

«УТВЕРЖДАЮ»

Генеральный директор

ООО «Смит энд Нефью»

«Смит энд Нефью»
LLC Smith & Nephew

Сябренко Е.М.

«20», декабря 2021 г.



ФОТОГРАФИЧЕСКИЕ ИЗОБРАЖЕНИЯ

МЕДИЦИНСКОГО ИЗДЕЛИЯ:

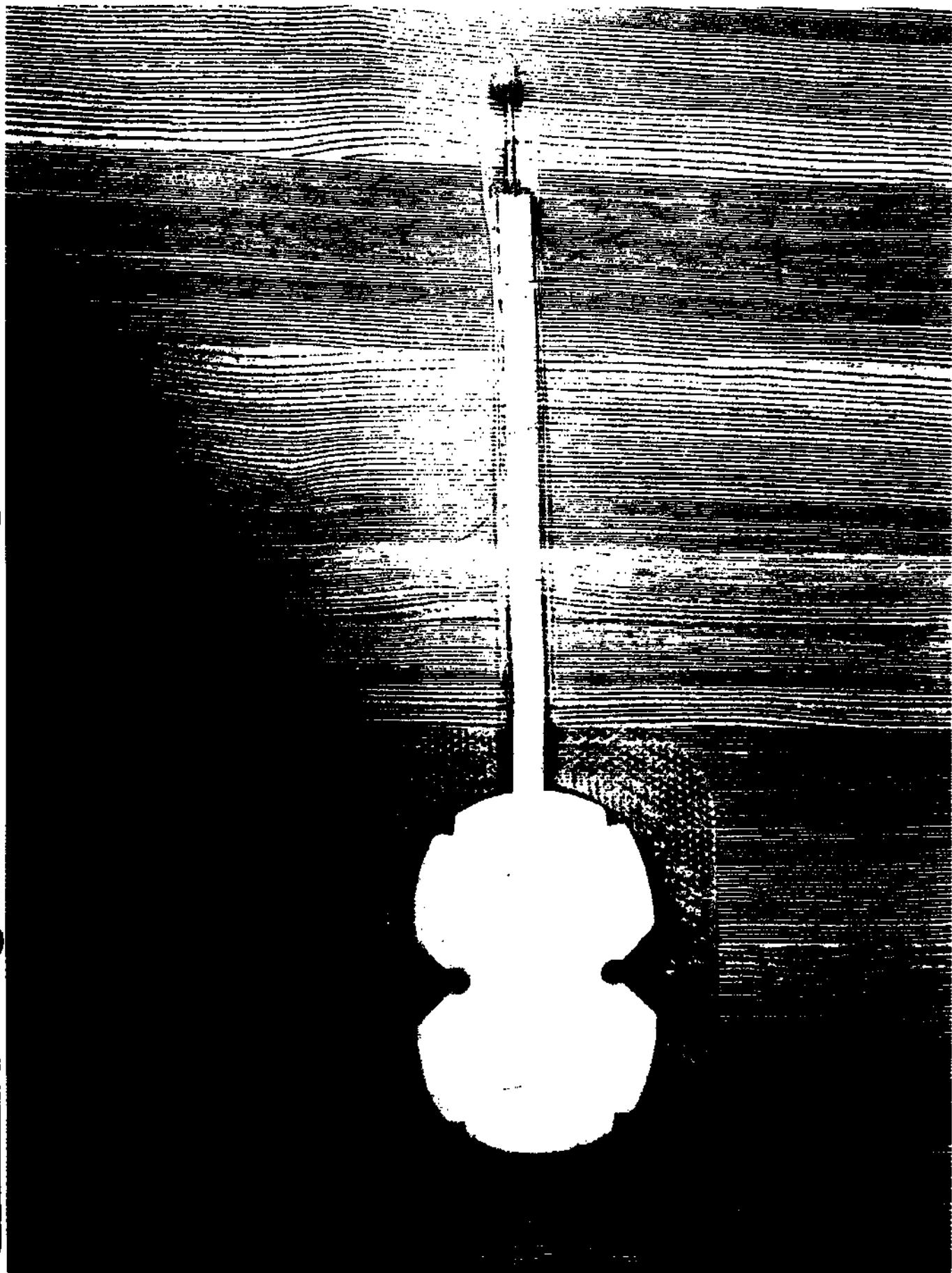
апарат для лечения ран отрицательным давлением PICO14 одноразовый, варианты исполнения»

