical characteristics of the medical device**

**MD Options, Versions**

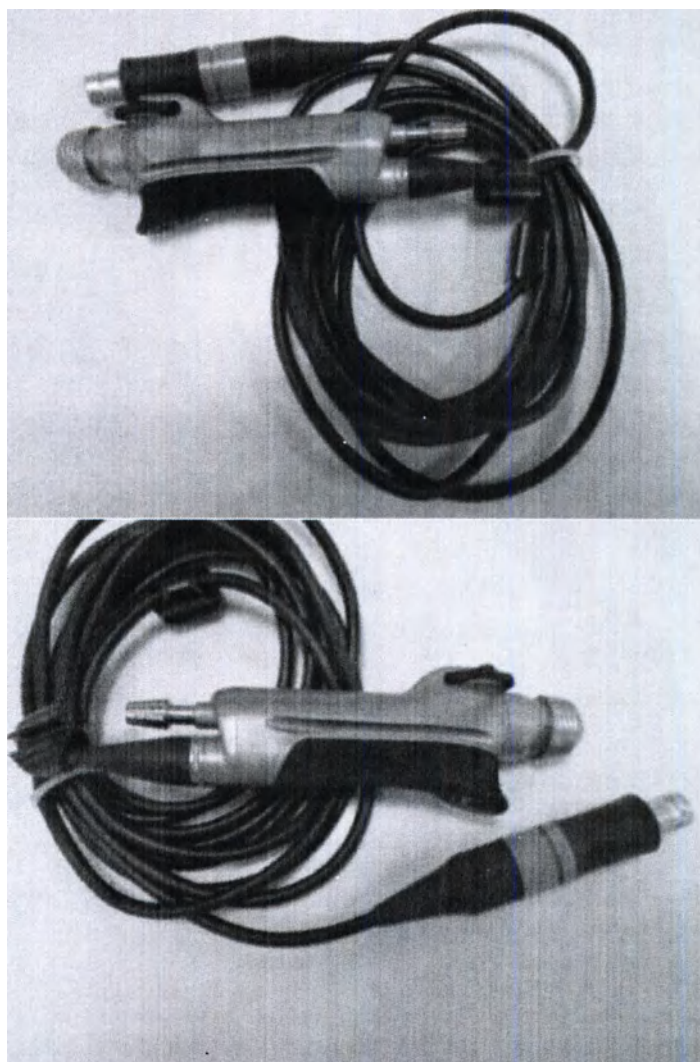
StraightShot M5 Microdebrider with accessories:

**I. StraightShot M5 Microdebrider**

**II. Accessories:**

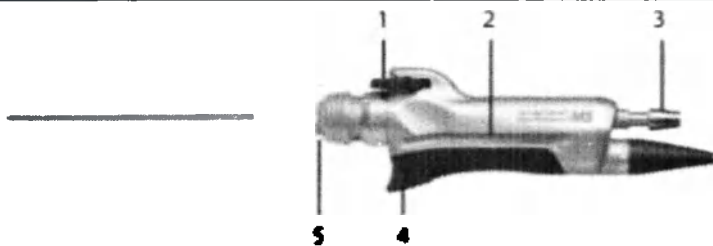
- Instrument Tray StraightShot M5

**Photo of the medical devices: StraightShot M5 Microdebrider**



Available upon request

Appendix to the Instruction for use  
Name of Medical Device



- 1 – Finger Wheel
- 2 – Irrigation tubing groove
- 3 – Suction barb
- 4 – Finger wheel lock
- 5 – Locking collar

**STRAIGHTSHOT M5 MICRODEBRIDER TECHNICAL PARAMETERS:**

|                             |                                                                                                                                                                     |
|-----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Size                        | 125mm in L x 20mm in H-W                                                                                                                                            |
| Weight                      | 203 g                                                                                                                                                               |
| Speed                       | 50-7500 rpm oscillate<br>50-30000 rpm forward                                                                                                                       |
| Duty Cycle for Applied Part | The StraightShot M5 handpiece under full load is rated for intermittent operation per the following:<br>Maximum On Time: 60 seconds<br>Minimum Off Time: 30 seconds |
| Continuous Stall Torque     | 22 mNm                                                                                                                                                              |
| Peak Torque                 | 160.3 mNm                                                                                                                                                           |
| Max Axial Force             | 11.1 N                                                                                                                                                              |
| Max Radial Force            | 113 N                                                                                                                                                               |
| Electrical                  | Rated Current 6 A (max)<br>Rated Voltage 48 Vdc<br>Maximum watt: 288 W                                                                                              |
| Noise level (db)            | 80 db MAX                                                                                                                                                           |

**Duty Cycle**

Duty Cycle

≤ 20°C Ambient (one cut period = 20 seconds on / 20 seconds off)

Oscillating: ≤ 4 cut periods3

> 20°C Ambient (one cut period = 20 seconds on / 40 seconds off)

Oscillating: ≤ 3 cut periods6

Time for cool down after maximum number of cut periods listed above: 25 minutes

**Surface Finish:**

Average roughness must be a Maximum of 32 micro-inches

7. Description of accessories, medical

**StraightShot M5 Instrument Tray**

Available upon request

devices or non-medical devices that are intended for use in combination with the medical device (if applicable)

**Indications for use**

Instrument trays are intended to provide a general configuration to organize, store, protect and transport medical devices for use in surgical procedures.

**Precautions**

If you choose to use the instrument tray as part of a sterilization system for reprocessing devices:

- Ensure that you validate the tray within your internal processes and systems.
- Follow all instructions for sterilization of the device(s) you are reprocessing.
- Gravity Steam sterilization must not be used for instrument trays as cycle times would be exceedingly long.
- STERRAD processing must not be used for Medtronic Xomed instrument trays.
- Instrument Trays are not intended to provide a sterile barrier to prevent recontamination of sterilized instruments; and must be double wrapped in hospital CSR wrap for this process to maintain the sterility of the instruments contained inside the tray.
- Remove instruments, loose internal tray components and lid prior to cleaning instruments and/or tray.
- Medtronic recommends incineration of devices that have directly contacted patients suspected or confirmed with Transmissible Spongiform Encephalopathy (TSE)/ CJD diagnosis. NHS Estates HTM 2010 Parts 4 & 6: Appendix 2, Items contaminated with TSE Agents and WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies refers to a TSE decontamination cycle using a steam autoclave at a temperature of 134-137°C for a single cycle of 18 minutes or repeated for a total of six 3-minute cycles.
- When applying dry times to Medtronic instrument trays and their accessories, dry times outside the standard healthcare prevacuum parameters may be required. The current recommended dry times may range from a standard 15 minutes to an extended time of 40 minutes. This is especially important for polymer-based (plastic) instrument trays. The user should have adequate means to verify drying time, such as visual inspection.

**Cleaning Note:**

To minimize water spotting, using deionized water for the final rinse is recommended. If practical, deionized water may be used for the entire cleaning process.

**Automated cleaning**

All trays shall be thoroughly rinsed with water prior to placement in the automatic washer. Remove instruments and equipment from any instrument trays before placing into washer baskets. Orient devices following recommendations of washer/disinfector manufacturers. Use neutral pH detergent recommended by washer/disinfector or detergent manufacturers.

| Phase       | Recirculation Time | Water Temperature | Detergent Type |
|-------------|--------------------|-------------------|----------------|
| Pre-wash 1  | 3 minutes          | cold water        | N/A            |
| Enzyme Wash | 5 minutes          | hot water         | neutral pH     |

Available upon request

Appendix to the Instruction for use  
Name of Medical Device

|         |           |                   |                            |
|---------|-----------|-------------------|----------------------------|
|         |           |                   | enzymatic<br>detergent     |
| Wash 1  | 5 minutes | 66°C set<br>point | neutral<br>pH<br>detergent |
| Rinse 1 | 3 minutes | hot water         | N/A                        |

**Manual cleaning**

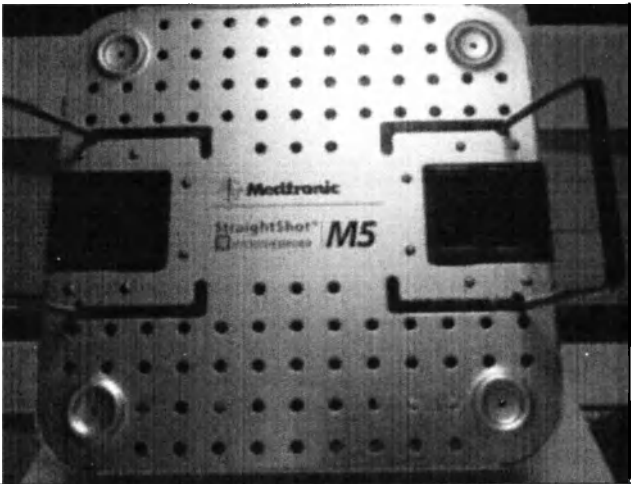
Soak in lukewarm (less than 43°C), mild (pH 7.0 - 8.5), enzymatic detergent and water for a minimum of 2 minutes. Use a soft instrument brush to scrub instrument trays while submerged in cleaning solution to remove organic matter. Rinse with water, then clean ultrasonically in a lukewarm (less than 43°C), mild (pH 7.0 - 8.5), detergent and water for 10 minutes.

Rinse thoroughly with water. Clean in this manner until no visible soil remains on the instrument tray.

Dry with compressed air, or wipe dry with a lint-free cloth. Examine instrument trays for any staining or deterioration; remove from use as appropriate.

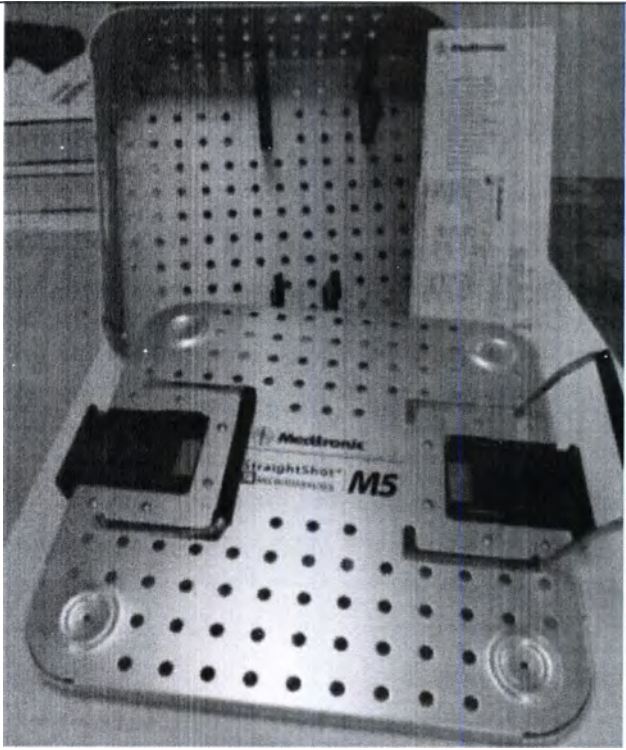
**Note:**

When using an ultrasonic cleaner or a spray washing machine, follow the manufacturer's recommendations for positioning of instrument trays. Following cleaning, lightly lubricate instrument trays with movable parts. Use a lubricant intended for sterilizable instruments such as a water-soluble instrument milk. Do not use silicone spray.



Available upon request

Appendix to the Instruction for use  
Name of Medical Device



Technical Parameters. Accessories: StraightShot M5 Instrument Tray Parameters:

| StraightShot M5 Instrument Tray | Dimensions                                                                | Weight   |
|---------------------------------|---------------------------------------------------------------------------|----------|
| Lid                             | 265mm x 254mm x 26mm                                                      | 0.735 kg |
| Base Tray                       | 260mm x 249mm x 60mm                                                      |          |
| Silicone Mat                    | 51mm x 50mm x 6,5mm<br>54.5mm x 49.5mm x 6.5mm<br>58.5mm x 49.5mm x 6.5mm |          |

| Name of the device               | Material                                                   | Body Contact                                                                                                                                                                                                                            |
|----------------------------------|------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| StraightShot M5<br>Microdebrider | Collet front inner ROHS - Stainless steel 17-4             | The base of the inner chuck, the base of the front chuck - part of the product, Briefly in contact with the internal environment of the body;<br>The rest of the device - No contact with the human body.<br>Medical staff working with |
|                                  | Collet cover - Medcoat                                     |                                                                                                                                                                                                                                         |
|                                  | Collet front inner ROHS - 303 stainless steel              |                                                                                                                                                                                                                                         |
|                                  | Collet cover - Medcoat                                     |                                                                                                                                                                                                                                         |
|                                  | Pins, Suction port - 303 stainless steel                   |                                                                                                                                                                                                                                         |
|                                  | Housing + overmolding, Lock actuator - Stainless steel 430 |                                                                                                                                                                                                                                         |
|                                  | Finger wheel lock, Cable, Cable clips,                     |                                                                                                                                                                                                                                         |
|                                  | Finger wheel - Liquid black Silicone Rubber                |                                                                                                                                                                                                                                         |

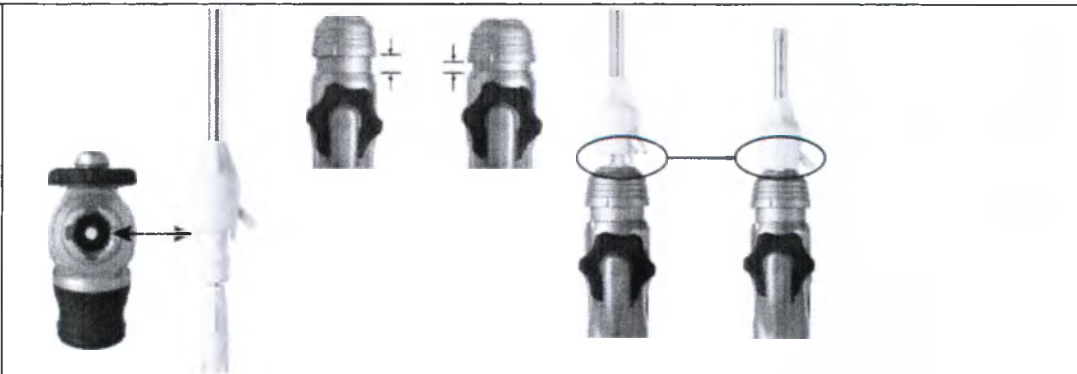
Available upon request



Appendix to the Instruction for use  
Name of Medical Device

|                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                      |                                                                                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
|                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>Silk-screen printing –</b><br>blue<br>Black                                                                                                                                                                                                                                                                                       | gloves.                                                                        |
|                                                                                                                                                                     | StraightShot<br>M5<br>Instrumental<br>Tray                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <b>Lid, Base -</b> Aluminum anodized<br><br><b>Handle -</b> Stainless steel AISI 302<br><br><b>Latches, Foot –</b><br>Polyphenylsulfone black<br><br><b>Rivets -</b> Stainless steel 430<br><br><b>Silkscreen Medtronik -</b> blue<br><br><b>Silkscreen line and text -</b> Black<br><br><b>Mount -</b> Liquid black Silicone Rubber | No contact with<br>the human body.<br>Medical staff<br>working with<br>gloves. |
| 9. Information on<br>the presence in the<br>medical device of a<br>medicinal product for<br>human use, human<br>and/or animal<br>materials                          | Not applicable                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                      |                                                                                |
| 10. Information on<br>the procedure of<br>installation,<br>adjustment, calibration<br>and other actions<br>necessary to put the<br>medical device into<br>operation | <b><u>ASSEMBLY REQUIREMENTS</u></b><br><b>STRAIGHTSHOT M5 BLADE OR BUR ASSEMBLY</b><br>1. Insert the tool aligning the tabs with the notches. Orientate the irrigation barb to the left or right side.<br><b>Note:</b> StraightShot M5 use a four-tab alignment system.<br><br>• For rotating straight blades, orient the irrigation barb at the 3 o'clock position for right-handed surgeons and 9 o'clock for left-handed surgeons.<br>• For rotating curved blades, orient the irrigation barb at 3 o'clock.<br><br>• For rotatable blades, adjust the finger wheel with small back-and-forth motions until the blade is engaged.<br>2. Press the locking collar<br>3. Release the locking collar.<br><b>Note:</b> If the collar does not return to full out position adjust the finger wheel with small back-and-forth motions until collar pops out.<br><br>4. Pull on the blade or the bur to ensure engagement and visually check to make sure the distal tip of the inner blade is in contact with the distal tip of the outer cannula.<br><br><b>Blade or Bur Assembly</b> |                                                                                                                                                                                                                                                                                                                                      |                                                                                |

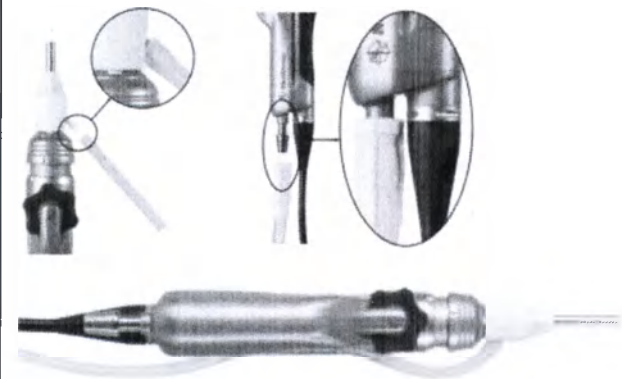
Available upon request



**STRAIGHTSHOT M5 SUCTION AND IRRIGATION TUBE ASSEMBLY**

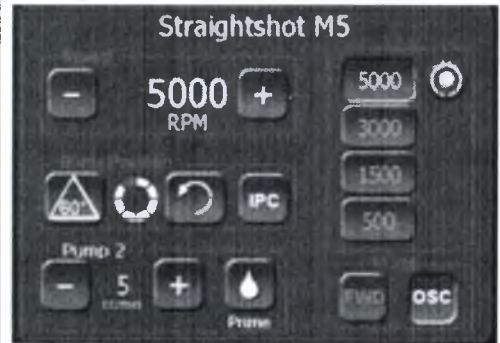
- 1. Attach a suction tube to the suction source and an irrigation tube on the irrigation barb.
- 2. Secure suction and irrigation in the irrigation groove on the handpiece

**Suction and Irrigation Assembly**



**STRAIGHTSHOT M5 TOUCHSCREEN CONTROLS**

**StraightShot M5 Touchscreen**



**Note:**

When you stop the blade, one of the following occurs:

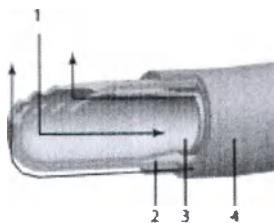
- If the IPC button is visible on the touchscreen, the inner blade returns to the same position it began.

