LUMITECH™ INCISIONAL WOUND DRESSINGS

INSTRUCTIONS FOR USE

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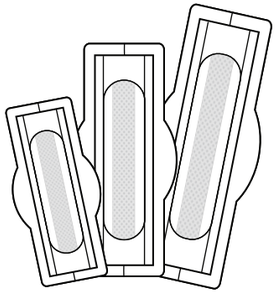


℞Only	Federal (USA) law restricts this device to sale by or on the order of a physician
	Single-Use. Do not re-use
	Temperature Limitation for Operation, Transport and Storage
	Humidity Limitation for Operation, Transport and Storage
	Keep Away From Sun
STERILE EO	Sterilized With Ethylene Oxide

IMPORTANT INFORMATION

Please read all instructions, warnings, and cautions before use. Correct application is essential for proper function of the product. The dressings should be used only as intended, and used only on the individual to whom the dressing was prescribed by a healthcare professional.

DESCRIPTION

The DeRoyal® Lumitech™ incisional wound dressing is a hydrophilic, absorbent, multi-layer surgical wound dressing. The dressing is composed of an integrated wound contact layer, fluid absorbent woven fibers, pressure-distributive polyurethane foam, and a protective, breathable, water-resistant polyurethane film border incorporating Lumina® Adhesive technology. Lumina® Adhesive technology is a patented UV light “switchable” adhesive film that supports long wear time with the option for a gentle dressing removal.

INTENDED USE

The Lumitech™ multi layer incisional wound dressing is intended to manage post-surgical wounds with low to medium exudate levels. The dressings are compatible with negative pressure wound therapy systems cleared for use with commercially available wound dressings as selected by a clinician based on the wound requirements or the physician’s prescription. The dressings create a barrier against contaminants, support the removal of exudate, and absorb exudate.

INDICATIONS

Lumitech™ incisional wound dressings are intended for acute closed surgical wounds.

CONTRAINDICATIONS

Lumitech™ wound dressings are contraindicated for use with:

- Third-degree burns
- Heavily bleeding wounds
- Individuals who are sensitive to or have had an allergic reaction to the dressing or its components
- Surgical procedures as a surgical sponge
- Heavily exudating wound incisions

WARNINGS

- Read and understand all warnings, cautions, and directions completely and carefully before use. Failure to do so may result in serious injury.
- DO NOT reuse, reprocess, or re-sterilize this dressing. This device is for single use only. Reuse, reprocessing, or re-sterilization may damage the dressing and may result in injury, infection, or death.
- DO NOT use if the individual package is opened or if the package or the dressing is damaged. Carefully inspect the dressing for damage or defects prior to use.
- Seek medical attention if you have signs of surgical site infection or allergic reaction such as fever, redness, pain, or swelling.
- If you have any signs of an allergic reaction, remove the dressing and rinse the incisional wound and surrounding skin.
- Ensure the dressing adheres to skin. Dressings with weak adhesives should be replaced immediately.
- If dressing is saturated and/or does not absorb, discard and replace.
- The adhesive border is composed of a “switchable” adhesive technology that reacts to specific UV/near UV light wavelengths. This feature supports comfort and ease of dressing removal. If the patient and/or users have sensitivities or other risks related to UV/near UV light wavelengths, do not use UV light when removing the dressing.

CAUTIONS

- Ensure the dressing fully covers your incisional wound. If the dressing rips, tears, or self-adheres prior to or during the application, discard the dressing and replace it.
- Take proper care when removing a dressing with adhesive as it may result in skin irritation. **NOTE:** To support ease of removal, the dressing incorporates a switchable adhesive technology that reacts to UV light. See “Dressing Removal” instructions.
- Dressing is water-resistant. Do not submerge dressing in water. If showering is cleared by the prescribing clinician, dressing can be used in light showering conditions with care to keep the dressing out of direct spray of shower water.

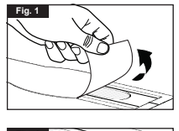
DIRECTIONS FOR USE

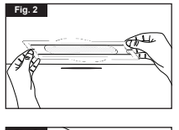
PRIOR TO APPLICATION

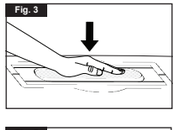
1. Carefully read the WARNINGS and CAUTIONS prior to use.
2. Inspect the packaging for damage or defects. Replace the entire dressing if the packaging is damaged.
3. Inspect Expiration Date on packaging; if expired, do not use.
4. Ensure the dressing is large enough to cover the incision length.
5. Clean the wound and peri wound area of excess drainage and fluid. Thoroughly dry skin around the wound.
6. Open the dressing package and remove the contents, following facility’s sterility protocols.

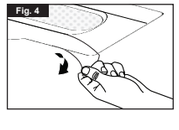
DRESSING APPLICATION

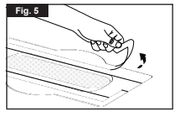
7. Peel the center release liner from the back of the adhesive dressing, exposing the adhesive (Fig 1).
8. Center the dressing over the incisional wound (Fig 2).
9. Gently press the dressing down over the incisional wound, minimizing wrinkles in the adhesive border (Fig 3).
10. Carefully remove the perimeter release liner strips one at a time, gently pressing down the adhesive film as each release liner strip is removed. Take care to minimize wrinkling of the adhesive border during this process (Fig 4).
11. Carefully peel away the top carrier layer sections and ensure the dressing is secure (Fig 5).
12. For additional dressing securement (recommended), apply the Lumitech™ dressing strips provided. Apply strips one a time around the entire perimeter of the dressing, overlapping the strips with skin and dressing border.
13. Protect dressing from direct exposure to sunlight (Fig 6).

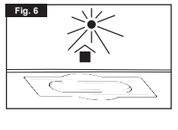






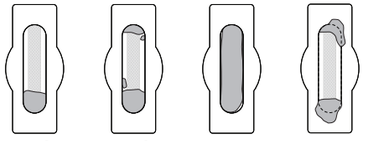






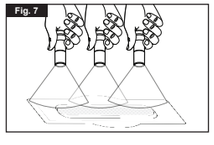
DRESSING REMOVAL

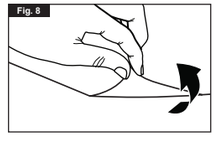
14. Change dressing as needed when wet, soiled, leaking, or as directed by a licensed clinician.



OKAY OKAY CHANGE CHANGE

15. To remove the dressing:
    NOTE: The dressing has an integrated switchable adhesive technology that reacts to specific UV/near UV light wavelengths to support ease of removal.
    a. If using UV light source (optional): Use the provided DeRoyal-labeled UV light or contact DeRoyal for options. Focus the UV light 1-2 cm above the adhesive border and allow for 3-5 seconds of exposure. Slowly sweep the UV light across the adhesive dressing border, allowing 3-5 seconds of exposure for each area of the dressing border (Fig. 7).
    b. Hold the edge of the adhesive border and carefully lift the dressing from the wound (Fig. 8).





16. Dispose of the dressing in accordance with facility’s protocol and local requirements.

STORAGE AND CONDITIONS

Store at room temperature and avoid excessive heat and humidity.
Avoid exposure to sunlight.

WARRANTY

DeRoyal® products are warranted for ninety (90) days from the date of shipment from DeRoyal as to product quality and workmanship. **DEROYAL'S WRITTEN WARRANTIES ARE GIVEN IN LIEU OF ANY IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.**

FEATURING: LUMINA Adhesive technology

DeRoyal Industries, Inc.
200 DeBusk Lane Powell, TN
1.800.251.9864
deroyal.com

Reprint # 0-1995 | Rev # 11/2023