

RespoSorb[®] Super, sterile

MEDICAL DEVICE

General Product Description/Intended Purpose

RespoSorb Super is a sterile superabsorbent dressing used on superficial, moderately to highly exuding wounds. The absorbent core absorbs and binds exudate. RespoSorb Super is a combined superabsorbent dressing which consists of four layers of different materials. On the wound side, the product features a soft, white, hydrophilic nonwoven (viscose and polyamide). The inner dressing core consists of soft cellulose fluff blended with liquid-retaining polyacrylate polymers. This absorbent core is enclosed in a thin nonwoven fabric that evenly distributes the liquid. On the side facing away from the wound, the product features a green layer of polypropylene nonwoven, which is water-repellent but permeable to air and allows for gas exchange.

Intended Purpose

Single use sterile superabsorbent dressing for long-term treatment of injured skin, acute and chronic, with moderate to high levels of exudate. It is used on adults only, by healthcare professionals in clinical or homecare environments. It can be combined with local antiseptics, primary and secondary dressings and used under compression bandages.

Application

- Select RespoSorb Super to match the wound size so that the dressing extends at least 1–2 centimeters beyond the wound margins.
- Place the white side of RespoSorb Super on the wound so that the green special nonwoven layer faces away from the wound.
- Secure the dressing e.g. with adhesive tape, conforming bandages or, if necessary, compression bandages.
- One dressing can remain on the wound for up to 5 days, depending on the condition of the wound. Change the dressing if clinically indicated or when exudate reaches the edges of the dressing or is noticeable through the green nonwoven top layer
- In case of infected wounds, a combination with e.g. Atrauman Ag is possible
- With decreasing amounts of exudate, the use of a suitable hydroactive wound dressing (e.g. HydroTac) is recommended.

Indications

RespoSorb Super is suitable for the treatment of superficial, moderately to highly exuding wounds: acute wounds (traumatic wounds, post-operative wounds, lymphatic wounds) and chronic wounds (decubitus/pressure sores, venous, arterial or mixed leg ulcers, tumour wounds). RespoSorb Super can be used under compression bandages.

Catalogue Numbers

| Packaging | 10x10 | 10x20 | 15x20 | 20x25 | 20x40 |
|-----------|--------|--------|--------|--------|---------|
| P10 | 685020 | 685021 | 685022 | 685023 | 685024* |

*The peel pack of the dressing is not intentionally made with natural rubber latex.

Residual Risks, Contra-Indications and Undesirable Side Effects, Warnings

Do not use RespoSorb Super on dry wounds or on exposed bones, muscles or tendons.
Do not use RespoSorb Super in case of hypersensitivity to any of its components.

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Cautions and precautions

- Do not cut the dressing.
- Medical assessment of the wound condition and the causes of wound-healing impairment is necessary before treating wounds with an impaired healing tendency. Treatment with RespoSorb Super cannot replace a causal treatment of the wound-healing impairment. If there are clinical signs of infection, the infection needs to be controlled with appropriate treatment before this dressing can be used.
- In all cases, follow the established clinical protocol.
- In the absence of available data supporting the use of this dressing on sensitive population groups such as infants, children, pregnant or nursing women, and in the absence of data to the contrary, on these population groups this dressing should be used with caution following a clinician's recommendation.
- For dressings which are packed in paper-paper peel packs: The sealed seam of the peel pack contains natural rubber latex, which may cause allergic reactions!

Sterile Device

Ethylene oxide sterilization.

Do not use if package is damaged.

Single-use device

Reusing a single-use medical device is dangerous. Reprocessing devices, in order to reuse them, may seriously damage their integrity and their performance. Information available on request.

Product disposal

In order to minimize the risk of potential infection hazards, or environmental pollution, disposable components of the medical device should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards. Dispose of the medical device with household waste.

Incident reporting

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation (EU) 2017/745 on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.

Product Performance Characteristics

| Product | | | | |
|-----------------------|---------------------|----------------------|--------------|------------------|
| Property | Test method | Unit | Requirements | Test results |
| Free absorption | EN 13726-1 chap 3.2 | g/100cm ² | 140-220 | 169 ¹ |
| | TM-404 | g/100cm ² | 140-220 | 185 ² |
| Absorption under load | TM-414 | g/100cm ² | 100-150 | 105 ² |
| Retention under load | TM-404 | g/100cm ² | 100-150 | 125 ² |

²Data from external lab, SMTL, UK


All data refer to sterile products.

Labelling

RespoSorb[®] Super, sterile

Lot-No. with 9+6 Digit Code

e.g.:

| | | | | | | | | | |
|---|------|-----------------------|-------------------------|-------|---------------|------|-----|-------|---------|
|  | X | XXX | XX | XX | X | XX | X | X | XX |
| | year | internal order number | charge of sterilization | plant | control digit | week | day | shift | machine |

Manufacturing Date

e.g.:

| | | | | | |
|---|------|---|-------|---|-----|
|  | 2020 | - | 07 | - | 18 |
| | year | | month | | day |

Use-by-Date

e.g.:

| | | | | | |
|---|------|---|-------|---|-----|
|  | 2025 | - | 07 | - | 01 |
| | year | | month | | day |

Shelf Life: 3 years

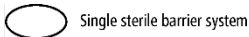
Medical Device



Unique Device Identifier



Single Sterile Barrier System



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