



NOBAMED Paul Danz AG

Bauchtuch

REF 890619

Product Description, Intended use, Application

Unsterilized lap sponges, **6 layers, pre-washed, white**, made of 20 thread dressing gauze, **size 10 cm x 90 cm, with loop and X-Ray chip**. The lap sponge is used for wound care in the OR area, for wound covering, for the absorption of blood and wound fluid and to keep back and hold organs and body tissues. The lap sponges are for single use

Composition

Cotton, bariumsulphate, PVC, DOTP

Contra-Indications

No contra-indications known.

The product should not be used in the case of a known allergy against the material.

Notes

The product must be sterilized in accordance with a validated sterilization method before use on open wounds. The product can be sterilized with moist heat at 121°C/ 134°C, 2 to 3 bar, according to DIN EN 17665, radiation according to DIN EN ISO 11137 or ethylene oxide according to DIN EN ISO 11135.

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 *MDD 93/42/EEC, MDR (EU) 2017/745*.

The lap sponges comply with the requirements of DIN EN ISO 14079.

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

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

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