Available upon request

|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <ul style="list-style-type: none"><li>• If the XPS button is visible on the touchscreen, the inner blade stops the current position.<br/>To set or adjust StraightShot controls, on the IPC touchscreen, in the StraightShot Handpiece control box, do the following:</li><li>• To change rotation mode, select OSC (oscillating) or FWD (forward).</li></ul> <p><b>Note:</b> The system displays the default oscillating or forward mode speed.</p> <ul style="list-style-type: none"><li>• To adjust speed, in the Speed control box, press the plus to increase speed or the minus button to decrease speed.<br/>Forward Mode: Default, 12000 rpm; variable adjustment from 50 to 30000 rpm.<br/>Oscillate Mode: Default, 5000 rpm; variable adjustment from 50 to 7500 rpm.</li><li>• To adjust the irrigation flow rate, in the Pump control box, press the plus button to increase flow rate or the minus button to decrease flow rate. If intermittent flow is available, pressing the plus or minus button progresses the system through intermittent and continuous flow. The system displays <b>Intermittent</b> when in intermittent flow mode.<br/>Forward Mode: Default, 30 cc per minute.<br/>Oscillate Mode: Default, 5 cc per minute.</li></ul> <p><b>Note:</b><br/>To adjust flow rate, you can use the touchscreen or the IntelliFlow Irrigation remote control.</p> <ul style="list-style-type: none"><li>• To rotate outer blade, use the finger wheel.</li></ul> <p><b>In oscillating mode only</b>, you can use the Blade Position control box to do any of the following:</p> <p><b>Note:</b> The motion indicator indicates rotation direction of the blade. </p> <p>To enable the multifunction foot pedal to change rotation displacement, press the delta button.  60° 180°</p> <p>To rotate inner blade in small increments, press the counter-clockwise buttons </p> <p><b>MICRODEBRIDER BLADE CONTROL</b></p> <p><b>Important:</b> If airway blade becomes clogged during use, 1-5 cc of irrigant could be aspirated by the patient before you detect the clog.</p> <p><b>Note:</b> Periodically submerge blade tip in sterile water, with suction on, to keep blades clear during the procedure.</p> <ul style="list-style-type: none"><li>• To rotate the outer blade, use the finger wheel.</li><li>• To rotate the inner blade, use the Blade Position control box on the IPC touchscreen.</li></ul> <p>Refer to the related accessory Controls topic for further information.</p> <p><b>Blade Dissection</b></p> |
|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Available upon request

Appendix to the Instruction for use  
Name of Medical Device



- 1) Suction flow in through inner blade irrigation flow between inner and outer blades  
2) Outer blade  
3) Inner blade  
4) Outer sleeve

|                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                           |                      |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|----------------------|
| 11. Requirements for the premises in which the installation of the medical device shall be carried out, as well as requirements for training or qualification of persons who install the medical device (if applicable) | Not applicable                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                           |                      |
| 12. Information necessary to verify the correct installation of the medical device and its readiness for safe operation, including:                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                           |                      |
| a. Maintenance and its frequency, including cleaning and disinfection of the medical device;                                                                                                                            | Containment and Transportation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | It is recommended that instruments are reprocessed as soon as is practical following use. |                      |
|                                                                                                                                                                                                                         | Preparation for Decontamination                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Remove the bur from the handpiece, otherwise disassembly is not required.                 |                      |
|                                                                                                                                                                                                                         | Cleaning: Automated (Do NOT use ultrasonic washer)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                           |                      |
|                                                                                                                                                                                                                         | • Remove instruments and equipment from any instrument trays. • Use alkaline (pH ≤10.5) or neutral pH detergent. • Do not immerse the handpiece. <b>Auto Wash Pre-Cleaning Instructions - Neutral Detergent</b> • Manually rinse the handpiece, cable, and tubing management clips with running tap water to remove all visible soil from the device. Using a soft bristled brush and a neutral detergent solution, gently and thoroughly clean the entire open lumen of the device. Actuate the collet while rinsing and turn the thumbwheel. Hold the handpiece with collet end down when rinsing and run stream of water through the suction port. • Place devices in the washer with the collet facing downward to facilitate drainage. |                                                                                           |                      |
|                                                                                                                                                                                                                         | <b>Auto wash Cycle - Neutral Enzymatic Detergent</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                           |                      |
| Phase                                                                                                                                                                                                                   | Minimum Time                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Temperature                                                                               | Detergent            |
| Pre-wash 1                                                                                                                                                                                                              | 02:00                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Cold tap water                                                                            | Not applicable       |
| Enzyme wash                                                                                                                                                                                                             | 05:00                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | < 50°C                                                                                    | neutral enzymatic pH |

Available upon request

Appendix to the Instruction for use  
Name of Medical Device

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |              |                  |                                                              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|------------------|--------------------------------------------------------------|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |              |                  | detergent,<br>manufacturer's<br>recommended<br>concentration |
| Rinse 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 01:00        | Hot tap water    | Not applicable                                               |
| Thermal rinse                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 01:00        | 82°C<br>minimum  | Not applicable                                               |
| Visually examine for cleanliness.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |              |                  |                                                              |
| <b>Auto Wash Pre-Cleaning Instructions - Alkaline Detergent</b> <ul style="list-style-type: none"><li>Manually rinse the handpiece, cable, and tubing management clips with running tap water to remove all visible soil from the device. Using a soft bristled brush and a neutral detergent solution, gently and thoroughly brush the entire open lumen of the device. Actuate the collet while rinsing and turn the thumbwheel. Hold the handpiece with collet end down when rinsing and run stream of water through the suction port.</li><li>Place devices in the washer with the collet facing downward to facilitate drainage.</li></ul> |              |                  |                                                              |
| <b>Auto wash Cycle - Alkaline Detergent</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |              |                  |                                                              |
| Phase                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Minimum Time | Temperature      | Detergent                                                    |
| Pre-wash 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 02:00        | Cold tap water   | Not applicable                                               |
| Wash 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 05:00        | 66°C (set point) | alkaline detergent<br>pH ≤ 10.5                              |
| Rinse 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 01:00        | Hot tap water    | Not applicable                                               |
| Thermal rinse                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 01:00        | 82°C<br>minimum  | Not applicable                                               |
| Visually examine for cleanliness.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |              |                  |                                                              |
| <b>Cleaning: Manual</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |              |                  |                                                              |
| • Remove instruments and equipment from instrument tray.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |              |                  |                                                              |

Available upon request



Appendix to the Instruction for use  
Name of Medical Device

- Do not immerse the handpiece.
  - Wipe the handpiece and cable with neutral detergent applied to a clean, non-abrasive cloth.
  - Manually rinse the handpiece, cable, and tubing management clips with running tap water to remove all visible soil from the device. Hold the handpiece with collet end down when rinsing and run stream of water through the suction port.
  - Use an enzymatic detergent solution to loosen and remove collected tissues from the unit.
  - Using an enzymatic detergent solution and a soft cloth dampened with the detergent, wipe the motor and cable. Gently clean the handpiece, cable, and tubing management clips with a soft bristle brush wetted with the enzymatic detergent. Using a soft bristled brush, gently and thoroughly clean the entire open lumen of the device. Actuate the collet while cleaning and turn the thumbwheel. Use the brush to thoroughly clean the tubing management clips.
  - Manually rinse the handpiece, cable, and tubing management clips with running tap water to remove all visible soil from the device.
  - Hold the handpiece with collet end down when rinsing the lumen thoroughly.\*
- \* Additional Cleaning Instructions for XPS Straightshot M5/M4/Spine Shaver Microdebrider:
- During the normal cleaning cycle, run a gentle stream of warm water into the collet (front end), and into the lock lever of the Straightshot M4/Spine Shaver handpiece.
  - While warm water is running into the collet, rotate the mechanism for several revolutions (rotate the wheel); and while water is running into the lock lever, actuate the lock lever several times (locking and unlocking).
  - Shake excess water from the handpiece.
  - PRECAUTION: Ensure the use of a very gentle stream of warm clean water during this additional cleaning step.

**Drying and Lubrication**

- Dry the handpiece and cable with a lint-free towel. Make sure to dry off the electrical connection on the cable ends.
- Apply a small amount of silicone spray into the front-end collet and outside of the handpiece.
- Sterilize the handpiece immediately after cleaning.

**Desinfection**

Do not cold soak in gluteraldehyde.

b. List of information provided by the manufacturer of the medical device, keys, access passwords, programs required for installation, adjustment, operation

Not applicable

Available upon request

Appendix to the Instruction for use  
Name of Medical Device

|                                                                                                                                                                                                                                 |                                                                                                                                                                                          |                                                |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------|
| and maintenance of the medical device;                                                                                                                                                                                          |                                                                                                                                                                                          |                                                |
| c. List of consumables (components, reagents), as well as the procedure for their use and replacement;                                                                                                                          | Not applicable                                                                                                                                                                           |                                                |
| d. Need for calibration to ensure the proper and safe operation of the medical device during its lifetime;                                                                                                                      | Not applicable                                                                                                                                                                           |                                                |
| e. Risk minimization methods associated with the installation, calibration or maintenance of the medical device;                                                                                                                | Not applicable                                                                                                                                                                           |                                                |
| f. Information on installation, adjustment, calibration and other actions necessary for putting the medical device into operation and its correct operation (application);                                                      | Not applicable                                                                                                                                                                           |                                                |
| g. Information on the list of the main characteristics for the operation (application) of the medical device, transportation and storage conditions (for example, temperature and humidity, lighting and other characteristics) | The medical device is intended for use at the standard conditions of hospital operating room environment by qualified surgeons.                                                          |                                                |
|                                                                                                                                                                                                                                 | Requirements for environmental conditions during operation                                                                                                                               | Value                                          |
|                                                                                                                                                                                                                                 | Air temperature, °C                                                                                                                                                                      | +10°C - +33°C                                  |
|                                                                                                                                                                                                                                 | Relative humidity                                                                                                                                                                        | 30% - 75%                                      |
|                                                                                                                                                                                                                                 | Atmosphere pressure, hPa                                                                                                                                                                 | 700 - 1060                                     |
|                                                                                                                                                                                                                                 | Requirements for environmental conditions during transport and storage                                                                                                                   | Value                                          |
|                                                                                                                                                                                                                                 | Air temperature, °C                                                                                                                                                                      | -40°C - +70°C                                  |
|                                                                                                                                                                                                                                 | Relative humidity                                                                                                                                                                        | 10% - 95%                                      |
|                                                                                                                                                                                                                                 | Atmosphere pressure, hPa                                                                                                                                                                 | 500 - 1060                                     |
|                                                                                                                                                                                                                                 | Packed by the manufacturer products are transported by all modes of transport in closed vehicles in accordance with the rules of carriage of goods, operating in each mode of transport. |                                                |
| h. List of national standards applied by the manufacturer                                                                                                                                                                       | Quality Systems                                                                                                                                                                          |                                                |
|                                                                                                                                                                                                                                 | BS EN ISO                                                                                                                                                                                | Medical devices - Quality management systems - |

Available upon request

Appendix to the Instruction for use  
Name of Medical Device

|  |                                   |                                                                                                                                          |
|--|-----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|
|  | 13485:2012                        | Requirements regulatory purposes                                                                                                         |
|  | BS EN ISO 14971:2012              | Medical Devices – Application of risk management to medical devices.                                                                     |
|  | <b>Labeling</b>                   |                                                                                                                                          |
|  | BS EN ISO 15223-1:2012            | Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements. |
|  | BS EN 1041:2008 + A1:2013         | Information supplied by the manufacturer with medical devices                                                                            |
|  | IEC TR 60878:2003                 | Graphic Symbols for Electrical Equipment in Medical Practice                                                                             |
|  | AENOR UNE-EN 60417-1:2002         | Graphical Symbols for Use on Equipment – Part 1: Overview and Application                                                                |
|  | <b>Biocompatibility</b>           |                                                                                                                                          |
|  | BS EN ISO 10993-1:2010            | Biological evaluation of medical devices – Part 1: Evaluation and testing                                                                |
|  | BS EN ISO 10993-2:2006            | Biological Evaluation of Medical Devices - Part 2: Animal Welfare Requirements                                                           |
|  | BS EN ISO 10993-5:2009            | Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity                                                         |
|  | BS EN ISO 10993-7:2008            | Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals                                                |
|  | BS EN ISO 10993-10:2010           | Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization                                         |
|  | BS EN ISO 10993-11:2006           | Biological evaluation of medical devices Part 11: Tests for systemic toxicity                                                            |
|  | BS EN ISO 10993-12:2012           | Biological evaluation of medical devices Part 12: Sample preparation and reference materials                                             |
|  | BS EN ISO 10993-18:2005           | Biological evaluation of medical devices Part 18: Chemical characterization of materials                                                 |
|  | <b>BS EN 556-1:2001</b>           | Sterilization of Medical Devices – Requirements for medical devices to be designated “STERILE”                                           |
|  | <b>Cleaning / Resterilization</b> |                                                                                                                                          |
|  | BS EN ISO 17664:2004              | Sterilization of medical devices -- Information to be provided by the manufacturer for the processing of resterilizable medical devices  |
|  | Electric Safety, other            |                                                                                                                                          |
|  | <b>IEC 60529:2013</b>             | Degrees of Protection Provided by Enclosures (IP Code) –                                                                                 |

Available upon request

Appendix to the Instruction for use  
Name of Medical Device

|                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                              |         |                  |              |  |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|------------------|--------------|--|
|                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                     | Edition 2.2                                                                                                                                                                                                                  |         |                  |              |  |
|                                                                                                                                                                                                                                                                                                       | IEC 60601-1-6: 2013                                                                                                                                                                                                                                                                                                                                                                 | Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability - Edition 3.1                                                                      |         |                  |              |  |
|                                                                                                                                                                                                                                                                                                       | BS EN 60601-1 + A12:2006                                                                                                                                                                                                                                                                                                                                                            | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - CORR: May 31, 2011; AMD: February 29, 2012; AMD: December 31, 2013; CORR: November 30, 2014; AMD: November 30, 2014 |         |                  |              |  |
|                                                                                                                                                                                                                                                                                                       | BS EN 60601-1-2:2007                                                                                                                                                                                                                                                                                                                                                                | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests - CORR: July 31, 2010                 |         |                  |              |  |
|                                                                                                                                                                                                                                                                                                       | BS EN 61000-4-3:2006 + A2:3.2010                                                                                                                                                                                                                                                                                                                                                    | Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test - AMD: May 30, 2008; CORR: October 31, 2009; AMD: August 31, 2010        |         |                  |              |  |
|                                                                                                                                                                                                                                                                                                       | IEC 61000-4-6, Edition 4.0 2013-10                                                                                                                                                                                                                                                                                                                                                  | Electromagnetic compatibility (EMC) – Part 4-6: Testing and measurement techniques – Immunity to conducted disturbances, induced by radio-frequency fields - Edition 4.0                                                     |         |                  |              |  |
| 13. Information on the sterile condition of the medical device, method of its sterilization and the procedure for dealing with a sterile package violation (if the medical device is delivered sterile), or if the medical device is not sterile, indication of the need for sterilization before use | Medical device is No sterile                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                              |         |                  |              |  |
| 14. Information on the procedure for the preparation of the medical device for its reuse, including cleaning, disinfection, packaging and, if necessary, method of re-sterilization (if the medical device is reusable), as well as criteria for the unfitness of the medical device for use          | The sterilization parameters given below should be used for devices that are fully disassembled when disassembly is possible. Use basic aseptic technique during post-sterilization assembly to maintain the sterility of the instrument(s). All steam sterilization cycles have been validated in the wrapped configuration and instruments can be sterilized wrapped or unwrapped |                                                                                                                                                                                                                              |         |                  |              |  |
| Steam sterillization                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                              |         |                  |              |  |
| Cycle                                                                                                                                                                                                                                                                                                 | Gravity*                                                                                                                                                                                                                                                                                                                                                                            | Gravity                                                                                                                                                                                                                      | Pre-Vac | Pre-Vac (FR/WHO) | Pre-vac (UK) |  |
| Temperature                                                                                                                                                                                                                                                                                           | 121 °C                                                                                                                                                                                                                                                                                                                                                                              | 132 °C                                                                                                                                                                                                                       | 132 °C  | 134 °C           | 134 °C       |  |
| Time                                                                                                                                                                                                                                                                                                  | 40 min                                                                                                                                                                                                                                                                                                                                                                              | 15 min                                                                                                                                                                                                                       | 4       | 18 min           | 3 min        |  |

Available upon request

Appendix to the Instruction for use  
Name of Medical Device

|                                                |                                         |  |     |               |  |
|------------------------------------------------|-----------------------------------------|--|-----|---------------|--|
|                                                |                                         |  | min |               |  |
| Drying                                         | 25 minutes, or until visibly dry        |  |     |               |  |
| 100% EtO Sterilization Parameters (set points) |                                         |  |     |               |  |
| Preconditioning                                | 54°C, 60% relative humidity, 60 minutes |  |     |               |  |
| Sterilization                                  | Temperature                             |  |     | 54°C          |  |
|                                                | Relative Humidity                       |  |     | 60 %          |  |
|                                                | Ethylene oxide concentration            |  |     | 725 mg/l      |  |
|                                                | Gas exposure time (full-cycle)          |  |     | 120 min       |  |
|                                                | Aeration                                |  |     | 54°C, 8 hours |  |

|                                 |                                                                                           |
|---------------------------------|-------------------------------------------------------------------------------------------|
| Containment and Transportation  | It is recommended that instruments are reprocessed as soon as is practical following use. |
| Preparation for Decontamination | Remove the bur from the handpiece, otherwise disassembly is not required.                 |

Cleaning: Automated (Do NOT use ultrasonic washer)

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |              |                |                                                                          |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|----------------|--------------------------------------------------------------------------|
| <ul style="list-style-type: none"><li>Remove instruments and equipment from any instrument trays.</li><li>Use alkaline (pH ≤10.5) or neutral pH detergent.</li><li>Do not immerse the handpiece. <b>Auto Wash Pre-Cleaning Instructions - Neutral Detergent</b></li><li>Manually rinse the handpiece, cable, and tubing management clips with running tap water to remove all visible soil from the device. Using a soft bristled brush and a neutral detergent solution, gently and thoroughly clean the entire open lumen of the device. Actuate the collet while rinsing and turn the thumbwheel. Hold the handpiece with collet end down when rinsing and run stream of water through the suction port.</li><li>Place devices in the washer with the collet facing downward to facilitate drainage.</li></ul> |              |                |                                                                          |
| Auto wash Cycle - Neutral Enzymatic Detergent                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |              |                |                                                                          |
| Phase                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Minimum Time | Temperature    | Detergent                                                                |
| Pre-wash 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 02:00        | Cold tap water | Not applicable                                                           |
| Enzyme wash                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 05:00        | < 50°C         | neutral enzymatic detergent, manufacturer's recommended concentration pH |
| Rinse 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 01:00        | Hot tap water  | Not applicable                                                           |
| Thermal rinse                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 01:00        | 82°C minimum   | Not applicable                                                           |
| Visually examine for                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |              |                |                                                                          |

Available upon request



Appendix to the Instruction for use  
Name of Medical Device

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                     |                    |                                 |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------|---------------------------------|
| cleanliness.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                     |                    |                                 |
| <b>Auto Wash Pre-Cleaning Instructions - Alkaline Detergent</b> • Manually rinse the handpiece, cable, and tubing management clips with running tap water to remove all visible soil from the device. Using a soft bristled brush and a neutral detergent solution, gently and thoroughly brush the entire open lumen of the device. Actuate the collet while rinsing and turn the thumbwheel. Hold the handpiece with collet end down when rinsing and run stream of water through the suction port. • Place devices in the washer with the collet facing downward to facilitate drainage. |                     |                    |                                 |
| <b>Auto wash Cycle • Alkaline Detergent</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                     |                    |                                 |
| <b>Phase</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>Minimum Time</b> | <b>Temperature</b> | <b>Detergent</b>                |
| <b>Pre-wash 1</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 02:00               | Cold tap water     | Not applicable                  |
| <b>Wash 1</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 05:00               | 66°C (set point)   | alkaline detergent<br>pH ≤ 10.5 |
| <b>Rinse 1</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 01:00               | Hot tap water      | Not applicable                  |
| <b>Thermal rinse</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 01:00               | 82°C minimum       | Not applicable                  |
| Visually examine for cleanliness.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                     |                    |                                 |
| <b>Cleaning: Manual</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                     |                    |                                 |
| <ul style="list-style-type: none"><li>• Remove instruments and equipment from instrument tray.</li><li>• Do not immerse the handpiece.</li><li>• Wipe the handpiece and cable with neutral detergent applied to a clean, non-abrasive cloth.</li><li>• Manually rinse the handpiece, cable, and tubing management clips with running tap water to remove all visible soil from the device. Hold the handpiece with collet end down when rinsing and run stream of water through the suction port.</li></ul>                                                                                 |                     |                    |                                 |

Available upon request

Appendix to the Instruction for use  
Name of Medical Device

|                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                     |                                                        |                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|--------------------------------------------------------|----------------|
|                                                                                                                                                                                                                                                                          | <ul style="list-style-type: none"><li>• Use an enzymatic detergent solution to loosen and remove collected tissues from the unit.</li><li>• Using an enzymatic detergent solution and a soft cloth dampened with the detergent, wipe the motor and cable. Gently clean the handpiece, cable, and tubing management clips with a soft bristle brush wetted with the enzymatic detergent. Using a soft bristled brush, gently and thoroughly clean the entire open lumen of the device. Actuate the collet while cleaning and turn the thumbwheel. Use the brush to thoroughly clean the tubing management clips.</li><li>• Manually rinse the handpiece, cable, and tubing management clips with running tap water to remove all visible soil from the device.</li><li>• Hold the handpiece with collet end down when rinsing the lumen thoroughly.*</li></ul> <p>* Additional Cleaning Instructions for XPS Straightshot M5/M4/Spine Shaver Microdebrider:</p> <ul style="list-style-type: none"><li>• During the normal cleaning cycle, run a gentle stream of warm water into the collet (front end), and into the lock lever of the Straightshot M4/Spine Shaver handpiece.</li><li>• While warm water is running into the collet, rotate the mechanism for several revolutions (rotate the wheel); and while water is running into the lock lever, actuate the lock lever several times (locking and unlocking).</li><li>• Shake excess water from the handpiece.</li><li>• PRECAUTION: Ensure the use of a very gentle stream of warm clean water during this additional cleaning step.</li></ul> |                     |                                                        |                |
|                                                                                                                                                                                                                                                                          | <p><b>Drying and Lubrication</b></p> <ul style="list-style-type: none"><li>• Dry the handpiece and cable with a lint-free towel. Make sure to dry off the electrical connection on the cable ends.</li><li>• Apply a small amount of silicone spray into the front-end collet and outside of the handpiece.</li><li>• Sterilize the handpiece immediately after cleaning.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                     |                                                        |                |
|                                                                                                                                                                                                                                                                          | <p><b>Desinfection</b></p> <p>Do not cold soak in gluteraldehyde.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                     |                                                        |                |
| 15. Information necessary for the identification of medical devices in order to obtain a safe combination, and information on known restrictions on concomitant use of medical devices (for medical devices intended for use with other medical devices and/or supplies) | <p><b>The possibility and ways of integrating with other medical products</b></p> <p>Straightshot M5 Microdebrider is intended to be used for IPC Console.</p> <p>Do not use any parts other than Medtronic system components as damage or substandard performance could result!</p> <p>Straightshot M5 Microdebrider works with:</p> <table><tr><td>30K high-speed burs</td></tr><tr><td>Factory-calibrated EM blades for Fusion ENT Navigation</td></tr><tr><td>Quadcut blades</td></tr></table>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 30K high-speed burs | Factory-calibrated EM blades for Fusion ENT Navigation | Quadcut blades |
| 30K high-speed burs                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                     |                                                        |                |
| Factory-calibrated EM blades for Fusion ENT Navigation                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                     |                                                        |                |
| Quadcut blades                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                     |                                                        |                |
| 16. Information on the nature, type, and                                                                                                                                                                                                                                 | <p><b>Not applicable</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                     |                                                        |                |