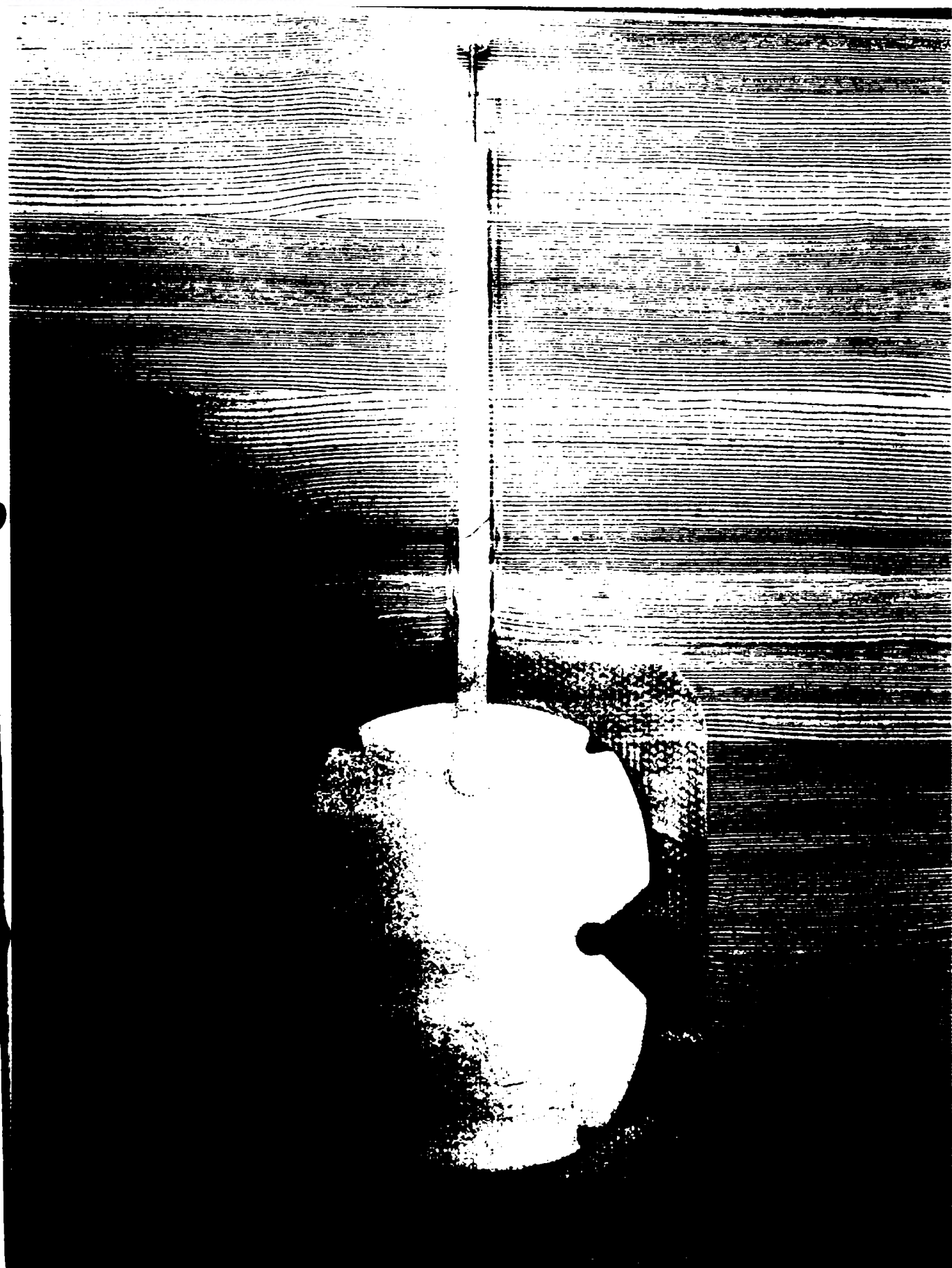
производства

Смит энд Нефью Медикал Лтд. / Smith & Nephew Medical Limited

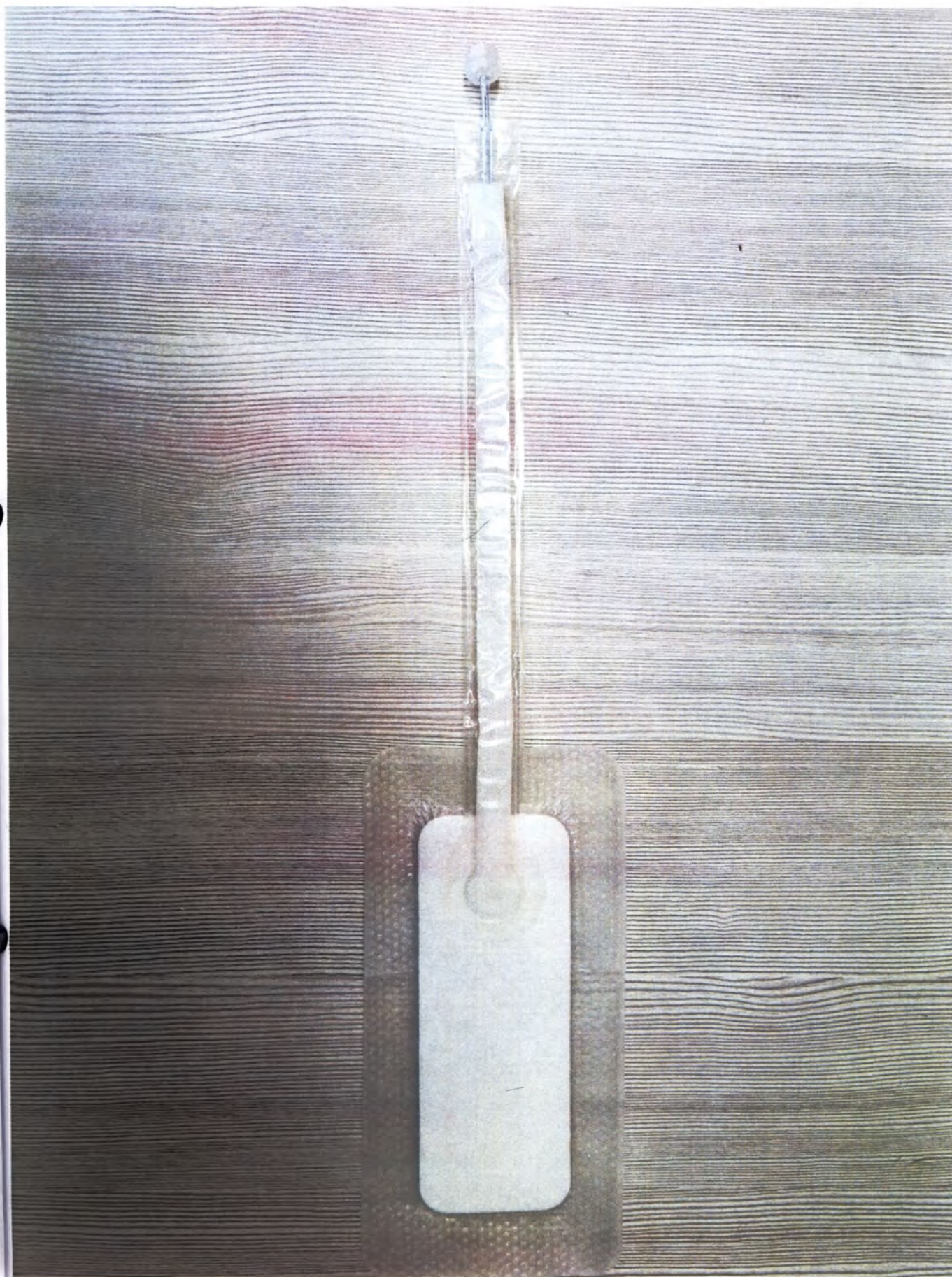
2021

Повязка Multisite 15см x 20см

