

Comfort Release® Surgical Drape for Clinical Study

Please read this document and keep it safe. Ensure that any individual using this product is familiar with and understands the information contained in this document.

INTENDED USE

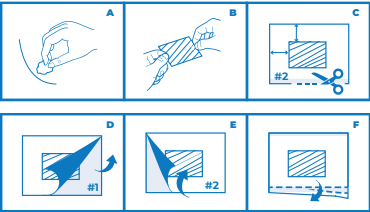
Comfort Release® Surgical Drape is an adhesive film dressing that can be used in negative pressure wound treatment (NPWT) with a NPWT device. The drape is sterile, intended for single use on intact (uninjured) skin. The drape is intended to secure sponge dressings and other dressings to the wound bed and allow for an airtight seal for NPWT and to protect the wound and promote a moist healing environment.

GENERAL INSTRUCTIONS

Apply the drape to clean, dry, and intact skin. Ensure the skin is free of lotions, oils, or creams. Protective barrier wipes are not necessary.

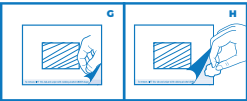
DRAPE APPLICATION

- Step 1 Assess the wound. Clean and prepare the wound bed and surrounding skin according to facility protocol. **(A)**
- Step 2 Apply the foam or dressing over the wound bed following the manufacturer's directions. **(B)**
- Step 3 Cut and place the drape to cover the foam or dressing, ensuring an additional 1" to 2" overlap onto intact periwound skin. While cutting the drape, maintain at least one edge with a portion of the blue #3 tab. **(C)**
- Step 4 Remove layer #1 to expose the adhesive side of the drape. Place the adhesive side down over the foam pad or wound dressing and onto the adjacent skin. Smooth the drape carefully over the skin, ensuring it adheres without creasing. **(D)**
- Step 5 Remove layer #2. **(E)** Next, to remove the blue #3 handling tab(s), hold the drape side of the perforation steady with one hand. Then, use your other hand to pull and remove the blue tab #3 along the perforation line. Ensure the section of the tab with the directions remains attached to the drape to assist with dressing removal later. **(F)** Pat down the drape to ensure a good seal.
- Step 6 Complete the application by following facility protocol and the manufacturer's directions.
- Step 7 Document the procedure and the patient's response to the treatment.



DRAPE REMOVAL

- Step 1 Lift the directions tab **(G)** and swipe underneath it using alcohol prep pads or alcohol swab sticks until the drape begins to lift easily from the skin. **(H)** Continue to apply alcohol to the underside of the drape where it adheres to the skin.
- Step 2 Use additional alcohol prep pads or swab sticks as needed to keep the underside edge of the drape moist, allowing it to loosen from the skin.
- Step 3 Carefully remove all foam or dressing pieces from the wound bed. Document the number of pieces removed according to facility protocol.
- Step 4 Discard the used drape and foam or dressing pieces according to facility protocol.
- Step 5 Document the procedure and the patient's response to the treatment.



REMOVAL NOTE

Ensure the adhesive edge remains wet with isopropyl alcohol until the drape is fully removed from the skin. The adhesive bond will return to the drape once the isopropyl alcohol evaporates.

CAUTION

INVESTIGATIONAL DEVICE. Limited by Federal Law to investigational use only. Do not use drape if the patient has a known allergy to hypersensitivity to acrylic adhesives or isopropyl alcohol.



For more instructions and information, visit our website www.comfortrelease.com or scan the QR code.

Symbols		
LOT	Batch code	 Do not re-use
REF	Catalog number	 Caution! Federal Law restricts this device in the USA to be used only on the order of a physician.
GTIN	Global Trade Item Number	 Consult instructions for use / booklet
MD	Medical Device	 Sterile
	Keep away from sunlight	 Do not use if damaged
	Keep dry	 Not for sale/not for commercial use.
Made in USA	Made in USA	

Ref GB141-A

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