Available upon request

Appendix to the Instruction for use  
Name of Medical Device

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>(if necessary) the intensity and distribution of radiation (electromagnetic, ionizing, other) of the medical device and methods for the protection of consumers and third parties from unintentional radiation during the operation of the medical device (if the medical device creates a dangerous or potentially hazardous radiation level when used as intended)</p>                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <p>17. Information on precautions taken in case of:</p> <p>a. Failures of the medical device, malfunction or deviations in the functioning that may affect the safety of the medical device, including those determined by external signs;</p> <p>b. Effects on the operation of the medical device of external factors associated with the use of the medical device in combination with other medical devices and/or equipment, or such predictable factors as external electromagnetic fields, electrostatic discharges, radiation (electromagnetic, ionizing, other), atmospheric pressure and its differences, humidity and air temperature;</p> <p>c. The risk of electromagnetic interference created by the medical device for other medical devices, equipment and</p> | <p><b>PRECAUTIONS</b></p> <p>P2 To prevent damage to curved tools, disconnect suction tube prior to changing tool during procedure.</p> <p>P3 When using an angled attachment, hold the handpiece assembly by the attachment so that the attachment does not inadvertently loosen from the handpiece.</p> <p>P8 Do not kink cables. Inspect cables and pins for cracks, tears or corrosion.</p> <p>P10 Disconnect cable from Midas Rex Legend EHS motor prior to sterilization.</p> <p>P11 The use of a washer-disinfector for cleaning may cause a pre-mature degradation in performance.</p> <p>P12 Remove devices from instrument case before placing into washer disinfector and allow devices to drain.</p> <p>P13 Orient devices in the washer-disinfector by following manufacturer recommendations.</p> <p>P14 DO NOT use low-temperature hydrogen peroxide gas plasma sterilization due to the lumen internal diameter and length restrictions.</p> <p>P15 DO NOT use low-temperature liquid peracetic acid sterilization due to immersion procedure.</p> <p>P17 Remove and discard accessories following local regulations for proper disposal of contaminated materials.</p> <p>P18 Disposable devices are for single-use only.</p> <p>P19 Clean the motor and cable while still connected together. This will help to reduce ingress of debris.</p> <p>P20 Use ONLY recommended cleaning agents.</p> <p>P23 When using a Y-Splitter, only one Multifunction Foot Pedal shall be active at a time.</p> <p>P24 Only one Y-Splitter shall be used at a time.</p> <p>P25 Ensure the blade or bur is fully engaged in the microdebrider. For blades, verify the tip is fully engaged with the outer cannula prior to use.</p> |

Available upon request

|                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| communication equipment during the conduct and evaluation of the results of diagnosis, treatment or its intended use (for example, electromagnetic radiation from a medical device that affects other equipment); | <ul style="list-style-type: none"><li>• Disconnect the power before cleaning.</li><li>• Do not fully immerse, or ultrasonically clean, this instrument.</li><li>• Do not cold soak sterilize this instrument in glutaraldehyde. This will void the warranty.</li><li>• Do not use organic solvents to clean the bur chuck.</li><li>• For Microdebrider handpiece cleaning, cover handpiece cable connector end with one of the following handpiece cable caps:<ul style="list-style-type: none"><li>• Handpiece Cleaning Cap, Universal - catalog number 3318520.</li><li>• Using 3318520 is optional for StraightShot M5.</li></ul></li><li>• After completion of the cleaning steps, remove Handpiece Cable Cap or other protective components installed prior to cleaning</li></ul> <p><b>System Warnings</b></p> <p>W1 It is important that the IPC system operator be familiar with the system User's Guide, its precautions, procedures and safety issues.</p> <p>W2 Do not use the IPC POWEREASE system in the presence of flammable anesthetics. Avoid potential ignition or explosion of gases.</p> <p>W3 When not operating handpiece, eliminate accidental foot control activation. Control energy to and through the handpiece to prevent unintended tissue, bone, or nerve resection.</p> <p>W4 Disconnect power to the IPC system before cleaning the unit to avoid electrical macro shock.</p> <p>W5 Do not attach unapproved components to the IPC system to avoid electrical macro shock.</p> <p>W6 To avoid the risk of electrical shock, achieve electrical grounding reliability with proper connections. Connect the IPC system to hospital grade receptacles only.</p> <p>W7 This medical device complies with EN60601-1-2 safety standard for electromagnetic compatibility, requirements and test. However, if this equipment is operated in the presence of high levels of electromagnetic interference (EMI) or highly sensitive equipment, interference may be encountered and the user should take whatever steps are necessary to eliminate or reduce the source of the interference. Diminished performance may lengthen operating time for the anesthetized patient.</p> <p>W8 Medical Electrical Equipment needs special Precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this Guide.</p> <p>W9 Portable and mobile RF communications equipment can affect Medical Electrical Equipment.</p> <p>W10 Do not operate the IPC POWEREASE system in the presence of Magnetic Resonance Imaging devices.</p> <p>W11 Use of accessories and cables other than those specified and sold by Medtronic may result in increased emissions and decreased immunity of this unit.</p> <p>W12 The IPC system should not be used adjacent to or stacked with other equipment. If</p> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Available upon request

adjacent or stacked use is necessary, the IPC system should be observed to verify normal operation in the configuration in which it will be used.

W13 Do not attempt to run the IPC POWEREASE system handpiece immediately after autoclaving. Allow an adequate “cool down” period (Typically 1 hour).

W14 Consult the Legend Bone Mill product insert before use with the IPC system.

W15 For metal transection, observe the following safety precautions:

W15a Eye wear protection is essential.

W15b Irrigate well to cool the cutting surfaces.

W15c Protect the wound site from metal debris.

W15d Use a clamp or grasping device to control loose fragments during transection of any metal component.

W16 Do not operate the IPC POWEREASE system without eye protection.

W17 All service must be performed by Medtronic qualified personnel only.

W18 Repair and/or modification to the IPC system by anyone other than qualified service personnel may significantly compromise the unit’s ability to perform effectively and/or void the equipment warranty.

#### **Component Warnings**

W19 Do not use any parts other than Medtronic system components as damage or substandard performance could result.

W20 Always inspect the components before and after use for any damage. If damage is observed, do not use damaged part until it is repaired or replaced. Damaged parts may deposit metal shavings on surgical site.

W22 Employ visualization, including use of imaging techniques (for example: fluoroscopy, image guided surgery) when using rotating powered accessories. Discontinue powered application in the event of lack of visualization of surgical site.

W24 Motors and attachments may fail due to extended use and allow a component to detach and fall from the motor or attachment, causing patient injury.

W25 Electrical contacts must be dry prior to use.

W26 Heavy side loads and/or long operating periods may cause the device to overheat.

W27 Do not use an overheated device, as it may cause thermal injury to the patient or operator.

W28 Use adequate irrigation. The use of a tool without irrigation may cause an inordinate amount of heat buildup resulting in a thermal injury to tissue. Depending on the amount of irrigation used, the drill bits and saw blades can achieve temperatures in excess of 50 °C.

W29 Do not attempt to change a dissecting tool, saw blade, or attachment while the motor is running, or when the motor or attachment is in an overheated state.

W30 Do not immerse the system components, except as noted.

W31 Do not place motor, attachment and tool on the patient or in an unsecured location during surgery.

W32 A system that is not functioning properly should not be used until all necessary

Available upon request



Appendix to the Instruction for use  
Name of Medical Device

|                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                                                                                                                                                                                                                                 | <p>repairs have been made and the unit is tested to ensure that it is functioning in accordance with Medtronic specifications.</p> <p>W33 Match the nomenclature and color code on the tool packaging to the same nomenclature and color code on the attachment.</p> <p>W34 Make sure that the attachment is still in the locked position after each adjustment of the tool exposure, as attempting to increase the tool exposure too far, may result in the attachment accidentally being unlocked.</p> <p>W36 Smoke and/or excessive heat may be generated if attachment is not in the fully locked position. This may result in thermal injury to the surgeon or staff.</p> <p>W38 DO NOT change accessory with handpiece running to prevent laceration of user and cross-contamination through compromised glove.</p> <p>W40 DO NOT modify accessories used with the handpiece. Performance could be diminished with modified accessories.</p> <p>W42 In order to ensure compliance with requirements of IEC 60601-1, use a Medtronic approved power cable.</p> <p>W43 To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.</p> <p>W45 Verify reusable device was sterilized prior to use. If not sterilized, do not use.</p> |
| 18. Warnings and/or precautions taken by the consumer in the application of the medical device containing a medicinal product for human use, human and/or animal material, materials that are carcinogenic, mutagenic or toxic, whose possible release or washing-out leads to sensitization, allergic reaction or negatively affects the reproductive function | Not applicable                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 19. Warnings and/or precautions taken by the consumer when disposing of the medical device, accessories and consumables used together with it (if any), including information about the infectious, microbial, environmental or physical hazard of the medical device                                                                                           | Remove and discard accessories following local regulations for proper disposal of contaminated materials.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 20. Information on                                                                                                                                                                                                                                                                                                                                              | The medical device is intended for use in medical-preventive and medical institutions by                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |

Available upon request

Appendix to the Instruction for use  
Name of Medical Device

|                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| the circumstances which should prompt the consumer to consult a health professional             | pecially trained, qualified specialists.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 21. Information on the initial release or the latest revision of the operational documentation; | No information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 22. Procedure and conditions for the disposal or destruction of a medical device.               | <p><b>Protection of the environment</b></p> <p>Requirements for environmental protection in the application of a medical device and the procedure for the implementation of disposal or destruction, indicating, if necessary, special precautions for the destruction of unused medical devices:</p> <p>Utilization of medical devices must be done depending on their degree of epidemiological, toxicological and radiation hazards, and the negative impact on the environment in accordance with SanPiN 2.1.7.2790-10. In accordance with SanPiN 2.1.7.2790-10 class of the medical waste is B.</p> <p>Medtronic recommends incineration of devices that have directly contacted patients suspected or confirmed with Transmissible Spongiform Encephalopathy (TSE)/ CJD diagnosis.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 23. Warranty                                                                                    | <p><b>LIMITED WARRANTY</b></p> <p>A. This LIMITED WARRANTY provides assurance for the customer who purchases a Medtronic Xomed Product (hereinafter the “Product”) that should the Product fail to function to Medtronic Xomed’s published specifications during the term of this LIMITED WARRANTY (one year from the date of shipment for new Product, 90 days from date of shipment for refurbished or used Product), Medtronic Xomed will either replace, repair, or issue a credit (adjusted to reflect the age of the Product) for the Product or any portion thereof. This LIMITED WARRANTY is extended only to the buyer purchasing the Product directly from Medtronic Xomed or from its affiliate or its authorized distributor or representative.</p> <p>B. To qualify for this LIMITED WARRANTY, the following conditions must be met:</p> <ol style="list-style-type: none"><li>1. The Product must be used on or before its “Use By” or “Use Before” date, if applicable.</li><li>2. The Product must be used in accordance with its labeling and may not be altered or subjected to misuse, abuse, accident or improper handling.</li><li>3. Medtronic Xomed must be notified in writing within thirty (30) days following discovery of a defect.</li><li>4. The Product must be returned to Medtronic Xomed within thirty (30) days of Medtronic Xomed receiving notice as provided for in (3) above.</li><li>5. Upon examination of the Product by Medtronic Xomed, Medtronic Xomed shall have determined that: (i) the Product was not repaired or altered by anyone other than Medtronic Xomed or its authorized representative, (ii) the Product was not operated under conditions other than normal use, and (iii) the prescribed periodic maintenance</li></ol> |

Available upon request

Appendix to the Instruction for use  
Name of Medical Device

|                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                            | <p>and services have been performed on the Product.</p> <p>C. This LIMITED WARRANTY is limited to its express terms. THIS LIMITED WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED WHETHER STATUTORY OR OTHERWISE, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. In no event shall Medtronic Xomed be liable for any consequential, incidental, prospective or other similar damage resulting from a defect, failure, or malfunction of the Product, whether a claim for such damage is based upon the warranty, contract, negligence or otherwise.</p> <p>D. The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. Users may benefit from statutory warranty rights under legislation governing the sale of consumer goods. If any part or term of this LIMITED WARRANTY is held by any court of competent jurisdiction to be illegal, unenforceable, or in conflict with applicable law, the validity of the remaining portion of the LIMITED WARRANTY shall not be affected, and all rights and obligations shall be construed and enforced as if this LIMITED WARRANTY did not contain the particular part or term held to be invalid.</p>                                                                     |
| 24. Security requirements (including methods and remedies) | <p>Do not use any parts other than Medtronic system components as damage or substandard performance could result.</p> <p>Always inspect the components before and after use for any damage. If damage is observed, do not use damaged part until it is repaired or replaced. Damaged parts may deposit metal shavings on surgical site.</p> <p>Motors and attachments may fail due to extended use and allow a component to detach and fall from the motor or attachment, causing patient injury.</p> <p>Electrical contacts must be dry prior to use.</p> <p>Heavy side loads and/or long operating periods may cause the device to overheat. Do not use an overheated device, as it may cause thermal injury to the patient or operator.</p> <p>Do not immerse the system components, except as noted.</p> <p>Do not place motor, attachment and tool on the patient or in an unsecured location during surgery.</p> <p>A system that is not functioning properly should not be used until all necessary repairs have been made and the unit is tested to ensure that it is functioning in accordance with Medtronic specifications.</p> <p>In order to ensure compliance with requirements of IEC 60601-1, use a Medtronic approved power cable.</p> <p>To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.</p> |

Available upon request

Verify reusable device was sterilized prior to use. If not sterilized, do not use.

### General System Troubleshooting

- Pump(s) does not run. Failed internal components. Contact Customer Service
- Little or no irrigation flow. Tubing Set improperly seated in pump. Reposition tubing in pump, verify pump lid is fully closed with the fluid flow from left to right. Tubing is pinched or kinked. Check tubing at side of pump, see Irrigation/Coolant Pumps. Check remaining tubing for pinched or kinked areas, if necessary replace tubing. Tubing clamps are restricting flow. Set tubing clamps in “open” position. Irrigation flow rate setting low. Adjust irrigation flow rate. Irrigator obstructed. Replace irrigator.
- Pump stall error. Tubing set improperly placed in pump. Reposition tubing in pump, verify pump lid is fully closed with the fluid flow from left to right. Tubing is pinched or kinked. Check tubing is not pinched or kinked on side of pump (see section on “Irrigation/Coolant Pumps”).
- Handpiece connected but console reads “Connect Handpiece.” Moisture in cable conflicts with handpiece recognition. Run a dry cycle when sterilizing.
- Handpiece connected but console displays incorrect handpiece.
- Console does not power up. Power cord not properly connected. Connect power cord. No power. Check power available (i.e. power strip is on, circuit breaker is closed, etc.). Power Inlet Fuses blown. Replace fuses with 5.00 A, 250 V, time delayed fuses (P/N 11270066 Fuse Kit 1898125 ). Failed internal components. Contact Customer Service.
- Power switch light is on but Touchscreen does not come on. Failed internal components. Contact Customer Service.
- Console does not power down. Power switch failure. Unplug power cord, Contact Customer Service.
- Touchscreen does not respond. Screen gasket displaced or failed internal components. Contact Customer Service.
- Touchscreen does not work properly. Touchscreen not calibrated. Calibrate Touchscreen.
- Console displays wrong handpiece / motor type. Console misidentified the handpiece / motor. Disconnect and reconnect the motor cable. Turn console off then on. Change motor, motor cable, or console to isolate the problem. Moisture in cable conflicts with handpiece recognition. Run a dry cycle when sterilizing.
- Foot control unit buttons or pedal does not respond. Faulty Y-Splitter. Disconnect Y-Splitter and connect FCU to IPC directly. Incorrect use. Press and hold buttons for at least 1 second, wait for console confirmation beep. Top button does not respond. One (1) handpiece connected (top button has no function with 1 handpiece connected). Connector not fully inserted. Disconnect and reconnect the FCU cable connector. Try different FCU or console to isolate the problem. Internal component

Available upon request

Appendix to the Instruction for use  
Name of Medical Device

|                                                                                     | <p>failure. Contact Customer Service.</p> <ul style="list-style-type: none"><li>• Handpiece fails to rotate. Failed foot switch. Disconnect foot switch, use manual start/stop rocker switch on rear of console. Failed handpiece motor or motor driver. Contact Customer Service. Cables are not property connected. Ensure handpiece cable is properly connected. Cables are damaged. Check cables for cracks, splits, or bent connector pins.</li><li>• Handpiece is too hot to touch/hold. Blade, bur, and/or attachment transferring heat to handpiece. Remove and reinstall or change blade, bur, and/or attachment. Ensure the part is properly seated before resuming use. Inadequate irrigation and/or coolant. Ensure adequate irrigation and/or coolant is present.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                     |                        |                                                                                     |                  |                                                                                     |                    |                                                                                     |                                            |  |                                           |  |  |                                         |                                  |  |  |  |
|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|------------------------|-------------------------------------------------------------------------------------|------------------|-------------------------------------------------------------------------------------|--------------------|-------------------------------------------------------------------------------------|--------------------------------------------|--|-------------------------------------------|--|--|-----------------------------------------|----------------------------------|--|--|--|
| 25. Customer Service                                                                | <p><b>Contact for all questions, including complaints, repair and service of medical devices the Authorized Representative in Russia:</b></p> <p><b>Medtronic, LLC,</b><br/>123317, Moscow, Presnenskaya Naberezhnaya., 10<br/>Tel.: (495) 580-73-77, Fax: (495) 580-73-78,<br/><a href="http://www.medtronic.ru">www.medtronic.ru</a></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                     |                        |                                                                                     |                  |                                                                                     |                    |                                                                                     |                                            |  |                                           |  |  |                                         |                                  |  |  |  |
| 26. Information in Russian sticker                                                  | <p>The final packaging for the Russian market is accompanied with additional sticker. Devices supplied in packaging marked with the following possible information:</p> <ul style="list-style-type: none"><li>• Name of medical device in Russian language;</li><li>• Name of the manufacturer;</li><li>• Country of origin;</li><li>• Code UPN (unique product number);</li><li>• Code CFN (customer facing number);</li><li>• Date and number of Registration Certificate;</li><li>• Sign of conformity in Russia;</li><li>• Warning and informing symbols and inscriptions (if applicable).</li></ul> <p>Sample of the sticker</p> <table><tr><td rowspan="5"></td><td colspan="2">Name of medical device</td></tr><tr><td>Manufacturer:</td><td>Code UPN</td></tr><tr><td>Country of origin:</td><td>Code CFN</td></tr><tr><td colspan="2">Manufacturer's authorized representative::</td></tr><tr><td colspan="2">Regestretion Certificate № _____ OT _____</td></tr><tr><td></td><td>Date of manuf../Lot/UBD:<br/>See on pack</td><td>See IFU<br/>See packaging symbols</td></tr><tr><td></td><td colspan="2"></td></tr></table> |  | Name of medical device |                                                                                     | Manufacturer:    | Code UPN                                                                            | Country of origin: | Code CFN                                                                            | Manufacturer's authorized representative:: |  | Regestretion Certificate № _____ OT _____ |  |  | Date of manuf../Lot/UBD:<br>See on pack | See IFU<br>See packaging symbols |  |  |  |
|  | Name of medical device                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                     |                        |                                                                                     |                  |                                                                                     |                    |                                                                                     |                                            |  |                                           |  |  |                                         |                                  |  |  |  |
|                                                                                     | Manufacturer:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                     | Code UPN               |                                                                                     |                  |                                                                                     |                    |                                                                                     |                                            |  |                                           |  |  |                                         |                                  |  |  |  |
|                                                                                     | Country of origin:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                     | Code CFN               |                                                                                     |                  |                                                                                     |                    |                                                                                     |                                            |  |                                           |  |  |                                         |                                  |  |  |  |
|                                                                                     | Manufacturer's authorized representative::                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                     |                        |                                                                                     |                  |                                                                                     |                    |                                                                                     |                                            |  |                                           |  |  |                                         |                                  |  |  |  |
|                                                                                     | Regestretion Certificate № _____ OT _____                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                     |                        |                                                                                     |                  |                                                                                     |                    |                                                                                     |                                            |  |                                           |  |  |                                         |                                  |  |  |  |
|                                                                                     | Date of manuf../Lot/UBD:<br>See on pack                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | See IFU<br>See packaging symbols                                                    |                        |                                                                                     |                  |                                                                                     |                    |                                                                                     |                                            |  |                                           |  |  |                                         |                                  |  |  |  |
|                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                     |                        |                                                                                     |                  |                                                                                     |                    |                                                                                     |                                            |  |                                           |  |  |                                         |                                  |  |  |  |
| 27. Symbols                                                                         | <table><tr><th>Symbol</th><th>Description</th></tr><tr><td></td><td>Catalogue number</td></tr><tr><td></td><td>Lot number</td></tr><tr><td></td><td>Manufacturer</td></tr></table>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Symbol                                                                              | Description            |  | Catalogue number |  | Lot number         |  | Manufacturer                               |  |                                           |  |  |                                         |                                  |  |  |  |
| Symbol                                                                              | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                     |                        |                                                                                     |                  |                                                                                     |                    |                                                                                     |                                            |  |                                           |  |  |                                         |                                  |  |  |  |
|  | Catalogue number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                     |                        |                                                                                     |                  |                                                                                     |                    |                                                                                     |                                            |  |                                           |  |  |                                         |                                  |  |  |  |
|  | Lot number                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                     |                        |                                                                                     |                  |                                                                                     |                    |                                                                                     |                                            |  |                                           |  |  |                                         |                                  |  |  |  |
|  | Manufacturer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                     |                        |                                                                                     |                  |                                                                                     |                    |                                                                                     |                                            |  |                                           |  |  |                                         |                                  |  |  |  |