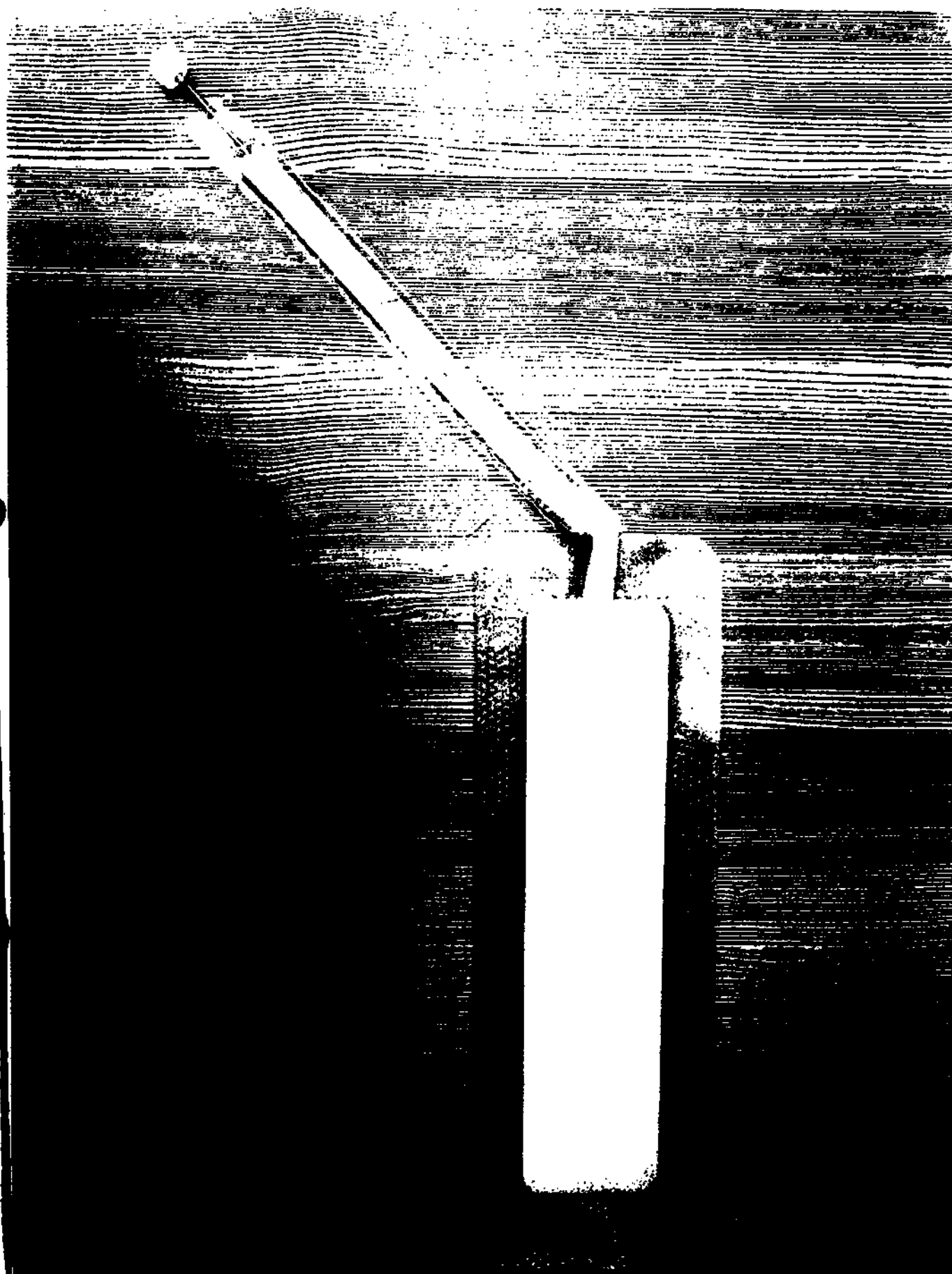




Повязка 10см х 20см



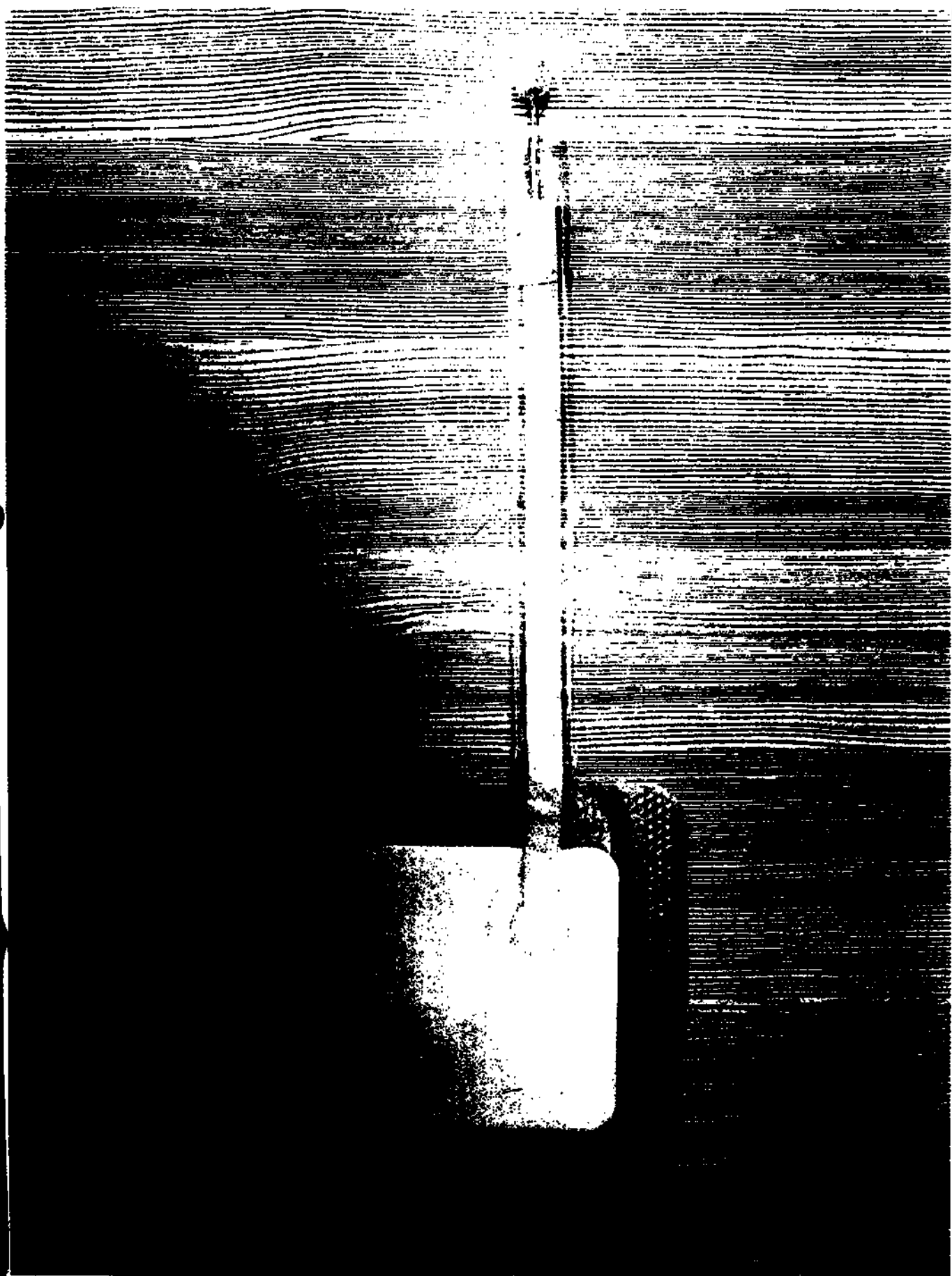
Повязка 10см x 30см



Повязка 10см х 40см



Повязка 15см x 15см



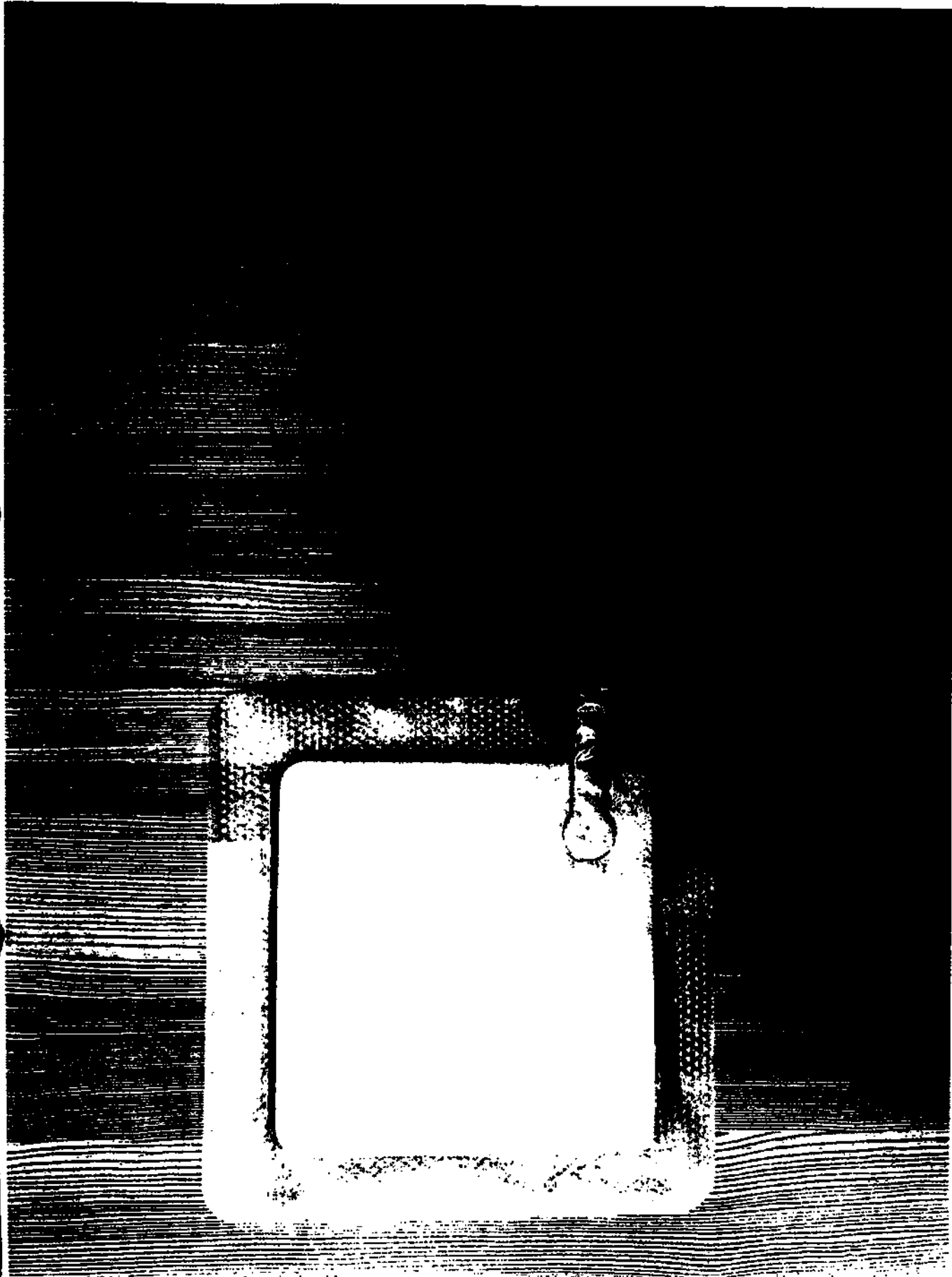
