NOBAMED Paul Danz AG

NOBALAN®

REF 405506

Product Description, Intended Use, Application

The brown, textile elastic, short stretch bandage, **size 6 cm x 5 m** (stretched length), has a stretchability of about 85%. Due to its short stretchability, NOBALAN® can be used for the application of a compression bandage to treat phlebological or lymphological diseases of the legs or arms. NOBALAN® can also be used for vein compression (according to Pütter). It is as well suited for the thrombose prophylaxis as it is for the postoperative therapy (for example varicose sclerotherapy, veinstripping). In cases of chronic wounds due to venous insufficiency (for example crural ulcer), a compression bandage placed over the wound bandage supports the venous return flow and therefore the healing of the wound. The rolled bandage is for single use and is **bulk packed** in a dispenser box.

Composition

Cotton

Contra-Indications

- Advanced peripheral arterial occlusive disease
- Decompensated cardiac insufficiency
- Septic phlebitis
- Phlegmasia coerulea dolens

Risks to be considered

- Paraesthesia of the extremities
- Material incompatibility
- Severe, weeping dermatoses
- Advanced peripheral neuropathy (e.g. diabetes mellitus)
- Primary chronic polyarthritis

Side Effects

The bandage must not cause bruises, lace furrows, increasing pain or shortness of breath, sweating, numbness and circulatory disturbances.

Notes

The product has been subjected to a validated microbial reduction process and is therefore pre-sterilized.

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.

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

Packaging

Primary packaging:	folding box made of cellulose
Secondary 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

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.