surgical suction set

with Yankauer cannula, standard, sterile

CANNULA

- $\bullet\,$ completely transparent for full possibility of observing the sucked secretion
- light and perfectly balanced handle ensures high comfort of work and reduces
- perfectly smooth inner surface prevents blocking or retaining the sucked content, ensuring correct and optimal flow
- · cannula with double bend of curvature
- four lateral eyes, which prevent the tip from sticking to the tissues and one $\,$ central opening
- universal stepped connector ensures tight connection with a wide range of suction connecting tubes

- made of soft and flexible PVC
- along the tube a special longitudinal reinforcement to prevent bending and sucking of the tube
- perfectly smooth inner surface of tube prevents the sucked content
- from settling on the walls, ensuring correct and optimal flow

 connector type funnel-funnel cut-to-fit with the possibility of cutting in the marked places of the connector and matching to any type of medical suction device (for the diameter of 8 mm to 18 mm)
- funnel connector equipped with a special bending system, enabling convenient manipulation of the tube
- tube connectors compatible with the standard suction cannulas, enabling their reliable, effective and tight connection

features

- available with or without suction control
- single-use
- · latex-free
- · EO sterilized
- packaging: 1 set/double packaging: internal- foil, external- paper-foil

• evacuating secretions and body fluids from the operating field in general surgery

REF	size	lenght of tube	connector
ZO-212400104	CH21/CH24	210 cm	without suction control funnel-funnel
ZO-212400114	CH21/CH24	210 cm	without suction control funnel-funnel
ZO-402423104	CH21/CH24	400 cm	without suction control funnel-funnel
ZO-402423114	CH21/CH24	400 cm	without suction control funnel-funnel
ZO-2124001041	CH21/CH24	210 cm	without suction control funnel-funnel cut-to-fit
ZO-2124001141	CH21/CH24	210 cm	without suction control funnel-funnel cut-to-fit







DRESSING TAPE

features

- made of hydrophobic non-woven
- · covered with hypoallergenic acrylic glue
- micropores in the structure of the non-woven provide adequate vapor permeability, thanks to which a proper gas exchange between the dressing and the skin takes place
- flexible, conforms to the body's contours, guarantees freedom of movement
- backing layer made of silicone paper
- · backing paper with metric scale facilitates the division of the tape and precise, painless and efficient application
- packed in a cardboard box a dispenser that allows dosing without removing the tape from the packaging

indication

- stabilization, protection and fixation of primary, non-adhesive dressings, applied directly to wounds and skin damages
- stabilization, protection and fixation of drains, catheters, medical tubes











adhesive non-woven dressing tape

elastopor



$n \cap$	n-steri	16
110	11 36611	

REF	dimensions	packaging unit box	bulk packaging carton
806009	2,5 cm x 10 m	1 pc.	200 pcs
806010	5 cm x 10 m	1 pc.	100 pcs
806011	10 cm x 10 m	1 pc.	50 pcs
806012	15 cm x 10 m	1 pc.	50 pcs
806013	20 cm x 10 m	1 pc.	25 pcs
806014	25 cm x 10 m	1 pc.	25 pcs
806015	30 cm x 10 m	1 pc.	25 pcs



elastopor E



non-sterile

REF	dimensions	packaging unit box	bulk packaging carton
* 806009E	2,5 cm x 10 m	1 pc.	200 pcs
806010E	5 cm x 10 m	1 pc.	100 pcs
806011E	10 cm x 10 m	1 pc.	50 pcs
806012E	15 cm x 10 m	1 pc.	50 pcs
806013E	20 cm x 10 m	1 pc.	25 pcs
806014E	25 cm x 10 m	1 pc.	25 pcs
806015E	30 cm x 10 m	1 pc.	25 pcs











wavy intersection of backing paper



SELF-ADHESIVE DRESSINGS WITH ABSORBENT PAD

features

- self-adhesive dressings with centrally situated absorbent pad, made of hydrophobic non-woven, covered with acrylic glue
- absorbent pad coated with a polyethylene mesh that prevents sticking to the wound, absorbs a small and medium amount of exudate and protects against the influence of external factors
- rounded edges prevent accidental removal of the dressing
- silicone backing paper facilitates the precise, painless and efficient application
- micropores in the structure of the non-woven provide adequate vapor permeability, thanks to which a proper gas exchange between the dressing and the skin takes place
- hypoallergenic











non-woven dressing with absorbent pad elastopor STERIL



sterile

indication

- especially recommended for covering surgical wounds
- · for treating wounds with a small and medium amount of exudate

