

Product Description

Procellera[®] is a single layer, broad-spectrum antimicrobial wound dressing. Embedded in the dressing are microcell batteries made of elemental silver and zinc applied in a dot-matrix pattern (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 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.

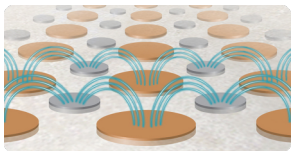


Figure 1

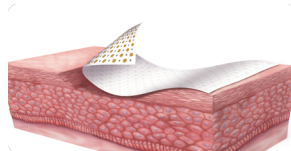


Figure 2

Indications

Procellera[®] antimicrobial wound dressing is intended for the management of wounds to provide a moist wound environment and is indicated for superficial wounds such as minor cuts, scrapes, irritations, abrasions, blisters, 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

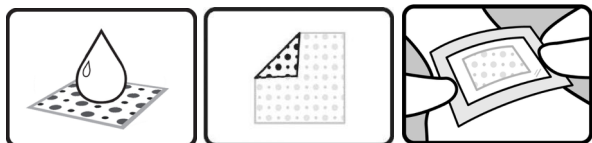
- Single use only.
- Do not use if the pouch is open or damaged prior to use.
- For external use only.
- Do not apply Procellera dressing when using topical agents such as antimicrobial ointments, enzymatic debriders, antibiotic creams, silver or zinc containing creams, oxidizing agents, or petroleum based products
- Secondary dressings should be used as stated in their Instructions for Use.
- Stop using the Procellera dressing and consult a physician if an allergy, irritation, increased pain, maceration or 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 contact with electrodes or conductive gels during electronic measurements; e.g., EEG (electroencephalogram) or ECG (electrocardiogram).
- Infected wounds should be treated under a physician's supervision.
- The safety of daily Procellera use for longer than 28 days has not been studied.

Instructions for OTC Use

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.
2. Remove Procellera from package and if needed, cut to a shape that will extend beyond wound edges 1 to 2 cm (1/2 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 to the wound site, **with the dotted side down**, in direct contact with the wound surface.
5. Cover Procellera with an appropriate secondary sterile dressing (such as a waterproof dressing) which will keep it in place and help maintain a moist wound environment. If needed, secure in place with an additional fixation dressing, using care not to restrict blood flow.
6. Keep Procellera moist by re-moistening as necessary (once a day, for dry wounds). Avoid over-soaking.
Note: It is not necessary to remove Procellera while showering.

Site Care and Dressing Change

- Procellera may be left in place for up to 7 days. Earlier and/or more frequent changes may be required, depending on the amount of exudate present, the condition of the wound and 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 sterile water until it can be removed without tissue damage.
- Consult a physician if any of the following occur: infection, bleeding, maceration (skin whitening and softening), hypergranulation (excessive tissue formation), irritation at the wound site or the skin surrounding the Procellera dressing, or if the wound increases in size after a few dressing changes.

Dressing Components

- The Procellera dressing is not made with natural rubber latex.
- The Procellera 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 according to local environmental procedures.

Made in the USA by:

Vomaris Wound Care, Inc.

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