



## NOBALITE®

REF 540412

### Product Description, Intended use, Application

The synthetic cast bandage (size 12.5 cm x 3.6 m, color: white) 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](http://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.