Procellera | HELIX®
Wound Care with Advanced Microcurrent Technology

Instructions for Prescription Use

Made in the USA by:
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VOMARIS

IFU-12 Rev. D

Product Description
Procellera Helix® 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 Helix is a three-layer dressing, comprising a primary contact layer BioElectric Dressing, an absorbent layer, and a semi-occlusive outer adhesive layer to keep the dressing 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.

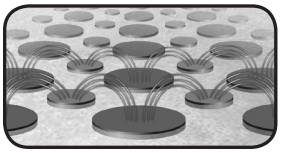


Figure 1

Indications
Procellera Helix 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.

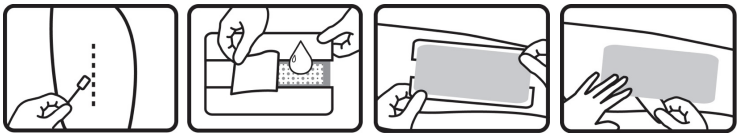
Contraindications
- Do not use on individuals with sensitivity or allergy to silver, zinc or other dressing components.

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.
- Gamma 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 Helix dressing prior to a MRI or HBOT procedure and apply a new dressing after the procedure.
- For external use only.
- Do not apply Procellera Helix 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 use of adhesive dressings on fragile or sensitive skin may pose a risk of skin damage upon removal of the dressing. To mitigate this risk, a skin prep may be applied on the wound perimeter prior to dressing application.
- The patient should stop using the dressing and consult a physician if allergy, irritation, increased pain, maceration, or any irregular skin discoloration occurs.
- Procellera Helix is not intended to be used on wounds with uncontrolled bleeding.
- Remove Procellera Helix 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 Helix may be used on infected wounds being clinically managed, as an adjunct to the local clinical protocol.
- The safety of daily Procellera Helix 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



NOTE: If dressing a joint, apply the dressing while the joint is in slight flexion.
1. Cleanse the wound area with an appropriate wound cleanser according to local clinical protocol.
2. For optimal adhesion results, apply skin prep to the area surrounding the wound (skin prep not included).
3. Peel back the center dressing liner to expose the dotted Procellera Helix pad, leaving the edges in place.
4. Moisten the dotted Procellera Helix pad with sterile saline, water, or a thin, even layer of water-based hydrogel (not included).
5. Position the dotted Procellera Helix pad over the wound and gently press down to ensure direct contact.
6. Remove the remaining liner and smooth the adhesive down over the skin.

Site Care and Dressing Change
- Procellera Helix 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 Helix dressing, lift one corner and stretch the adhesive film, gently pulling back in the direction of the wound. 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.
- Primary contact layer: polyester substrate containing 0.9 mg of elemental silver and 0.3 mg of elemental zinc per square centimeter of dressing.
- Absorbent layer: polyester or polyurethane.
- Adhesive layer: polyurethane.

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.