Повязка 15см х 20см



Повязка 15см х 30см



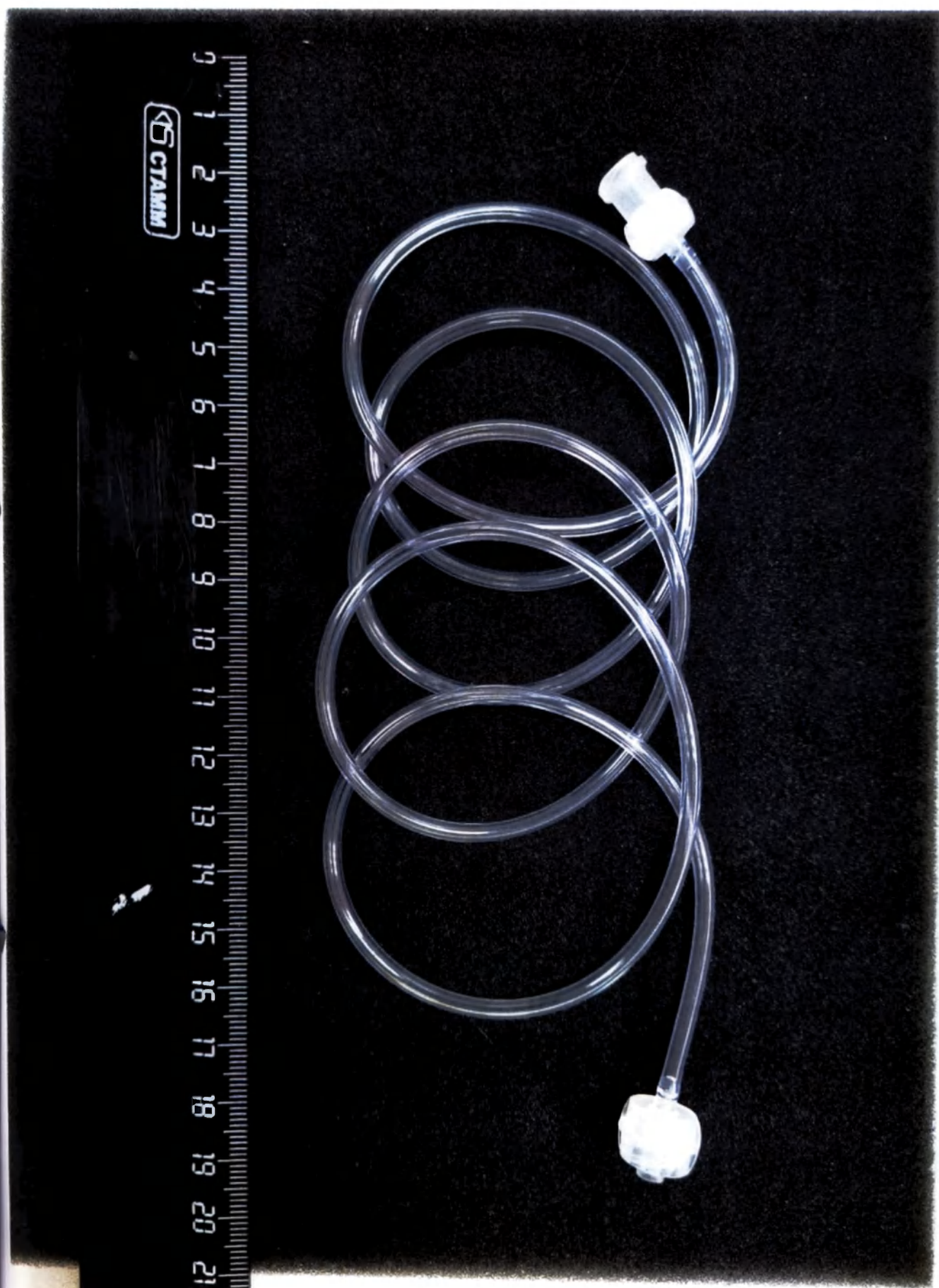
Повязка 20см x 20см



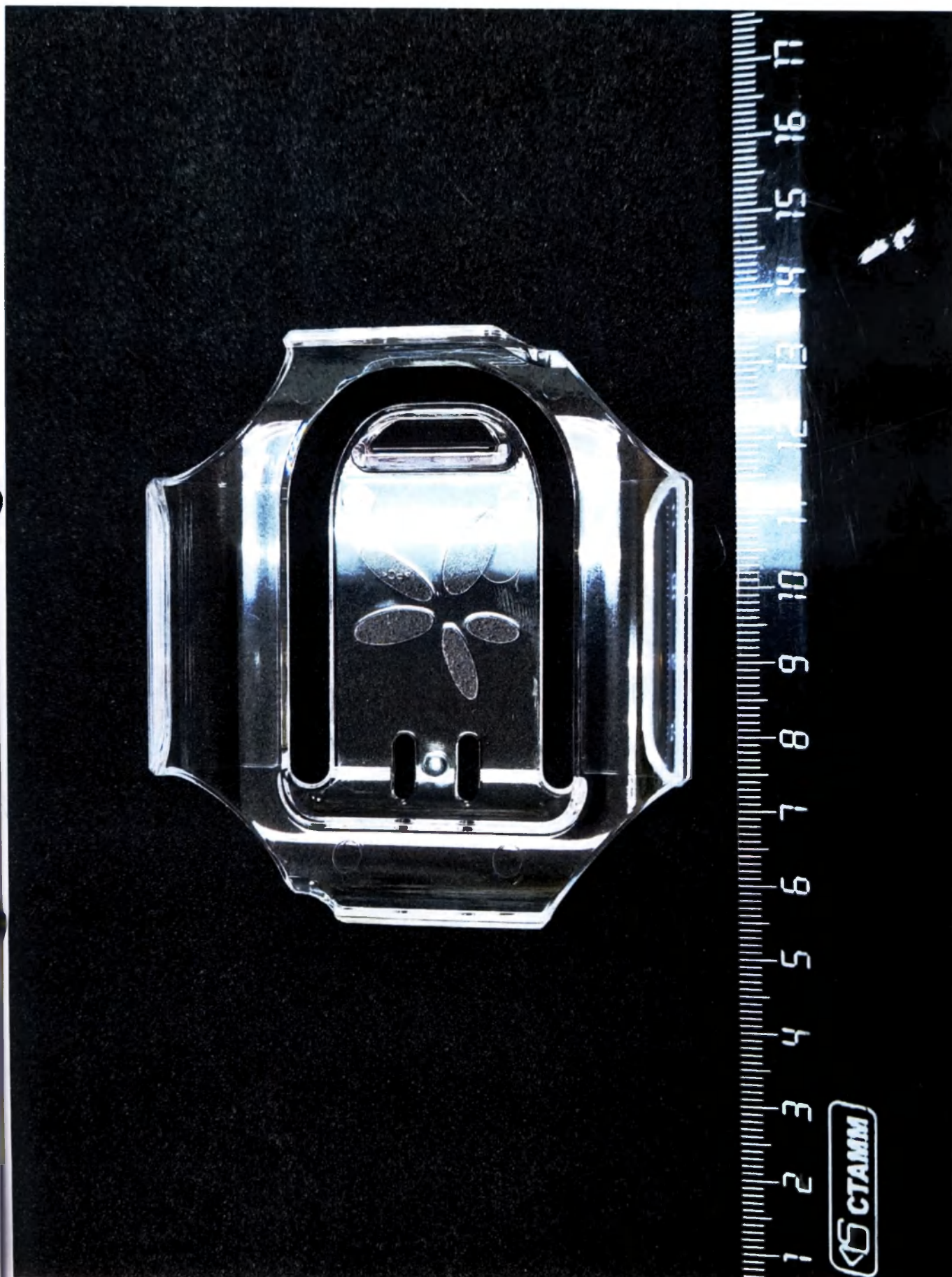
Повязка 25см х 25см

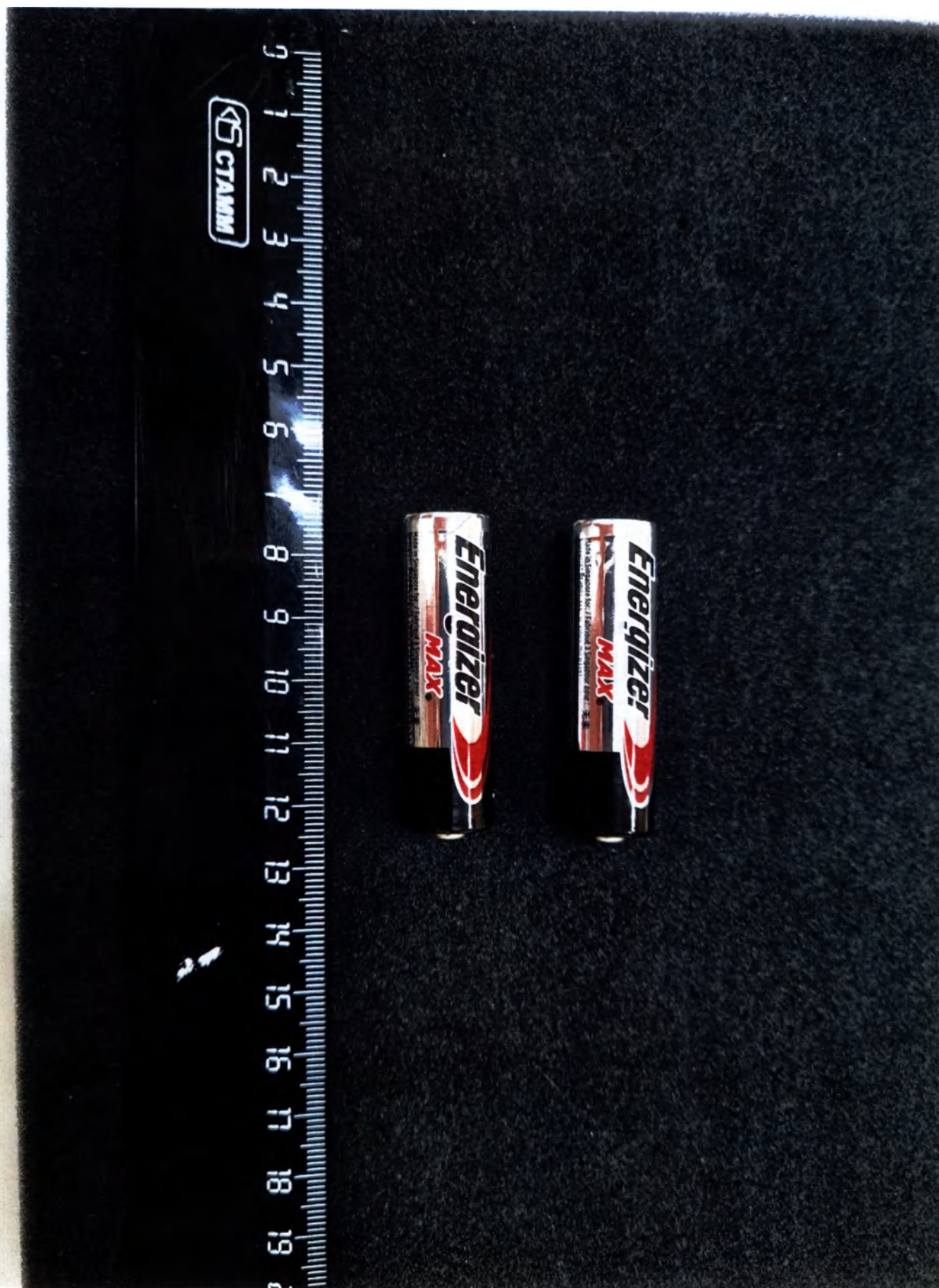












Hand this Leaflet to Patient after Dressing Application

PICO® 14 is intended for use by or on the direction of a trained and licensed physician in accordance with these instructions for use.



