NOBAMED Paul Danz AG

NOBA®-Extensionsverband (SKIN TRACTION KIT)

with adhesive

REF 944870

Product Description, Intended Use, Application

NOBA®-EXTENSIONSVERBAND (SKIN TRACTION KIT) **with adhesive** is a ready-to-use extension bandage for **children,** consisting of a stirrup lined with foam, two highly adhesive extension strappings, an affixed string and a bandage. The skin traction kit is used for the treatment of factures of the thigh or lower leg bones. It is affixed to the lower leg and additionally secured 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®-EXTENSIONS-VERBAND is for single use and is individually packed.

Composition

Polyester, cotton, polyurethane, polypropylene, polyamide, synthetic zinc oxide adhesive

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.

Product Data Sheer: January 04, 2022 [REV5] replaces March 25,.2020 [REV4]