

NOBAMED Paul Danz AG

NOBASANA[®]

REF 510415

Product Description, Intended use, Application

The white foam bandage (Width: 15 cm, 0.4 cm thick) has a high elasticity and serves as an underlay for a compression bandage. It distributes the pressure of the above-positioned compression bandage evenly so that constrictions will be avoided, provided the bandage has been applied correctly. The bandage also prevents the slipping out of position of the above compression bandage. The bandage is 2.5 m long (unstretched).

Composition

Polyurethane foam

Contraindications

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

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 *MDD* 93/42/EEC, *MDR* (EU) 2017/745.

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

Packaging

Primary:

folding box made of cellulose

Secondary:

carton made of cellulose

Symbols used in labelling Explanation at <u>www.nobamed.com</u>



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

Storage and Transport

Dry and dustfree, protect from sunlight.

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 March 01, 2022 [Rev4], replaces: April 01, 2020 [Rev3]