SUPRASORB® F

Film Wound Dressing, sterile

REF 20465, 20466

March 2016

Translation: Peritus
Revision: MI / S. Golz

1. Composition of the product

The SUPRASORB® F Film Wound Dressing consists of:

- polyurethane film
- polyacrylate adhesive
- polyethylene
- siliconized paper
- grasping edge, printed in red, with paper coated with polyacrylate adhesive

This product data sheet covers the following items:

REF 20465	Suprasorb® F Film Wound Dressing, sterile	15 x 20 cm / 6 in. x 8 in.
REF 20466	Suprasorb® F Film Wound Dressing, sterile	20 x 30 cm / 8 in. x 12 in.

2. Packaging, structure and composition

2.1 Unit container

- peel pouch consisting of cellulose and polyethylene

2.2 Shelf container

- instructions for use (cellulose)
- folding box (cellulose)

2.3 Transit container

- corrugated cardboard box (cellulose)

3. Manufacture

SUPRASORB® F Film Wound Dressing is produced according to specification in hygienic conditions and individually packed as described in its relevant packaging specification. The product is sterilized with ethylene oxide in compliance with DIN EN ISO 11135-1.

4. Description

SUPRASORB® F Film Wound Dressing consists of a polyurethane film which is coated with a polyacrylate adhesive. The coated side is covered with a paper that is coated with PE on both sides and siliconized on one side. The wound dressing is equipped with a red, perforated grasping edge. The product is available in two different sizes.

5. Properties

The SUPRASORB® F Film Wound Dressing is a machine-cut, folded, extensible, waterproof, permeable to water vapour film coated with an skin-friendly adhesive, which is free of **natural latex**, colophony and colophony derivates.
SUPRASORB® F Film Wound Dressing is for single use only. The product is sterile as long as the package remains unopened and undamaged.

Natural rubber latex is not an intentional ingredient in the production of the above mentioned products or its packaging. However, to the best of our knowledge we can't completely exclude any potential contaminations with latex traces from the production or the environment.

6. Intended purpose (see valid instructions for use)

The SUPRASORB® F Film Wound Dressing is intended to be used for the management of slightly exuding, superficial wounds, for the protection of new epithelial tissue and as a secondary dressing, e.g. for Suprasorb X.

7. Medical device classification

SUPRASORB® F Film Wound Dressing is a medical device of Class IIa 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 SUPRASORB® F Film Wound Dressing are safe if the product is used appropriately and for the purposes intended.

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 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 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.

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signed by
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