INSTRUCTION FOR USE

Radiation Attenuating Surgical Gloves NEWMARSGROUP

Version 2017.01

Content

1. Name of the device

Radiation Attenuating Surgical Gloves NEWMARSGROUP

of the following sizes: 6.5; 7; 7.5; 8; 8.5; 9

2. Information about the developer, manufacturer and authorized representative of the manufacturer

Developer

International Biomedical Ltd., USA
8206 Cross Park Drive, Austin, Texas 78754, USA
Tel.: +1(512)873-0033, Fax: +1(512)873-9090
E-mail: sales@int-bio.com
www.int-bio.com

Manufacturer

International Biomedical Ltd., USA
8206 Cross Park Drive, Austin, Texas 78754, USA
Tel.: +1(512)873-0033, Fax: +1(512)873-9090
E-mail: sales@int-bio.com
www.int-bio.com

Place of manufacture of the medical device
2725 North Main St., Cleburne, Texas 76033, USA

Authorized representative of the manufacturer in the Russian Federation

Limited Liability Company "Newmars Group Rus" (LLC "Newmars Group Rus")
Room 74, Building 1, House 111, Leninsky Avenue, Moscow, 119421, Russian Federation
Tel./Fax: +7(495)230-87-77; +7(495)189-07-77
E-mail: info@newmarsgroup.com

3. Purpose and application of the device.

The Radiation Attenuating Surgical Gloves NEWMARSGROUP are designed to protect medical personnel and the patient if there is a risk of infection upon direct contact with the patient.

In addition to their protective properties, the gloves were designed and manufactured in such a way that they attenuate potentially hazard radiation effects during procedures involving X-ray imaging.

The Radiation Attenuating Surgical Gloves NEWMARSGROUP should be used only in the environment of medical facilities, in X-ray operating rooms.

The Radiation Attenuating Surgical Gloves NEWMARSGROUP should be used only by trained medical personnel in accordance with the instruction for use.

4. Principle of operation and design.

Sterile, disposable, airtight gloves.

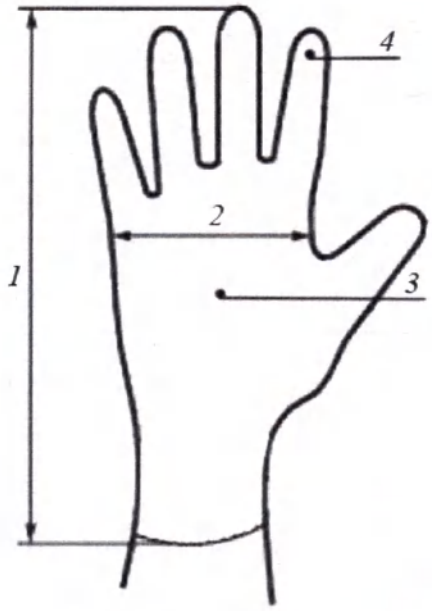
Type: the gloves are made of neoprene (chloroprene rubber) with the addition of tungsten powder that paints the gloves black. No dye is used in the manufacture.

Design: an anatomically correct glove with a thumb in the direction of the palm, the fingers are curved.

Finish: the surface is smooth, powder-free. The cuff of the glove is cut off.

As an agent for ease of donning, a lubricant consisting of a silicone emulsion and a lubricating substance is used.

Completeness: the gloves are supplied in pairs (left and right) in a sterile individual package.
Sizes: 6.5; 7; 7.5; 8; 8.5; 9



1. Glove Length;
2. Glove Width;
3. Palm Thickness;
4. Finger Thickness;

High elasticity of the gloves combined with an excellent anatomical fit provides optimal tactile sensitivity during surgeon's work.

The tungsten powder, as the component of the gloves, helps to attenuate the scattered radiation effects during radiographic procedures.

5. Indications, contraindications and potential side effects

Indications: Radiation Attenuating Surgical Gloves NEWMARSGROUP are used:
- during any surgery performed using a source of radiation;
- to protect medical personnel and the patient if there is a risk of infection upon direct contact with the patient (his body fluids), his mucous membranes, damaged skin, which are potentially or obviously contaminated by microorganisms.

Contraindications: there are no known contraindications, people with allergies to certain rubber compounds should use gloves made of a material with an alternative composition.

Side effects: there are no known side effects. People with allergies to certain rubber compounds should use gloves made of a material with an alternative composition.

6. Precautions.

- Before use, inspect visually the outer package. The package with visible damage (holes, cuts, tears) should be disposed of and replaced with a new one.
- Before use, inspect visually the gloves. If the glove has visible defects (cuts or tears), it should be disposed of and replaced with a new one.
- Make sure the correct glove size is selected. The size is specified on the package.
- It is necessary to apply the correct technique of putting the gloves on in accordance with the instructions for use.
- The gloves are a disposable product; re-sterilization is inadmissible.
- Do not use after the expiry date specified on the device package.

