Procellera®
Wound Care with Advanced Microcurrent Technology

Instructions for Prescription Use

Made in the USA by:
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VOMARIS

IFU-01 Rev. K

Product Description
Procellera® is a broad-spectrum antimicrobial wound dressing featuring Advanced Microcurrent Technology®. Embedded in the dressing are microcell batteries made of elemental silver and zinc applied in a dot-matrix pattern to a polyester substrate (Figure 1). In the presence of a conductive medium such as wound exudate, water-based hydrogels or saline, microcurrents are generated at the dressing surface, due to its inherent design.

Procellera is a primary contact layer BioElectric Dressing (Figure 2); it should be used under a secondary dressing or bandage (not provided), to keep it in place and help maintain a moist wound environment.

Silver and zinc in the dressing minimize or prevent the growth of microorganisms within the dressing, not at the wound site, and help preserve the dressing.

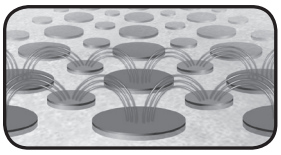


Figure 1

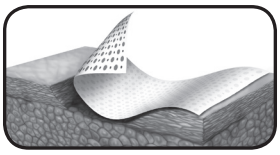


Figure 2

Indications
Procellera antimicrobial wound dressing is intended for the management of wounds to provide a moist wound environment and is indicated for partial and full-thickness wounds such as pressure ulcers, venous ulcers, diabetic ulcers, first and second degree burns, surgical incisions, donor and recipient graft sites, etc.

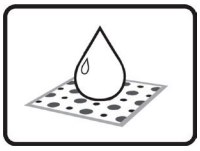
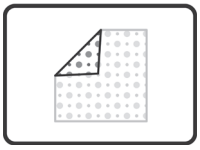
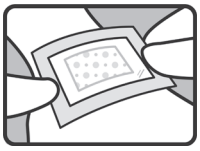
Contraindications
- Do not use on individuals with sensitivity or allergy to silver or zinc.

Warnings
- Frequent or prolonged use of this product may result, in rare occasions, in temporary discoloration of the skin.

Precautions
- **Caution:** Federal law restricts this device to sale by or on the order of a physician.
- Single use only.
- Electron beam irradiation sterilized. Opening the dressing pack compromises the sterile barrier. Do not use if the pouch is open or damaged prior to use.
- Remove Procellera dressing prior to a MRI or HBOT procedure and apply a new dressing after the procedure.
- For external use only.
- Do not apply Procellera dressing in conjunction with topical agents such as antimicrobial ointments, enzymatic debriders, antibiotic creams or ointments, silver- or zinc-containing creams, oxidizing agents, or petroleum-based products.
- Secondary dressings should be used as stated in their Instructions for Use.
- The patient should stop using the dressing and consult a physician if allergy, irritation, increased pain, maceration, or any irregular skin discoloration occurs.
- Procellera is not intended to be used on wounds with uncontrolled bleeding.
- Remove Procellera dressing during energy-based procedures (such as radiofrequencies, ultrasound, or radiation) where the dressing may interfere with delivery.
- Avoid direct dressing contact with electrodes or conductive gels during electronic measurements; e.g., EEG or ECG.
- Procellera may be used on infected wounds being clinically managed, as an adjunct to the local clinical protocol.
- The safety of daily Procellera use for longer than 28 days has not been studied.

Preparation
Follow local hygiene procedures prior to, during and following dressing application and change.

Application

1. Cleanse the wound area with an appropriate wound cleanser according to local clinical protocol.
2. Remove Procellera from package and if needed, cut to a shape that will extend beyond wound edges 1 cm to 2 cm (½ inch to 1 inch). **Caution:** Cutting may result in fraying of the dressing.
3. Moisten Procellera with sterile saline, water, or a thin, even layer of water-based hydrogel (not included).
4. Apply Procellera dressing **with the dotted side down**, in direct contact with the wound.
5. Cover Procellera with an appropriate secondary sterile dressing to help maintain a moist wound environment. If needed, secure in place with an additional fixation dressing, using care not to restrict blood flow. The choice of secondary dressing should be determined by the amount of wound exudate, for example:
   - For DRY wounds; waterproof, semi-permeable, or hydrogel-like dressings are recommended to ensure moisture maintenance.
   - For EXUDATING wounds; cover Procellera with layer(s) of sterile gauze or foam dressing to absorb excessive moisture and prevent maceration. Then apply a semi-permeable or hydrogel-like dressing.
6. Keep the dressing moist by re-moistening as necessary. Avoid over-soaking, for example:
   - DRY wounds may require more frequent dressing re-moistening.
   - EXUDATING wounds may require dressing re-moistening only if exudate decreases and the dressing becomes dry.

Site Care and Dressing Change
- Procellera may be left in place for up to 7 days (or longer, at the discretion and instruction of the treating clinician). Earlier and/or more frequent changes may be required, depending on the amount of exudate present and the condition of the wound and/or the surrounding skin. Inspect the wound site periodically.
- To remove the Procellera dressing, gently pull it back. If it adheres to the wound surface, do not force it off; moisten or soak the dressing with sterile saline or water until it can be removed without tissue disruption.
- The patient should consult a physician if any of the following occur: infection, bleeding, maceration, hypergranulation, irritation at the wound and/or the surrounding skin, or if the wound increases in size after a few dressing changes.

Dressing Components
- The dressing is not made with natural rubber latex.
- The dressing consists of a polyester substrate containing 0.9 mg of elemental silver and 0.3 mg of elemental zinc per square centimeter of dressing.

Storage and Disposal
- Store in dry conditions at controlled room temperature. Controlled room temperature is 20°C to 25°C (68°F to 77°F). Excursions are permitted between 15°C and 30°C (59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.
- Protect from light.
- Dispose of dressing according to local environmental procedures.