Available upon request



Appendix to the Instruction for use  
Name of Medical Device

|                                                                                    |                                                                                             |
|------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|
|   | Non sterile                                                                                 |
| Rx Only                                                                            | Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. |
|   | Caution                                                                                     |
|   | Consult Instructions for Use                                                                |
| SN                                                                                 | Serial Number                                                                               |
| x1                                                                                 | Quantity                                                                                    |
|   | Date of manufacture                                                                         |
|   | Temperature Limitations                                                                     |
|   | Compliant with European Council Directive MDD 93/42/EEC                                     |
|  | Do not dispose to unsorted municipal waste.                                                 |

Available upon request

# Medtronic

Medtronic  
Medtronic Xomed, Inc.  
6743 Southpoint Drive North  
Jacksonville, Florida 32216  
USA  
www.medtronic.ru

## Приложение к Инструкции по применению

|                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. Наименование медицинского изделия                                                            | Микродебридер StraightShot M5 с принадлежностями                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 2.1 В отношении производителя (изготовителя) медицинского изделия                               | <p><b>Разработчик:</b><br/>Medtronic Xomed, Inc.,<br/>6743 Southpoint Drive North, Jacksonville, FL, 32216-0980, USA<br/>Тел. / Tel: 817-788-6400, Факс / Fax: 817-788 6401<br/><a href="http://www.medtronic.com">www.medtronic.com</a></p> <p><b>Производитель:</b><br/>Medtronic Xomed, Inc.,<br/>6743 Southpoint Drive North, Jacksonville, FL, 32216-0980, USA<br/>Тел. / Tel: 817-788-6400, Факс / Fax: 817-788 6401<br/><a href="http://www.medtronic.com">www.medtronic.com</a></p> <p><b>Адреса мест производства медицинского изделия</b><br/>1. «Медтроник Ксомед, Инк» (Medtronic Xomed, Inc),<br/>6743 Southpoint Drive North, Jacksonville, FL, 32216-0980, USA</p> |
| 2.2 В отношении уполномоченного представителя производителя (изготовителя) медицинского изделия | <p><b>Юридическое лицо, на имя которого может быть выдано регистрационное удостоверение</b><br/>ООО «Медтроник», 123317, Россия, г. Москва, Пресненская наб., д. 10<br/>ИНН: 7703655356; ОГРН: 1087746137247<br/>тел.: (495) 580-73-77, факс: (495) 580-73-78, <a href="http://www.medtronic.ru">www.medtronic.ru</a></p> <p><b>Уполномоченный представитель производителя:</b><br/>ООО «Медтроник», 123317, Россия, г. Москва, Пресненская наб., д. 10<br/>ИНН: 7703655356; ОГРН: 1087746137247<br/>тел.: (495) 580-73-77, факс: (495) 580-73-78, <a href="http://www.medtronic.ru">www.medtronic.ru</a></p>                                                                     |
| 3. Назначение медицинского изделия с указанием потенциального потребителя                       | <p>Применяется для проведения эндоназальных эндоскопических операций на носовых пазухах и основании черепа.</p> <p>Медицинское изделие предназначено для использования в лечебно-профилактических и медицинских учреждениях специально обученными, квалифицированными специалистами.</p>                                                                                                                                                                                                                                                                                                                                                                                          |
| 4. Функциональные характеристики и назначение медицинского изделия                              | <p>Электрические системы сосредоточены вокруг системы объединенного пульта управления электроприводами (IPC) – системы IPC, которая обеспечивает питание микродебридера StraightShot M5.</p> <p>Принцип работы основан на подключении инструментов к портам на панели разъемов системы IPC. Это активное медицинское оборудование – для его работы требуется</p>                                                                                                                                                                                                                                                                                                                  |

Предоставляется по требованию

Приложение к Инструкции по применению  
Название медицинского изделия

|                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                                   | <p>электропитание.</p> <p>Система состоит из пульта управления электроприводами, ножной педали, соединительных кабелей и разнообразных рукояток для привода различных боров, лезвий, сверл, рашпелей, канюль и пил. В состав системы входят интегрированные ирригационные насосы, предназначенные для орошения лезвий и боров, а также для охлаждения электродвигателя.</p> <p>Микродебридер StraightShot M5 – это рукоятка с возможностью выполнения кругового разреза на 360°, используемая для проведения эндоназальных эндоскопических операций на носовых пазухах и основании черепа. Микродебридер StraightShot M5 первый и единственный микродебридер имеющий скорость в 30 000 об/мин. Кабель микродебридера несъемный.</p> <p>Микродебридер StraightShot M5 предназначена для работы только с борами и лезвиями производства компании «Медтроник».</p> <p><b>Показания:</b></p> <p>Применяется для проведения эндоназальных эндоскопических операций на носовых пазухах и основании черепа.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 5. Риски применения медицинского изделия, противопоказания, ожидаемые и предсказуемые побочные явления связанные с применением медицинского изделия по назначению | <p><b>Противопоказания:</b> Нет никаких известных противопоказаний при использовании Микродебридер StraightShot M5.</p> <p><b>Возможные побочные действия (потенциальные осложнения)</b></p> <p>При использовании медицинского изделия в соответствии с инструкцией по применению каких-либо потенциальных осложнений выявлено не было.</p> <p><b>Анализ рисков</b></p> <p>Согласно результатам проведенного поиска публикаций, частотность нежелательных явлений после любого типа хирургического вмешательства с использованием электрических систем в современных условиях является низкой. Анализ публикаций не выявил каких-либо новых рисков в сравнении с отчетом об оценке рисков, связанных с изделием.</p> <p>Клиническая польза перевешивает риски использования систем сверления и соответствующих насадок в определенных случаях. Результаты анализа публикаций и низкий уровень претензий и нежелательных явлений указывают на то, что использование электрических систем производства компании «Медтроник» и соответствующих насадок и инструментов является целесообразным и эффективным хирургическим вариантом лечения широкого круга медицинских состояний.</p> <p><b>Потенциальные опасности и управление рисками:</b></p> <p><b>Акустическое повреждение</b></p> <p>Авторы сопоставили результаты собственного исследования с бельгийскими нормативами по воздействию производственного шума, в соответствии с которыми уровень воздействия шума не должен превышать 87 дБА при пиковом уровне 140 дБС. Для уровней шумового воздействия, превышающих 85 дБА, требуется применение средств защиты слуха (защитных наушников). Авторы этого исследования приходят к</p> |

Предоставляется по требованию

выводу о том, что уровни звука соответствуют международным нормативам по воздействию производственного шума, однако в связи с дискомфортом, испытываемым медработниками, неблагоприятное воздействие по-прежнему может проявляться.

#### ***Тепловое повреждение***

Исследования, проведенные Лайсоном с соавт. и Ямамото с соавт., выявили, что высокоскоростные дрели вырабатывают количество тепла, достаточное для потенциального результата в виде серьезных нежелательных явлений. Эти исследования определили, что данный риск можно снизить путем выполнения сверления в прерывистом режиме наряду с частой промывкой оперируемого участка физиологическим раствором. В своем исследовании Такэнака с соавт. установили, что снижение температуры физиологического раствора, используемого для охлаждения и очистки оперируемого участка, приводит к значительному снижению процента возникновения определенных послеоперационных осложнений. Эти исследования демонстрируют, что, хотя существуют серьезные риски, связанные с применением высокоскоростной дрели, могут быть приняты эффективные меры по снижению этих рисков.

#### ***Сопутствующее повреждение тканей***

Пейтел и Говиндарадж представляют обзор литературы и рекомендации по предупреждению и ликвидации последствий осложнений хирургии решетчатого лабиринта.<sup>35</sup> Одним из таких осложнений является повреждение глазничной пластинки, в особенности после использования силовых инструментов (например, хирургической дрели). Авторы предполагают, что силовые инструменты не должны быть направлены под углом непосредственно на пластинку и что «традиционные инструменты» могут быть более удачным вариантом для скелетирования медиальной стенки глазницы.

#### ***Инфекция***

В рамках проспективного обзора Минамидэ с соавт. задокументировали клинические результаты микроэндоскопической ламинотомии, проведенной на пациентах со стенозом позвоночного канала в поясничном отделе (СПКП).<sup>48</sup> В этом исследовании был указан один случай (0,3%) инфекции. Авторы не расценили это осложнение как значимое.

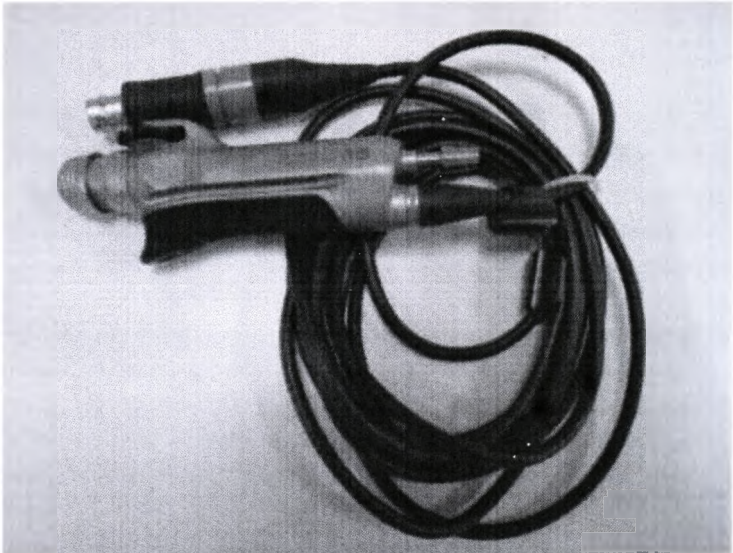
#### ***Риски, характерные для микродебридер-ассистированной хирургии***

Авторы исследования отмечают серьезность указанных осложнений и строят предположения о том, что подобные осложнения могут в недостаточной мере освещаться в литературе, однако они признают возможность наличия систематической ошибки в своем исследовании. Более того, они признают, что данное исследование не являлось истинным описанием серии случаев, и что его скорее следует рассматривать как экспертное заключение. Для точного установления встречаемости осложнений, связанных с применением ларингологического микродебридера, требуется провести проспективно-направленное исследование. Тем временем, для минимизации рисков следует проявлять повышенную осторожность при подборе подходящего типа микродебридера под конкретного пациента и вид хирургического вмешательства, а также при надлежащем применении микродебридера в ходе проведения операции.

#### ***Кровотечение***

Предоставляется по требованию

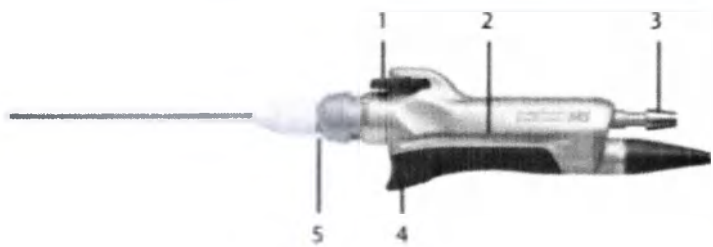
Приложение к Инструкции по применению  
Название медицинского изделия

|                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                           | <p>Обильное кровотечение является распространенным хирургическим осложнением и поэтому часто проявляется в ходе проведения процедур, требующих использования силового оборудования. Ни один из исследователей, сообщивших о случаях кровотечения, не установил связь между значительно повышенным риском кровотечения и применением силового оборудования в хирургии. Более того, ни одна конкретная марка силового оборудования не была признана связанной с повышенным риском кровотечения.</p> <p><b>Заключение по оценке рисков</b></p> <p>Настоящий поиск литературы показывает, что на сегодняшний день частота наступления нежелательных явлений после любого типа хирургического вмешательства с использованием силового оборудования является низкой. Обзор литературы не выявил никаких новых рисков, которые не рассматриваются в оценке рисков для продукта</p> |
| <p>6. Технические характеристики медицинского изделия</p> | <p><b>Варианты исполнения</b></p> <p>Микродебридер StraightShot M5 с принадлежностями:</p> <p><b>I. Микродебридер StraightShot M5</b></p> <p><b>II. Принадлежности:</b></p> <ul style="list-style-type: none"> <li>- Лоток для инструментов StraightShot M5</li> </ul> <p><b>Фотография медицинского изделия: Микродебридер StraightShot M5</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                     |

Предоставляется по требованию



Приложение к Инструкции по применению  
Название медицинского изделия



- 1 – Колесико индексирования
- 2 – Паз для ирригационной трубки
- 3 – Аспирационное отверстие
- 4 – Блокировка упора для пальца
- 5 – Запорное кольцо

**Технические характеристики Микродебрiderа Straightshot M5**

|                             |                                                                                                                                                                                                                                                                      |
|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Размер                      | Длина 125 мм x радиус 20 мм                                                                                                                                                                                                                                          |
| Масса                       | 203 г                                                                                                                                                                                                                                                                |
| Скорость                    | 50-7500 об/мин в режиме колебаний<br>50-30 000 об/мин при поступательном движении                                                                                                                                                                                    |
| Режим работы рабочей части  | Рукоятка StraightShot M5 при полной нагрузке рассчитана на работу с перерывами при следующих условиях<br>Максимальная продолжительность нахождения во включённом состоянии: 60 секунд<br>Минимальная продолжительность нахождения в выключенном состоянии: 30 секунд |
| Непрерывный крутящий момент | 22 мНм                                                                                                                                                                                                                                                               |
| Пиковый крутящий момент     | 160,3 мНм                                                                                                                                                                                                                                                            |
| Максимальная осевая         | 11,1 Н                                                                                                                                                                                                                                                               |

Предоставляется по требованию

Приложение к Инструкции по применению  
Название медицинского изделия

|                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                                      | сила                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                   |
|                                                                                                                                                                      | Максимальная радиальная сила                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 113 Н                                                                                                             |
|                                                                                                                                                                      | Электрические характеристики                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Номинальная сила тока: 6 А (максимум)<br>Номинальное напряжение: 48 В пост. тока<br>Максимальная мощность: 288 Вт |
|                                                                                                                                                                      | Уровень шума (дБ)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 80 дБ макс                                                                                                        |
|                                                                                                                                                                      | <p><b>Режим работы</b><br/>Режим работы<br/>Температура окружающей среды <math>\leq 20^{\circ}\text{C}</math> (один период резки = включение на 20 секунд / отключение на 20 секунд)<br/>Режим колебаний: <math>\leq 4</math> периодов резки 3<br/>Температура окружающей среды <math>&gt; 20^{\circ}\text{C}</math> (один период резки = включение на 20 секунд / отключение на 40 секунд)<br/>Режим колебаний: <math>\leq 3</math> периодов резки 6<br/>Время для охлаждения после максимального количества указанных выше периодов резки: 25 минут</p> <p><b>Шероховатость поверхности</b><br/>Средняя шероховатость должна быть максимум 0,8 мкм (32 микро дюйм)</p> <p><u><b>Допуски (погрешности)</b></u><br/>На все характеристики распространяется погрешность <math>\pm 5\%</math></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                   |
| 7. Описание принадлежности ей, медицинских изделий или изделий, не являющихся медицинскими, но предусмотренных для использования в комбинации с медицинским изделием | <p><b>Показания к применению</b><br/>Лоток для инструментов предназначен для общего расположения, хранения, защиты и транспортировки медицинских изделий для хирургических процедур.</p> <p><b>Меры предосторожности</b><br/>Если вы используете Лоток для инструментов как часть системы стерилизации для изделий, подлежащих повторной обработке:</p> <ul style="list-style-type: none"> <li>• убедитесь, что лоток валидирован для ваших внутренних процессов и систем;</li> <li>• соблюдайте все инструкции по стерилизации изделий, подлежащих повторной обработке;</li> <li>• не используйте лоток для инструментов в самотечных паровых системах стерилизации, т. к. циклы в этих системах имеют очень большую продолжительность;</li> <li>• не используйте стерилизацию облучением для лотков для инструментов компании «Медтроник Ксомед»;</li> <li>• лотки для инструментов не предназначены для сохранения стерильности инструментов, прошедших стерилизацию; лотки для инструментов дважды оборачивают стерилизационным оберточным материалом, чтобы сохранить стерильность инструментов в лотке;</li> <li>• перед очисткой инструментов и(или) лотка достаньте инструменты, незакрепленные компоненты внутри лотка и снимите крышку;</li> <li>• компания «Медтроник» рекомендует сжигать изделия, которые непосредственно контактировали с пациентами, у которых есть подозрения или подтверждена трансмиссивная губчатобразная энцефалопатия (ТГЭ) / болезнь Крейтцфельда-Якоба.</li> </ul> |                                                                                                                   |

Предоставляется по требованию

В частях 4 и 6 NHS Estates HTM 2010: Приложение 2, Инструкции по ВОЗ по обращению с изделиями, заражёнными возбудителями ТГЭ, и контролю заражения трансмиссивной губчатообразной энцефалопатией указывается цикл обеззараживания ТГЭ с помощью паровой стерилизации в автоклаве при температуре 134-137 °С в течение одного цикла продолжительностью 18 минут или шести циклов по 3 минуты;

- время сушки для лотков для инструментов и вспомогательных принадлежностей «Медтроник» может выходить за пределы стандартных параметров предварительной вакуумной обработки медицинских изделий. Рекомендованное время сушки может варьироваться от 15 минут до 40 минут. Соблюдение этого времени особенно важно для лотков для инструментов на основе полимеров (пластмасс). Пользователь должен использовать достаточные меры для проверки времени сушки, например, осмотр.

**Примечание по мойке**

Использование деионизированной воды при последнем ополаскивании позволит избежать образования разводов. Деионизированную воду можно использовать для всего процесса очистки, если это удобно.

**Автоматическая мойка**

Прежде чем поместить лотки в автоматическую моечную машину, необходимо тщательно ополоснуть их водой. Помещайте лотки для инструментов в моечную корзину пустыми, без инструментов и оборудования. Изделия располагаются в соответствии с рекомендациями производителя моющего / дезинфицирующего средства.

| Этап                    | Время циркуляции | Температура воды    | Тип моющего средства                        |
|-------------------------|------------------|---------------------|---------------------------------------------|
| Предварительная мойка 1 | 3 минуты         | холодная вода       | н/п                                         |
| Ферментная мойка        | 5 минут          | горячая вода        | ферментное моющее средство с нейтральным рН |
| Мойка 1                 | 5 минут          | установлена на 66°C | моющее средство с нейтральным рН            |
| Ополаскивание 1         | 3 минуты         | горячая вода        | н/п                                         |

**Ручная мойка**

Замочите в тёплой (менее 43 °С) мягкой (рН 7,0-8,5) воде с ферментным моющим средством не менее чем на 2 минуты. Для удаления органических остатков используйте

Предоставляется по требованию

Приложение к Инструкции по применению  
Название медицинского изделия

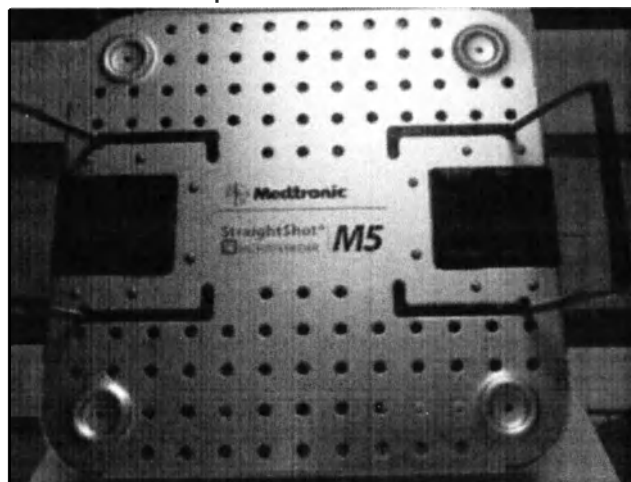
мягкую щётку, при этом лотки для инструментов должны быть погружены в чистящий раствор. Ополосните водой и проведите очистку ультразвуком в тёплой (менее 43 °С) мягкой (рН 7,0-8,5) воде с ферментным моющим средством не менее чем в течение 10 минут.

Тщательно ополосните водой. Выполняйте очистку таким образом до тех пор, пока с лотков для инструментов не удалятся все загрязнения.

Просушите сжатым воздухом или протрите насухо безворсовой тканью. Проверьте лотки для инструментов на наличие сколов или повреждений; изымайте из использования по мере необходимости.

