

NOBAMED Paul Danz AG

# **NOBACAST®**

### **REF 531405**

## Product Description, Intended use, Application

The synthetic cast bandage (size 5.0 cm x 3.6 m, color: blue) is individually packed and consists of a polyester 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. NO-BACAST<sup>®</sup> 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 circular cast, splint, orthosis and also to provide patients with the braces technique.

### Composition

Polyester, 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), NOBACAST<sup>®</sup> may not be used as a circular bandage. After the bandage has set, it must be split completely. 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:

aluminiumcoated 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 15223-1and 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.