

INDICATIONS

Proceller[™] 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

Proceller[™] 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 Proceller[™] a unique wound dressing is that a small amount of current is produced and it occurs because it is inherent to the design. In the presence of exudate, the device should be used with an appropriate secondary dressing to maintain a moist wound healing environment.

INGREDIENTS

Each square inch of dressing contains 2.4 micrograms of silver and 2.4 micrograms of zinc.

WARNINGS

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

CONTRAINDICATIONS

- Proceller[™] 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 and ECG.
- Do not use during delivery of electricity, radiofrequencies, or electromagnetic treatment to the body by any method of delivery.
- Remove Proceller[™] during any surgeries.
- Do not use in the presence of active bleeding.

• **PRECAUTIONS**

- 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 and/or opened prior to use. Do not use if the immediate product packaging is open and/or damaged.
- Store at room temperature (10°C – 25°C/50°F -77°F), in a dry location.
- Proceller[™] 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.
- Proceller[™] may not be compatible with topical antimicrobials.
- The patient should stop using the dressing and contact a healthcare professional if any of the following occur:
 - The wound continues to grow larger after the first few dressing changes;
 - There are any signs of infection (increased pain, increased redness, increased wound drainage, increased warmth or odor);
 - Bleeding;
 - A change in wound color and/or odor;
 - Irritation (increased redness and/or inflammation);
 - Maceration (skin whitening and/or softening);
 - Hypergranulation (excessive tissue formation);
 - Any changes in the skin surrounding or adjacent to the dressing;

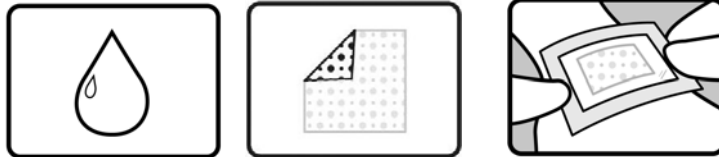
- Sensitivity (allergic reaction);
- If there are no signs of healing after several days of use.
- Secondary dressings should be used as stated in their Directions for Use.
- Wounds located over joint surfaces might heal causing limited joint movement. Any dressing should be carefully applied and monitored to minimize this risk.
- Appropriate supportive measures should be taken where indicated (e.g., use of graduated compression in the management of venous leg ulcers, pressure relief measures in the management of pressure ulcers, systemic antibiotics, frequent monitoring in the treatment of wound infection, control of blood glucose for diabetic ulcers, etc.).
- If there is any difficulty removing the dressing, it should be soaked with sterile water or sterile saline until it removes easily. **Do not force the bandage off of wound surface.** Continue to dampen the Procellera™ dressing until it is easily **removed without injuring underlying tissue.**

INSTRUCTIONS FOR USE:

Preparation

1. Before applying the dressing, cleanse the wound area with an appropriate wound cleanser.
2. 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



Dry Wound	Exudating Wound	Deep Wound
<ol style="list-style-type: none"> 1. Moisten the dressing with sterile water or sterile saline.* 2. Apply to the wound site, with the dotted side against and directly contacting the wound surface. 3. Cover with a sterile semi-occlusive dressing. 4. Re-moisten as necessary.* 	<p>Note: No dressing moistening is necessary.</p> <ol style="list-style-type: none"> 1. Apply to the wound site, with the dotted side against and directly contacting the wound surface. 2. Cover with a dry gauze or a foam dressing.** 3. Cover with a sterile semi-occlusive dressing. 	<ol style="list-style-type: none"> 1. Moisten the dressing with sterile water or sterile saline.* 2. Insert into wound cavity, with the dotted side against and directly contacting the wound surface. 3. Pack with gauze, ensuring contact between the dressing and the wound. 4. Cover with a sterile semi-occlusive dressing.

*Do not soak the Procellera™ dressing; remove excess moisture.

**Replace the saturated gauze or foam dressing as needed.

Site Care

1. Inspect the wound periodically.
2. Remove and/or replace the Procellera™ dressing after 7 days of use, or if the dressing becomes soiled, or when clinically indicated - see also "Precautions".

Removal

Gently pull back the dressings. If the dressing adheres to the wound surface, moisten or soak it with sterile saline or sterile water until it can be removed **without tissue damage.**

For further information please contact us:
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