

NOBAMED Paul Danz AG

# **NOBASTEP<sup>®</sup>**

## **REF 944601**

# Product Description, Intended use, application

The medical walking cast shoe (size S, shoe size 35-38) is used with a thigh bandage or lower leg bandage (made of cast or of synthetic material). It enables walking with a support bandage and allows secure fixation thanks to the three Velcro fasteners NOBASTEP<sup>®</sup> may be used on the left or on the right. The material is water and dirt resistant. NOBASTEP<sup>®</sup> is washable at 30°C.

#### Composition

PVC, TPR (thermoplastic styrene, butadiene plastic), polystyrole, naphthenic oil, calcium carbonate, zinc stearate, black dye), cardboard, EVA (ethylene vinyl acetate), polyester and nylon

#### **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** 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 DIN EN ISO 20417.

**Storage and transport** No special conditions

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.