REF	dimensions	packaging unit paper-paper	bulk packaging box
801001	5 cm x 7,2 cm	1 pc.	100 x 1 pc.
801012	6 cm x 10 cm	1 pc.	50 x 1 pc.
801002	8 cm x 10 cm	1 pc.	30 x 1 pc.
801013	10 cm x 10 cm	1 pc.	30 x 1 pc.
801021	10 cm x 12 cm	1 pc.	30 x 1 pc.
801014	10 cm x 15 cm	1 pc.	30 x 1 pc.
801003	6 cm x 15 cm	1 pc.	50 x 1 pc.
801004	8 cm x 15 cm	1 pc.	30 x 1 pc.
801005	8 cm x 20 cm	1 pc.	30 x 1 pc.
801015	10 cm x 20 cm	1 pc.	25 x 1 pc.
801016	10 cm x 25 cm	1 pc.	25 x 1 pc.
801017	10 cm x 30 cm	1 pc.	25 x 1 pc.
801018	10 cm x 35 cm	1 pc.	25 x 1 pc.







non-woven IV cannula dressing

elastopor IV



sterile

features

- centrally situated absorbent pad protects the non-woven material from sticking to the injection site
- non-woven lining should be placed under cannula's wings, which prevents it from causing damage to the skin

indication

- dressing application around the inserted cannula
- stabilization, protection and fixation of intravenous cannulas

REF	dimensions	packaging unit paper-paper	bulk packaging box	
811013	6 cm x 8 cm	1 pc.	100 x 1 pc.	
811012	5,1 cm x 7,6 cm	1 pc.	100 x 1 pc.	
811023	6 cm x 8 cm	1 pc.	50 x 1 pc.	
811022	5.1 cm x 7.6 cm	1 nc	50 x 1 pc	



elastic tubular net bandage

elastoNET



non-sterile

features

- elastic net bandage in the form of a tube
- · contains polyamide and elastomer
- · high stretchability and strength of returning to pre-stretch state
- elastic and very soft
- · easy and quick to use
- · length before stretching:
 - 1 m, stretched: 2,5 m
 - 10 m, stretched: 25 m

ndication

- fixation of all dressings on the patient's body, replacing the traditional bandage
- the use of tubular net bandage reduces the time of wound dressing and makes it easier to fix the dressing to the patient's body

REF	lenght before stretching	size	indication	packaging unit box - dispenser
SO-0101	1 m	1	finger	1 pc.
SO-0110	10 m	1	finger	1 pc.
SO-0201	1 m	2	hand, toe	1 pc.
SO-0210	10m	2	hand, toe	1 pc.
SO-0301	1 m	3	hand, foot	1 pc.
SO-0310	10 m	3	hand, foot	1 pc.
SO-0401	1 m	4	lower leg, knee, arm, foot, elbow	1 pc.
SO-0410	10 m	4	lower leg, knee, arm, foot, elbow	1 pc.
SO-0601	1 m	6	head, shoulder, lower leg, knee	1 pc.
SO-0610	10 m	6	head, shoulder, lower leg, knee	1 pc.
SO-0801	1 m	8	thigh, head, hips	1 pc.
SO-0810	10 m	8	thigh, head, hips	1 pc.
SO-1001	1 m	10	hips, trunk	1 pc.
SO-1010	10 m	10	hips, trunk	1 pc.
SO-1401	1 m	14	chest, trunk	1 pc.
SO-1410	10 m	14	chest, trunk	1 pc.

FIRST AID FOR DRESSING WOUNDS USING BANDAGES

Hippocrates' achievements in treating head wounds were so widespread and advanced that they are still used today. The Hippocrates cap also called "mitra is a headgear that allows you to hold the dressing and stop bleeding of the head wound. It is made of two bandage tapes. The main purpose of using the Hippocrates cap is to hold the dressing directly protecting the bleeding head wound, seal and warm the head, hold the compress applied to the skull area, compression, strengthening and immobilization after surgery and additional protection against the external environment. This solution is used in the absence of access to dressings such as elastic dressings and scarves.



How to make a HIPOCRATES CAP?

RULES FOR BANDAGING

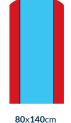
- 1. Prepare a two-head bandage about 5-6 cm wide by sewing together two bands or by twisting the free end to the middle.
- Put the two-headed bandage on the back of the head and drive bandage to the forehead a circular move.
- 3. Cross the bandages on the forehead and drive one through the top of the head towards the occiput by a longitudinal move.
- 4. Drive the other bandage above the ear to the occiput also (half-round).
- 5. Scroll the longitudinal course through the circular course bandage.
- 6. Drive back the longitudinal course bandage across the top of the head to the forehead.
- 7. Drive the circular course bandage around the other ear to the forehead
- 8. Continue longitudinal and circular moves, the circular course bandage wraps around the scalp
- 9. Little by little, move the longitudinal course bandage towards the temples
- 10. After covering the whole area with a two-head bandage, fix the ends of bandage