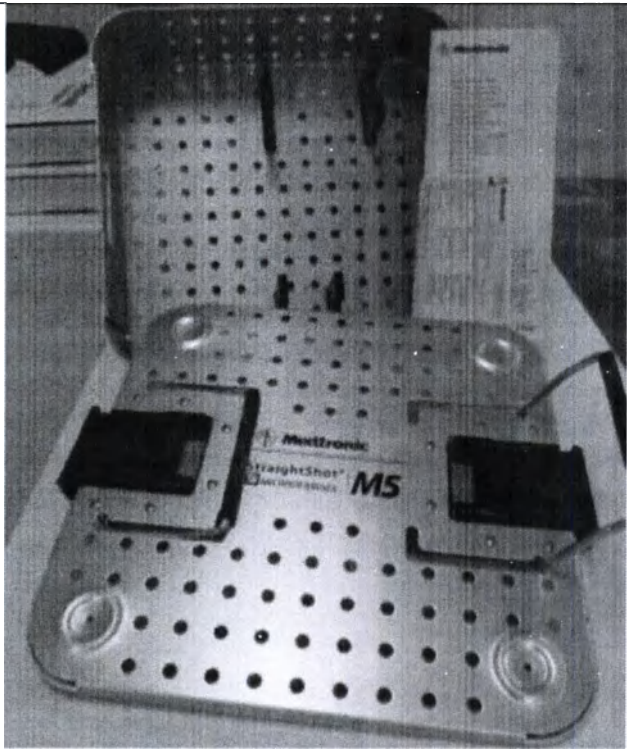
**Примечание.**

При использовании ультразвукового устройства очистки или распыляющей моющей машины соблюдайте рекомендации производителя по расположению лотков для инструментов. После очистки нанесите немного смазки на подвижные части лотка для инструментов. Используйте смазку, предназначенную для стерилизуемых инструментов, например, водорастворимый инструментальный латекс. Не используйте силиконовый спрей.



Предоставляется по требованию

Приложение к Инструкции по применению  
Название медицинского изделия



Технические параметры  
Принадлежности  
Параметры лотка для инструментов StraightShot M5:

| Лоток для инструментов<br>StraightShot M5 | Размеры                                                                            | Масса    |
|-------------------------------------------|------------------------------------------------------------------------------------|----------|
| Крышка                                    | 265 мм x 254 мм x 26 мм                                                            | 0,735 кг |
| Основание контейнера                      | 260 мм x 249 мм x 60 мм                                                            |          |
| Силиконовый держатель                     | 51 мм x 50 мм x 6,5 мм<br>54,5 мм x 49,5 мм x 6,5 мм<br>58,5 мм x 49,5 мм x 6,5 мм |          |

| 8.<br>речень<br>описание<br>материалов<br>медицинского<br>изделия,<br>вступающих в<br>непосредственн<br>ый или<br>опосредованны<br>й контакт с<br>организмом<br>пациента<br>(телом<br>человека) | Пе<br>и                                                                                                                                                                                                                          |                                                                                                                                                         |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                                                                 |                                                                                                                                                                                                                                  |                                                                                                                                                         |
| Наименование<br>изделия                                                                                                                                                                         | Материал                                                                                                                                                                                                                         | Контакт с<br>организмом<br>человека                                                                                                                     |
| Микродебридер<br>StraightShot M5                                                                                                                                                                | Единое неделимое изделие:<br>Основание внутреннего зажимного<br>патрона - нержавеющая сталь 17-4<br>+ хромированное покрытие<br><br>Основание переднего зажимного патрона<br>- нержавеющая сталь 303<br>+ хромированное покрытие | Основание<br>внутреннего<br>зажимного<br>патрона, основание<br>переднего<br>зажимного патрона<br>– части изделия,<br>кратковременно<br>контактирующие с |

Предоставляется по требованию



Приложение к Инструкции по применению  
Название медицинского изделия

|                                                                                                                                                                                                  |                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                    |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                                                                  |                                                               | <p><b>Штырьки, Аспирационное отверстие -</b><br/>нержавеющая сталь 303</p> <p><b>Основание корпуса микродебридера,</b><br/><b>Привод блокировки -</b> нержавеющая сталь 430</p> <p><b>Основание упора для пальца, Оплетка</b><br/><b>кабеля, Зажимы для крепления кабеля,</b><br/><b>Колесико индексирования -</b> силикон<br/>черный</p> <p><b>Шелкография -</b><br/>краситель серый<br/>краситель черный</p>                 | <p>внутренней средой<br/>организма;<br/>остальные части<br/>изделия - нет<br/>контакта с<br/>пациентом.<br/>Медицинский<br/>персонал работает<br/>в перчатках.</p> |
|                                                                                                                                                                                                  | Лоток для инструментов<br>StraightShot M5                     | <p><b>Основа крышки и контейнера -</b><br/>анодированный алюминиевый лист</p> <p><b>Ручки контейнера -</b><br/>Нержавеющая сталь 302</p> <p><b>Оплетка ручек контейнера,</b><br/><b>Силиконовые держатели -</b> силикон<br/>черный</p> <p><b>Защелки крышки -</b><br/>полифенилсульфон черный</p> <p><b>Зажимы крышки -</b><br/>нержавеющая сталь 430</p> <p><b>Шелкография -</b><br/>краситель синий<br/>краситель черный</p> | <p>Изделие не<br/>контактирует с<br/>пациентом.<br/>Медицинский<br/>персонал работает<br/>в перчатках</p>                                                          |
| 9. Информа<br>ция о наличии в<br>медицинском<br>изделии<br>лекарственного<br>средства для<br>медицинского<br>применения,<br>материалов<br>животного и<br>(или)<br>человеческого<br>происхождения | Не применимо                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                    |
| 10. Информа<br>ция о порядке<br>установки,                                                                                                                                                       | УСТАНОВКА ЛЕЗВИЯ ИЛИ БОРА В STRAIGHTSHOT M4 И STRAIGHTSHOT M5 |                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                    |

Предоставляется по требованию

монтажа,  
настройки,  
калибровки и  
иных  
действиях,  
необходимых  
для ввода  
медицинского  
изделия в  
эксплуатацию

1. Вставьте инструмент, совмещая выступы с углублениями. Сориентируйте патрубок с бородками для ирригационной системы влево или вправо.

**Примечание.** В StraightShot M5 используется система выравнивания, состоящая из четырех выступов.

- Для обеспечения вращения прямых лезвий сориентируйте патрубок с бородками для ирригационной системы в положение 3 часов для хирургов-правшей и в положение 9 часов для хирургов-левшей.

- Для обеспечения вращения изогнутых лезвий сориентируйте патрубок с бородками для ирригационной системы в положение 3 часов.

- Для вращающихся лезвий: поворачивайте колесико пальцем вперед и назад с небольшой амплитудой до полной установки лезвия.

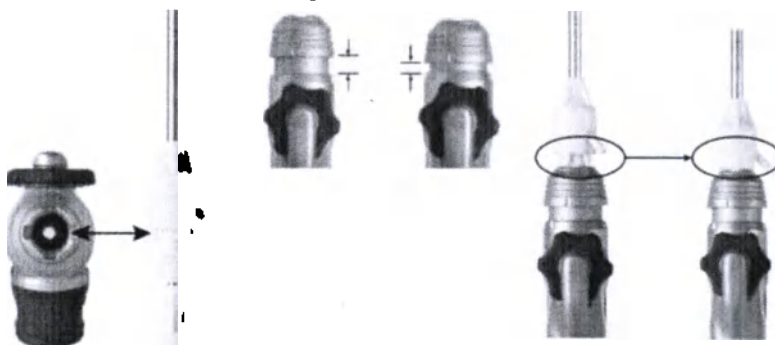
2. Нажмите запорное кольцо.

3. Отпустите запорное кольцо.

**Примечание.** Если кольцо не возвращается назад до конца, отрегулируйте его положение с помощью колесика, слегка вращая его пальцем взад и вперед, пока кольцо не поднимется полностью.

4. Проверьте фиксацию лезвия или бора, потянув его, и визуально убедитесь, что дистальный кончик внутреннего лезвия соприкасается с дистальным концом внешней канюли

#### Установка лезвия или бора

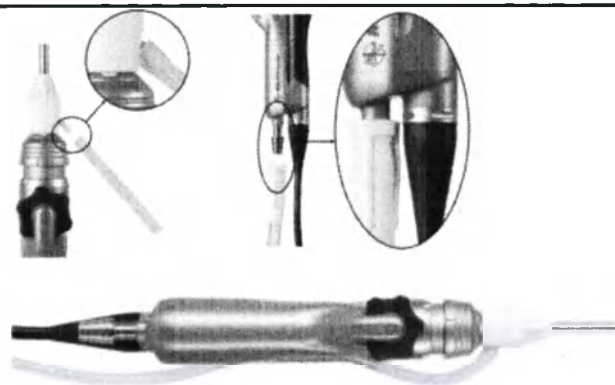


#### ПОДСОЕДИНЕНИЕ АСПИРАЦИОННЫХ И ИРРИГАЦИОННЫХ ТРУБОК К STRAIGHTSHOT M5

1. Подсоедините трубку отсоса к механизму отсасывания, а ирригационную трубку к патрубку с бородками для ирригационной системы

2. Закрепите трубки отсоса и ирригации в пазу для ирригационной трубки на рукоятке.

#### отсоединение трубок отсоса и ирригации



### ЭЛЕМЕНТЫ УПРАВЛЕНИЯ M5, НА СЕНСОРНОМ ЭКРАНЕ

Сенсорный экран StraightShot на IPC



#### Примечание.

Если вы останавливаете вращение лезвия, происходит одно из следующих действий.

- Если на сенсорном экране видна кнопка IPC, внутреннее лезвие вернется в положение, с которого было начато вращение.
- Если на сенсорном экране видна кнопка XPS, внутреннее лезвие остановится в текущем положении. Чтобы задать или настроить элементы управления StraightShot, выполните следующие действия на сенсорном экране IPC в поле управления рукояткой StraightShot.

Сенсорный экран StraightShot на IPC

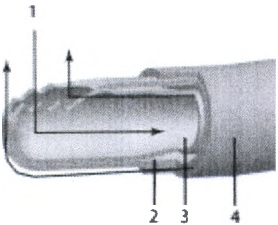
- Для изменения направления вращения выберите OSC (колебания) или FWD (вперед).

#### Примечание.

Система отображает значение скорости по умолчанию для режима вращения вперед или режима колебаний.

- Чтобы настроить скорость, следует нажать в поле управления Speed (Скорость) на кнопки «плюс» или «минус». + Режим прямого вращения: по умолчанию, 12 000 об./мин.; возможна настройка в пределах от 50 до 12 000 об./мин. Режим колебаний: по умолчанию, 5000 об./мин.; возможна настройка в пределах от 50 до 5000 об./мин.
- Чтобы увеличить или уменьшить скорость ирригационного потока, следует нажимать кнопки «плюс» или «минус» в поле управления Pump (Помпа)

Предоставляется по требованию

|                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                         | <p>соответственно. Если в системе есть функция прерывистой ирригации, нажатие кнопки «плюс» или «минус» переключает режим ирригации между прерывистым и постоянным. В режиме прерывистой ирригации система отображает надпись <b>Intermittent</b> (Прерывистый). Режим Forward (Прямая резка): значение по умолчанию, 30 куб. см/мин. Режим Oscillate (Колебания): значение по умолчанию, 5 куб. см/мин.</p> <p><b>Примечание.</b><br/>Для регулирования скорости потока можно использовать сенсорный экран или пульт дистанционного управления ирригацией IntelliFlow.</p> <ul style="list-style-type: none"><li>• Для вращения внешнего лезвия вращайте колесико пальцем.</li></ul> <p><b>Только в режиме колебаний</b><br/>можно выполнить любые следующие действия в поле управления Blade Position (Положение лезвия):</p> <p><b>Примечание.</b> Индикатор направления движения указывает направление вращения лезвия. </p> <p>Чтобы включить опцию поворота лезвия с помощью multifunctional foot pedal, нажмите кнопку со знаком «дельта». 60°  180° </p> <p>Для вращения внутреннего лезвия с небольшим шагом нажимайте кнопки со стрелками, направленными по и против часовой стрелки. </p> <p><b>УПРАВЛЕНИЕ ЛЕЗВИЕМ МИКРОДЕБРИДЕРА Важная информация!</b> Если при вмешательствах на дыхательных путях засоряется лезвие, то пациент может аспирировать в дыхательные пути 1—5 куб. см. ирригационного раствора до обнаружения засора.</p> <p><b>Примечание.</b> Периодически погружайте кончик лезвия в стерильную воду, не выключая аспирации, чтобы на протяжении всего вмешательства лезвия оставались чистыми.</p> <ul style="list-style-type: none"><li>• Для вращения внешнего лезвия вращайте колесико пальцем.</li><li>• Для вращения внутреннего лезвия воспользуйтесь настройками в поле управления Blade Position (Положение лезвия) на сенсорном экране IPC. Для получения подробной информации см. темы, посвященные управлению соответствующим инструментом</li></ul> <p><b>Лезвия в разрезе</b></p> <div></div> <div><p>1 Направление отсоса внутри внутреннего лезвия</p><p>Ирригационный поток между внутренним и внешним лезвиями</p><p>2 Внешнее лезвие</p><p>3 Внутреннее лезвие</p><p>4 Внешний патрубок</p></div> |
| II. Требования к помещению, в которых предполагается установка (монтаж) | Не применимо                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

Предоставляется по требованию

Приложение к Инструкции по применению  
Название медицинского изделия

|                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                   |                 |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|-----------------|
| медицинского изделия, а также требования к подготовке или квалификации лиц, осуществляющих их установку (монтаж) медицинского изделия (при наличии) |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                   |                 |
| 12. Информация для проверки правильности установки (монтажа) медицинского изделия и его готовности к безопасной эксплуатации                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                   |                 |
| а) Содержание и периодичность технического обслуживания, включая очистку и дезинфекцию медицинского изделия;                                        | Защита от загрязнений и транспортировка                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Рекомендуется выполнять обработку инструментов немедленно после их использования. |                 |
|                                                                                                                                                     | Подготовка к обеззараживанию                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Извлеките бор из рукоятки, другая разборка не требуется.                          |                 |
|                                                                                                                                                     | <b>Очистка Автоматизированные методы (НЕ используйте ультразвуковой моечный аппарат)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                   |                 |
|                                                                                                                                                     | <ul style="list-style-type: none"><li>• Извлеките инструменты и оборудование из лотков для инструментов.</li><li>• Используйте щелочные моющие средства (<math>\text{pH} \leq 10,5</math>) или средства с нейтральным pH.</li><li>• Не погружайте рукоятку в жидкость. <b>Инструкции по предварительной очистке перед автоматической мойкой с помощью нейтрального моющего средства</b></li><li>• Вручную ополосните рукоятку, кабель и зажимы для трубок под струей водопроводной воды, чтобы удалить с устройства все видимые загрязнения. С помощью щетки с мягкой щетиной и раствора нейтрального моющего средства осторожно и тщательно прочистите весь просвет устройства. Во время ополаскивания запустите зажимной патрон и поверните дисковый переключатель. При ополаскивании держите рукоятку зажимным патроном вниз. Промойте струей воды аспирационное отверстие.</li><li>• Разместите устройства в моечной машине зажимным патроном вниз, чтобы обеспечить свободное стекание с них воды.</li></ul> |                                                                                   |                 |
|                                                                                                                                                     | <b>Автоматическая мойка с помощью нейтрального ферментативного моющего средства</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                   |                 |
|                                                                                                                                                     | Фаза                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Минимальное время                                                                 | Температура     |
|                                                                                                                                                     | Моющее средство                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                   | Моющее средство |
|                                                                                                                                                     | Замачивание 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 02:00                                                                             | Холодная        |
|                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                   | Неприменимо     |

Предоставляется по требованию



Приложение к Инструкции по применению  
Название медицинского изделия

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |       |                            |                                                                                               |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|----------------------------|-----------------------------------------------------------------------------------------------|
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |       | водопроводная вода         |                                                                                               |
| Мойка ферментативным раствором                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 05:00 | < 50° C                    | Ферментативное моющее средство с нейтральным pH в рекомендованной производителем концентрации |
| Ополаскивание 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 01:00 | Горячая водопроводная вода | Неприменимо                                                                                   |
| Термическое ополаскивание                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | 01:00 | не менее 82 °C             | Неприменимо                                                                                   |
| Визуально проверьте на предмет чистоты.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |       |                            |                                                                                               |
| Инструкции по предварительной очистке перед автоматической мойкой с помощью щелочного моющего средства • Вручную ополосните рукоятку, кабель и зажимы для трубок под струей водопроводной воды, чтобы удалить с устройства все видимые загрязнения. С помощью щетки с мягкой щетиной и раствора нейтрального моющего средства осторожно и тщательно прочистите весь просвет устройства. Во время ополаскивания запустите зажимной патрон и поверните дисковый переключатель. При ополаскивании держите рукоятку зажимным патроном вниз. Промойте струей воды аспирационное отверстие. • Разместите устройства в моечной машине зажимным патроном вниз, чтобы обеспечить |       |                            |                                                                                               |

Предоставляется по требованию

Приложение к Инструкции по применению  
Название медицинского изделия

|                                                                  |                          |                              |                                            |
|------------------------------------------------------------------|--------------------------|------------------------------|--------------------------------------------|
| свободное стекание с них воды.                                   |                          |                              |                                            |
| <b>Автоматическая мойка с помощью щелочного моющего средства</b> |                          |                              |                                            |
| <b>Фаза</b>                                                      | <b>Минимальное время</b> | <b>Температура</b>           | <b>Моющее средство</b>                     |
| <b>Замачивание 1</b>                                             | 02:00                    | Холодная водопроводная вода  | Неприменимо                                |
| <b>Мойка 1</b>                                                   | 05:00                    | 66 °С<br>(заданное значение) | Щелочное моющее средство<br>$pH \leq 10,5$ |
| <b>Ополаскивание 1</b>                                           | 01:00                    | Горячая водопроводная вода   | Неприменимо                                |
| <b>Термическое ополаскивание</b>                                 | 01:00                    | не менее 82 °С               | Неприменимо                                |
| Визуально проверьте на предмет чистоты.                          |                          |                              |                                            |

**Очистка Ручные методы**

- Извлеките инструменты и оборудование из лотков для инструментов.
  - Не погружайте рукоятку в жидкость.
  - Протрите рукоятку и кабель чистой мягкой тканью, смоченной нейтральным моющим средством.
  - Вручную ополосните рукоятку, кабель и зажимы для трубок под струей водопроводной воды, чтобы удалить с устройства все видимые загрязнения. При ополаскивании держите рукоятку зажимным патроном вниз. Промойте струей воды аспирационное отверстие.
  - Для разрыхления и удаления из инструмента скопившихся тканей используйте раствор ферментативного моющего средства.
  - Протрите электродвигатель и кабель с помощью мягкой ткани, смоченной в растворе ферментативного моющего средства. Осторожно протрите рукоятку, кабель и зажимы для трубок с помощью щетки с мягкой щетиной, смоченной в ферментативном моющем средстве. С помощью щетки с мягкой щетиной осторожно и тщательно прочистите весь просвет устройства. Во время очистки запустите зажимной патрон и поверните дисковый переключатель. С помощью щетки тщательно очистите зажимы для трубок.
  - Вручную ополосните рукоятку, кабель и зажимы для трубок под струей водопроводной воды, чтобы удалить с устройства все видимые загрязнения.
  - Удерживая рукоятку зажимным патроном вниз, тщательно ополосните просвет.\*
- \* Дополнительные инструкции по очистке микродебридера XPS StraightShot M5/M4/спинального шейвера.
- Во время обычного цикла очистки пропустите слабый поток теплой воды в зажимной патрон (передний конец) и в запорный рычаг StraightShot M4/спинального шейвера.

