

Sorbsan Silver Silver Alginate Wound Dressing

STERILE R

CE
2797

Manufactured by:
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Sorbsan Silver

Dressing Change and Removal

1. Sorbsan Silver Alginate Wound Dressing can remain in situ up to 7 days, dependent on patient condition and the level of exudate. Initially it may be necessary to change the dressing every 24 hours or whenever good wound care practice dictates that the dressing should be changed.
2. Reapply Sorbsan Silver Alginate Wound Dressing when the secondary dressing has reached its absorbent capacity or whenever good wound care practice dictates that the dressing should be changed.
3. To reapply, gently remove the secondary dressing. If the wound appears dry, saturate the dressing with sterile saline solution prior to removal.
4. Gently remove the dressing from the wound bed and discard.
5. Irrigate the wound site with a suitable wound cleanser prior to application of a new dressing.

Storage

Store in a cool, dry place under 25°C/77°F.

The use by date of this product is printed on the packaging.

SYMBOLS USED ON LABELLING



Attention, see instructions for use.



Keep away from sunlight



Keep Dry



Single Use



Do not Re-sterilise



Do not use if package is open or damaged

STERILE R sterilized using irradiation



Manufacturer



Use by: year and month



Batch number



Product reference



Not made with natural rubber latex



Storage Conditions

EC REP EC Representative



CE mark



MR unsafe



Medical Device



Sorbsan Silver

Product Description

Sorbsan Silver Alginate Wound Dressing is a highly absorbent, sterile, single use, nonwoven pad or ribbon composed of calcium alginate and 0.95% ionic silver. The silver in the dressing kills a broad spectrum of wound bacteria, and aids in creating an antimicrobial environment. The dressing absorbs high amounts of wound fluid and the microorganisms contained in the wound fluid. The absorbed wound fluid creates a soft and cohesive gel which assists in maintaining a moist environment and aids in the removal of non-viable tissue from the wound (autolytic debridement). The moist wound healing environment and control of dressing microorganisms supports the body's healing process and may help reduce the risk of wound infection. The dressing is intended for use on moderate to heavily exuding wounds.

Sorbsan Silver Alginate Wound Dressing has been proven in vitro to kill wound microorganisms within the dressing and help to create an antimicrobial environment. It has shown antibacterial effect against relevant wound bacteria, such as Methicillin-Resistant Staphylococcus epidermidis (MRSE), Vancomycin-Resistant Enterococcus faecalis (VRE), Staphylococcus aureus, Escherichia coli, Pseudomonas aeruginosa, and Klebsiella pneumonia ssp pneumonia. It has shown antifungal effect against Candida albicans in in vitro setting^{1, 2}.

Sorbsan Silver Alginate Wound Dressing is designed to be le7 in place over a wound for up to 7 days.

Indications

Under the supervision of a healthcare professional, Sorbsan Silver Alginate Wound Dressing may be used for the management of:

- Wounds where there is an infection or an increased risk of infection;
- Partial thickness (second degree) burns;
- Diabetic foot ulcers, leg ulcers, and pressure ulcers/sores (partial & full thickness);
- Surgical wounds left to heal by secondary intention;
- Traumatic wounds;
- Wounds that are prone to bleeding, such as wounds that have been mechanically or surgically debrided.

Contra-indications

- Sorbsan Silver Alginate Wound Dressing is not indicated for use on the following:
- Surgical implantation
 - Dry wounds
 - To control heavy bleeding
 - Individuals who are sensitive to or who have had an allergic reaction to alginate or silver
 - Use during MRI (Magnetic Resonance Imaging) procedures
 - Third-degree burns

