

SUPRASORB® F Film Wound Dressing, rolled

REF 20467, 20468, 20469, 18993

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1. Composition of the product

The SUPRASORB® F Film Wound Dressing, rolled consists of:

- film: polyurethane film, coated with a polyacrylate adhesive
- support film: polyester, coated on both sides with polyethylene and siliconized on one side
- cover paper: siliconized paper
- adhesive strips: polyester film and polyacrylate adhesive
- application aid: red paper strip

This product data sheet covers the following items:

REF 20467 Suprasorb® F Film Wound Dressing, rolled 10 cm x 1 m / 4 in. x 1.1 yd.

REF 20468 Suprasorb® F Film Wound Dressing, rolled 10 cm x 10 m / 4 in. x 11 yd.

REF 20469 Suprasorb® F Film Wound Dressing, rolled 15 cm x 10 m / 6 in. x 11 yd.

REF 18993 Suprasorb® F roll 1050 mm x 100 m - *custom-made item* -

2. Packaging, structure and composition

2.1 Unit container

- see 2.2

2.2 Shelf container

- REF 20468, 20469: Cardboard core (cellulose)
- REF 20467, 20468, 20469: Folding box (cellulose)
- REF 18993: see 2.3

2.3 Transit container

- REF 18993: Cardboard core (cellulose)
Plastic insert (polypropylene)
Plastic centering bush (polypropylene)
Polyethylene side-gusseted bag
- REF 20467, 20468, 20469, 18993: Corrugated cardboard box (cellulose)

3. Manufacture

Suprasorb® F Film Wound Dressing, rolled is produced according to specification in hygienic conditions and packed as described in its relevant packaging specification.

4. Description

The film dressing consists of a polyurethane film which is coated with a polyacrylate adhesive.

The product is equipped with a support film made of polyester which is covered on both sides with PE and siliconized on one side. The adhesive side is covered with a white siliconized paper.

Transparent adhesive strips are affixed along the long sides of the support film and cover paper.

A red paper strip is adhered lengthwise to the middle of the cover paper as an application aid. The application aid and cover paper are separated in the middle.

The product is available in various sizes.

5. Properties

Transparent, elastic film dressing that is permeable to water vapour with adhesive that is free of natural latex, colophony and colophony derivatives.

The product can be sterilized if needed with ethylene oxide in compliance with DIN EN ISO 11135-1.

6. Intended purpose (see valid instructions for use)

Suprasorb® F Film Wound Dressing, rolled is intended for prophylaxis (especially of decubitus ulcers) and for fixation during wound management.

7. Medical device classification

Suprasorb® F Film Wound Dressing, rolled is a medical device of Class I in terms of Rule 4.

(Council Directive 93/42/EEC concerning medical devices, Annex IX)

8. Biological evaluation and biocompatibility (DIN EN ISO 10993)

The starting materials used in the manufacture of the film dressing are safe if the product is used appropriately and for the purposes intended.

To date this company has received no notification of incidents involving this Lohmann & Rauscher product, neither has there been need for a recall for reasons of quality.

The purpose of this documentation and the statements made therein is to show that there is no risk involved in the use of the medical device Suprasorb® F Film Wound Dressing, rolled and that it is designed, manufactured and packaged in such a way that it will not compromise the clinical condition or the safety of patients, or the safety and health of users and other persons when used under the conditions and for the purposes intended.

9. Stability

Stored appropriately Suprasorb® F Film Wound Dressing, rolled has a shelf life of 5 years.

10. Disposal

The user is advised to observe current national legislation, norms and guidelines, regulating the disposal of medical refuse.

Packaging materials must also be disposed of in compliance with applicable national requirements.

Lohmann & Rauscher International GmbH & Co. KG
D-56579 Rengsdorf
signed by
Dr. Martin Abel
(Medical & Regulatory Affairs)