Предоставляется по требованию

Приложение к Инструкции по применению  
Название медицинского изделия

|                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                                                                                               | <ul style="list-style-type: none"><li>• При попадании теплой воды в зажимной патрон выполните несколько оборотов механизма (вращайте колесо), а при попадании воды в запорный рычаг несколько раз задействуйте его (зажимая и отжимая рычаг).</li><li>• Вытряхните остатки воды из рукоятки.</li><li>• МЕРА ПРЕОСТОРОЖНОСТИ. На этой дополнительной фазе очистки поток теплой воды должен быть очень слабым.</li></ul> <p><b>Сушка и смазка</b></p> <ul style="list-style-type: none"><li>• Протрите насухо наконечник и кабель безворсовым полотенцем. Убедитесь в том, что электрические разъемы на концах кабеля сухие.</li><li>• Распылите небольшое количество силиконового спрея на передний зажимной патрон и наружный конец рукоятки.</li><li>• Сразу же после очистки простерилизуйте рукоятку.</li></ul> <p><b>Дезинфекция</b></p> <p>Не выдерживайте в низкотемпературном растворе глютаральдегида.</p> |
| б) Перечень предоставленных производителем (изготовителем) медицинского изделия сведений, ключей, паролей доступа, программ, необходимых для монтажа, наладки, эксплуатации и технического обслуживания медицинского изделия; | Не применимо                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| в) Перечень расходных материалов (компонентов, реагентов), а также процедуру их применения и замены;                                                                                                                          | Не применимо                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| г) Необходимость калибровки для обеспечения надлежащей и безопасной работы медицинского изделия в течение срока его службы;                                                                                                   | Не применимо                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |

Предоставляется по требованию

Приложение к Инструкции по применению  
Название медицинского изделия

|                                                                                                                                                                                 |              |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| д) Методы снижения рисков, связанных с установкой, калибровкой или техническим обслуживанием медицинского изделия;                                                              | Не применимо |
| е) Информация о монтаже, наладке, настройке, калибровке и иным действиям, необходимым для ввода медицинского изделия в эксплуатацию и его правильной эксплуатации (применения); | Не применимо |

Предоставляется по требованию

Приложение к Инструкции по применению  
Название медицинского изделия

|                                                                                                                                                                            |                                                                                                                                                                                                |                                                                                                                                                                                                                               |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ж) Информа-<br>ция о перечне<br>основных<br>характеристик<br>по<br>эксплуатации<br>(применению)<br>медицинского<br>изделия,<br>условиям<br>транспортиров-<br>ки и хранения | Медицинское изделие предназначено для использования квалифицированными хирургами в обычных для больничных операционных условиях окружающей среды.                                              |                                                                                                                                                                                                                               |
|                                                                                                                                                                            | <b>Требования к условиям окружающей среды во время эксплуатации</b>                                                                                                                            | <b>Значение</b>                                                                                                                                                                                                               |
|                                                                                                                                                                            | Температура воздуха, °С                                                                                                                                                                        | От +10°С до +33°С                                                                                                                                                                                                             |
|                                                                                                                                                                            | Влажность воздуха (относительная), без образования конденсата                                                                                                                                  | От 30% до 75%                                                                                                                                                                                                                 |
|                                                                                                                                                                            | Атмосферное давление, гПа                                                                                                                                                                      | От 700 до 1060                                                                                                                                                                                                                |
|                                                                                                                                                                            | <b>Требования к условиям окружающей среды во время транспортирования и хранения</b>                                                                                                            | <b>Значение</b>                                                                                                                                                                                                               |
|                                                                                                                                                                            | Температура воздуха, °С                                                                                                                                                                        | От -40°С до +70°С                                                                                                                                                                                                             |
|                                                                                                                                                                            | Влажность воздуха (относительная), без образования конденсата                                                                                                                                  | От 10% до 95%                                                                                                                                                                                                                 |
|                                                                                                                                                                            | Атмосферное давление, гПа                                                                                                                                                                      | От 500 до 1060                                                                                                                                                                                                                |
|                                                                                                                                                                            | Упакованные производителем продукты перевозятся всеми видами транспорта на закрытых транспортных средствах в соответствии с правилами перевозки грузов, действующими в каждом виде транспорта. |                                                                                                                                                                                                                               |
| з) Перечень<br>применяемых<br>производителем<br>(изготовителем)<br>медицинского<br>изделия<br>национальных<br>стандартов                                                   | Международные Стандарты:                                                                                                                                                                       |                                                                                                                                                                                                                               |
|                                                                                                                                                                            | <b>Системы обеспечения качества / Quality Systems</b>                                                                                                                                          |                                                                                                                                                                                                                               |
|                                                                                                                                                                            | BS EN ISO 13485:2012                                                                                                                                                                           | Медицинские изделия – Системы управления качеством – Требования для целей регулирования / Medical devices - Quality management systems - Requirements regulatory purposes                                                     |
|                                                                                                                                                                            | BS EN ISO 14971:2012                                                                                                                                                                           | Медицинские изделия – Применение процедуры управления рисками к медицинским изделиям / Medical Devices – Application of risk management to medical devices.                                                                   |
|                                                                                                                                                                            | <b>Этикетка / Labeling</b>                                                                                                                                                                     |                                                                                                                                                                                                                               |
|                                                                                                                                                                            | BS EN ISO 15223-1:2012                                                                                                                                                                         | Медицинские изделия – Символы, используемые на этикетках медицинских изделий, маркировка и предоставляемая информация – Часть 1: Общие требования / Medical devices – Symbols to be used with medical device labels, labeling |

Предоставляется по требованию



Приложение к Инструкции по применению  
Название медицинского изделия

|  |                                            |                                                                                                                                                                                      |
|--|--------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  |                                            | and information to be supplied – Part 1: General requirements.                                                                                                                       |
|  | BS EN 1041:2008 + A1:2013                  | Информация, предоставляемая производителями медицинских изделий / Information supplied by the manufacturer with medical devices                                                      |
|  | IEC TR 60878:2003                          | Графические обозначения для электрооборудования медицинского назначения / Graphic Symbols for Electrical Equipment in Medical Practice                                               |
|  | AENOR UNE-EN 60417-1:2002                  | Графические обозначения, применяемые для оборудования - Часть 1: Обзор и применение / Graphical Symbols for Use on Equipment – Part 1: Overview and Application                      |
|  | <b>Биосовместимость / Biocompatibility</b> |                                                                                                                                                                                      |
|  | BS EN ISO 10993-1:2010                     | Биологическая оценка медицинских изделий – Часть 1: Оценка и испытания / Biological evaluation of medical devices – Part 1: Evaluation and testing                                   |
|  | BS EN ISO 10993-2:2006                     | Биологическая оценка медицинских изделий – Часть 2: требования по гуманному обращению с животными / Biological Evaluation of Medical Devices - Part 2: Animal Welfare Requirements   |
|  | BS EN ISO 10993-5:2009                     | Биологическая оценка медицинских изделий – Часть 5: Испытания цитотоксичности in vitro / Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity            |
|  | BS EN ISO 10993-7:2008                     | Биологическая оценка медицинских изделий – Часть 7: Остаточное содержание веществ при стерилизации этиленоксидом / Biological evaluation of medical devices – Part 7: Ethylene oxide |

Предоставляется по требованию

Приложение к Инструкции по применению  
Название медицинского изделия

|  |                                                                      |                                                                                                                                                                                                                  |
|--|----------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  |                                                                      | sterilization residuals                                                                                                                                                                                          |
|  | BS EN ISO 10993-10:2010                                              | Биологическая оценка медицинских изделий – Часть 10: Испытания раздражающего действия и кожной сенсибилизации / Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization |
|  | BS EN ISO 10993-11:2006                                              | Биологическая оценка медицинских изделий – Часть 11: Испытания системной токсичности / Biological evaluation of medical devices Part 11: Tests for systemic toxicity                                             |
|  | BS EN ISO 10993-12:2012                                              | Биологическая оценка медицинских изделий – Часть 12: Подготовка образцов и эталонные материалы / Biological evaluation of medical devices Part 12: Sample preparation and reference materials                    |
|  | BS EN ISO 10993-18:2005                                              | Биологическая оценка медицинских изделий – Часть 18: Химическая характеристика материалов / Biological evaluation of medical devices Part 18: Chemical characterization of materials                             |
|  | BS EN 556-1:2001                                                     | Стерилизация медицинских изделий – Требования к медицинским изделиям отмеченным как «СТЕРИЛЬНЫЕ» / Sterilization of Medical Devices – Requirements for medical devices to be designated “STERILE”                |
|  | <b>Очистка / повторная стерилизация / Cleaning / Resterilization</b> |                                                                                                                                                                                                                  |
|  | BS EN ISO 17664:2004                                                 | Стерилизация медицинских изделий – Информация, предоставляемая производителем, об обработке изделий, подлежащих повторной стерилизации / Sterilization of medical                                                |

Предоставляется по требованию

Приложение к Инструкции по применению  
Название медицинского изделия

|  |                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|--|-------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  |                                                             | devices -- Information to be provided by the manufacturer for the processing of resterilizable medical devices                                                                                                                                                                                                                                                                                                                                                                                                                  |
|  | Электрическая безопасность, прочее / Electric Safety, other |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|  | <b>IEC 60529:2013</b>                                       | Степени защиты, обеспечиваемые корпусами (код IP) – редакция 2.2 / Degrees of Protection Provided by Enclosures (IP Code) – Edition 2.2                                                                                                                                                                                                                                                                                                                                                                                         |
|  | <b>IEC 60601-1-6: 2013</b>                                  | Электрическое оборудование медицинского назначения – Часть 1-6: Общие требования к основной безопасности и главным показателям производительности – Вспомогательный стандарт: применимость – редакция 3.1 / Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability - Edition 3.1                                                                                                                                                             |
|  | <b>BS EN 60601-1 + A12:2006</b>                             | Электрическое оборудование медицинского назначения – Часть 1: Общие требования к основной безопасности и главным показателям производительности Поправка: 31 мая 2011 г.; Изменение: 29 февраля 2012 г.; Изменение: 31 декабря 2013 г.; Поправка: 30 ноября 2014 г.; Изменение: 30 ноября 2014г. / Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - CORR: May 31, 2011; AMD: February 29, 2012; AMD: December 31, 2013; CORR: November 30, 2014; AMD: November 30, 2014 |
|  | <b>BS EN 60601-1-2:2007</b>                                 | Электрическое оборудование медицинского назначения – Часть 1-2: Общие требования к основной безопасности и главным показателям производительности – Вспомогательный стандарт: электромагнитная                                                                                                                                                                                                                                                                                                                                  |

Предоставляется по требованию

Приложение к Инструкции по применению  
Название медицинского изделия

|                                                                                                                             |                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-----------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                             |                                           | совместимость – Требования и испытания – Поправка: 31 июля 2010 г. / Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests - CORR: July 31, 2010                                                                                                                                                                                                            |
|                                                                                                                             | <b>BS EN 61000-4-3:2006 + A2:3.2010</b>   | Электромагнитная совместимость (ЭМС) – Часть 4-3: Испытания и способы измерения – Испытание устойчивости к воздействию излучаемого, радиочастотного и электромагнитного поля – Изменение: 30 мая 2008 г.; Поправка: 31 октября 2009 г.; Изменение: 31 август 2010 г. / Electromagnetic compatibility (EMC) - Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test - AMD: May 30, 2008; CORR: October 31, 2009; AMD: August 31, 2010 |
|                                                                                                                             | <b>IEC 61000-4-6, Edition 4.0 2013-10</b> | Электромагнитная совместимость (ЭМС) – Часть 4-3: Испытания и способы измерения – Устойчивость к кондуктивным помехам, вызываемым радиочастотными полями – редакция 4.0 / Electromagnetic compatibility (EMC) – Part 4-6: Testing and measurement techniques – Immunity to conducted disturbances, induced by radio-frequency fields - Edition 4.0                                                                                                                                           |
| 13. Информация о стерильном состоянии медицинского изделия, методе его стерилизации и о порядке действий в случае нарушения | <b>Медицинское изделие не стерильно</b>   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |

Предоставляется по требованию

Приложение к Инструкции по применению  
Название медицинского изделия

| стерильной упаковки                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                           |                                                         |                                                                   |                                                                          |  |  |      |                                                            |                                                           |                                                         |                                                                   |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                            |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |  |  |      |  |  |                         |  |  |      |  |                           |  |  |          |  |                                                                       |  |  |         |  |         |  |  |               |  |                                         |                                                                                   |                              |                                                          |                                                                                                                                                                                                                                                                                                |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------|---------------------------------------------------------|-------------------------------------------------------------------|--------------------------------------------------------------------------|--|--|------|------------------------------------------------------------|-----------------------------------------------------------|---------------------------------------------------------|-------------------------------------------------------------------|--------------------------------------------------------------------------|-------------|--------|--------|--------|--------|--------|-------|--------|--------|-------|--------|-------|-------|------------------------------------------------------------|--|--|--|--|----------------------------------------------------------------|--|--|--|--|--|---------------------------|-----------------------------------------------------------|--|--|--|--|--------------|-------------|--|--|------|--|--|-------------------------|--|--|------|--|---------------------------|--|--|----------|--|-----------------------------------------------------------------------|--|--|---------|--|---------|--|--|---------------|--|-----------------------------------------|-----------------------------------------------------------------------------------|------------------------------|----------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 14. Информация о порядке обработки медицинского изделия для его повторного использования, включая очистку, дезинфекцию, упаковку и при необходимости метод повторной стерилизации (если медицинское изделие предназначено для многократового использования), а также критерии непригодности медицинского изделия для применения; | <p>Указанные ниже параметры стерилизации должны применяться для стерилизации устройств в полностью разобранном виде, если разборка возможна. После стерилизации применяйте стандартные стерильные способы сборки устройств, чтобы сохранить стерильность инструментов. Валидацию прошли все циклы паровой стерилизации инструментария в обертке, при этом инструменты можно стерилизовать как в обертке, так и без нее</p> <table><tr><th colspan="6">Стерилизация паром</th></tr><tr><th>Цикл</th><th>Паровая стерилизация с гравитационным вытеснением воздуха*</th><th>Паровая стерилизация с гравитационным вытеснением воздуха</th><th>Паровая стерилизация с предварительной откачкой воздуха</th><th>Паровая стерилизация с предварительной откачкой воздуха (Франция)</th><th>Паровая стерилизация с предварительной откачкой воздуха (Великобритания)</th></tr><tr><td>Температура</td><td>121 °C</td><td>132 °C</td><td>132 °C</td><td>134 °C</td><td>134 °C</td></tr><tr><td>Время</td><td>40 мин</td><td>15 мин</td><td>4 мин</td><td>18 мин</td><td>3 мин</td></tr><tr><td>Сушка</td><td colspan="5">25 минут или до появления визуальных признаков высушивания</td></tr><tr><td colspan="6">Параметры стерилизации 100 % этиленоксидом (заданные значения)</td></tr><tr><td>Предварительная обработка</td><td colspan="5">При температуре 54°C, относительной влажности 60%, 60 мин</td></tr><tr><td>Стерилизация</td><td colspan="3">Температура</td><td colspan="2">54°C</td></tr><tr><td rowspan="4"></td><td colspan="3">Относительная влажность</td><td colspan="2">60 %</td></tr><tr><td colspan="3">Концентрация этиленоксида</td><td colspan="2">725 мг/л</td></tr><tr><td colspan="3">Время воздействия газа (полный цикл) / Gas exposure time (full-cycle)</td><td colspan="2">120 мин</td></tr><tr><td colspan="3">Аэрация</td><td colspan="2">54°C, 8 часов</td></tr></table> <table><tr><td>Защита от загрязнений и транспортировка</td><td>Рекомендуется выполнять обработку инструментов немедленно после их использования.</td></tr><tr><td>Подготовка к обеззараживанию</td><td>Извлеките бор из рукоятки, другая разборка не требуется.</td></tr></table> <p>Очистка Автоматизированные методы (НЕ используйте ультразвуковой моечный аппарат)</p> <table><tr><td><ul style="list-style-type: none"><li>• Извлеките инструменты и оборудование из лотков для инструментов.</li><li>• Используйте щелочные моющие средства (pH ≤ 10,5) или средства с нейтральным pH.</li><li>• Не погружайте рукоятку в жидкость. <b>Инструкции по предварительной</b></li></ul></td></tr></table> | Стерилизация паром                                        |                                                         |                                                                   |                                                                          |  |  | Цикл | Паровая стерилизация с гравитационным вытеснением воздуха* | Паровая стерилизация с гравитационным вытеснением воздуха | Паровая стерилизация с предварительной откачкой воздуха | Паровая стерилизация с предварительной откачкой воздуха (Франция) | Паровая стерилизация с предварительной откачкой воздуха (Великобритания) | Температура | 121 °C | 132 °C | 132 °C | 134 °C | 134 °C | Время | 40 мин | 15 мин | 4 мин | 18 мин | 3 мин | Сушка | 25 минут или до появления визуальных признаков высушивания |  |  |  |  | Параметры стерилизации 100 % этиленоксидом (заданные значения) |  |  |  |  |  | Предварительная обработка | При температуре 54°C, относительной влажности 60%, 60 мин |  |  |  |  | Стерилизация | Температура |  |  | 54°C |  |  | Относительная влажность |  |  | 60 % |  | Концентрация этиленоксида |  |  | 725 мг/л |  | Время воздействия газа (полный цикл) / Gas exposure time (full-cycle) |  |  | 120 мин |  | Аэрация |  |  | 54°C, 8 часов |  | Защита от загрязнений и транспортировка | Рекомендуется выполнять обработку инструментов немедленно после их использования. | Подготовка к обеззараживанию | Извлеките бор из рукоятки, другая разборка не требуется. | <ul style="list-style-type: none"><li>• Извлеките инструменты и оборудование из лотков для инструментов.</li><li>• Используйте щелочные моющие средства (pH ≤ 10,5) или средства с нейтральным pH.</li><li>• Не погружайте рукоятку в жидкость. <b>Инструкции по предварительной</b></li></ul> |
| Стерилизация паром                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                           |                                                         |                                                                   |                                                                          |  |  |      |                                                            |                                                           |                                                         |                                                                   |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                            |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |  |  |      |  |  |                         |  |  |      |  |                           |  |  |          |  |                                                                       |  |  |         |  |         |  |  |               |  |                                         |                                                                                   |                              |                                                          |                                                                                                                                                                                                                                                                                                |
| Цикл                                                                                                                                                                                                                                                                                                                             | Паровая стерилизация с гравитационным вытеснением воздуха*                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | Паровая стерилизация с гравитационным вытеснением воздуха | Паровая стерилизация с предварительной откачкой воздуха | Паровая стерилизация с предварительной откачкой воздуха (Франция) | Паровая стерилизация с предварительной откачкой воздуха (Великобритания) |  |  |      |                                                            |                                                           |                                                         |                                                                   |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                            |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |  |  |      |  |  |                         |  |  |      |  |                           |  |  |          |  |                                                                       |  |  |         |  |         |  |  |               |  |                                         |                                                                                   |                              |                                                          |                                                                                                                                                                                                                                                                                                |
| Температура                                                                                                                                                                                                                                                                                                                      | 121 °C                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 132 °C                                                    | 132 °C                                                  | 134 °C                                                            | 134 °C                                                                   |  |  |      |                                                            |                                                           |                                                         |                                                                   |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                            |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |  |  |      |  |  |                         |  |  |      |  |                           |  |  |          |  |                                                                       |  |  |         |  |         |  |  |               |  |                                         |                                                                                   |                              |                                                          |                                                                                                                                                                                                                                                                                                |
| Время                                                                                                                                                                                                                                                                                                                            | 40 мин                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 15 мин                                                    | 4 мин                                                   | 18 мин                                                            | 3 мин                                                                    |  |  |      |                                                            |                                                           |                                                         |                                                                   |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                            |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |  |  |      |  |  |                         |  |  |      |  |                           |  |  |          |  |                                                                       |  |  |         |  |         |  |  |               |  |                                         |                                                                                   |                              |                                                          |                                                                                                                                                                                                                                                                                                |
| Сушка                                                                                                                                                                                                                                                                                                                            | 25 минут или до появления визуальных признаков высушивания                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                           |                                                         |                                                                   |                                                                          |  |  |      |                                                            |                                                           |                                                         |                                                                   |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                            |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |  |  |      |  |  |                         |  |  |      |  |                           |  |  |          |  |                                                                       |  |  |         |  |         |  |  |               |  |                                         |                                                                                   |                              |                                                          |                                                                                                                                                                                                                                                                                                |
| Параметры стерилизации 100 % этиленоксидом (заданные значения)                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                           |                                                         |                                                                   |                                                                          |  |  |      |                                                            |                                                           |                                                         |                                                                   |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                            |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |  |  |      |  |  |                         |  |  |      |  |                           |  |  |          |  |                                                                       |  |  |         |  |         |  |  |               |  |                                         |                                                                                   |                              |                                                          |                                                                                                                                                                                                                                                                                                |
| Предварительная обработка                                                                                                                                                                                                                                                                                                        | При температуре 54°C, относительной влажности 60%, 60 мин                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                           |                                                         |                                                                   |                                                                          |  |  |      |                                                            |                                                           |                                                         |                                                                   |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                            |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |  |  |      |  |  |                         |  |  |      |  |                           |  |  |          |  |                                                                       |  |  |         |  |         |  |  |               |  |                                         |                                                                                   |                              |                                                          |                                                                                                                                                                                                                                                                                                |
| Стерилизация                                                                                                                                                                                                                                                                                                                     | Температура                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                           |                                                         | 54°C                                                              |                                                                          |  |  |      |                                                            |                                                           |                                                         |                                                                   |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                            |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |  |  |      |  |  |                         |  |  |      |  |                           |  |  |          |  |                                                                       |  |  |         |  |         |  |  |               |  |                                         |                                                                                   |                              |                                                          |                                                                                                                                                                                                                                                                                                |
|                                                                                                                                                                                                                                                                                                                                  | Относительная влажность                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                           |                                                         | 60 %                                                              |                                                                          |  |  |      |                                                            |                                                           |                                                         |                                                                   |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                            |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |  |  |      |  |  |                         |  |  |      |  |                           |  |  |          |  |                                                                       |  |  |         |  |         |  |  |               |  |                                         |                                                                                   |                              |                                                          |                                                                                                                                                                                                                                                                                                |
|                                                                                                                                                                                                                                                                                                                                  | Концентрация этиленоксида                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                           |                                                         | 725 мг/л                                                          |                                                                          |  |  |      |                                                            |                                                           |                                                         |                                                                   |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                            |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |  |  |      |  |  |                         |  |  |      |  |                           |  |  |          |  |                                                                       |  |  |         |  |         |  |  |               |  |                                         |                                                                                   |                              |                                                          |                                                                                                                                                                                                                                                                                                |
|                                                                                                                                                                                                                                                                                                                                  | Время воздействия газа (полный цикл) / Gas exposure time (full-cycle)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                           |                                                         | 120 мин                                                           |                                                                          |  |  |      |                                                            |                                                           |                                                         |                                                                   |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                            |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |  |  |      |  |  |                         |  |  |      |  |                           |  |  |          |  |                                                                       |  |  |         |  |         |  |  |               |  |                                         |                                                                                   |                              |                                                          |                                                                                                                                                                                                                                                                                                |
|                                                                                                                                                                                                                                                                                                                                  | Аэрация                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                           |                                                         | 54°C, 8 часов                                                     |                                                                          |  |  |      |                                                            |                                                           |                                                         |                                                                   |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                            |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |  |  |      |  |  |                         |  |  |      |  |                           |  |  |          |  |                                                                       |  |  |         |  |         |  |  |               |  |                                         |                                                                                   |                              |                                                          |                                                                                                                                                                                                                                                                                                |
| Защита от загрязнений и транспортировка                                                                                                                                                                                                                                                                                          | Рекомендуется выполнять обработку инструментов немедленно после их использования.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                           |                                                         |                                                                   |                                                                          |  |  |      |                                                            |                                                           |                                                         |                                                                   |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                            |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |  |  |      |  |  |                         |  |  |      |  |                           |  |  |          |  |                                                                       |  |  |         |  |         |  |  |               |  |                                         |                                                                                   |                              |                                                          |                                                                                                                                                                                                                                                                                                |
| Подготовка к обеззараживанию                                                                                                                                                                                                                                                                                                     | Извлеките бор из рукоятки, другая разборка не требуется.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                           |                                                         |                                                                   |                                                                          |  |  |      |                                                            |                                                           |                                                         |                                                                   |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                            |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |  |  |      |  |  |                         |  |  |      |  |                           |  |  |          |  |                                                                       |  |  |         |  |         |  |  |               |  |                                         |                                                                                   |                              |                                                          |                                                                                                                                                                                                                                                                                                |
| <ul style="list-style-type: none"><li>• Извлеките инструменты и оборудование из лотков для инструментов.</li><li>• Используйте щелочные моющие средства (pH ≤ 10,5) или средства с нейтральным pH.</li><li>• Не погружайте рукоятку в жидкость. <b>Инструкции по предварительной</b></li></ul>                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                           |                                                         |                                                                   |                                                                          |  |  |      |                                                            |                                                           |                                                         |                                                                   |                                                                          |             |        |        |        |        |        |       |        |        |       |        |       |       |                                                            |  |  |  |  |                                                                |  |  |  |  |  |                           |                                                           |  |  |  |  |              |             |  |  |      |  |  |                         |  |  |      |  |                           |  |  |          |  |                                                                       |  |  |         |  |         |  |  |               |  |                                         |                                                                                   |                              |                                                          |                                                                                                                                                                                                                                                                                                |

