

# **NOBAMED Paul Danz AG**

# **NOBAFILM®**

#### **REF 173040**

# 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 30 cm x 40 cm total size, 24 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.