

NOBAMED Paul Danz AG

SUSPENSORIUM

RFF 950004

Product Description, Intended use, Application

The medical suspensory, size 4= XS, is provided with a detachable bag. It is washable and is used for the fixation of the scrotum after operations or in the case of oedema.

Composition

Cotton, clip made of iron, buttons made of polypropylene

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 Legal Requirements

Medical Device according to MDD 93/42/EEC, MDR (EU) 2017/745.

The product does not contain dangerous toxic substances according to REACH.

Sizes

Size 4-6 child

Size 8 adolescent and adult

Size 10-12 seniors

Packaging

Primary: folding box made of

cellulose

Secondary: carton made of

cellulose

Symbols used in labelling

Explanation at www.nobamed.com







Marking on all packaging levels with CE and according to DIN EN ISO 15223-1 and ISO 20417.

Storage and Transport

Dry and dustfree

Single use device

Intended for use on one patient. 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.