

# Procellera™

## Antimicrobial Pin Site Dressing

### Instructions for Prescription Use



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### Antimicrobial Pin Site Dressing

#### Description

Set components include:

1. Procellera Antimicrobial Wound Dressing (Procellera) - a broad-spectrum antimicrobial wound contact layer
  2. Absorbent pad - a polyester-based absorbent layer
  3. Clip - to keep the dressings in place and help maintain a moist wound environment
- Note: Product is not made with natural rubber latex.

The Procellera Antimicrobial Wound Dressing component features V.Dox Technology. Embedded in the dressing are microcell batteries made of elemental silver and elemental zinc applied in a dot-matrix pattern to a polyester substrate. In the presence of a conductive medium such as wound exudate, water-based wound hydrogels, saline, or water, microcurrents are generated at the dressing surface due to its inherent design. Silver and zinc in the dressing help to preserve it and minimize or prevent the growth of bacteria within the dressing.

#### Indications

Procellera Antimicrobial Pin Site Dressing is intended for the management of wounds to provide a moist wound environment and is indicated for partial and full-thickness wounds, including surgical incisions.

#### Contraindications

Do not use on individuals with sensitivity or allergy to silver, zinc, or other dressing components.

#### Warnings

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

#### Precautions

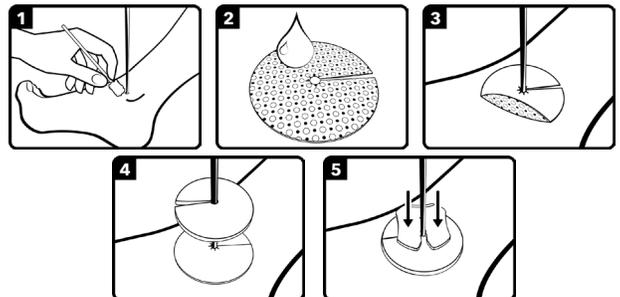
- Caution: Federal law restricts this device to sale by or on the order of a physician.
- Single use only. For external use only.
- Electron beam irradiation sterilized. Opening the dressing pack compromises the sterile barrier. Do not use if the pouch is open or damaged prior to use.
- Do not apply the 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.
- The patient should stop using the dressing and consult a physician if allergy, irritation, increased pain, maceration, or any irregular skin discoloration occurs.
- The dressing is not intended to be used on wounds with uncontrolled bleeding.
- Remove the dressing during energy-based procedures (such as radiofrequency, ultrasound, or radiation) where the dressing may interfere with delivery.
- MR unsafe. Remove the dressing prior to a MRI or HBOT procedure and apply a new dressing after the procedure.
- The dressing has been used safely directly over sutures, wound closure strips, staples, and liquid skin adhesives and with bioengineered skin substitutes, negative pressure wound therapy, and multilayer compression therapy.
- Avoid direct dressing contact with electrodes or conductive gels during electronic measurements; e.g., EEG or ECG.
- The dressing may be used on infected wounds being clinically managed, as an adjunct to the local clinical protocol.
- The safety of daily dressing 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 pin site area with an appropriate wound cleanser according to local clinical protocol.
2. Moisten the dotted Procellera dressing with sterile saline, water, or a thin, even layer of hydrogel (not included).
3. Position the Procellera dressing dots down around pin site and gently press down to ensure direct skin contact.
4. Position absorbent pad on top of Procellera dressing around pin site with slit opposite the Procellera slit.
5. Slide clip onto pin. Push clip down to apply gentle compression and secure dressings in place.



#### Site Care and Dressing Change

- The dressing 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 and the condition of the wound and/or the surrounding skin. Inspect the wound site periodically.
- To remove dressing, gently slide the clip up or pull it off the pin, then remove the dressing. If dressing 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.

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