



NOBAMED Paul Danz AG

NOBA[®]-KNIESCHIENE

REF 376357

Product Description, Intended use, Application

NOBA[®]-Knieschiene (size M – 57 cm) is a coat-shaped knee splint with a 15° flexion. It is used to immobilize the joint in the case of traumatic or degenerative changes of the knee joint, in the rehabilitation phase after knee operations or treatments with P.O.P. bandages, for stabilization after knee joint endoprosthesis implantation, after ruptures of the crucial ligament, in the case of complete instability and minor or medium range instability of the ligaments. The flexion of the splint can be adapted individually. The splint consists of three parts and can therefore be adapted to the different leg circumferences.

Composition

Cotton, polyamide, polyester, aluminium

Note

The knee splint is washable at max. 30° C, hook and loop fasteners closed, if used domestically. Due to its material composition, the product may not be treated chemo-thermally and may therefore not be used on different patients.

Contraindication

The product should not be used in case of risk of stasis edema and thrombosis, as well as in case of existing allergy to the material. It should not be used directly on injured or damaged skin.

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:	PE bag
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 DIN EN ISO 20417

Storage and Transport

Dry and dustfree

Single use device

Intended for use on one patient. The reprocessing of single use devices for reuse can decrease the product's performance significantly. Reusing a single use device can lead to microbiological danger.

Disposal

According to locally applicable legal regulations and standards of infection prophylaxis.