



GILCHRIST-BANDAGE

REF 375360

Product Description, Intended use, Application

The bandage (**XXL – women's size 52/54 or men's size 60/62**) serves to immobilize the upper arm and shoulder region. The area of application are fractures in the upper arm region (e.g. subcapital fracture of the humerus), luxation of upper arm, dislocation of the acromioclavicular joint and postoperative care following surgical treatment of osteosynthesis of the upper arm area. It can be applied postoperatively or directly after a trauma. It consists of a permanent elastic tube bandage which is adjacent to a stabilizing shoulder padding. The bandage is split over the healthy shoulder to allocate the weight of the arm to it. The bandage ends are fixed by means of hook-and-loop fasteners. The interior side of this bandage is provided with a terry cloth cover. The bandage can be washed during domestic use at max. 60°C with closed fasteners. Due to its material composition, the product may not be treated chemo-thermally and may therefore not be used on different patients.

Composition

Cotton, Polyester, Polyamide, Polyurethane

Contraindications

With severe dislocation of the bone fragments which can only be reduced by operation.

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.

Packaging

Primary: folding box made of cellulose

Secondary: box 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 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.