CURAPOR® transparent

Surgical Wound Dressing, sterile

REF 13099 - 13105

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1. Composition of the product

CURAPOR® transparent consists of:

- Adhesive film:	Polyurethane film coated with polyacrylate adhesive
- Wound pad:	Absorbent layer consisting of viscose/polyester and a layer of polyester/polyethylene which does not stick to the wound
- Support film:	Polyester, coated with polyethylene on both sides, siliconized on one side
- Release paper:	Siliconized paper
- Transparent adhesive strips:	Polyester film and polyacrylate adhesive

The adhesive side is covered with two white centered overlapping silicone papers. The supporting film and the two cover papers are adhered on both long sides with a transparent adhesive strip made of polyester film/polyacrylate adhesive.

This product data sheet covers the following items:

REF 13099	Curapor® transparent, surgical wound dressing, sterile	
	7 x 5 cm	5 units/SC
REF 13101	Curapor® transparent, surgical wound dressing, sterile	
	7 x 5 cm	50 units/SC
REF 13100	Curapor® transparent, surgical wound dressing, sterile	
	10 x 8 cm	5 units/SC
REF 13102	Curapor® transparent, surgical wound dressing, sterile	
	10 x 8 cm	25 units/SC
REF 13103	Curapor® transparent, surgical wound dressing, sterile	
	10 x 15 cm	25 units/SC
REF 13104	Curapor® transparent, surgical wound dressing, sterile	
	10 x 20 cm	25 units/SC
REF 13105	Curapor® transparent, surgical wound dressing, sterile	
	10 x 25 cm	25 units/SC

2. Packaging, structure and composition

2.1 Unit container

- peel pouch consisting of cellulose and polyethylene

2.2 Shelf container

- folding box made of cellulose

2.3 Transit container

- corrugated cardboard box made of cellulose

3. Manufacture

CURAPOR® transparent surgical wound dressing is produced according to specification in hygienic conditions and individually packed into peel pouches as described in the packaging specification.
The product is sterilized by ethylene oxide in accordance with DIN EN ISO 11135-1.

4. Description

CURAPOR® transparent surgical wound dressing consists of a film which is coated with an adhesive, a wound pad, a support film, the cover paper, as well as a transparent adhesive strip.
The product is available in various sizes.

5. Properties

Transparent, waterproof wound dressing, free of natural latex, colophony and colophony derivates. The 7 x 5 cm and 10 x 8 cm sizes have rounded corners.

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

CURAPOR® transparent surgical wound dressing is intended for sterile care of postoperative wounds, accidental injuries, as well as small cuts and abrasions.

7. Medical device classification

CURAPOR® transparent surgical wound dressing is a medical device of Class Is 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 wound dressing are safe when the products are used appropriately and for the purposes intended.

The product is free of natural latex, colophony and colophony derivates.

To date this company has received no notification of incidents involving this Lohmann & Rauscher product, neither has there been need for a recall for reasons of quality.

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 CURAPOR® transparent surgical 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 – CURAPOR® transparent surgical 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
Dr. Martin Abel
(Medical & Regulatory Affairs)