

VLIWASORB® Superabsorbent wound dressing, sterile

REF 24501 – 24503, 26904, 34500, 34522, 34523

February 2016

Translation: Peritus
Revision: MI / M. Fuchs

1. Composition of the product

VLIWASORB® superabsorbent wound dressing consists of:

- Wound contact layer: polyethylene film
- Non-woven distribution layer: polypropylene fibers
- Absorbent core: cellulose with embedded superabsorber (sodium polyacrylate)
- Non-woven clothing protection: polypropylene fibers
- Adhesive: synthetic raw materials

This product data sheet covers the following products:

International

REF 34500	VLIWASORB® superabsorbent wound dressing, sterile	7.5 x 7.5 cm
REF 24501	VLIWASORB® superabsorbent wound dressing, sterile	10 x 10 cm
REF 24502	VLIWASORB® superabsorbent wound dressing, sterile	10 x 20 cm
REF 24503	VLIWASORB® superabsorbent wound dressing, sterile	20 x 20 cm
REF 26904	VLIWASORB® superabsorbent wound dressing, sterile	20 x 30 cm

Lokal

REF 34522	VLIWASORB® superabsorbent wound dressing, sterile	10 x 20 cm
REF 34523	VLIWASORB® superabsorbent wound dressing, sterile	20 x 20 cm

2. Packaging, structure and composition

2.1 Unit container

- peel pouch consisting of:
 - o Sterilization paper with grid lacquer coating
 - o Kraft paper with polyethylene

2.2 Shelf container

- folding box (cellulose)
- instructions for use (cellulose)

2.3 Transit container

- corrugated cardboard box (cellulose)

3. Manufacture

VLIWASORB® superabsorbent wound dressing is produced according to specification in hygienic conditions, individually packed as described in its relevant packaging specification, and sterilized by ethylene oxide in compliance with DIN EN ISO 11135-1.

4. Description

A VLIWASORB® wound dressing consists of a wound contact layer, a non-woven distribution layer, an absorbent core and a non-woven clothing protection (blue) on the back. The wound contact layer and the non-woven clothing protection completely envelop the non-woven distribution layer and absorbent core and are adhered along all four edges by means of a hotmelt adhesive. The dressing is available in 5 sizes.

5. Properties

VLIWASORB® superabsorbent wound dressing is a rectangular wound dressing that is closed on all four sides.

6. Intended purpose (see valid instructions for use)

VLIWASORB® superabsorbent wound dressing is indicated for the treatment of heavily exuding wounds such as pressure sores, arterial ulcers, venous leg ulcers, diabetic ulcers, postoperative wounds healing by second intention, laparotomy wounds, on fistulae, and superficial 2nd degree burns.

7. Medical device classification

VLIWASORB® superabsorbent wound dressing is a medical device of Class IIb 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 VLIWASORB® superabsorbent wound dressing are safe if the product is used appropriately and for the purposes intended.

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 VLIWASORB® superabsorbent 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 VLIWASORB® superabsorbent 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.

Lohmann & Rauscher International GmbH & Co. KG
D-56579 Rengsdorf
signed by
Dr. Martin Abel
(Medical & Regulatory Affairs)