- The gloves should be protected from mechanical damage.

7. Usage procedure.

7.1. In accordance with the standard procedure and the intrahospital standards.

- Make sure the correct glove size is selected. The size is specified on the package.
- Open the outer package of the sterile gloves in advance, before scrub-up. The assistant wearing the sterile gloves takes out the gloves from the sterile package and gives them to the surgeon, opening the glove with both hands.
- The surgeon gently pushes his hand into the glove, not touching its outer surface and the assistant's gloves.
- The assistant helps to wear both gloves. Then the surgeon can adjust them without assistance, so that the glove fits the arm tightly.
  Part of the sleeve should be inside the glove, it is desirable that its cuff slightly covers the arm below the wrist. The length of the surgical gown sleeves should be such that the sleeves are not pulled out from the glove when moving.

7.2. The procedure for self-donning of the sterile gloves.

- Open the outer package with the gloves before scrub-up.
- Unwrap the package and proceed to scrubbing and applying an antiseptic.
- The treated hands should be kept in the sleeves of a sterile surgical coat. Carefully take the glove through the gown and bring it to the other hand, gradually pushing the hand into it
- Then, slowly pushing your fingers into the glove, gently, helping with the other hand, don it on your left hand, holding the glove by the turned-out cuff.
- Pulling cuffs with fingers from the inside, adjust them in turn on both hands.
  Part of the sleeve should be inside the glove, it is desirable that its cuff slightly covers the arm below the wrist. The length of the surgical gown sleeves should be such that the sleeves are not pulled out from the glove when moving.

8. Functional characteristics

- A sterile disposable device.
- The gloves are powder-free - as an agent for ease of donning, a special coating is used (an alternative to powdering). This helps to reduce the risk of allergies in the surgeon, and there is no additional aggressive factor when the powder gets on the wound bed.
- The use of neoprene instead of latex in the manufacture of the gloves makes it possible to avoid the common latex allergies.
- The tungsten powder, as the component of the gloves, helps to attenuate the radiation effects during radiographic procedures.
- Elasticity of the gloves contributes to the improvement of tactility during surgeon's work in surgeries.
- The absence of dyes in the manufacture of the device makes it possible to avoid allergies associated with it. The gloves are black due to the tungsten powder as their component.
- The device is lead-free.
- Weight of the powdering agent is not more than 0,63 mg.

9. Specifications.

9.1. Dimensional and mass specifications.

Specification	Size						Error
	6.5	7	7.5	8	8.5	9	
Length, mm	280	280	280	280	280	280	Not less than
Width, mm	83	89	95	102	108	114	+/- 5 mm
Palm thickness, mm	0.18	0.18	0.18	0.18	0.18	0.18	Not less than
Thickness of the fingers, mm	0.18	0.18	0.18	0.18	0.18	0.18	Not less than
Weight of one glove, g	32.5	34.5	36.5	39	44.5	45.5	+/- 5 %

9.2. Strength specifications

Specification	Before aging	After aging
Tensile strength	Not less than 17 MPa	Not less than 19 MPa
Ultimate elongation	Not less than 900 %	Not less than 800 %
Stress at 500 % elongation	Not more than 1.5 MPa	Not more than 2.35 MPa

9.3. Attenuation performance

9.3.1. Minimum lead equivalent, not less than, mm Pb

Lead equivalent	0.05 mm

9.3.2. Degree of protection

Source voltage	Half-value layer (HVL), Al	Degree of protection
60 kV	2.9 mm	56.5 %
80 kV	4.0 mm	47.1 %
100 kV	5.1 mm	41.6 %
120 kV	6.2 mm	37.7 %
Tested to ASTM F2547-06		

10. Usage, transportation and storage conditions.

The gloves are transported using all modes of transport in covered vehicles in accordance with the transportation rules applicable for this mode of transport.

The material and the process of manufacturing the glove packaging ensure sufficient protection of the medical device against mechanical damage during long-term transport.

Usage, transportation and storage conditions:

- ambient temperature: + 10°C to + 27°C;
- there are no special requirements to air humidity.

11. Sterilization.

The gloves are sterilized at accredited gamma-ray sterilizing companies.

If sterility is compromised, the gloves should not be used, but disposed of.

Re-use and re-sterilization of the devices are inadmissible.

12. Disposal.

After using the medical device for its intended purpose, it must be disposed of as

potentially hazardous Class B waste in accordance with the rules in force in medical facilities.

