

# Procellera™ FlexEFit™

## ANTIBACTERIAL WOUND DRESSING

### Instructions for Use



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IFU-114 Rev A

## Description

Procellera™ FlexEFit™ Antibacterial Wound Dressing 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 superficial wounds such as minor cuts, scrapes, irritations, abrasions, blisters, 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

- Single use only.
- For external use only.
- Do not apply Procellera FlexEFit with topical agents such as enzymatic debriders, antibiotic creams or ointments, 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 (not included).
- Stop using Procellera FlexEFit 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 (electroencephalogram) or ECG (electrocardiogram).
- Infected wounds should be treated under a physician's supervision.
- The safety of daily Procellera FlexEFit use for longer than 28 days has not been studied.

## Application

- Cleanse wound area with an appropriate wound cleanser.
- 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 (figures 1-5):

- Remove #1 liners and apply, pressing gently to ensure direct contact of Procellera pad with the wound bed.
- Fold back #2 panel (do not remove liner).
- If using only 1 dressing, proceed to step 4. 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.

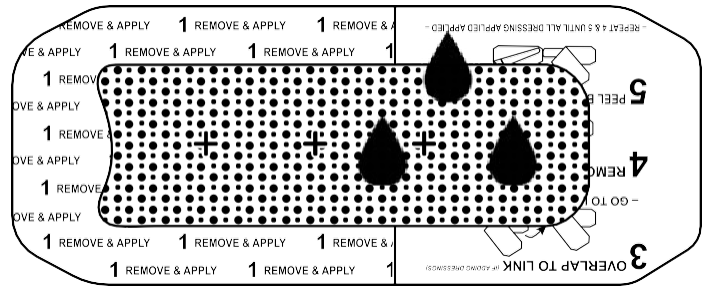
- Remove instructional liner and affix dressing to skin. Gently press and rub adhesive to firmly adhere.
- Pull either blue tab toward the other to remove backing.

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

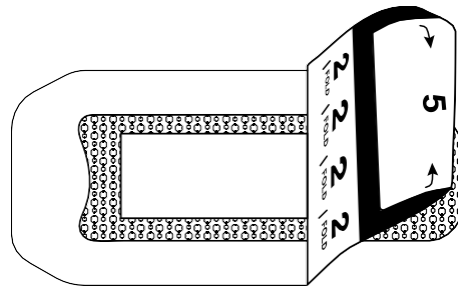
## Site Care and Dressing Change

- 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 drainage 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.
- Consult a physician if any of the following occur: infection, bleeding, maceration (skin whitening and softening), hypergranulation (excessive tissue formation), irritation at the wound and/or the surrounding skin, or if the wound increases in size.

- Moisten pad, remove liners, and apply

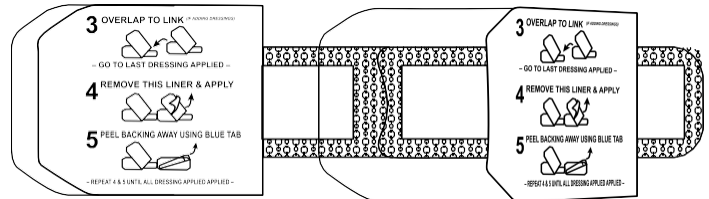


- Fold



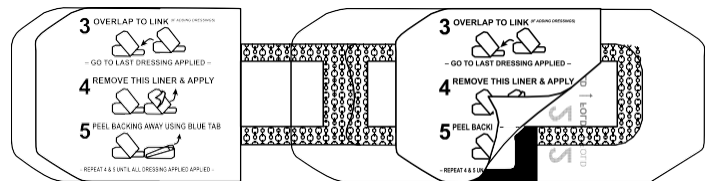
If using only 1 dressing, proceed to step 4.

- Overlap to link (if adding dressing)

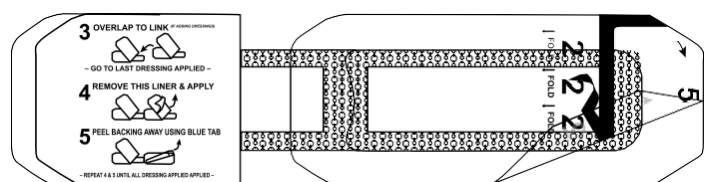


Go to last dressing applied

- Remove this liner and apply



- Peel backing away using blue tab



Repeat steps 4 and 5 until all dressings are applied