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STERILE MAYO STAND COVER, REINFORCED - RED

ref.	dimensions	packaging unit
AT-SD-S 2 RED	80cm x 140cm	1 pc.
	(a)	



bulk packaging:

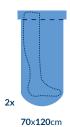


STERILE SET OF LIMB COVERS

ref.	dimensions	packaging unit
AT-SD-S 9	70cm x 120cm	2 pcs

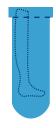


bulk packaging: 20 sets



STERILE LIMB COVERS

ref.	dimensions	packaging unit	bulk packaging
AT-SD-S 6	30cm x 60cm	1 pc. + OP tape 10cm x 50cm	200 pcs
AT-SD-S 7	30cm x 80cm	1 pc. + OP tape 10cm x 50cm	120 pcs
AT-SD-S8	35cm x 120cm	1 pc. + OP tape 10cm x 50cm	100 pcs





STERILE CAMERA CABLE COVERS - PERFORATED, WITH 2 ADHESIVE TAPES

ref.	dimensions	packaging unit	bulk packaging
AT-SP-S 3	14cm x 250cm	1 pc.	160 pcs
AT-SP-S 4	16cm x 200cm	1 pc.	200 pcs
AT-SP-S 5	16cm x 250cm	1 pc.	160 pcs
AT-SP-S 6	16cm x 300cm	1 pc.	200 pcs







sterile camera cover

STERILE CAMERA CABLE COVER - UNPERFORATED, WITHOUT ADHESIVE TAPE

ref.	dimensions	packaging unit
AT-SP-S 7	7cm x 120cm	1 pc.



bulk packaging: 200 pcs



STERILE ABSORBENT DRAPE

ref.	dimensions	packaging unit	
AT-BT	75cm x 80cm	1 pc.	



bulk packaging: 80 pcs







75x**80**cm

STERILE INCISE FILM elastoFILM

ref.	total dimensions	adhesive filed dimensions	packaging unit	bulk packaging
808067	56cm x 84cm	56cm x 78cm	1 pc.	6 pcs
808066	40cm x 42cm	40cm x 36cm	1 pc.	20 pcs
808065	45cm x 55cm	45cm x 49cm	1 pc.	20 pcs
808064	45cm x 28cm	45cm x 22cm	1 pc.	20 pcs
808063	30cm x 28cm	30cm x 22cm	1 pc.	20 pcs
808062	15cm x 28cm	15cm x 22cm	1 pc.	40 pcs
808061	14cm x 25cm	14cm x 21cm	1 pc.	40 pcs
805018	55cm x 55cm	55cm x 51cm	1 pc.	20 pcs
805025	30cm x 40cm	30cm x 36cm	1 pc.	20 pcs
805016	20cm x 30cm	20cm x 26cm	1 pc.	30 pcs







- thin incise film made of polyurethane
- flexible
- perfectly fits the patient's body
- double packed: externally paper-foil, internally paper



CELLULOSE

Cellulose is a solid with typically fiber structure. Two-step process is used for industrial manufacturing of cellulose fibers, which was developed in 1892. Cellulose raw material is used in different industries as textiles and paper as well as in production of explosives.



EC Certificate Directive 93/42/EEC Annex V Production Quality Assurance Medical Devices

Registration No.: DD 60139535 0001

Report No.: 26300232 017

Manufacturer: ZARYS International Group

Spolka z ograniczona odpowiedzialnoscia,

spolka komandytowa ul. Pod Borem 18 41-808 Zabrze

Polska

Products: (see attachments for products and sites included)

Replaces EC Certificate, Registration No.: DD 60117020 0001

Expiry Date: 2024-05-27

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2019-06-09

Date: 2019-05-27

Rafal Byczkowski

Notified Body

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC
concerning medical devices with the identification number 0197.



TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Doc. 1/6, Rev. 0

Attachment to Certificate

Registration No.: Report No.:

DD 60139535 0001 26300232 017

Manufacturer:

ZARYS International Group

Spolka z ograniczona odpowiedzialnoscia,

spolka komandytowa ul. Pod Borem 18 41-808 Zabrze

Polska

Products included:

- Sterile and non-sterile cutting gauze
- Non-sterile dressing gauze
- Sterile and non-sterile gauze swabs (with or without X-ray thread)
- Sterile and non-sterile gauze lap sponges (with X-ray thread/ with X-ray chip)
- Sterile and non-sterile gauze balls (with or without X-ray thread)
- Sterile and non-sterile gauze rolls (with or without X-ray thread)
- Sterile and non-sterile non-woven swabs (with or without X-ray thread)
- Sterile paraffin gauze dressings
- Sterile three-way stopcocks
- Sterile transfusion sets for single use
- Sterile infusion sets for single use
- Sterile extension tubes for infusion pump

