

# **SUPRASORB® F**

## Film Wound Dressing, sterile

REF 20460 – 20464

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### **1. Composition of the product**

The SUPRASORB® F Film Wound Dressing consists of:

- film, coated with adhesive: polyurethane film, coated with a polyacrylate adhesive (free of colophony and colophony derivatives, latex-free)
- support film: polyester coated with polyethylene on both sides, siliconized on one side
- cover paper: silicone paper

The adhesive side is covered with two white, centered overlapping silicone papers. The support film is stuck together with the two release papers by a transparent adhesive tape made of polyester film/polyacrylate adhesive.

This product data sheet covers the following items:

REF 20460	Suprasorb® F Film Wound Dressing, sterile	5 x 7 cm	10 pcs / SC
REF 20461	Suprasorb® F Film Wound Dressing, sterile	5 x 7 cm	100 pcs / SC
REF 20462	Suprasorb® F Film Wound Dressing, sterile	10 x 12 cm	10 pcs / SC
REF 20463	Suprasorb® F Film Wound Dressing, sterile	10 x 12 cm	50 pcs / SC
REF 20464	Suprasorb® F Film Wound Dressing, sterile	10 x 25 cm	10 pcs / SC

### **2. Packaging, structure and composition**

#### **2.1 Unit container**

- peel pouch made 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

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

## 4. Description

The SUPRASORB® F Film Wound Dressing consists of an adhesive-coated film, a support film, and the cover paper. The product is available in various sizes. The sizes 5 x 7 cm and 10 x 12 cm have curved corners.

## 5. Properties

Transparent, extensible, waterproof, permeable to water vapour film coated with an, **natural latex**, colophony and colophony derivatives free adhesive.

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

The 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 the SUPRASORB® F Film Wound Dressing are safe when the product is used appropriately and for the intended purpose.

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 – at temperatures not exceeding 25°C – 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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