

## Suprasorb® F - Film Wound Dressing, sterile

REF 20465, 20466 / 82801, 82062

November 2019

### 1. Composition of the product

The Suprasorb® F - Film Wound Dressing consists of:

- film: polyurethane film,  
coated with a polyacrylate adhesive
- 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	REF*	product description	Size	Package Size / SC
20465	*82801	Suprasorb® F Film Wound Dressing	15 x 20 cm	10
20466	*82062	Suprasorb® F Film Wound Dressing	20 x 30 cm	10

\* (French market)

### 2. Packaging, structure and composition

#### 2.1 Unit container

1 piece = 1 peel pouch  
made of cellulose and polyethylene

#### 2.2 Shelf container

1 folding box, made of cellulose  
1 instructions for use (cellulose)

Packaging unit / content see product table above

### 2.3 Transit container

1 corrugated cardboard box (cellulose)

REF	pieces	folding boxes
20465	400	40
20466	180	18

### 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 is a self-adhesive, transparent wound dressing that readily adapts to any challenging body contours and offers high wearing comfort. The transparent film dressing makes the wound easy to monitor and protects fresh epithelial tissue from external factors such as microbes and liquid. Suprasorb F maintains a moist wound environment and thus promotes wound healing.

### 5. Properties

- simple application
- high wearing comfort due to secure and flexible hold
- Protection against external influences (e.g. bacteria)
- as a primary dressing enables control of the wound

#### Indications:

- for the treatment of non-infected superficial wounds
- to protect fresh epithelial tissue
- as a secondary dressing, e.g. for Suprasorb® X.
- as prevention (incl. of pressure ulcers)
- for retention

### 6. Intended purpose (see valid instructions for use)

The Suprasorb® F Film Wound Dressing is intended for covering and protecting superficial wounds, provided that they are lightly exuding. Suprasorb® F Film Wound dressing can also be used for fixation in wound treatment.

## 7. Medical device classification

The Suprasorb® F Film Wound Dressing is a medical device of Class IIa in terms of Rule 4, Case 3.

## 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 – keep dry, protected from dust and sun – Suprasorb® F Film Wound Dressing has a shelf life of 5 years from the date of manufacture.

## 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  
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signed by  
Dr. Klemens Schulz  
Executive Board/ Chief Portfolio Officer