Warnings

- For single use.
- Do not re-use. Do not re-sterilize. Do not use if individual pouch is damaged/ opened.
- For external use only. The dressing should be used under the supervisions of medical professionals.
- Sorbsan Silver Alginate Wound Dressing is not compatible with oil-based products, such as petrolatum.
- Sorbsan Silver Alginate Wound Dressing is not intended for use as a surgical sponge.
- The dressing is not intended to be used cumulatively for a period of longer than 30 days.
- Due to the sterilization process there may be a slight odor on opening the primary packaging.
- Clinicians / Healthcare Professionals should be aware that there are very limited data on prolonged and repeated use of silver-containing dressings, particularly in children and neonates.
- Do not moisten Sorbsan Silver Alginate Wound Dressing with hydrogen peroxide or povidone iodine.
- When used with infected wounds additional inspection and treatment as per clinical protocols may be required.
- The use of the dressing on infected wounds does not negate the need to follow local practices with regards to infection management and use of the systemic antibiotics.
- Silver alginate wound dressing should not be used during pregnancy and cautious use is advised during lactation, because of the lack of data.

Precautions

- Avoid contact with electrodes or conductive gels during electronic measurements, e.g. electrocardiograms (ECG) and electroencephalograms (EEG). The dressing must be removed prior to patients undergoing Magnetic Resonance Imaging (MRI) examinations.



Sorbsan Silver

- During the body's normal healing process, non-viable tissue is removed from the wound (autolytic debridement), which could initially make the wound appear larger. If the wound continues to grow larger after the first few dressing changes, consult a healthcare professional. The wound should be inspected during dressing changes. Consult a healthcare professional if you see:
 - a) signs of infection (increased pain, increased redness, wound drainage),
 - b) bleeding,
 - c) a change in wound color and/or odor,
 - d) irritation (increased redness and/or inflammation),
 - e) maceration (skin whitening),
 - f) hypergranulation (excessive tissue formation),
 - g) sensitivity (allergic reaction),
 - h) no signs of healing.
- If you have difficulty removing the dressing, it should be soaked with sterile saline solution until it removes easily.
- Secondary dressings should be used as stated in the DIRECTIONS FOR USE Section.
- Appropriate supportive measures should be taken where indicated (e.g., use of graduated compression bandaging in the management of pressure ulcers/sores).
- In cavity wounds, the ribbon dressing may be used to pack the wound. For wounds such as fistulae and sinus tracts, employ appropriate techniques during the insertion and removal of the dressing.

¹ The biocompatibility of Sorbsan Silver Alginate Wound Dressing has been demonstrated through appropriate in vivo and in vitro tests.
² Antimicrobial activity has been demonstrated by relevant in vitro microbiological assays.

Microorganism	7-day Sustained Activity Test (Simulated Wound Model)
Methicillin-Resistant Staphylococcus epidermidis (MRSE)	✓
Vancomycin-Resistant Enterococcus faecalis (VRE)	✓
Staphylococcus aureus	✓
Escherichia coli	✓
Pseudomonas aeruginosa	✓
Klebsiella pneumonia ssp pneumonia	✓
Candida albicans	✓

The studies to demonstrate that a reduction in colonization of microorganism growth on the device correlate with a reduction in infections in patients have not been performed.

Directions for use

Site Preparation

- Debride when necessary and irrigate/clean the wound site in accordance with standard protocols
- Remove excess solution from surrounding skin

Dressing Selection

Select a size of Sorbsan Silver Alginate Wound Dressing that is slightly larger than the wound.

Dressing Application

1. Cut (using clean scissors) or fold the dressing to fit the wound. Loosely fill deep wounds, ensuring the dressing does not overlap the wound margins.
2. When using Sorbsan Silver Alginate Wound Dressing ribbon in cavity wounds, leave at least 2.5cm (1 inch) outside the wound for easy retrieval.
3. For heavily exuding wounds, apply to wound bed directly.
4. This primary dressing should be used with a secondary cover dressing. Apply the dressing to the wound and cover with a moisture retentive dressing, foam dressing, gauze, or other appropriate dressing. See individual cover dressing package inserts for complete instructions for use. All wounds should should be inspected frequently. Remove the Sorbsan Silver Alginate Wound Dressing when clinically indicated (i.e., leakage, excessive bleeding, increased pain) or after a maximum of 7 days.