

Procellera™ FlexEFit™

ANTIBACTERIAL WOUND DRESSING

Instructions for Prescription Use

Description

Procellera™ FlexEFit™ Antibacterial Wound Dressing (Procellera FlexEFit) 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.

Procellera FlexEFit is a three-layer dressing, comprising a broad-spectrum antibacterial contact layer, a polyester-based absorbent layer, and a polyurethane semi-occlusive outer adhesive layer to keep the dressing in place and help maintain a moist wound environment. Note: Product is not made with natural rubber latex

Silver and zinc in the dressing help to preserve it and minimize or prevent the growth of bacteria within the dressing.

Indications

Procellera FlexEFit Antibacterial 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.
- For external 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.
- Do not apply Procellera FlexEFit 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 (not included).
- The patient should stop using the dressing and consult a physician if allergy, irritation, increased pain, maceration, or any irregular skin discoloration occurs.
- Procellera FlexEFit is not intended to be used on wounds with uncontrolled bleeding.
- Remove Procellera FlexEFit during energy-based procedures (such as radiofrequency, ultrasound, or radiation) where the dressing may interfere with delivery.
- MR unsafe. Remove Procellera FlexEFit prior to a MRI or HBOT procedure and apply a new dressing after the procedure.
- Avoid direct dressing contact with electrodes or conductive gels during electronic measurements; e.g., EEG or ECG.
- Procellera FlexEFit may be used on infected wounds being clinically managed, as an adjunct to the local clinical protocol.
- The safety of daily Procellera FlexEFit use for longer than 28 days has not been studied.

Preparation

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

(See reverse side for application instructions.)

Site Care and Dressing Change

- Procellera FlexEFit 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 Procellera FlexEFit, lift one corner and gently pull 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.

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Application

- Cleanse wound area with an appropriate wound cleanser according to local clinical protocol.
- Moisten the dotted Procellera pad with sterile saline, water, or a thin, even layer of hydrogel (not included). Apply immediately after moistening by following instructions printed on dressing liners:

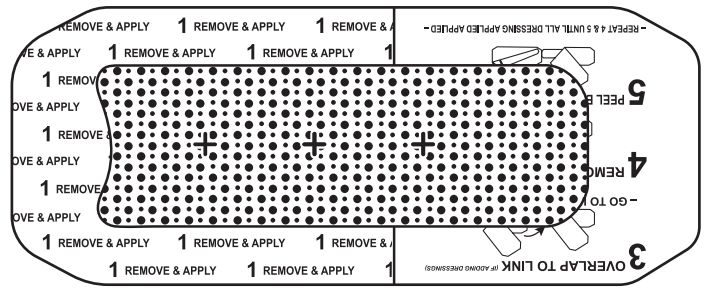
1. Remove #1 liners and apply, pressing gently to ensure direct contact of Procellera pad with the wound bed.
2. Fold back #2 panel (do not remove liner).
3. If additional Procellera FlexEfit dressings are needed, repeat steps 1-2 to add one dressing at a time until the wound or incision is covered.

Go to last dressing applied.

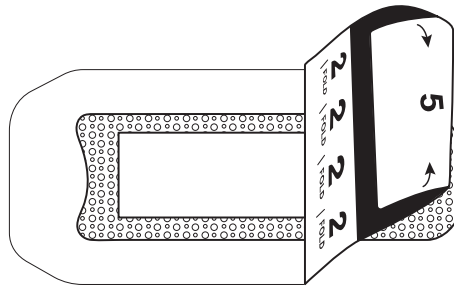
4. Remove instructional liner and affix dressing to skin. Gently press and rub adhesive to firmly adhere.
5. Pull either blue tab toward the other to remove backing.

Repeat 4 and 5 to complete application of the adjacent dressing. Continue 4 and 5 until all dressings are applied.

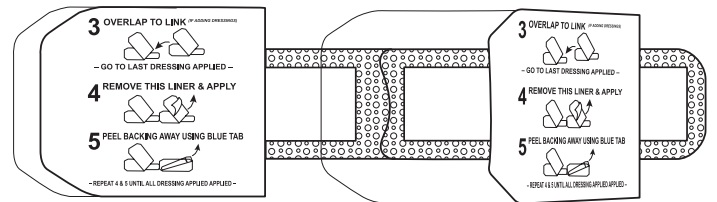
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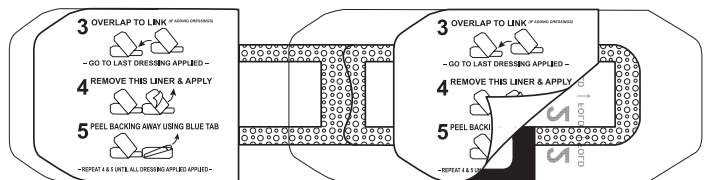
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