

## Suprasorb® F

### Film Wound Dressing, sterile

REF 20460 – 20464  
82799, 82899, 82061

September 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
20460	*82799	Suprasorb® F Film Wound Dressing	5 x 7 cm	10
20461		Suprasorb® F Film Wound Dressing	5 x 7 cm	100
20462	*82800	Suprasorb® F Film Wound Dressing	10 x 12 cm	10
20463		Suprasorb® F Film Wound Dressing	10 x 12 cm	50
20464	*82061	Suprasorb® F Film Wound Dressing	10 x 25 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
20460, 82799	380	38
20461	1000	10
20462, 82800	100	10
20463	200	4
20464, 82061	140	14

## 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 highly supple, self-adhesive dressing. The product consists of a polyurethane film which is coated with a skin-friendly polyacrylate adhesive and covered by siliconized paper. A plastic film with holding edges serves as an application aid and makes dressing application easy.

## 5. Properties

The Suprasorb® F Film Wound Dressing is:

- impermeable to bacteria
- permeable to oxygen and water vapour
- waterproof
- transparent
- extensible

### Indications:

- slightly exuding wounds
- superficial wounds
- for the protection of new epithelial tissue as a secondary dressing, e.g. for Suprasorb® X.

**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.

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signed by

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Director Global Portfolio Management