1. Description

PICO 14 consists of a pump, coded extension tubing, batteries, sterile dressings and fixation strips. The PICO 14 pump maintains negative pressure wound therapy (NPWT) at 80 mmHg (normal) to the wound surface. Exudate is managed by the dressing through a combination of absorption and evaporation of moisture through the outer film. The PICO 14 system is intended to be used for up to 14 days. For low exuding wounds each PICO dressing is intended to be used for up to 7 days. For moderately exuding wounds additional dressings will be required. For heavily exuding wounds additional dressings will be required. The PICO soft port dressing is designed with an integrated filter to prevent liquid ingress into the soft port tubing and into the PICO pump.

Low exuding wounds are considered to be up to 0.4 g of liquid exudate/cm² of wound area/24 hours. Moderate exuding wounds are considered to be up to 1.1 g of liquid exudate/cm² of wound area/24 hours. High exuding wounds are considered to be up to 1.1 g of liquid exudate/cm² of wound area/24 hours. The frequency of dressing changes can be affected by multiple factors such as wound type, wound size, rate or volume of exudate, orientation or environmental conditions. Additional dressings are available to purchase separately, as required.

2. Indications for use

PICO 14 is indicated for patients who would benefit from a suction device (NPWT) as it may promote wound healing via removal of low to moderate levels of exudate and infectious materials. Appropriate wound types include:

- Chronic
- Acute
- Traumatic
- Subacute and dehiscent wounds
- Exposed arteries, veins, nerves or organs
- Exposed anastomotic sites
- Partial-thickness burns
- Ulcers (such as diabetic or pressure)
- Rips and pulls
- Surgically closed incision sites

PICO 14 single use negative pressure systems are suitable for use both in a hospital and homecare setting.

3. Contraindications

PICO 14 is contraindicated for:

- Patients with malignancy in the wound bed or margins of the wound except in palliative care to enhance quality of life
- Previously confirmed and untreated osteomyelitis
- Non-sterile and unexplored fistulas
- Necrotic tissue with eschar present
- Exposed arteries, veins, nerves or organs
- Exposed anastomotic sites
- PICO 14 should not be used for the purpose of:
- Emergency airway aspiration
- Pneumothorax, mediastinal or chest tube drainage
- Surgical suction

4. Pump Placement Warning

The PICO 14 Pump contains a MAGNET. Keep the PICO 14 pump at least 10cm (4 inches) away from other medical devices at all times. Failure to do so can cause the other medical device to fail which can result in serious harm including death. See Section 5 Magnet Warning.

5. Warnings

1. Magnet Warning

The PICO 14 pump contains a MAGNET that can cause other medical devices in close proximity to fail, leading to serious harm including death. The PICO 14 pump must be positioned at least 10cm (4 inches) away from other medical devices that could be affected by magnetic interference. These include but are not limited to:

- Implantable Cardioverter-Defibrillator (ICD)
- Pacemakers
- Neurostimulators
- Cochlear Implants
- Shunt Valves
- Insulin Pumps

THIS WARNING APPLIES AT ALL TIMES TO ALL USERS. This applies to both Patients and Carers. You must keep the PICO 14 pump at least 10cm (4 inches) away from other devices.

- If you have an electronic medical device and are helping take care of somebody else using the PICO 14 system.
- If the patient is wearing the PICO 14 pump in a public area where they may come in close contact with someone else who has an electronic medical device.

2. Certain patients are at high risk of bleeding complications which, if uncontrolled, could potentially be fatal.

Patients must be closely monitored for bleeding. If suction or increased bleeding is observed, immediately disconnect pump, leave dressing in place, take appropriate measures to stop bleeding and seek immediate medical assistance.

Hemostasis must be achieved before applying the dressing, although the use of anticoagulants does not mean a patient is inappropriate for treatment with PICO 14. Patients suffering from difficult haemostasis or who are receiving anticoagulant therapy have an increased risk of bleeding. During therapy, avoid using haemostatic products that may increase the risk of bleeding. If disrupted, frequent assessment must be maintained throughout the therapy.

3. At all times care should be taken to ensure that the pump, tubing and connectors do not:

- Lie in a position where they could cause pressure damage to the patient.
- Trail across the floor where they could present a trip hazard or become contaminated.
- Present a risk of strangulation or a tourniquet to patients.
- Rest on or pass over a source of heat.
- Become twisted or trapped under clothing or bandages so that the therapy is blocked.

4. Sharp edges or bone fragments in a wound must be covered or removed prior to using PICO 14 due to risk of puncturing organs or blood vessels while under negative pressure wound therapy.

5. In the event that debridement is required, remove the dressing if it is positioned in a location that will interfere with debridement.

6. The PICO 14 pump is not MR compatible. Remove the PICO 14 pump from the dressing before entering the MR suite. Do not bring PICO 14 into the MR suite. The device presents a projectile hazard.

7. PICO 14 has not been studied on paediatric patients. Patient size and weight should be considered when prescribing this therapy.

8. PICO 14 is unsuitable for use in areas where there is danger of explosion e.g. oxygen rich environments such as hyperbaric oxygen units.

9. The system contains small parts which could represent a choking hazard for young children. Keep out of the reach of children.

10. PICO 14 is not suitable for use in the presence of flammable anaesthetic medium with oxygen or nitrous oxide.

11. PICO dressings should only be applied and changed by a healthcare professional. The patient must not remove their dressing unless the healthcare professional believes it to be clinically appropriate.

12. Each PICO dressing (including Multistep) must be used to dress one wound only.

13. Keep PICO away from pets, pests and other animals that could damage the PICO device.

14. No modification of this equipment is allowed.

6. Precautions

1. Precautions should be taken in the following types of patients who are at high risk of bleeding complications:

- Receiving anticoagulant therapy or platelet aggregation inhibitors or actively bleeding.
- Having untreated or fragile blood vessels or organs in or around the wound as a result of, but not limited to: anastomoses, infection, trauma or radiation.
- Suffering from difficult wound haemostasis.
- Unwashed for medication.
- Non-compliant or combative.

2. Suffering from wounds in close proximity to blood vessels or delicate tissues.

3. If pain, redness, odour, sensitization or a sudden change in the volume or colour of wound fluid occur during use, contact your healthcare professional right away.

6. Precautions (continued)

3. Where PICO 14 is used to deliver skin grafts, it is important to visually inspect the system regularly, especially in the first week of treatment to ensure that negative pressure wound therapy is continually applied and a seal is maintained.

4. Where PICO dressings are used on infected wounds, more frequent dressing changes may be required. Regular monitoring of the wound should be maintained to check for signs of infection.

5. If deemed clinically appropriate, care should be taken that the application of a circumferential dressing or the use of negative pressure wound therapy on ischaemic limbs does not compromise circulation.

