

NOBAMED Paul Danz AG

NOBALASTIK®-steril

REF 731512

Product Description, Intended use, Application

The sterile, white, soft, medium-stretch bandage is 12 cm wide and 5 m long when stretched, with a stretchability of approx. 90 ± 10 %. It has sewn ends and woven edges. Due to its material and weave, the bandage is elastic and therefore suitable for functional support and relief bandages or for fixation with additional compression effect. For example, splints of any kind can be fixed with the bandage. It exerts a supporting and compressing effect in the case of sport injuries. In surgery it is used, for example, for thorax compression in cases of rib fractures or for the stabilization of wound dressings. In the area of phlebology, the bandage is employed, owing to its easy handling, to support treatments. The rolled-up bandage is intended for single use and is individually sealed.

Composition

Polyester, elastane

Contraindications

The product should not be used in the case of a known allergy against the material.

Notes

After application, ensure that the dressing does not cause pressure marks, lacerations, pain, numbness, or circulatory disturbances.

Incident reporting

According to MDR (EU) 2017/745, if serious incidents occur in relation to the device, they must be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Normative and Regulative Requirements, Common Standards

Medical device according to the MDD 93/42/EEC and MDR (EU) 2017/745.

Sterilisation is carried out according to DIN EN 11135.

The product does not contain dangerous toxic substances according to REACH.

Packaging

Primary packaging: paper-film

packaging

Secondary packaging: folding box

made of cellulose

Tertiary packaging: carton made of

cellulose

Symbols used in labelling

Explanations at www.nobamed.com











Marking on all packaging levels with CE and according to DIN EN ISO 15223-1 and ISO 20417.

Storage and Transport

To be stored in a dry and dust-free environment

Sterile device

Before using a sterile product, visually inspect the packaging to ensure that it is intact.

Single use device

Reusing a single use medical device can lead to microbiological danger. Reprocessing, for reuse can decrease the product's performance significantly.

Disposal

According to locally applicable legal regulations and standards of infection prophylaxis.

Product Data Sheet: November 10, 2022 [REV 5] replaced: October 27, 2017 [Rev 4]