



NOBAMED Paul Danz AG

X-RAY MULLKOMPRESSEN

REF 821113

Product Description, Intended Use, Application

Non-sterile packed gauze swabs, **12 ply, pre-washed**, made of 17 thread dressing gauze, **size 10 cm x 12.5 cm, packed per 100 pcs**, with X-Ray thread applied in snake-shape, raw edges folded back. The gauze swabs are used for wound care in the OR area. They are used for absorbing blood and body fluids and for wound cleansing. The gauze swabs are Intended for single use only.

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.

Note

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 Regulative Requirements, Common Standards

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

The gauze swabs comply with the requirements of DIN EN ISO 14079.

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

Packaging

Primary packaging:

sterilizable
paper pouch
carton made
of cellulose

Secondary packaging:

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.