Upon the shelf life expiration and/or damage of the sealed package integrity, the medical device must be disposed of as Class A medical waste in accordance with the rules in force in medical facilities.

The devices must be disposed of in accordance with the requirements of legislation and regulations concerning the disposal of products, adopted in the country of application of the medical device.

13. List of international regulatory documents/standards the medical device conforms to.

Standard	Name
ISO 13485	Medical devices. Quality management systems. Requirements for regulatory purposes
EN 10993-1	Biological evaluation of medical devices. Part 1: Evaluation and testing within a risk management process
EN 388	Protective gloves against mechanical risks
EN 420	Protective gloves. General requirements and test methods
EN 374	Protective gloves against chemicals and microorganisms.
EN 421	Protective gloves against ionizing radiation and radioactive contamination.
EN 455	Medical gloves for single use
EN 61331-1	Protective devices against diagnostic medical X-radiation. Part 1: Determination of attenuation properties of materials
ASTM D3577	Standard Specification for Rubber Surgical Gloves
ASTM D6124	Standard Test Method for Residual Powder on Medical Gloves
ASTM F2547	Standard Test Method for Determining the Attenuation Properties in a Primary X-ray Beam of Materials Used to Protect Against Radiation Generated During the Use of X-ray Equipment
ASTM D7866	Standard Specification for Radiation Attenuating Protective Gloves

14. Shelf life.

Shelf life of the Radiation Attenuating Surgical Gloves NEWMARSGROUP is 5 years from the date of sterilization.

Do not use after the expiry date.

15. Maintenance and repair.

The Radiation Attenuating Surgical Gloves NEWMARSGROUP are single-use products. The devices should not be subject to repair and maintenance.

16. Warranty Obligations

Before using the device, you should carefully read the instructions for use. The manufacturer guarantees the sterility of the goods, as well as its conformity with the requirements of

international and national standards throughout the product shelf-life, provided that the transportation, storage rules, as well as usage conditions, established by the manufacturer are observed. The manufacturer shall not be liable for the use of the medical device for purposes other than as intended.

If the sterile package integrity is damaged, or if there are other defects in the package or the device itself, it must be disposed of and replaced with a new one.

Concerning product quality, please contact International Biomedical Ltd., 8206 Cross Park Drive, Austin, Texas 78754, USA, phone: 512-873-0033, fax: 512-873-9090, or its authorized representative in the Russian Federation: Limited Liability Company "Newmars Group Rus" (LLC "Newmars Group Rus»), Room 74, Building 1, House 111, Leninsky Avenue, Moscow, 119421, Russian Federation, tel/fax +7(495) 230-87-77, +7(495) 189-07-77, e-mail: info@newmarsgroup.com

17.Marks and symbols

	Quantity		Size
LOT	Batch Code		Use-by Date
	Catalog Number		Manufacturer
	Do Not Reuse		Latex-Free
	Powder-Free		Lead-Free
	Sterilized Using Irradiation		Temperature Limit
EN 421:2010 	Ionizing Radiation Protection	EN 374-2:2003 	Biological Hazard Protection
EN 374-3:2003 	Chemical Hazard Protection	EN 388:2003 	Physical Impact Protection

The State of Texas

Secretary of State

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4. and bears the seal/stamp of	JULIE ESQUELL, Notary Public, State of Texas, Commission Expires: 07-18-20

CERTIFIED

5. at Austin, Texas
6. on June 1, 2018
7. by the Secretary of State of Texas
8. Certificate No. 11549580
9. Seal
10. Signature:

Rolando B. Pablos
Secretary of State

GF/els

ADDITION 1
for instruction for use for Radiation Attenuating Surgical Gloves NEWMARSGROUP (Version 2017.01)

1. **Addition for chapter 8 «Functional characteristics»:**

- Tractability - level 5
- Waterproof
- Seamless

Amy Pieper
International Biomedical

State of Texas
County of Travis

Subscribed and sworn (affirmed) before me on this 30th day of May, 2018.

Julie Esquell
Notary Public

JULIE ESQUELL
Notary Public, State of Texas
Comm. Expires 07-18-2020
Notary ID 130742990

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ДОПОЛНЕНИЕ 1

к инструкции по применению на Перчатки хирургические для защиты от ионизирующего излучения NEWMARSGROUP (версия 2017.01)

1. Дополнение к разделу 8 «Функциональные характеристики»:

- Удобство манипулирования – уровень 5
- Водонепроницаемые
- Бесшовные

/подпись/

Эми Пайпер

Интернэшнл Биомедикал

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Округ Трэвис

Подписано в моем присутствии
30 мая 2018 г.
Джули Эскель */подпись/*
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Тринадцатого июня две тысячи восемнадцатого года.

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Тринадцатого июня две тысячи восемнадцатого года.

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