



NOBAMED Paul Danz AG

NOBA[®] EXTENSIONSVERBAND (SKIN TRACTION KIT)

without adhesive

REF 944900

Product Description, Intended Use, Application

NOBA[®]-EXTENSIONSVERBAND (SKIN TRACTION KIT) **without adhesive** is a ready-to-use extension bandage for **children**, consisting of a stirrup lined with foam, two extension strappings, an affixed string and a bandage. Both extension strappings are provided with foam material so that they do not slip out of position on the skin. The skin traction kit is used for the treatment of fractures of the thigh or lower leg bones. It is fixed to the lower leg with the enclosed bandage. Weights can be attached to the affixed strings via a suitable roller system. This allows for a continuous longitudinal traction that is exerted on the injured extremity. The skin traction kit is adequately padded in the ankle area. NOBA[®]-EXTENSIONSVERBAND is for single use and is individually packed.

Composition

Polyester, cotton, synthetic latex, polyurethane, polypropylene, polyamide

Contraindications

In the case of an enormous dislocation of the bone fragments which can only be reduced by means of a surgical intervention, and in cases of comminuted fractures.

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 packaging: bandage in OPP-film and folding box made of cellulose

Secondary packaging: 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 DIN EN ISO 20417.

Storage and Transport

To be stored in a dry and dust-free environment, protected against direct sunlight

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