NOBAMED Paul Danz AG

NOBAFILM®

REF 174040

Product Description, Intended use, Application

The sterile incision film is made of a transparent, hypoallergenic polyurethane film which is coated with a hypoallergenic adhesive. NOBAFILM® is waterproof, but steam and air permeable. The dimensions are 40 cm x 40 cm total size, 34 cm x 40 cm adhesive surface. Bacteria cannot permeate the film. The product is used to cover the operation area in a sterile way. Owing to the fingerlifts on both sides, the surgical site can be optimally covered. The mechanical barrier function minimizes the introduction of germs into the surgical site.

Composition

Polyurethane film, polyacrylate adhesive

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 MDR (EU) 2017/745.
Sterilization of the product complies with DIN EN ISO 11135.
The product does not contain dangerous toxic substances according to REACH.

Symbols used in labelling

Explanation 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

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.