



NOBAMED Paul Danz AG

Woundhook cover

REF 324019 (as of LOT 138923)

Product Description, Intended use, Application

Disposable single-layer white covers sewn of medically bleached knitted cotton fabric, **2,5 cm x 18 cm**, packed per 20 pcs, with worked in X-ray thread and with bands. The bands are used to fix the covers at the wound hook. Prior to sterilization they are slipped over the instruments to protect them during sterilization. If they are left on the wound hooks during their use they will reduce light reflections caused by surgical lights and protect sensitive tissue against sharp edges.

Composition

cotton, x-ray thread made of barium sulfate, PVC, phthalate-free plasticizer

Note

Before use on open wounds, the product must be sterilized in accordance with a validated sterilization method (Moist Heat in accordance with DIN EN ISO 17665, Radiation in accordance with DIN EN ISO 11137, or Ethylene Oxide in accordance with DIN EN ISO 11135).

Contraindications

Allergy caused by 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 Regulatory Requirements, Common Standards

Medical Device according to MDR (EU) 2017/745.

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

Packaging

Primary packaging: PE bag

Secondary packaging: 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 DIN EN ISO 20417

Storage and Transport

Dry and dustfree, protect from 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

Used material is disposed of in accordance with the requirements of statutory regulations. This is the responsibility of the respective institution.