NOBASET®

BAUCHTUCH

REF 603519 (as of LOT 37338)

Contents of this procedure pack:

5 x lap sponge, 10 x 90 cm, 4 layers, green, X-Ray chip, pre-washed, with loop,
MD CE 0123

1 x NOBAWRAP 38 x 38 cm, MD CE

Product Description, Intended use, Application
The sterile procedure pack consists of 5 lap sponges and NOBAWRAP® as sterile underlay. The lap sponges are 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 for single use

This product is for single and temporary use on one patient and must be applied by specially trained medical personnel. Any information for use that is available for individual products must be observed!

Normative and Legal Requirements
Procedure Pack according to Art. 22, Medical Device Regulation (EU) 2017/745, risk class IIa

The compatibility of the customized medical devices or other products has been assessed with due regard for the indications of the respective manufacturers, and operations have been performed in accordance with the aforementioned indications.

The manufacturers' intended use is not changed.

The systems and procedure packs are packed in compliance with a validated procedure.

All activity is properly monitored and controlled as part of our QM system, in accordance with DIN EN ISO 13485

A validated sterilization process is used for sterile procedure packs, taking into account the manufacturers' instructions, so that product functionality and product safety of the components are maintained after a system or procedure pack has been compiled and sterilized.

Sterilization and packaging are subject to supervision of our Notified Body TÜV Süd PS 0123 pursuant to Annex XI, Part A.

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

CE and DIN EN ISO 15223-1 markings of the components can be found on all packaging levels.

Storage and Transport
Dry and dustfree, protect from sunlight.

Symbols used in labelling
Explanation at www.nobamed.com