



NOBAMED Paul Danz AG

RUDAFILM®-steril

REF 073590

Product Description, Intended use, Application

The carrier material of the sterile wound dressing (size: 15 cm x 10 cm) consists of a transparent, elastic polyurethane film and is coated with a hypoallergenic polyacrylate adhesive. The wound pad does not adhere to the wound and is completely protected by the film, which is waterproof and water vapor permeable. The film protects the wound from germs and water. The patient is able to manage his daily body care without soaking the dressing with water. As the film is transparent the moisture status of the wound pad can be assessed without removing the dressing. The dressing is individually packed in sterile packaging.

Composition

Polyurethane, viscose, polyester, polyethylene, 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 Regulatory Requirements, Common Standards

Medical Device according to MDD 93/42/EEC and MDR (EU) 2017/745.

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

Sterilization of the product complies with DIN EN ISO 11135.

Packaging

Primary: paper packaging

Secondary: folding box made of cellulose

Tertiary: carton made of cellulose

Symbols used in labelling

Explanation at www.nobamed.com



Kennzeichnung auf allen Verpackungsstufen mit CE und nach DIN EN ISO 15223-1 und DIN EN ISO 20417.

Storage and Transport

Dry and dustfree, protect from sunlight.

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.