NOBAMED Paul Danz AG

NOBALITE®

REF 543407

Product Description, Intended use, Application

The synthetic cast bandage (size 7.5 cm x 3.6 m, color: black) is individually packed and consists of a fibreglass fabric which is impregnated with a polyurethane resin. After its reaction with water, the resin hardens quickly. The finished bandage is characterized by high stability and low weight. It is X-ray translucent.
NOBALITE® provides rigid external immobilization for fractures, fissures, inflammations in the extremities, injuries and operations on the ligaments and further orthopaedic indications. It is suitable for use as a splint dressing, orthotic dressing or as a circular cast.

Composition

Fibreglass, Polyurethane resin

Contraindications

Where there is a danger of hematoma, edema or increased swelling (for example if used for the primary treatment of a fracture), NOBALITE® may not be used as a circular bandage. After the bandage has set, it must be split completely.
The product should not be applied 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:	aluminium-coated pouch
Secondary:	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

No specific storage conditions to be observed.

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.