






LUMITECH™

LUMITECH® FILM DRESSINGS

INSTRUCTIONS FOR USE

	USE BY DATE
	DO NOT REUSE
	DO NOT RE-STERILIZE
	STERILIZED WITH ETHYLENE OXIDE
	NOT MADE WITH NATURAL RUBBER LATEX
RX ONLY	FEDERAL U.S.A. LAW RESTRICTS THIS DEVICE TO SALE OR USE BY OR ON THE ORDER OF A PHYSICIAN OR PROPERLY LICENSED PRACTITIONER.

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

DeRoyal Lumitech Film Dressings are composed of a protective, breathable, water-resistant polyurethane film incorporating Lumina® Adhesive technology. Lumina Adhesive technology is a patented UV-Light “switchable” adhesive film that supports long wear time with the option for gentle removal.

INTENDED USE

DeRoyal Lumitech Film Dressings provide a sterile, water resistant barrier to protect intact skin and can be used to secure/protect wound dressings and sealed wound closure devices (e.g. skin glue adhesive), and for non-critical tubing securement.

CONTRAINDICATIONS

Lumitech Film Dressings are contraindicated for the following applications:

- » As a replacement for sutures and other primary wound closure methods
- » For use on patients with known polyurethane allergies

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 the 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.
- » **DO NOT** use outside of intended use.
- » **DO NOT** use expired product.
- » **DO NOT** store in direct sunlight or in a wet/humid environment.
- » **DO NOT** place in contact with breached skin.
- » Seek medical attention if there are signs of infection or allergic reaction such as fever, redness, pain, or swelling.
- » If there are any signs of an allergic reaction, remove the dressing and rinse the wound and surrounding skin.
- » Ensure the dressing adheres to skin. If dressing does not adhere, replace immediately.
- » The dressing is composed of a “switchable” adhesive technology that reacts to specific UV/near UV light wavelengths to support comfort and ease of dressing removal. **DO NOT** use UV-light when removing the dressing if sensitive to, or have other specific risks related to, UV/near UV wavelengths. **DO NOT** use non-DeRoyal approved flashlight.
- » Discard materials according to facility protocol, federal, state and local law.

CAUTIONS

- » Follow **Instructions for Use** provided with all medical devices being used in conjunction with Lumitech Film Dressings.
- » Ensure the dressing fully covers the application area. 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.
- » Dressing will lose adhesive properties if exposed to UV light, including sunlight. Take care to cover dressing in UV barrier such as clothing during use.

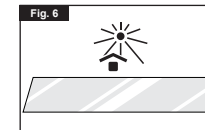
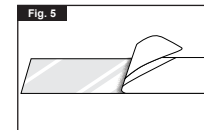
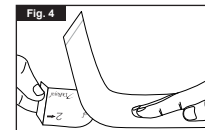
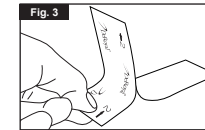
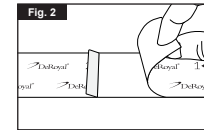
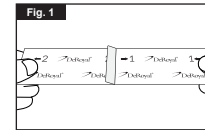
DIRECTIONS FOR USE

PRIOR TO APPLICATION

1. Carefully read the **WARNINGS** and **CAUTIONS** prior to use.
2. Inspect all 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 film dressing is large enough to cover intended area.
5. Clean application area according to facility protocol.
6. Open the package and remove film dressing, following facility's sterility protocols.

DRESSING APPLICATION

7. Peel release liner #1 from the back of the film dressing, exposing the adhesive underneath.
8. Center the film dressing over the application area.
9. Gently press the film dressing down over the application area.
10. Carefully remove release liner #2 from the back of the film dressing, and gently press down over the remaining application area.
11. Carefully peel away the top carrier layer sections, and ensure the film dressing is secure.
12. Protect film dressing from direct exposure to sunlight. **CAUTION:** Dressing will lose adhesive properties if exposed to UV light, including sunlight. Take care to cover dressing in UV barrier such as clothing during use.



STORAGE AND TRANSPORT

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



KEEP DRY

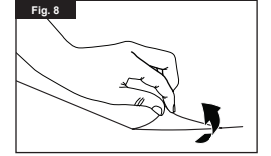
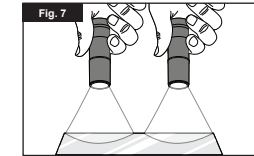


KEEP AWAY FROM SUNLIGHT

In addition to the competent authority in the country where the patient resides, serious incidents must be reported to DeRoyal Industries, Inc.

DRESSING REMOVAL

13. Change dressing as needed as directed by a licensed clinician.
14. 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 film dressing and allow for 3-5 seconds of exposure. Slowly sweep the UV-light across the adhesive film dressing, allowing 3-5 seconds of exposure for each area of the dressing. (Fig. 7).
 - b. Hold the edge of the adhesive border and carefully lift the dressing from the application area (Fig. 8).
15. Dispose of the dressing in accordance with facility's protocol and local requirements.



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.**

 DeRoyal®

FEATURING:

 **LUMINA™**
Adhesive technology



Lumitech® Film Dressing
Application & Removal

 Manufactured by:
DeRoyal Industries, Inc.
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Powell, TN 37849 USA
888.938.7828 or (001) 865.938.7828
www.deroyal.com

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