



NOBATRAST® OP-Set Tupfer

REF 635625 (as of LOT 140055)

Product Description, Intended use, Application

The double packed sterile gauze balls, diameter **3.5 cm**, with silicone ring, are made of 20-thread dressing gauze and have an X-ray thread. The set contains **10 gauze balls**. They are used to absorb blood and secretion in the operative area and to clean the operation wound from blood and secretion. 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, silicone, X-Ray-thread contains barium sulfate, PVC, DOTP

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 MDR 2017/745.

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

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

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 DIN EN 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.