





WUNDHAKENBEZUG

REF 644224 (ab LOT 36008)

Contents of this procedure pack:

2 x wound hook cover, 4.5 x 24 cm,
NOBAMED Paul Danz AG, 

1 x wrapping material 30 x 30 cm,
VP Feuchtwangen, 

Product description, Intended use, Application

The sterile procedure pack consists of two white, single layer wound hook covers with bands for fixation and worked-in x-ray threads and a wrapping material that can be used as sterile underlay. The wound hook covers are sewn from medically bleached knitted cotton fabric. The covers are put directly on the sterile wound hooks. They reduce light reflections caused by the metal due to the operation lamp. Sensitive tissue is protected against the instruments' edges. The covers also protect the instruments until it they are used on the patient.

Composition:

cotton, x-ray thread made of barium sulfate, PVC, phthalate-free plasticizer.



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 13485:2016.

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

Storage and transport

To be stored in a dry and dust-free environment, protect from sunlight.

The product bears following labels and symbols

