

INDICATIONS

Procellera™ antimicrobial wound dressing is indicated for professional use for partial and full-thickness wounds such as: pressure ulcers, venous ulcers, diabetic ulcers, burns, surgical incisions, and donor and/or recipient graft sites.

PRODUCT DESCRIPTION

Procellera™ is applied as a single layer dressing, consisting of a woven absorbent polyester containing elemental silver and zinc, and provides an effective barrier to microbial penetration for partial and full-thickness wounds.

The characteristic which makes Procellera™ a unique wound dressing is that, in the presence of exudate (moisture), a small amount of current is produced, and it occurs because it is inherent to the design.

Procellera™ dressing should be used under a secondary dressing or bandage (not provided), which keeps it in place and helps maintain a moist wound environment.

INGREDIENTS

Procellera™ contains 1 mg/cm² silver and 0.5 mg/cm² zinc.

WARNINGS

Frequent or prolonged use of silver may result in permanent discoloration of skin and mucous membranes (e.g., argyria).

CONTRAINDICATIONS

- Procellera™ dressing should not be used on individuals who are sensitive to or who have had an allergic reaction to the dressing or its components.
- Do not use on patients with a known sensitivity to silver or zinc.
- Do not use on patients during MRI (Magnetic Resonance Imaging) examination.
- Avoid contact with electrodes or conductive gels during electronic measurements, e.g. EEG or ECG.
- Do not use during delivery of electricity, radiofrequencies, ultrasound or other energy-based treatments to the body by any method of delivery.
- Remove during any surgeries.
- Do not use on actively bleeding wound(s).

STORAGE AND DISPOSAL

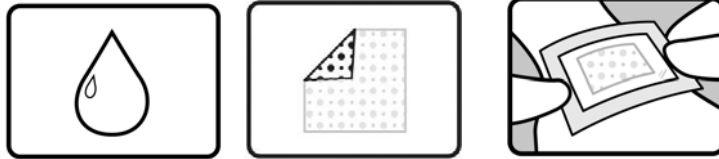
- Store at room temperature (10°C – 25°C/50°F -77°F), in a dry location.
- Disposal should be handled according to local environmental procedures.

INSTRUCTIONS FOR USE

Preparation

- Please note that local hygiene procedures should be followed prior to and following dressing application and change.
- Before applying the dressing, cleanse the wound area with an appropriate wound cleanser.
- Remove the Procellera™ dressing from package and if needed, cut it to a shape that will extend beyond wound edges approximately 1-2 cm.

Application



Important:

The application procedure varies according to the wound type, as indicated by the physician. For optimal results, apply the procedure that best corresponds to the nature of the wound, as follows:

DRY WOUND

1. Moisten the Procellera™ dressing with sterile saline or sterile water. Avoid over-soaking.
2. Apply Procellera™ dressing to the wound site, **with the dotted side against and directly contacting the wound surface.**
3. Cover with a secondary sterile dressing, which will help maintain a moist wound healing environment (such as waterproof or semi-permeable type dressings). If needed, secure in place with a bandage or other fixation. Do not apply secondary dressing or fixation too tightly, or in a manner that will restrict blood flow.
4. Re-moisten as necessary. Avoid over-soaking.

EXUDATING WOUND (liquid producing)

1. Apply Procellera™ dressing to the wound site, **with the dotted side against and directly contacting the wound surface.** (No dressing moistening is necessary.)
2. Cover with a sterile dry gauze or a foam dressing, which will help absorb extra fluid; replace as needed.
3. If needed, secure the dressing(s) in place with a bandage or other fixation. Do not apply secondary dressing or fixation too tightly, or in a manner that will restrict blood flow.

DEEP WOUND

1. Moisten the Procellera™ dressing with sterile saline or sterile water. Avoid over-soaking.
2. Insert the Procellera™ dressing into the wound space, **with the dotted side against and directly contacting the wound surface.**
3. Pack with sterile gauze, ensuring contact between the Procellera™ dressing and the wound.
4. Cover with a secondary sterile dressing, which will help maintain a moist wound healing environment (such as waterproof or semi-permeable type dressings). If needed, secure in place with a bandage or other fixation. Do not apply secondary dressing or fixation too tightly, or in a manner that will restrict blood flow.
5. Re-moisten as necessary. Avoid over-soaking.

Site Care and Dressing Change

- Inspect the wound site periodically and consult your physician if any signs of infection or other complications are observed (see *Precautions*).
- Change the dressing according to institution protocol, as needed (when the dressing becomes soiled, or after 7 days of use).

Removal

- Gently pull back the dressing(s). If the dressing adheres to the wound surface, do not force it off. Moisten or soak it with sterile saline or sterile water until it can be removed **without tissue damage**.

PRECAUTIONS

- Procellera™ dressing should be used under the supervision of a qualified health care professional.
- The safety of use longer than 28 days has not been studied.
- For external use only. Single use only.
- Sterility is guaranteed, unless pouch is damaged or opened prior to use. Do not use if the immediate product packaging is open or damaged.
- Procellera™ dressing may be used on infected wounds which are being managed in accordance with institutional clinical protocols for infection abatement as an adjunct to the standard treatment regimen.
- Do not use Procellera™ dressing with topical agents such as antimicrobial ointments, enzymatic debriders, antibiotic creams, silver or zinc containing creams, oxidizing agents, etc.
- Secondary dressings should be used as stated in their Instructions for Use. Do not apply secondary dressings or fixations too tightly, or in a manner that will restrict blood flow.
- The local use of Procellera™ dressing is not intended in any way to replace existing systemic therapies or other standard procedures planned for the patient, based on his/her clinical needs. Follow physician's directions to manage existing medical conditions.
- If there is any difficulty removing the dressing, it should be soaked with sterile water or sterile saline until it can be easily removed, **without injuring underlying tissue. Do not force the bandage off of wound surface.**
- The patient should stop using the dressing and contact a health care professional if any of the following occur:
 - Sensitivity (allergic reaction);
 - Irritation (increased redness and/or inflammation);
 - Infection signs (increased pain, increased redness, increased wound drainage, increased warmth or unusual odor);
 - Bleeding;
 - Maceration (skin whitening and softening);
 - Hypergranulation (excessive tissue formation);
 - Any changes in the skin surrounding or adjacent to the dressing;
 - Wound increases in size after few dressing changes;
 - No signs of healing after several days of use.

For further information please contact us:

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