



NOBAMED Paul Danz AG

NOBATRAST® OP-Set Präpariertupfer

REF 645708 (as of LOT 135255)

Product Description, Intended use, Application

The double packed preparation balls made of 24-thread dressing gauze, 8 cm x 8 cm, (size M), packed per 20 pcs, have a woven-in X-ray thread. They are used to prepare delicate tissue in the surgical field (for example blood vessels, fine tendons).

Owing to a counting card on the inner packaging and a second counting card on the outer packaging, the counting may be checked quickly and safely.

Composition

Cotton, X-Ray-thread contains barium sulfate, polypropylene

Contraindications

The product should not be used in the case of a known allergy against 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 Regulative Requirements, Common Standards

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

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

The gauze complies with the requirements of DIN EN 14079 type 24.

Sterilization of the product complies with DIN EN ISO 11135.

Packaging

Primary packaging: paper wrap

Secondary packaging: paper-film packaging

Tertiary packaging: folding box made of cellulose

Quaternary packaging: carton made of cellulose

Symbols used in labelling

Explanations at www.nobamed.com



Marking on all packaging levels with CE and according to DIN EN ISO 15223-1- and ISO 20417.

Storage and Transport

Dry and dustfree, protect from sunlight.

Sterile device

Before using a sterile product, visually inspect the packaging to ensure that it is intact.

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.