Предоставляется по требованию



Приложение к Инструкции по применению  
Название медицинского изделия

| <p><b>очистке перед автоматической мойкой с помощью нейтрального моющего средства</b></p> <ul style="list-style-type: none"> <li>Вручную ополосните рукоятку, кабель и зажимы для трубок под струей водопроводной воды, чтобы удалить с устройства все видимые загрязнения. С помощью щетки с мягкой щетиной и раствора нейтрального моющего средства осторожно и тщательно прочистите весь просвет устройства. Во время ополаскивания запустите зажимной патрон и поверните дисковый переключатель. При ополаскивании держите рукоятку зажимным патроном вниз. Промойте струей воды аспирационное отверстие.</li> <li>Разместите устройства в моечной машине зажимным патроном вниз, чтобы обеспечить свободное стекание с них воды.</li> </ul> |                   |                             |                                                                                               |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|-----------------------------|-----------------------------------------------------------------------------------------------|
| <p><b>Автоматическая мойка с помощью нейтрального ферментативного моющего средства</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                   |                             |                                                                                               |
| Фаза                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Минимальное время | Температура                 | Моющее средство                                                                               |
| Замачивание 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 02:00             | Холодная водопроводная вода | Неприменимо                                                                                   |
| Мойка ферментативным раствором                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 05:00             | < 50° C                     | Ферментативное моющее средство с нейтральным pH в рекомендованной производителем концентрации |
| Ополаскивание 1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 01:00             | Горячая водопроводная вода  | Неприменимо                                                                                   |
| Термическое ополаскивание                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 01:00             | не менее 82 °C              | Неприменимо                                                                                   |
| Визуально проверьте на предмет чистоты.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                   |                             |                                                                                               |
| <p><b>Инструкции по предварительной очистке перед автоматической мойкой с помощью щелочного моющего средства</b></p> <ul style="list-style-type: none"> <li>Вручную ополосните рукоятку, кабель и зажимы для трубок под струей водопроводной воды, чтобы удалить с устройства все видимые загрязнения. С помощью щетки с мягкой щетиной и раствора нейтрального моющего средства</li> </ul>                                                                                                                                                                                                                                                                                                                                                      |                   |                             |                                                                                               |

Предоставляется по требованию

Приложение к Инструкции по применению  
Название медицинского изделия

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                 |                                      |                                               |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|--------------------------------------|-----------------------------------------------|
| <p>осторожно и тщательно прочистите весь просвет устройства. Во время ополаскивания запустите зажимной патрон и поверните дисковый переключатель. При ополаскивании держите рукоятку зажимным патроном вниз. Промойте струей воды аспирационное отверстие. • Разместите устройства в моечной машине зажимным патроном вниз, чтобы обеспечить свободное стекание с них воды.</p>                                                                                                                                                                                                                                                                                     |                                 |                                      |                                               |
| <p><b>Автоматическая мойка с помощью щелочного моющего средства</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                 |                                      |                                               |
| <p><b>Фаза</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <p><b>Минимальное время</b></p> | <p><b>Температура</b></p>            | <p><b>Моющее средство</b></p>                 |
| <p><b>Замачивание 1</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <p>02:00</p>                    | <p>Холодная водопроводная вода</p>   | <p>Неприменимо</p>                            |
| <p><b>Мойка 1</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <p>05:00</p>                    | <p>66 °C<br/>(заданное значение)</p> | <p>Щелочное моющее средство<br/>pH ≤ 10,5</p> |
| <p><b>Ополаскивание 1</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <p>01:00</p>                    | <p>Горячая водопроводная вода</p>    | <p>Неприменимо</p>                            |
| <p><b>Термическое ополаскивание</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <p>01:00</p>                    | <p>не менее 82 °C</p>                | <p>Неприменимо</p>                            |
| <p>Визуально проверьте на предмет чистоты.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                 |                                      |                                               |
| <p><b>Очистка Ручные методы</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                 |                                      |                                               |
| <ul style="list-style-type: none"> <li>• Извлеките инструменты и оборудование из лотков для инструментов.</li> <li>• Не погружайте рукоятку в жидкость.</li> <li>• Протрите рукоятку и кабель чистой мягкой тканью, смоченной нейтральным моющим средством.</li> <li>• Вручную ополосните рукоятку, кабель и зажимы для трубок под струей водопроводной воды, чтобы удалить с устройства все видимые загрязнения. При ополаскивании держите рукоятку зажимным патроном вниз. Промойте струей воды аспирационное отверстие.</li> <li>• Для разрыхления и удаления из инструмента скопившихся тканей используйте раствор ферментативного моющего средства.</li> </ul> |                                 |                                      |                                               |

Предоставляется по требованию

Приложение к Инструкции по применению  
Название медицинского изделия

|                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                             |                                                                   |                  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|-------------------------------------------------------------------|------------------|
|                                                                                                                                                                                                    | <ul style="list-style-type: none"><li>• Протрите электродвигатель и кабель с помощью мягкой ткани, смоченной в растворе ферментативного моющего средства. Осторожно протрите рукоятку, кабель и зажимы для трубок с помощью щетки с мягкой щетиной, смоченной в ферментативном моющем средстве. С помощью щетки с мягкой щетиной осторожно и тщательно прочистите весь просвет устройства. Во время очистки запустите зажимной патрон и поверните дисковый переключатель. С помощью щетки тщательно очистите зажимы для трубок.</li><li>• Вручную ополосните рукоятку, кабель и зажимы для трубок под струей водопроводной воды, чтобы удалить с устройства все видимые загрязнения.</li><li>• Удерживая рукоятку зажимным патроном вниз, тщательно ополосните просвет.*</li></ul> <p>* Дополнительные инструкции по очистке микродебридера XPS StraightShot M5/M4/спинального шейвера.</p> <ul style="list-style-type: none"><li>• Во время обычного цикла очистки пропустите слабый поток теплой воды в зажимной патрон (передний конец) и в запорный рычаг StraightShot M4/спинального шейвера.</li><li>• При попадании теплой воды в зажимной патрон выполните несколько оборотов механизма (вращайте колесо), а при попадании воды в запорный рычаг несколько раз задействуйте его (зажимая и отжимая рычаг).</li><li>• Вытряхните остатки воды из рукоятки.</li><li>• МЕРА ПРЕОСТОРОЖНОСТИ. На этой дополнительной фазе очистки поток теплой воды должен быть очень слабым.</li></ul> |                             |                                                                   |                  |
|                                                                                                                                                                                                    | <p><b>Сушка и смазка</b></p> <ul style="list-style-type: none"><li>• Протрите насухо наконечник и кабель безворсовым полотенцем. Убедитесь в том, что электрические разъемы на концах кабеля сухие.</li><li>• Распылите небольшое количество силиконового спрея на передний зажимной патрон и наружный конец рукоятки.</li><li>• Сразу же после очистки простерилизуйте рукоятку.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                             |                                                                   |                  |
|                                                                                                                                                                                                    | <p><b>Дезинфекция</b></p> <p>Не выдерживайте в низкотемпературном растворе глютаральдегида.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                             |                                                                   |                  |
| 15. Информация, необходимая для идентификации медицинских изделий с целью получения безопасной комбинации, и информация об известных ограничениях по совместному использованию медицинских изделий | <p><b>Возможность и способы интеграции с другими медицинскими изделиями</b></p> <p>Микродебридер Straightshot M5 предназначен для использования с системой IPC. Используйте только компоненты системы производства компании «Медтроник»; использование других компонентов может привести к повреждениям или ухудшению производительности.</p> <p>Микродебридер Straightshot M5 работает с:</p> <table><tr><td>Высокооборотными борами 30К</td></tr><tr><td>ЭМ лезвиями заводской калибровки для навигационной станции Fusion</td></tr><tr><td>Лезвиями Quadcut</td></tr></table>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Высокооборотными борами 30К | ЭМ лезвиями заводской калибровки для навигационной станции Fusion | Лезвиями Quadcut |
| Высокооборотными борами 30К                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                             |                                                                   |                  |
| ЭМ лезвиями заводской калибровки для навигационной станции Fusion                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                             |                                                                   |                  |
| Лезвиями Quadcut                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                             |                                                                   |                  |
| 16. Информация о природе,                                                                                                                                                                          | <p><b>Не применимо</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                             |                                                                   |                  |

Предоставляется по требованию

Приложение к Инструкции по применению  
Название медицинского изделия

|                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>типе, а также (при необходимости) об интенсивности и распределении излучения (электромагнитное, ионизирующее, иное) медицинского изделия и способах защиты потребителей и третьих лиц от непреднамеренного излучения в процессе эксплуатации медицинского изделия</p>                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <p>17. Информация о мерах предосторожности, предпринимаемых в случае:</p> <p>а) Неисправности медицинского изделия, сбоя в его работе или отклонений в функционировании, которые могут влиять на безопасность медицинского изделия, в том числе определяемых по внешним признакам;</p> <p>б) Воздействия на функционирование медицинского изделия внешних факторов, связанных с применением медицинского изделия в</p> | <p><b>МЕРЫ ПРЕДОСТОРОЖНОСТИ</b></p> <p>R2 Для предотвращения повреждения изогнутых инструментов необходимо отсоединить аспирационную трубку, прежде чем менять инструмент в ходе операции.</p> <p>R3 При работе с угловой насадкой держите узел рукоятки за насадку, чтобы она случайно не выпала из рукоятки.</p> <p>R8 Запрещается перегибать кабели. Следует проверять кабели и штырьки разъемов на предмет отсутствия трещин, следов износа или коррозии.</p> <p>R11 Применение мойки-дезинфектора эндоскопов может привести к преждевременному ухудшению рабочих характеристик.</p> <p>R12 Прежде чем помещать устройства в мойку-дезинфектор эндоскопов, их нужно извлечь из футляра для инструментов, затем им надо дать обсохнуть.</p> <p>R13 Устройства должны размещаться в мойке-дезинфекторе эндоскопов с соблюдением ориентации, рекомендованной производителем.</p> <p>R14 Из-за ограниченного внутреннего диаметра просвета и длины трубки <b>ЗАПРЕЩАЕТСЯ</b> применять стерилизацию в низкотемпературной газовой плазме перекиси водорода.</p> <p>R15 <b>ЗАПРЕЩАЕТСЯ</b> стерилизовать в низкотемпературной жидкой надуксусной кислоте, так как эта процедура включает погружение.</p> <p>R17 Выведение из эксплуатации и утилизация насадок должны осуществляться в соответствии с местными нормативными актами, регулирующими утилизацию зараженных материалов.</p> <p>R19 Очистка электродвигателя и кабеля выполняется без отсоединения их друг от друга. Это снижает вероятность попадания загрязнений внутрь электродвигателя.</p> <p>R20 Разрешается использовать <b>ТОЛЬКО</b> рекомендованные чистящие средства.</p> <p>R23 При использовании У-образного делителя сигнала одновременно может быть активна только одна многофункциональная ножная педаль.</p> <p>R24 Одновременно можно использовать только один У-образный делитель сигнала.</p> <p>R25 Убедитесь, что лезвие или бор полностью установлены в микродебридер. Для</p> |

Предоставляется по требованию

Приложение к Инструкции по применению  
Название медицинского изделия

|                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>комбинации с другими медицинскими изделиями и (или) оборудованием, или таких предсказуемых факторов, как внешние электромагнитные поля, электростатические разряды, излучение (электромагнитное, ионизирующее, иное), атмосферное давление и его перепады, влажность и температура воздуха;</p>                                       | <p>лезвий: перед использованием убедитесь, что кончик полностью контактирует с внешней канюлей.</p> <ul style="list-style-type: none"> <li>• Перед очисткой отсоединяйте шнур питания от сети.</li> <li>• Не погружайте этот инструмент полностью в жидкость и не выполняйте ультразвуковую чистку.</li> <li>• Не выполняйте стерилизацию в низкотемпературном растворе глютаральдегида. В противном случае гарантия будет аннулирована.</li> <li>• Не используйте органические растворители для чистки зажимного устройства бора.</li> <li>• При очистке рукоятки Microdebrider закройте разъем кабеля рукоятки одним из следующих колпачков для кабелей рукояток: <ul style="list-style-type: none"> <li>• Колпачок для очистки рукоятки, универсальный — номер по каталогу 3318520.</li> <li>• Использование 3318520 со StraightShot M5 является опциональным.</li> <li>• После завершения очистки снимайте колпачок кабеля</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <p>в) Риска электромагнитных помех, создаваемых медицинским изделием для других медицинских изделий, оборудования и средств связи при проведении и оценке результатов диагностики, лечения или его применении по назначению (например, электромагнитное излучение медицинского изделия, оказывающее влияние на другое оборудование);</p> | <p><b>Предупреждения, относящиеся к системе</b></p> <p>W1 Оператору системы IPC необходимо ознакомиться с руководством пользователя, содержащимися в нем мерами предосторожности, процедурами и сведениями по безопасности.</p> <p>W2 Запрещается пользоваться системой IPC в присутствии огнеопасных анестетиков. Следует избегать возможности воспламенения или взрыва газов.</p> <p>W3 Если рукоятка не используется, необходимо устранить возможность случайного срабатывания ножного управления. Во избежание непреднамеренного рассеечения ткани, кости или нерва следует контролировать усилие, прилагаемое к рукоятке, и скорость ее работы.</p> <p>W4 Во избежание общего поражения электрическим током следует отключать питание системы IPC перед очисткой.</p> <p>W5 Во избежание общего поражения электрическим током запрещается подсоединять к системе IPC не утвержденные производителем компоненты. W6 Во избежание поражения электрическим током необходимо надежно и правильно подключить заземление. Систему IPC следует подключать только к специализированным розеткам для больниц.</p> <p>W7 Это медицинское устройство соответствует требованиям стандарта безопасности EN 60601-1-2 к электромагнитной совместимости, электромагнитному излучению и прохождению контрольных испытаний. Тем не менее, если данное оборудование эксплуатируется в присутствии электромагнитных помех высокого уровня или высокочувствительного оборудования, возможно возникновение помех, и необходимо предпринять все необходимые меры по уменьшению помех или устранению их источника. Ухудшение рабочих характеристик может привести к увеличению продолжительности операции на пациенте под наркозом.</p> <p>W8 Медицинское электрооборудование требует особых мер предосторожности в отношении ЭМС и должно устанавливаться и вводиться в эксплуатацию с учетом сведений по ЭМС, приведенных в данном руководстве.</p> <p>W9 На работу медицинского электрооборудования может оказывать помехи портативное и мобильное РЧ коммуникационное оборудование.</p> <p>W10 Запрещается эксплуатировать систему IPC в присутствии устройств для магнитно-резонансной томографии.</p> <p>W11 Разрешается использовать только принадлежности и кабели, указанные и</p> |

Предоставляется по требованию



Приложение к Инструкции по применению  
Название медицинского изделия

|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>продаваемые корпорацией Medtronic. В противном случае возможно повышение излучения и снижение помехоустойчивости данного устройства.</p> <p>W12 Систему IPC нельзя использовать вблизи другого оборудования, ставить ее на другие устройства и использовать как подставку для других устройств. Если систему IPC необходимо разместить рядом с другим оборудованием, над или под ним, необходимо убедиться, что система нормально работает в предполагаемой конфигурации.</p> <p>W13 Запрещается запускать рукоятку системы IPC непосредственно после обработки в автоклаве. Нужно подождать, пока она остынет (обычно 1 час).</p> <p>W14 Перед работой с системой IPC следует прочитать вкладыш, прилагаемый к костной мельнице Legend.</p> <p>W15 Правила техники безопасности при рассечении металла.</p> <p>W15a Необходимо использовать средства защиты глаз.</p> <p>W15b Необходимо охлаждать режущие поверхности, тщательно промывая их.</p> <p>W15c Область раны должна быть защищена от металлических обрезков.</p> <p>W15d Подвижные фрагменты любого разрезаемого металлического компонента необходимо удерживать фиксатором или зажимом.</p> <p>W16 Запрещается работать с системой IPC без средств защиты глаз.</p> <p>W17 Все работы по техническому обслуживанию должны выполняться только квалифицированными специалистами корпорации Medtronic.</p> <p>W18 Работы по ремонту или модернизации системы IPC должны выполняться только квалифицированными специалистами сервисной службы. Иначе возможно значительное ухудшение рабочих характеристик устройства или аннулирование гарантии на оборудование.</p> <p><b>Предупреждения, относящиеся к компонентам</b></p> <p>W19 Запрещается использовать любые детали, кроме утвержденных компонентов системы Medtronic. Иначе возможно повреждение устройства или нарушение стандартных рабочих характеристик.</p> <p>W20 До и после работы следует осматривать устройство на предмет повреждения. В случае обнаружения повреждения запрещается использовать вышедшую из строя деталь, пока она не будет отремонтирована или заменена. Металлические стружки от поврежденных деталей могут попасть в операционное поле.</p> <p>W22 При использовании вращающихся инструментов с электроприводом следует прибегать к помощи визуализации, в том числе, к средствам формирования изображения (например, рентгеноскопии, эндовидеохирургии). Если визуализация операционного поля недостаточна, необходимо прервать работу с электроприводными инструментами.</p> <p>W24 При продолжительном использовании возможен выход из строя электродвигателя и насадок, детали которых могут отсоединиться и выпасть, причинив травму пациенту.</p> <p>W25 Перед началом работы электрические контакты должны быть сухими.</p> <p>W26 Интенсивные боковые нагрузки и/или длительное функционирование могут привести к перегреву устройства.</p> <p>W27 Не используйте перегретое устройство, поскольку это может привести к термической травме пациента или врача.</p> <p>W28 Применяйте надлежащую ирригацию. Применение инструмента без ирригации может привести к чрезмерному нагреву и термической травме ткани. В зависимости от объема ирригации температура сверл и лезвий пил может превысить 50 °C.</p> |
|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Предоставляется по требованию

Приложение к Инструкции по применению  
Название медицинского изделия

|                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                                                                                                             | <p>W29 Запрещается менять инструмент для препарирования, лезвия пилы или насадку во время работы электродвигателя, а также в случае перегрева электродвигателя или насадки.</p> <p>W30 Не погружайте компоненты системы в жидкость, за исключением особых указаний.</p> <p>W31 Во время хирургической операции запрещается класть электродвигатель, насадку или инструмент на пациента или неподготовленное место.</p> <p>W32 Запрещается использовать неправильно работающую систему до проведения всех необходимых ремонтных работ и последующего испытания на соответствие рабочих характеристик техническим требованиям корпорации Medtronic.</p> <p>W33 Номенклатура и цветовой код на упаковке инструмента и на насадке должны совпадать.</p> <p>W34 После каждой регулировки длины выступающей части инструмента необходимо убедиться, что насадка остается в заблокированном положении, поскольку попытка сильного увеличения длины выступающей части инструмента может привести к случайному разблокированию насадки.</p> <p>W36 Если насадка не зафиксирована, возможно появление дыма и/или перегрев насадки. Это может привести к термическому ожогу хирурга или персонала.</p> <p>W38 Во избежание нанесения рваных ран пользователю и перекрестного инфицирования через порванную перчатку ЗАПРЕЩАЕТСЯ менять насадку на включенной рукоятке.</p> <p>W40 ЗАПРЕЩАЕТСЯ изменять конструкцию инструментов, используемых с рукоятками. Изменение инструментов может привести к ухудшению рабочих характеристик.</p> <p>W42 Для обеспечения соответствия требованиям стандарта IEC 60601-1 необходимо использовать силовой кабель, утвержденный корпорацией Medtronic.</p> <p>W43 Во избежание поражения электрическим током данное оборудование необходимо подключать только к электрическим сетям с защитным заземлением.</p> <p>W45 Многоразовые устройства подлежат обязательной стерилизации перед каждым использованием. Запрещается использовать нестерилизованные устройства</p> |
| 18. Предупреждения и (или) меры предосторожности, предпринимаемые потребителем при применении медицинского изделия, содержащего лекарственное средство для медицинского применения, материал животного и (или) человеческого происхождения, | Не применимо                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |

