



NOBAMED Paul Danz AG

X-RAY-PRÄPARIERTUPFER

REF 878412

Product Description, Intended use, Application

Non-sterile preparation balls, size XL, packed per 1000 pcs, provided with an X-ray thread with a minimum content of barium sulfate of 60 %. They are used to prepare delicate tissue in the surgical field (for example blood vessels, fine tendons). Before use the preparation 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 24.

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.