6. PICO 14 does not contain audible alerts. The pump should be carried so that it is accessible and the patient/healthcare professional can check the status routinely.

7. Although PICO dressings can be used under clothing/bedding, it is important that occlusive materials e.g. film dressings, are not applied over the pad area of the dressing as this will impair the intended evaporation of moisture through its outer layer.

8. The PICO dressing should not be removed by rigid immobilization devices or casts which might apply excessive pressure and cause tissue injury at the wound site, especially where the tubing enters the dressing.

9. Prolonged placement of rigid or opaque materials over the PICO dressing may prevent the regular inspection and assessment of the wound, and disrupt scheduled or required dressing changes.

10. Where PICO dressings are used on patients with fragile skin, a skin protectant such as SCDURA® No-Sting Barrier Film should be used on areas of skin where fixation strips are to be applied. Inappropriate use or repeated application of fixation strips may otherwise result in skin stripping.

11. Do not use PICO dressings with oil based products such as petroleum as it may compromise establishing an effective seal.

12. The use of negative pressure wound therapy presents a risk of tissue ingrowth into team when this is used as a wound filler. When using foam filler with PICO 14, tissue ingrowth may be reduced by using a non-adherent wound contact layer or by increasing the frequency of dressing changes.

13. PICO 14 only be used in conjunction with single drain provided the dressing is not placed over tubing when it seals the skin. Any surgical drain should be routed under the skin away from the edge of the dressing and function independently of the PICO 14 system.

14. The pump must be protected from sources of fluid e.g. from incontinence or spillages. Disconnect PICO 14 use if fluid ingress is observed.

15. When showering the PICO 14 pump should be stopped and disconnected from the dressing. Whilst disconnected, ensure the end of the tubing attached to the dressing is lying down so that water does not enter the tube.

16. Do not take the pump apart.

17. The PICO dressing should only be used with PICO pumps.

18. Do not alter or cut tubing configuration or pull on the tubing or soft port.

19. Do not cut the PICO dressing used as this may lead to loss of negative pressure wound therapy application.

20. Always ensure that the PICO dressing is positioned centrally over the wound. The soft port should be positioned upmost on intact skin and not extend over the wound so that the risk of fluid collecting around the soft port and potentially blocking the therapy is minimized.

21. The potential for electromagnetic interference in all environments cannot be eliminated. Use caution if PICO is near RFID Radio Frequency Identification readers, anti-theft equipment or metal detectors.

22. CT scans and x-ray have the potential to interfere with some electronic medical devices. Where possible, move the pump out of the area or scanner range. If the pump has been taken into the CT scan or x-ray range, check that the system is functioning correctly following the procedure.

23. The PICO 14 system is single use only. Use of any part of this system on more than one patient may result in cross contamination that may lead to infection. Dressings should not be applied if they have passed their expiry date or have been stored outside of their sterile pouch. Dressings must not be used if they have become contaminated.

24. High temperatures and humidity may reduce wear times of PICO dressings.

25. The PICO 14 system is intended for use in a hospital and homecare setting. The system can also be used in aircraft, car, train, and boat transportation. During transport, there is a potential for radio frequency interference that could affect PICO 14 performance. If the pump malfunctions, replace batteries. If not corrected, contact your healthcare professional to replace the system.

26. When applying dressings next to one another, ensure the dressing borders do not overlap.

7. Adverse reactions

Excessive bleeding is a serious risk associated with the application of suction to wounds which may result in death or serious injury. Careful patient selection, in view of the above stated contraindications, warnings and precautions is essential. Carefully monitor the wound and dressing for any evidence of a change in the blood loss status of the patient. Notify the healthcare professional of any sudden or abrupt changes in the volume or colour of exudate.

8. Instructions for use

8.1 Guidance on wound suitability

PICO dressings should be used on wounds which fit comfortably within the area of the pad, observing precautions on infect skin and not extending over the wound. PICO Multistep dressings are designed to enhance conformity when dressing unusual anatomical areas. PICO dressings including Multistep must be used to dress one wound only.

Depth - wounds greater than 0.5cm (1/4 in) in depth are likely to require a firm or gauge negative pressure wound therapy. Use to ensure adequate treatment of all the wound surfaces. Wounds greater than 2cm (3/4 in) in depth must be treated with the use of a filler along with the PICO 14 system to ensure adequate contact with the wound.

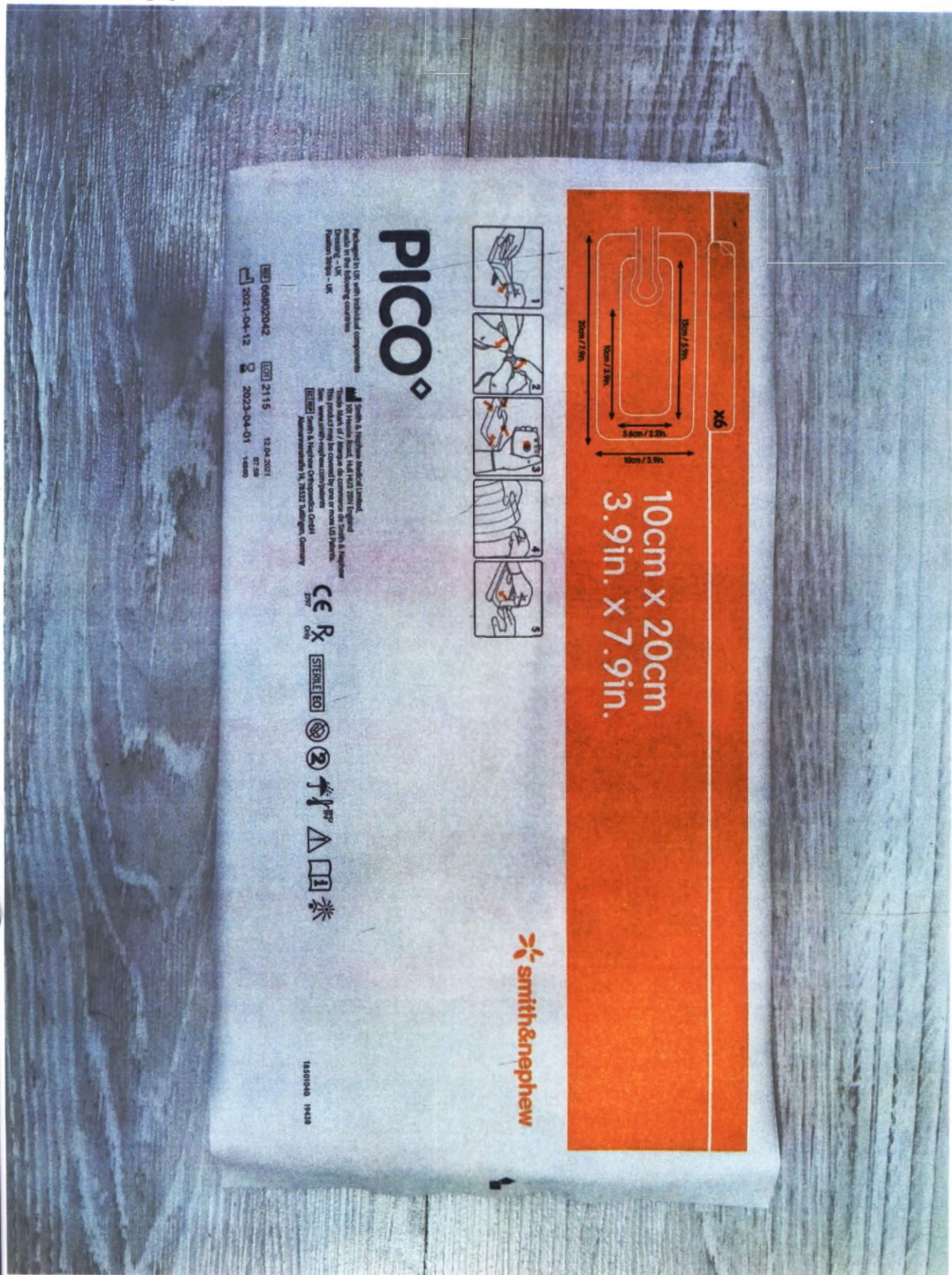
Exudate - PICO 14 is intended for use on wounds where the level of exudate is low up to 0.4 g of liquid exudate/cm² of wound area/24 hours to moderate up to 1.1 g of liquid exudate/cm² of wound area/24 hours. High exuding wounds are considered to be up to 1.1 g of liquid exudate/cm² of wound area/24 hours. The size of the wound should generally be no more than 25% of the dressing pad area.