Предоставляется по требованию

Приложение к Инструкции по применению  
Название медицинского изделия

|                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                     |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| материалы, которые являются канцерогенными, мутагенными или токсичными, возможное выделение или вымывание которых приводит к сенсibilизации, аллергической реакции или отрицательно влияет на репродуктивную функцию                                                                                          |                                                                                                                                                                     |
| 19. Предупреждения и (или) меры предосторожности, предпринимаемые потребителем при утилизации медицинского изделия, принадлежностей и расходных материалов, используемых вместе с ним (при наличии), включая сведения об инфекционной, микробной, экологической или физической опасности медицинского изделия | Выведение из эксплуатации и утилизация насадок должны осуществляться в соответствии с местными нормативными актами, регуливающими утилизацию зараженных материалов. |
| 20. Информация об обстоятельствах, при которых потребитель должен проконсультироваться с медицинским работником                                                                                                                                                                                               | Медицинское изделие предназначено для использования в лечебно-профилактических и медицинских учреждениях специально обученными, квалифицированными специалистами.   |
| 21. Информация о первоначально                                                                                                                                                                                                                                                                                | Информация отсутствует                                                                                                                                              |

Предоставляется по требованию

Приложение к Инструкции по применению  
Название медицинского изделия

|                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>м выпуске или последнем пересмотре эксплуатационной документации</b></p>      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <p><b>22. Порядок и условия утилизации или уничтожения медицинского изделия</b></p> | <p><b>Защита окружающей среды</b></p> <p>Требования к охране окружающей среды при применении медицинского устройства и порядок осуществления утилизации или уничтожения с указанием, при необходимости, особых мер предосторожности при уничтожении неиспользуемых медицинских изделий:</p> <p>Использование медицинских устройств должно осуществляться в зависимости от степени их эпидемиологической, токсикологической и радиационной опасности, а также от негативного воздействия на окружающую среду в соответствии с СанПиН 2.1.7.2790-10. Класс Б медицинских отходов в соответствии с СанПин 2.1.7.2790-10.</p> <p>Компания Medtronic рекомендует сжигание устройств, которые находились в непосредственном контакте с пациентами, имеющими предполагаемый или подтвержденный диагноз трансмиссивной губчатой энцефалопатии (ТГЭ) или болезни Крейтцфельда-Якоба (БКЯ).</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <p><b>23. Гарантийные обязательства</b></p>                                         | <p><b>ОГРАНИЧЕННАЯ ГАРАНТИЯ</b></p> <p>А. Данная ОГРАНИЧЕННАЯ ГАРАНТИЯ обеспечивает клиенту, который приобретает изделие производства компании «Медтроник Ксомед» (далее – «Изделие»), что в том случае, если изделие не будет работать в соответствии с опубликованными спецификациями компании «Медтроник Ксомед» в течение срока действия данной ОГРАНИЧЕННОЙ ГАРАНТИИ (один год со дня доставки нового изделия, 90 дней со дня доставки обновленного или бывшего в использовании изделия), то компания «Медтроник Ксомед» произведёт замену или ремонт изделия или вернет часть или всю стоимость изделия (в зависимости от срока использования изделия). Данная ОГРАНИЧЕННАЯ ГАРАНТИЯ распространяется только на покупателей, которые приобрели изделия непосредственно в компании «Медтроник Ксомед» или в её отделениях, или у уполномоченных дистрибуторов или представителей.</p> <p>В. Чтобы воспользоваться данной ОГРАНИЧЕННОЙ ГАРАНТИЕЙ, необходимо соблюдать указанные далее требования.</p> <ol style="list-style-type: none"> <li>1. Изделие должно использоваться не позднее даты «Использовать до», если применимо.</li> <li>2. Изделие должно использоваться в соответствии с указаниями на этикетке; запрещено вносить изменения в изделие, использовать его не по назначению, злоупотреблять им; следует также избегать случайного и неправильного использования изделия.</li> <li>3. При обнаружении дефекта необходимо уведомить об этом компанию «Медтроник Ксомед» в течение 30 (тридцати) дней.</li> <li>4. Изделие необходимо вернуть компании «Медтроник Ксомед» в течение тридцати 30 (тридцати) получения компанией уведомления, упомянутого в пункте (3).</li> <li>5. После осмотра изделия «Медтроник Ксомед», компания «Медтроник Ксомед» должна определить, что: (i) изделие не ремонтировалось и не изменялось никем, кроме компании «Медтроник Ксомед» или её уполномоченных представителей; (ii) изделие не использовалось в условиях, не соответствующих нормальному режиму работы; (iii) изделие регулярно обслуживалось в соответствии с рекомендациями.</li> </ol> <p>С. Данная ОГРАНИЧЕННАЯ ГАРАНТИЯ ограничивается указанным сроком. ДАННАЯ ОГРАНИЧЕННАЯ ГАРАНТИЯ ЗАМЕНЯЕТ СОБОЙ ВСЕ ДРУГИЕ ГАРАНТИИ, ЯВНО ВЫРАЖЕННЫЕ И КОСВЕННЫЕ, ЗАКОНОДАТЕЛЬНЫЕ И</p> |

Предоставляется по требованию

Приложение к Инструкции по применению  
Название медицинского изделия

|                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|----------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                | <p>ИНЫЕ, ВКЛЮЧАЯ ЛЮБЫЕ КОСВЕННЫЕ ГАРАНТИИ ПРИГОДНОСТИ ДЛЯ ПРОДАЖИ ИЛИ ПРИГОДНОСТИ ДЛЯ ОПРЕДЕЛЁННЫХ ЦЕЛЕЙ. Компания «Медтроник Ксомед» ни при каких обстоятельствах не несёт ответственности за любой косвенный, случайный, возможный или иной ущерб, вытекающий из дефектов, неисправностей или нарушений в работе изделия, независимо от того, на чём основано требование о компенсации такого ущерба, на гарантии, договоре, или вытекает из случая небрежности или иных причин.</p> <p>D. Указанные выше исключения и ограничения не предусматриваются (и не должны толковаться так таковые) для того, чтобы нарушать обязательные положения применимого законодательства. Пользователь может воспользоваться своими законными правами, предусмотренными законодательством в области потребительских товаров. Если компетентный суд признаёт какую-либо часть или положение данной ОГРАНИЧЕННОЙ ГАРАНТИИ незаконными, неприменимыми или противоречащими законодательству, это не отменяет остальных положений данной ОГРАНИЧЕННОЙ ГАРАНТИИ, а все права и обязанности должны толковаться и исполняться таким образом, как если бы данная ОГРАНИЧЕННАЯ ГАРАНТИЯ не содержала части или положения, которые были признаны недействительными.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| 24. Требования безопасности (включая методы и средства защиты) | <p>Не следует использовать какие-либо детали или компоненты производства не компании «Медтроник». Это может привести к повреждениям и потере производительности.</p> <p>Перед каждым использованием, а также после него следует проводить осмотр компонентов на предмет наличия повреждений. При обнаружении повреждений не использовать поврежденную деталь до ее ремонта или замены. Поврежденные детали могут оставить в операционном поле металлическую стружку.</p> <p>При длительном использовании электродвигателей или насадок они могут отказать, может произойти отсоединение компонентов и их падение, что может привести к травмированию пациента.</p> <p>Перед использованием изделия электрические контакты должны быть сухими.</p> <p>Устройство может перегреться из-за высоких боковых нагрузок и/или при длительной работе.</p> <p>Не использовать перегретое устройство, т.к. оно может обжечь пациента или оператора.</p> <p>Не следует погружать в жидкость компоненты системы, за исключением тех, для которых это предусмотрено.</p> <p>Во время проведения операции не следует оставлять электродвигатель, насадку или инструмент на пациенте, а также в незакрепленном месте.</p> <p>Неправильно функционирующая система не должна использоваться до тех пор, пока не будут проведен необходимый ремонт, а устройство не будет проверено на работоспособность в соответствии со спецификациями компании «Медтроник».</p> <p>В целях обеспечения соблюдения требований IEC 60601-1 следует использовать кабель питания, одобренный компанией «Медтроник».</p> <p>С целью недопущения риска поражения электрическим током оборудование должно подключаться к сети питания с защитным заземлением.</p> <p>Перед использованием многоразовых устройств следует проверить их стерилизацию. Не использовать, если не стерилизованы.</p> <p><b>Поиск и устранение общих неисправностей системы</b></p> |

Предоставляется по требованию



Приложение к Инструкции по применению  
Название медицинского изделия

- Помпа(-ы) не работает(-ют). Вышли из строя внутренние компоненты. Обратитесь в службу технической поддержки.
- Поток в системе ирригации слабый или отсутствует. Комплект трубок неправильно подключен к помпе. Поменяйте местами трубки помпы и убедитесь, что крышка полностью закрыта, а поток движется слева направо. Защемлена или перегнута трубка. Проверьте трубки сбоку помпы. См. раздел «Помпы для ирригации и охлаждающей жидкости». Проверьте остальную часть трубок на предмет защемления или перегиба. При необходимости замените трубки. Зажимы трубок ограничивают поток. Откройте зажимы трубки. Задано низкое значение скорости ирригационного потока. Отрегулируйте скорость ирригационного потока. Засорился ирригатор. Замените ирригатор.
- Ошибка из-за потери скорости помпы. Комплект трубок неправильно подключен к помпе. Поменяйте местами трубки помпы и убедитесь, что крышка полностью закрыта, а поток движется слева направо. Защемлена или перегнута трубка. Проверьте трубку сбоку помпы на защемление или перегиб (см. раздел «Помпы для ирригации и охлаждающей жидкости»).
- Микродебридер подсоединен, но на пульте управления отображается сообщение «Connect Handpiece» (Подключите рукоятку). Попадание влаги в кабель мешает распознаванию рукоятки. При стерилизации используйте сухой жар.
- Микродебридер подсоединен, но на пульте управления отображается другая рукоятка.
- Пульт управления не включается. Неправильно подсоединен шнур питания. Подсоедините шнур питания. Нет питания. Проверьте наличие питания (т. е. разветвитель питания включен, автоматический выключатель замкнут и т. д.). Сгорел предохранитель на входе питания. Вместо сгоревших установите новые замедленные предохранители на 5,00 А, 250 В (номер детали: 11270066 комплект плавких предохранителей 1898125). Вышли из строя внутренние компоненты. Обратитесь в службу технической поддержки.
- Лампочка включения питания горит, но на сенсорном экране нет изображения. Вышли из строя внутренние компоненты. Обратитесь в службу технической поддержки.
- Пульт управления не выключается. Вышел из строя выключатель питания. Отсоедините шнур питания от сети и обратитесь в службу технической поддержки.
- Сенсорный экран не реагирует на касание. Смещение прокладки экрана или выход из строя внутренних компонентов. Обратитесь в службу технической поддержки.
- Сенсорный экран работает неправильно. Сенсорный экран не откалиброван. Откалибруйте сенсорный экран.
- На пульте управления отображается неверный тип рукоятки или электродвигателя. Пульт управления неправильно определяет рукоятку или электродвигатель. Отсоедините и снова подсоедините кабель электродвигателя. Выключите и снова включите пульт управления. Замените электродвигатель, кабель электродвигателя или пульт управления, чтобы выявить неполадку. Попадание влаги в кабель мешает распознаванию рукоятки. При стерилизации используйте сухой жар.
- Кнопки или педаль модуля ножного управления не реагируют на нажатие. Неисправность У-образного делителя сигнала Отсоедините У-образный делитель сигнала и подсоедините МНУ непосредственно к РС. Неправильное использование модуля. Нажмите и удерживайте кнопки не менее 1 секунды, подождите пока не

Предоставляется по требованию

Приложение к Инструкции по применению  
Название медицинского изделия

|                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                     |                               |  |                |         |                       |         |                                   |  |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------|--|----------------|---------|-----------------------|---------|-----------------------------------|--|
|                                                                                     | <p>раздастся подтверждающий тональный сигнал пульта управления. Не реагирует верхняя кнопка. Подсоединена одна (1) рукоятка (верхняя кнопка не работает, когда подключена 1 рукоятка). Не полностью вставлен разъем. Отсоедините и снова подсоедините кабель модуля ножного управления. Попробуйте подключить другой модуль ножного управления или пульт управления, чтобы выявить неполадку. Вышли из строя внутренние компоненты. Обратитесь в службу технической поддержки.</p> <ul style="list-style-type: none"><li>• Рукоятка не вращается. Вышел из строя ножной переключатель. Отсоедините ножной переключатель и воспользуйтесь тумблером ручного пуска и остановки на задней панели пульта управления. Вышел из строя электродвигатель рукоятки или привод электродвигателя. Обратитесь в службу технической поддержки. Неправильно подсоединены кабели. Убедитесь, что кабель рукоятки подсоединен надлежащим образом. Повреждены кабели. Проверьте, нет ли трещин или разрывов на кабелях и не погнуты ли штырьки разъемов.</li><li>• Рукоятка слишком горячая, чтобы ее можно было касаться или держать. Лезвие, бор и/или насадка передает тепло рукоятке. Снимите и переустановите или замените лезвие, бор и/или насадку. Перед возобновлением использования убедитесь, что деталь установлена надлежащим образом. Недостаточная ирригация и/или охлаждение. Убедитесь в наличии достаточного потока жидкости для ирригации и/или охлаждения.</li></ul> |                                                                                     |                               |  |                |         |                       |         |                                   |  |
| 25. Служба работы с клиентами                                                       | <p><b>По всем вопросам, включая жалобы на продукцию, ремонт и техобслуживание, обращаться к Уполномоченному Представителю в Российской Федерации:</b></p> <p><b>ООО «Медтроник»</b><br/>123317, Российская Федерация, Москва,<br/>Пресненская набережная, 10<br/>Тел.: (495) 580-73-77, Факс: (495) 580-73-78,<br/><a href="http://www.medtronic.ru">www.medtronic.ru</a></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                     |                               |  |                |         |                       |         |                                   |  |
| 26. Информация на русскоязычном стикере                                             | <p>Для продажи на территории Российской Федерации финальная упаковка сопровождается дополнительным стикетром. Следующая информация должна быть нанесена на русскоязычном стикере (порядок слов и шрифт текста, могут изменяться):</p> <ul style="list-style-type: none"><li>• Название медицинского изделия на русском языке;</li><li>• Название завода производителя;</li><li>• Страна происхождения;</li><li>• Код UPN (уникальный код продукта);</li><li>• Код CFN (номер модели);</li><li>• Дата и номер Регистрационного удостоверения;</li><li>• Знак соответствия в России;</li><li>• Предупредительные и информирующие знаки и надписи (если применимо).</li></ul> <p><b>Образец стикера</b></p> <table><tr><td rowspan="4"></td><td colspan="2">Название медицинского изделия</td></tr><tr><td>Производитель:</td><td>Код UPN</td></tr><tr><td>Страна происхождения:</td><td>Код CFN</td></tr><tr><td colspan="2">Представитель производителя в РФ:</td></tr></table>                                                                                                                                                                                                                                                                                                                                                                                                       |  | Название медицинского изделия |  | Производитель: | Код UPN | Страна происхождения: | Код CFN | Представитель производителя в РФ: |  |
|  | Название медицинского изделия                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                     |                               |  |                |         |                       |         |                                   |  |
|                                                                                     | Производитель:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                     | Код UPN                       |  |                |         |                       |         |                                   |  |
|                                                                                     | Страна происхождения:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                     | Код CFN                       |  |                |         |                       |         |                                   |  |
|                                                                                     | Представитель производителя в РФ:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                     |                               |  |                |         |                       |         |                                   |  |

Предоставляется по требованию

Приложение к Инструкции по применению  
Название медицинского изделия

|                          |                                                                                     |                                                                                                                            |  |
|--------------------------|-------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|--|
|                          | Регистрационное Удостоверение № _____<br>от _____                                   |                                                                                                                            |  |
|                          | Дата<br>изгот./Серия/Годеи<br>до: см. упаковку                                      | См. Инструкцию<br>См. символы на<br>упаковке                                                                               |  |
|                          |                                                                                     |                                                                                                                            |  |
| 27. Обозначение символов | Символ                                                                              | Расшифровка                                                                                                                |  |
|                          |    | Номер по каталогу                                                                                                          |  |
|                          |    | Номер партии                                                                                                               |  |
|                          |    | Производитель                                                                                                              |  |
|                          |    | Нестерильно                                                                                                                |  |
|                          | Rx Only                                                                             | Внимание! Согласно федеральному закону США, реализация данного изделия производится только врачам или по предписанию врача |  |
|                          |   | Внимание                                                                                                                   |  |
|                          |  | См. инструкцию по применению                                                                                               |  |
|                          | SN                                                                                  | Серийный номер                                                                                                             |  |
|                          | x1                                                                                  | Количество                                                                                                                 |  |
|                          |  | Дата производства                                                                                                          |  |
|                          |  | Температурные пределы                                                                                                      |  |
|                          |  | Соответствует Директиве Совета ЕС MDD 93/42/ЕЕС                                                                            |  |
|                          |  | Утилизация с несортированными отходами запрещена                                                                           |  |

Предоставляется по требованию

[Перевод с английского языка на русский язык]

[На бланке компании «Медтроник Ксомед, Инк.»]

«Медтроник» (Medtronic)  
«Медтроник Ксомед, Инк.» (Medtronic Xomed Inc.)  
6743 Саутпойнт Драйв Норт  
Джексонвилл, Флорида 32216 США  
(6743 Southpoint Drive North  
Jacksonville, Florida, 32216 USA)  
www.medtronic.com  
тел. 800 874 5797

Хранитель документов:

/подпись/

Александра Оливер

Помощник специалиста по нормативно-правовому регулированию  
компании «Медтроник Ксомед, Инк.»

Дата: 16 августа 2017 г.

Приложение к Инструкции по применению  
Микродебридер StraightShot M5 с принадлежностями

УДОСТОВЕРЕНИЕ

ШТАТ ФЛОРИДА  
ОКРУГ ДУВАЛ

Сегодня, 16 августа 2017 г., я удостоверяю, что прилагаемый или предшествующий документ является верной, точной, полной и неизменной фотокопией, сделанной мною с документа «Приложение к Инструкции по применению», выпущенного компанией «Медтроник Ксомед, Инк.» и представленного мне хранителем документа, Александрой Оливер, а также, что, исходя из имеющейся у меня информации, оригинал документа, с которого сделана фотокопия, не носит публичного характера, не подлежит регистрации в публичных реестрах и не относится к документам, копии которых могут быть заверены определенными официальными органами, а не нотариусом.

Нотариус:

/подпись/

Официальная подпись нотариуса

Подписано под присягой в моем присутствии сегодня, 16 августа 2017 г.

[Штамп:

«Медтроник Ксомед, Инк.»  
6743 Саутпойнт Драйв Норт  
Джексонвилл, Флорида 32216-0980 США  
www.medtronic.com  
Тел.: 817-788-6400]

[Штамп:

Мишель Г Хьюз  
Нотариус – штат Флорида  
Моя лицензия действительна до 09 сентября 2017 г.  
Лицензия № FF 41831  
Профессиональная ответственность застрахована Национальной ассоциацией нотариусов]

2017 г.





[Далее следует текст документа «Приложение к Инструкции по применению. Микродебридер StraightShot M5 с принадлежностями», представленного на английском и русском языках.]

Перевод данного текста сделан мной, переводчиком Клепневым Виктором Игоревичем

**ПОДПИСЬ**

Российская Федерация

Город Москва

Двадцать девятого августа две тысячи семнадцатого года

Я, Акимов Глеб Борисович, нотариус города Москвы, свидетельствую подлинность подписи переводчика Клепнева Виктора Игоревича.

Подпись сделана в моем присутствии.

Личность подписавшего документ установлена.

Зарегистрировано в реестре: № 2-41/159

Взыскано государственной пошлины (по тарифу): 100 руб.

Уплачено за оказание услуг правового и технического характера: ---- руб.

**ПОДПИСЬ**

Г.Б. Акимов

Гербовая печать  
нотариуса г.Москвы  
Акимова Г.Б

Всего прошнуровано, пронумеровано  
и скреплено печатью 36 лист(а)(ов)

Нотариус

**ПОДПИСЬ**

Российская Федерация  
Город Москва

Двадцать девятого августа две тысячи семнадцатого года.

Я, Акимов Глеб Борисович, нотариус города Москвы, свидетельствую  
верность копии с представленного мне документа.

Зарегистрировано в реестре: № 2-41/160

Взыскано государственной пошлины (по тарифу): 300 руб. 00 коп.

Уплачено за оказание услуг правового и технического характера:  
руб. 00 коп.

Г.Б. Акимов

Всего прошито, пронумеровано, скреплено  
печатью 36 лист(а) (о в)

Нотариус