

# SUPRASORB® P adhesive PU self-adhesive foam dressing, sterile

REF 20415 – 20419, 121906, 121907, 31262, 31263, 31266

May 2015

Translation: Peritus  
Revision: MI / M. Fuchs

## 1. Composition of the product

The SUPRASORB® P adhesive PU self-adesive foam dressing consists of:

- micro-porous polyurethane support layer, skin colored
- polyacrylate adhesive
- polyurethane foam layer
- perforated polyurethane film, transparent
- silicone paper, white

This product data sheet covers the following items:

REF 20416	Suprasorb® P adhesive PU self-adesive foam dressing, sterile	7.5 x 7.5 cm
REF 20417	Suprasorb® P adhesive PU self-adesive foam dressing, sterile	10 x 10 cm
REF 20418	Suprasorb® P adhesive PU self-adesive foam dressing, sterile	15 x 15 cm
REF 20419	Suprasorb® P adhesive PU self-adesive foam dressing, sterile	15 x 20 cm
REF 20415	Suprasorb® P adhesive PU self-adesive foam dressing sacrum, sterile	18 x 20.5 cm
REF 121907	Suprasorb® P adhesive PU self-adesive foam dressing, sterile	7.5 x 7.5 cm
REF 121906	Suprasorb® P adhesive PU self-adesive foam dressing, sterile	10 x 10 cm
REF 31262	Suprasorb® P adhesive PU self-adesive foam dressing, sterile	15 x 15 cm
REF 31263	Suprasorb® P adhesive PU self-adesive foam dressing, sterile	15 x 20 cm
REF 31266	Suprasorb® P adhesive PU self-adesive foam dressing sacrum, sterile	18 x 20.5 cm

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

### **2.1 Unit Container**

- peel pouch consisting of cellulose and polyethylene

### **2.2 Shelf Container**

- cellulose folding box  
- instructions for use, made from cellulose

### **2.3 Transit Container**

- corrugated cardboard box made from cellulose

## **3. Manufacture**

The SUPRASORB® P adhesive PU self-adhesive foam dressing is manufactured to specification under hygienic conditions and packaged as described in its respective packaging specifications.

The device is sterilized with ethylene oxide in compliance with DIN EN ISO 11135-1.

## **4. Description**

The SUPRASORB® P adhesive PU self-adhesive foam dressing consists of a skin-coloured, micro-porous polyurethane support layer coated with a polyacrylate adhesive. A white polyurethane foam layer is affixed at the centre of the adhesive side. The PU foam is equipped with a perforated, transparent polyurethane film on the wound side. This PU film is bonded to the PU foam by means of a polyacrylate adhesive.

The adhesive side of the product is covered with silicone papers.

The product is available in different sizes.

## **5. Properties**

Flexible, permeable to vapor foam dressing with an adhesive edge and rounded corners.

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

The SUPRASORB® P adhesive PU self-adhesive foam dressing can be used for the treatment of all wounds provided that they are moderately exuding and superficial e.g. ulcers or bedsores.

## **7. Medical device classification**

The SUPRASORB® P adhesive PU self-adhesive foam dressing is a medical device of Class IIb in terms of Rule 4.  
(Council Directive 93/42/EEG concerning medical devices, Annex IX)

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

The starting materials used in the manufacture of SUPRASORB® P adhesive PU self-adhesive foam dressing are safe if the product is used for the purposes intended.

The purpose of this documentation and the statements made herein is to show that there is no risk involved in the use of the product SUPRASORB® P adhesive PU self-adhesive foam 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), the foam dressings have a shelf life of 3 years.

## **10. Disposal**

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