NOBAMED Paul Danz AG

NOBASPLINT®

REF 529312

Product Description, Intended use, Application

The ready-for-use cast splint, 7.5 cm x 30 cm, for the forearm, is padded on both sides. It consists of 7 layers of fibreglass impregnated with polyurethane resin. After reaction with water, the resin hardens after a short time. Despite its stability, the cast has a low weight. The nonwoven cover dries quickly and provides the splint with the necessary soft padding.

As different splint lengths are available for different applications, the splint material doesn't need to be cut to length. It is therefore not necessary to trim the material, or at least the necessity of so doing is limited to a few moves. NOBASPLINT® is used for immobilization of fractures, fissural fractures, contusions and distortions.

Composition

Fibreglass, polyurethane resin, polypropylene nonwoven

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: 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.