

NOBAMED Paul Danz AG

NOBASPLINT[®]-Longuette

REF 527455

Product Description, Intended use, Application

The cast longuette is padded on both sides and consists of 7 layers of fibreglass impregnated with polyurethane resin. The cast is covered with a polypropylene nonwoven. The length required for application is cut from the roll (5 cm x 4.5 m). After its 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.

NOBASPLINT®-longuette 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:

aluminiumcoated pouch

Secondary:

carton made of cellulose

Symbols used in labelling

Explanations at <u>www.nobamed.com</u>



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.