

PRODUCT DESCRIPTION

Procellera™ is an antimicrobial wound dressing. It must be prescribed or provided to you by a health care professional.

Procellera™ is applied as a single layer dressing, and contains silver and zinc. Procellera™ should be used with an appropriate secondary dressing, to maintain a moist wound environment.

The characteristic which makes Procellera™ a unique wound dressing is that, in the presence of moisture, a small amount of current is produced at the surface of the dressing.

INTENDED USE

Procellera™ antimicrobial wound dressing is indicated for partial and full-thickness wounds such as: pressure ulcers, venous ulcers, diabetic ulcers, burns, surgical incisions, donor and/or recipient graft sites.

WARNING

Repeated or long-term use of silver may cause argyria (skin and mucous membranes become stained and turn gray).

CONTRAINDICATIONS

- Do not use Procellera™ if you are sensitive or allergic to silver, zinc, and/or polyester.
- Do not use Procellera™ during Magnetic Resonance Imaging (MRI), electrocardiogram (ECG), electroencephalogram (EEG), or if you are using any other medical device that delivers electricity, radio waves, microwaves and/or energy of any other source to your body.
- Remove Procellera™ prior to any surgeries.
- Do not use Procellera™ for an actively bleeding wound.

PRECAUTIONS

- Procellera™ should be used under the supervision of a qualified health care professional.
- The safety of use longer than 28 days has not been studied.
- For external use only.
- Single use only. Do not re-sterilize.
- Sterility is guaranteed, unless pouch is damaged and/or opened prior to use. Do not use if the immediate product packaging is open and/or damaged.
- In the event of clinical infection, Procellera™ does not replace the need for systemic therapy or other adequate infection treatment, which may be prescribed by your physician.
- The use of Procellera™ with other topical antimicrobial treatments has not been studied. Procellera™ may not be compatible with topical antimicrobials.
- Secondary dressings should be used as stated in their Instructions for Use. Do not apply secondary dressings / fixations tightly over joints or moving parts, or in a manner that will restrict blood flow.
- If there is any difficulty removing the dressing, do not force it off the wound surface. It should be soaked with sterile saline or water, until it can be easily removed without injuring the wound or the surrounding skin area.

- Stop using the dressing and contact your health care provider if any of the following happen:
 - You have an allergic reaction;
 - You notice irritation (increased redness and/or inflammation);
 - Your wound continues to grow larger;
 - You notice signs of infection (increased pain, increased redness, increased wound drainage, increased warmth or odor);
 - Your wound starts to bleed;
 - You notice a troublesome change in how the wound looks (e.g. change in color) or smells (e.g. bad odor)
 - Skin whitening and softening (maceration);
 - There seems to be too much skin or scab growing;
 - You see no signs of healing after several days of using the dressing.

INSTRUCTIONS FOR USE:

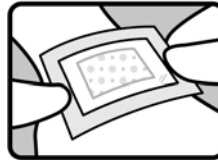
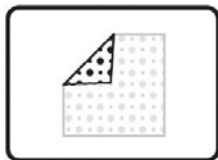
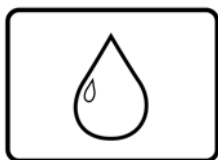
Note that local hygiene procedures should be followed prior to and following the dressing change.

Preparation

Before applying the dressing, cleanse the wound area with an appropriate wound cleanser.

Remove the Procellera™ dressing from its package and, if needed, cut it to a shape/size that will extend beyond wound edges approximately 1-2 cm.

Application



Note: The application procedure varies depending on the type of your wound. Your health care provider should instruct you as to which procedure to follow.

Dry Wound:

1. Moisten the Procellera™ dressing with sterile saline or water. Do not soak it; remove excess moisture.
2. Apply Procellera™ dressing to the wound site, **with the dotted side against and directly contacting the wound surface.**
3. Cover with a secondary sterile dressing, which will help maintain a moist wound healing environment (such as waterproof or semi-permeable type dressings). If needed, secure in place with a bandage or other fixation. Do not apply secondary dressing or fixation tightly over joints or moving parts, or in a manner that will restrict blood flow.
4. Re-moisten as necessary. Do not soak it; remove excess moisture.

Exudating (fluid producing) Wound

1. Apply Procellera™ dressing to the wound site, **with the dotted side against and directly contacting the wound surface.** (No dressing moistening is necessary.)
2. Cover with a sterile dry gauze or a foam dressing, which will help absorb extra fluid; replace as needed.
3. If needed, secure the dressings in place with a bandage or other fixation. Do not apply secondary dressing or fixation tightly over joints or moving parts, or in a manner that will restrict blood flow.

Deep Wound:

1. Moisten the Procellera™ dressing with sterile saline or water. Do not soak it; remove excess moisture.
2. Insert the Procellera™ dressing into the wound space, **with the dotted side against and directly contacting the wound surface.**
3. Pack with sterile gauze, ensuring contact between the Procellera™ dressing and the wound.
4. Cover with a secondary sterile dressing, which will help maintain a moist wound healing environment (such as waterproof or semi-permeable type dressings). If needed, secure in place with a bandage or other fixation. Do not apply secondary dressing or fixation tightly over joints or moving parts, or in a manner that will restrict blood flow.
5. Re-moisten as necessary. Do not soak it; remove excess moisture.

Site Care and Dressing Change

Inspect the wound/s periodically. Remove and/or replace the Procellera™ dressing:

- after 7 days of use (depending on the condition of the wound and surrounding skin); or
- if the dressing becomes soiled, or
- when clinically indicated - see “Precautions”.

Note: It is not necessary to remove the Procellera™ dressing while showering.

Removal

Gently pull back the dressings. If the dressings adhere to the wound surface, moisten or soak them with sterile saline or water until they can be removed **without tissue damage. Do not force the bandage/s off the wound surface.**

STORAGE AND DISPOSAL:

Store at room temperature (10°C – 25°C/50°F -77°F), in a dry location.

Disposal should be handled according to local environmental procedures.

INGREDIENTS

Each square inch of dressing contains 2.4 micrograms of silver and 2.4 micrograms of zinc.

For further information, please contact us:

VOMARIS Wound Care, Inc.

3100 W. Ray Rd., Suite 148, Chandler, AZ 85226, USA

(866) 4 Your Health (480) 921-4948 www.vomaris.com www.procellera.com

Patent # US 7,457,667 B2 Patents pending. Made in the USA

All Rights Reserved.

Copyright 05/2009