

# POSIFECT<sup>®</sup> RD bio-electric wound care dressing

## I Product Description

POSIFECT<sup>®</sup> uses the principle of bio-electric stimulation. The dressing contains a miniature electrical circuit that will deliver a microcurrent to the wound bed. This microcurrent is derived from non-rechargeable coin cell batteries. The dressing will remain active for a minimum of 48 hours.

## II Treatment Regimen

The recommended treatment regimen for POSIFECT<sup>®</sup> is 3 weeks on therapy followed by 1 week off. This regimen may be repeated as necessary based on wound response and clinical judgement for up to 8 weeks.

## III Indications

The POSIFECT<sup>®</sup> RD bio-electric wound care dressing is indicated for the management of chronic wounds where conventional therapies have failed.

## IV Contraindications

- Do not place over the neck or head region
- Do not use if the patient has a demand-type cardiac pacemaker
- Do not use if patient has a sensitivity to hydrogels, hydrocolloid, or colophony.

## V Warnings

- Keep the POSIFECT<sup>®</sup> RD bio-electric wound care dressing out of the reach of children
- Electronic monitoring equipment (such as ECG monitors and ECG alarms) may not operate properly when the POSIFECT<sup>®</sup> RD bio-electric wound care dressing is in use.
- Do not use active or other advanced wound care products, such as hydrogels or silver dressings, in combination with this therapy
- Do not use dressing if package integrity is compromised.
- The effect of using this product with topical or systemic drugs has not been evaluated, however the theoretical risk associated with this dressing remains very small.
- Do not immerse, shower, or expose dressing to direct water contact.

## VI Precautions

- Do not use when visible signs of infection are present.
- Do not use in the presence of medical imaging equipment, such as MRI or X-Ray
- Isolated cases of skin irritation may occur at the site of electrode placement following long-term application.
- Do not use if pregnant or planning to become pregnant.



Do not resterilize or reuse.



Do not use if individual pouch is visibly damaged or opened.



Avoid exposure to direct sunlight during storage.



Avoid extreme temperatures and high humidity during storage.



Store in room temperature.



Use prior to the 'Use before' date.

IPX4

Protected against splashing water.



Type BF equipment.

## VII Potential Complications

Potential complications include, but are not limited to:

- Signs of sensitivity or irritation
- Infection
- Chronic inflammation

## VIII Use

- 1 Rinse the wound according to normal practice.
- 2 Gently dry the surrounding skin.
- 3 Open the package and remove the dressing. (fig 1)
- 4 Remove the black pull-tab and confirm that the red light is flashing. *NOTE: If the red light is not flashing DO NOT use the dressing.* (fig 2)
- 5 Using the tabs of the protective liner to facilitate aseptic application, remove the protective liner. (fig 3)
- 6 Place the adhesive side of the dressing, which looks like a ring, onto the non-wounded skin around the wound and press firmly. (fig 4) If required, non-adherent padding should be used underneath the battery case to reduce the risk of local skin damage.
- 7 Open the lid and carefully remove the protective liner from the center electrode (cathode) and place directly into the wound itself, ensuring this center electrode is in contact with the wounded tissue at or near the center of the wound or wound bed. (fig 5 & 6)
- 8 Optional step – If desired, pack the wound with a suitable non adherent packing material to absorb excess exudate. Ensure the wound packing is placed over the central electrode taking care not to disturb the contact this central electrode is making with the wound.
- 9 Remove the protective liner from the lid, and close the lid, sealing the lid to the dressing and covering any packing material and the central electrode. (fig 7 & 8)
- 10 On application it may take 2-3 minutes for the dressing to warm through and for a good contact to be made. The red light will continue to flash until this happens.

- 11 Confirm that the red light is no longer flashing. (fig 9) *NOTE: If the red light continues flashing after applying the dressing, be sure entire dressing is lying flat against the non wounded skin and that the central electrode is in contact with the wound. If the red light continues to flash, DO NOT use the dressing.*
- 12 If at any time during application the red light begins flashing, check that the entire dressing is lying flat against the skin and make any adjustments necessary. If the red light continues to flash, remove the dressing and apply a new one.
- 13 Change the dressing as needed to maintain a moist, clean wound area. In cases where there is excessive exudate, clinical judgement should be used and the dressing changed more frequently if required. Maximum wear time for the dressing is 96 hours. *NOTE: Rotate the dressing with each application to ensure that the location of the battery case is varied. This is particularly important when a compression dressing is applied over the top of POSIFECT<sup>®</sup> RD. For larger wounds, reposition the dressing with each application to ensure that the wound receives full coverage. Ensure center gel disc is removed from wound bed during dressing changes.*
- 14 Disposal – used dressings should be treated as normal clinical waste.

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Fig 1



Fig 2



Fig 3



Fig 4



Fig 5



Fig 6



Fig 7



Fig 8

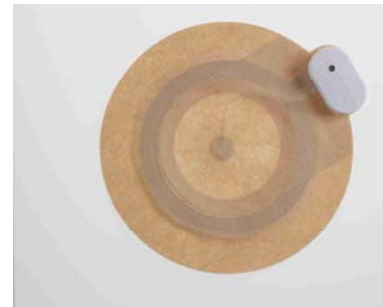


Fig 9