8.2 Application

The dressing should only be applied by a healthcare professional.

1. Remove any excess hair to ensure close approximation of the dressing to the wound. If necessary, irrigate the wound with sterile saline and pat the wound dry.
2. Using a clean technique, peel off the first release handle and place the dressing centrally over the wound to reduce the chance of wound fluid coming into contact with the soft port. Ensure the dressing lies flat to the wound and the surrounding skin. The dressing should be applied with the soft port positioned higher than the wound depending on the patient's primary position, placed on intact skin and not extending over the wound to prevent fluid seeping around the soft port and blocking the therapy. Remove the other remaining handles and smooth the dressing around the wound to prevent creasing. Reposition if required to ensure border is not creased.
3. Once the dressing is in place, remove the pump and the batteries from the tray. The direction in which the batteries should be placed is inside the battery compartment. Insert the batteries. Replace the cover. Following this all four indicators should illuminate for 3 seconds.
4. Join the pump and dressing tubing by holding together the connectors. The soft tube can be directly connected to the pump if long tubing is not required. Press the orange button to start the application of NPWT. The green OK indicator and orange air leak indicator will start to flash together indicating pump working to establish NPWT. Depending on the size of the wound, the pump should take up to 100 seconds to establish NPWT. If after 100 seconds the system has not established NPWT, lift the orange air leak indicator to troubleshoot refer to section 14.
5. If using SCDURA® No-Sting Barrier Film prior to application of the fixation strips, see Precautions 12. Peel the area surrounding the dressing and adhesive skin to dry.
6. Apply the fixation strips all the way around the dressing border. Remove the carrier on the strips each one has been applied. These strips maintain the seal over the wear time of the dressing. In awkward areas, it may be useful to apply the strips to help achieve a seal prior to switching on the pump. Place each strip so that it overlaps the dressing border by approximately 1cm. Ensure tubing is not twisted or trapped between clothing. Please note that if at any time the fixation strips are removed, the dressing should also be replaced. If desired, gel patches may be applied in addition to the fixation strips to help achieve or maintain a seal.

Индивидуальная упаковка повязки (пакет), на примере варианта исполнения повязки 10см x 20см. Вид сверху



Индивидуальная упаковка повязки (пакет), на примере варианта исполнения повязки 10см х 20см. Вид снизу





CE
2707

Segurança
 
 OCP 0004 INMETRO

Rx only **STERILEEO**             18303736 25583

18303736 25583

 x1
  x1
  x1
  x2

14

LOT 2115

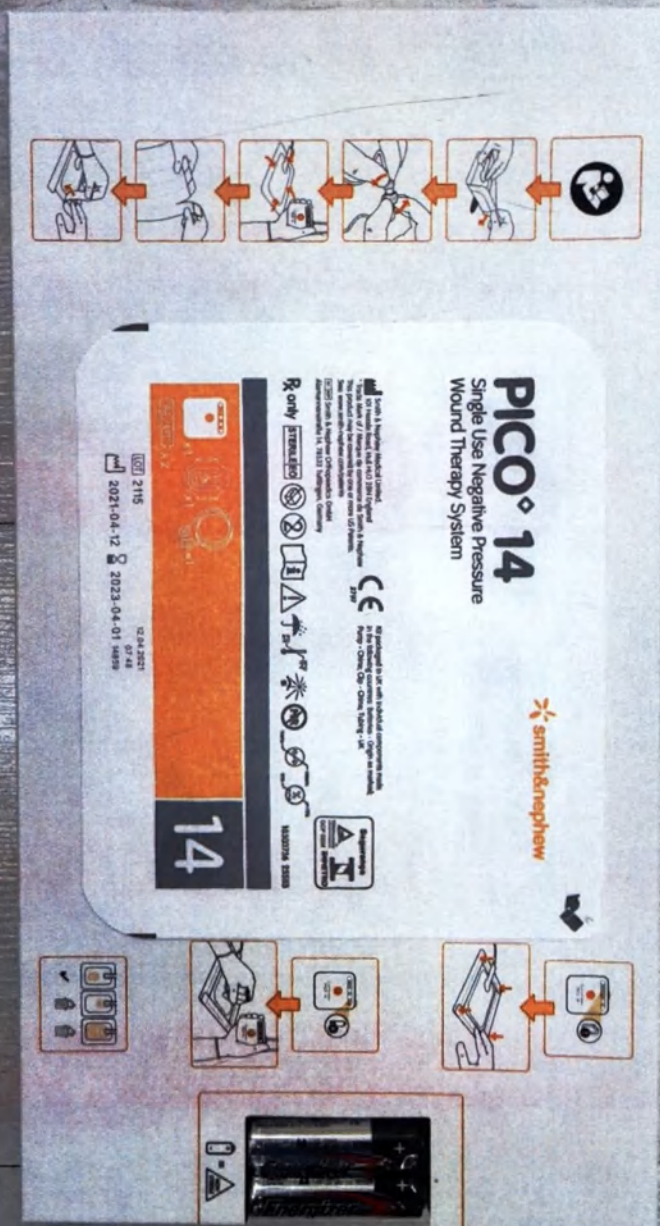
12.04.2021

07:48

2021-04-12 2023-04-01 14859

Индивидуальная упаковка аппарата (лоток). Вид снизу





Картонный лоток. Вид снизу



Отдельная коробка, на примере варианта исполнения повязки 10см x 20см. Вид сверху



REF 66802042

10cm x 20cm / 3.9in. x 7.9in.



14

PICO¹⁴

Single Use Negative Pressure
Wound Therapy System



smith&nephew

PICO® 14 Single Use Negative Pressure Wound Therapy System

REF 66802042

10cm x 20cm / 3.9in. x 7.9in.



Транспортная упаковка (на примере варианта исполнения повязки 10см x 20см)



