



NOBAOPHTHALM®

REF 646110 (ab LOT 35906)

Contents of this procedure pack:

10 x NOBAOPHTHALM® Ophthalmological arrow sponges, NOBAMED Paul Danz AG, CE

1 x plastic bowl, NOBAMED Paul Danz AG, MD CE

1 x NOBAWRAP®, NOBAMED Paul Danz AG, MD CE

Product Description, Intended use, Application

The sterile procedure pack consists of medical ophthalmological sponges, NOBAWRAP® as sterile underlay and a white plastic bowl for keeping the ophthalmological sponges before they are used on the patient.

The arrow sponge is used to absorb exudate during ophthalmological surgery. It consists of PVA foam which swells up when liquids are absorbed and retains them.

Composition

Arrow sponge: PVA, polypropylene

Plastic bowl: PET

NOBAWRAP®: cellulose, polyethylene



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 I.

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.

If a sterilization is intended, a validated sterilization procedure will be used, 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, protected from sunlight.

The product bears following labels and symbols

