NOBAMED Paul Danz AG

NOBAFORM®

REF 526506

Product Description, Intended use, Application

NOBAFORM® is a fixed plaster bandage which has been manufactured without the use of solvents, with a size of **6 cm x 2 m.** It is used for immobilization. Owing to its properties, such as excellent shapeability and easy finishing, the plaster bandage is likewise suited for the treatment of reduced fractures (as a split plaster), as well as for their after-treatment (as a circular cast bandage). It can also be used for the temporary immobilization of inflammatory processes such as epicondylitis humeri, tendovaginitis or bursitis. Due to the plaster's longer open time it is easy to process. The rolled bandage is for single use and is individually packed.

Composition

Cotton, gypseous alabaster (calcium sulphate semi-hydrate)

Contra-Indications

A circular cast bandage is contraindicated for recent injuries, postoperatively or if there is any risk of swelling of the soft tissues, as the bandage does not yield in case of a posttraumatic swelling tendency.
Open and infected wounds are contra-indications, too. In both cases so-called plaster splints or split plaster casts can be used instead.

The product should not be used if there is a known hypersensitivity to one of the below-mentioned ingredients.

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 packaging:	PE-coated paper
Secondary packaging:	folding box made of cellulose
Tertiary packaging:	carton made of cellulose

Symbols used in labelling

Explanation at www.nobamed.com

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