



NOBAMED Paul Danz AG

NOBATRAST®-Vakuum-OP-Set Bauchtuch

REF 606519

Product Description and Purpose

Sterile double packed **white lap sponges** made of cotton gauze 20 threads, **6 layers, pre-washed, size 10 cm x 90 cm, with loop and X-Ray chip**. The disposable lap sponge from the NOBATRAST®-vacuum OR sets is used for wound care in the OR area, for wound covering, for the absorption of blood and wound fluid and to keep back and hold organs and body tissues. The lap sponges are vacuum-packed in two transparent film-film packages. They are firmly positioned in the package. Owing to a green counting card on the inner packaging, and a second green counting card on the inner side of the outer packaging, the counting may be checked quickly and safely. The vacuum of the inner and outer packaging guarantees the sterility of the set until it is used.

Contra-Indications

No contra-indications known, unless there is an allergy attributable to cotton. The X-Ray chip is covered in full by the gauze and is firmly sewn-in. There is no direct contact between the X-Ray chip and the soft tissue or organ tissue.

Composition

Cotton, bariumsulphate, PVC, DINP

Normative and Legal Requirements

NOBATRAST®-Vakuum-OP-Set Bauchtuch is a class IIa, rule 7, medical product according to the MDD, the directive 93/42/EEC and the MDR (EU) 2017/745. The lap sponges comply with the requirements of the DIN EN 14079.

According to the European standard DIN EN ISO 10993-1 „Biological Evaluation of Medical Devices“, lap sponges are medical products in contact with the body from the outside (vascular system, indirect), and they are classified with the duration of contact A (less than 24 h).

Sterilization of the product complies with DIN EN ISO 11137.

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

It has CE marking and DIN EN ISO 15223-1 and EN 1041 labels on all its packaging.

Packaging

Primary packaging:	film-film-packaging
Secondary packaging:	film-film-packaging
Tertiary packaging:	folding box made of cellulose
Quaternary packaging:	carton made of cellulose

Storage

To be stored in a dry and dust-free environment, protected against direct sunlight

The product bears the following labels and symbols



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