Procellera®
Antimicrobial Wound Dressing

Instructions for OTC Use

Procellera Helix® Product Description

Procellera Helix is a 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 Helix is a three-layer dressing, comprising a primary contact layer BioElectric Dressing, an absorbent layer, and 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.

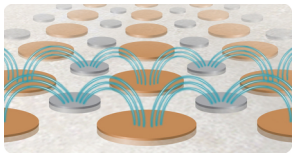

Figure 1

Indications

Procellera Helix antimicrobial wound dressing is intended for the management of wounds to provide a moist wound environment and is indicated for 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 Helix dressing when using topical agents such as antibiotic ointments, enzymatic debriders, antibiotic creams, silver or zinc 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.
- Stop using the Procellera Helix dressing and consult a physician if an allergy, irritation, increased pain, maceration or 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 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 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.

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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.
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 wound 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. 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 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.
- 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 Helix dressing, or it the wound increases in size after a few dressing changes.

Dressing Components

- The Procellera Helix 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: spun polyester.
- 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 according to local environmental procedures.

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