

NOBAMED Paul Danz AG

X-RAY-MULLTUPFER

REF 877425

Product Description, Intended use, Application

The non-sterile gauze balls, diameter 3.5 cm, packed per 250 pcs, have an X-ray thread. They are used to absorb blood and body fluids in the operative area and to clean the operation wound from blood and body fluids. The gauze is twisted into a round shape without using any rubber ring. Before use the gauze balls must be sterilized with a validated procedure (moist heat at 121°C/134°C, 2 to 3 bar, 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).

Composition

Cotton, X-ray-thread contains barium sulfate, PVC, DOTP

Contra-Indications

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

Note Sterilize before use

Normative and Regulative

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

The gauze complies with the requirements of DIN EN 14079 type 20.

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 <u>www.nobamed.com</u>



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.