Notified Body

TÜVRheinlar

rinziorung

Rafal Byczkowski



TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Doc. 2/6, Rev. 0

Attachment to Certificate

Registration No.: Report No.:

DD 60139535 0001 26300232 017

Manufacturer:

ZARYS International Group

Spolka z ograniczona odpowiedzialnoscia,

spolka komandytowa ul. Pod Borem 18 41-808 Zabrze

Polska

Products included:

- Sterile endotracheal tubes
- Sterile tracheostomy tubes
- Sterile breathing circuits
- Sterile catheter mounts
- Non-sterile anaesthetic masks
- Sterile laryngeal masks
- Sterile oxygen masks
- Sterile Multi-Vent masks
- Sterile non-rebreath masks
- Sterile nebulizer masks
- Sterile nasal oxygen cannulas
- Sterile nebulizer sets
- Sterile oxygen tubing
- Sterile suction catheters
- Sterile abdominal drains
- Sterile feeding tubes
- Sterile stomach and duodenal tubes
- Sterile urology catheters
- Sterile surgical suction sets
- Sterile surgical suction cannulas
- Sterile syringes for single use

Date: 2019-05-27



Rafal Byczkowski



TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Doc. 3/6, Rev. 0

Attachment to Certificate

Registration No.: Report No.:

DD 60139535 0001 26300232 017

Manufacturer:

ZARYS International Group

Spolka z ograniczona odpowiedzialnoscia,

spolka komandytowa ul. Pod Borem 18 41-808 Zabrze

Polska

Products included:

- Sterile insulin syringes
- Sterile tuberculin syringes
- Sterile hypodermic needles
- Sterile insulin pen needles
- Sterile blood lancets
- Sterile IV cannulas
- Sterile needle free valves
- Sterile surgical gloves

Notified Body

TÜVRheinlan

Rafal Byczkowski



TÜVRheinland

tinzierung

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Doc. 4/6, Rev. 0

Attachment to Certificate

Registration No.: Report No.:

DD 60139535 0001 26300232 017

Manufacturer:

ZARYS International Group

Spolka z ograniczona odpowiedzialnoscia,

spolka komandytowa ul. Pod Borem 18 41-808 Zabrze

Polska

Products included:

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Adhesive cannulla fixation dressings
- Adhesive wound dressings
- Eye pads
- Incise films
- Transparent film dressings
- Foam dressings
- Absorbent wound dressings
- Surgical gowns
- Surgical drapes
- Sets of surgical drapes
- Fluid collection pouches
- Nelaton catheters

Notified Body

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Meierungs

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Doc. 5/6, Rev. 0

Attachment to Certificate

Registration No.: Report No.:

DD 60139535 0001 26300232 017

Manufacturer:

ZARYS International Group

Spolka z ograniczona odpowiedzialnoscia,

spolka komandytowa ul. Pod Borem 18 41-808 Zabrze

Polska

Products included:

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Vaginal speculums
- Cervical brushes
- Urine bags
- Tongue depressors
- Guedel airways
- Intubation stylets
- Endotracheal tube holders
- Suction tubes
- Withdrawal cannulas
- Alginate dressings
- Cannula stoppers
- Umbilical cord clamps

Notified Body

Rafal Byczkowski



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TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Doc. 6/6, Rev. 0

Attachment to Certificate

Registration No.:

DD 60139535 0001 26300232 017

Manufacturer:

Report No.:

ZARYS International Group

Spolka z ograniczona odpowiedzialnoscia, spolka komandytowa ul. Pod Borem 18 41-808 Zabrze Polska

Products included:

ZARYS International Group Spolka z ograniczona odpowiedzialnoscia, spolka komandytowa ul. Gustawa Eiffel'a 15 44-109 Gliwice Poland

Activity: Production

Date: 2019-05-27

Notified Body

Rafal Byczkowski

Certificate

TÜVRheinland

Quality Management System EN ISO 13485:2016

Registration No.:

SX 1023663-1

Organization:

ZARYS International Group

Spółka z ograniczoną odpowiedzialnością,

spółka komandytowa ul. Pod Borem 18 41-808 Zabrze

Poland

Scope:

Design and development, manu acture and distribution of sterile:

surgical kits, procedure sets, surgical drapes and sets of surgical

drapes.

Wajid A

Manufacture and distribution of sterile and non-sterile disposable

medical devices and non sterile reusable medical devices.

Distribution of in-vitto medical devices.

The Conffication Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quarty management system for medical devices.

Process the been furnished that the requirements specified in the above mentioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.:

84947434 020

Effective date:

2020-06-10

Expiry date:

2023-06-08

Issue date:

2020-06-10





Rafał Byczkowski TR LGA Products GmbH Tillystraße 2 · 90431 Nürnberg · Germany

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