

Instructions for Use



<https://medicaldevicesinc.com/ifu/>



Product Description

Halo XLs are medical devices that consist of an adhesive hydrogel layer and an adhesive (non-latex) backing layer. Halo XLs do not contain any medicinal substances and are not constructed from animal or human derivatives. Halo XLs are impermeable to liquids and seals the wound. Halo XLs are intended to be used until the patient can be transported to a health care facility where they will be removed for patient evaluation and post care.

Indications for Use

Halo XLs are designed to cover and protect wounds. Do not use the dressing as a replacement for sutures and other primary wound closure methods. Halo XLs are a single use product and attempts to reuse Halo XLs, may introduce contamination and infection.

Intended Use/Intended Purpose

Halo XLs are occlusive wound dressings, intended to cover a wound and to provide a mechanical barrier. Halo XLs aid in the prevention of a tension pneumothorax, potentially caused by penetrating thoracic trauma.

Patient Profile

Halo XLs are intended to be used in patients with a potential thoracic wound.

Application

- Clean and dry area.
- Remove clear liner. Do not place on secondary surface before application to prevent contamination.
- Place Halo XL gel side down centered over the wound.
- Use light pressure - do not stretch during application.
- Continue to assess patient and monitor action of chest seal. Monitor patient for symptoms of the development of tension pneumothorax.

These symptoms may include:

- Sharp thoracic pain, increased respiratory rate, shortness of breath, tachycardia, a fast resting heart rate, or low blood pressure.
- Blue or discolored skin, lips, or nails or jugular vein distention — a bulge in the veins running down the right side of a person's neck.

- Re-seal Halo XL, if required.
- If additional thoracic wounds are present, repeat steps 1-4 with another Halo XL product.
- Transport patient to emergency care facility for post treatment and evaluation.
- Dispose after use, per local medical device waste guidelines.

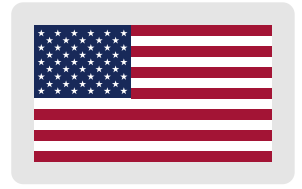


Please contact or report any serious incidents regarding this product to the manufacturer and regulatory authorities.
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Warnings

- Ensure Halo XL completely seals the perimeter of the wound to prevent air, liquids, and debris entering. Persons who have thoracic injuries should be immediately transported to a healthcare or trauma facility for evaluation.
- Do not use Halo XL as a replacement for sutures and other primary wound closure methods.
- Attempts to re-use Halo XL may introduce contamination and infection.
- Dispose after use, per local medical device waste guidelines.
- Do not place over protruding objects, as this may worsen injury.

Contraindications

Do not use for post-surgical applications.

Performance Characteristics

- Adheres to the skin surface in extreme conditions and temperature ranges, even in the presence of moisture, pleural fluids and or blood.
- Dressing is designed to effectively seal the perimeter of the wound to cover and protect it.
- Seals the thoracic cavity and is impermeable to liquids, air, and debris that may penetrate the wound from the external environment.

Clinical Benefits

- Reduces risk of ingress of air, liquid, or debris that may contaminate the wound.
- Provides additional time in emergency cases until the patient is transported to a health facility.
- Reduced risk of tension pneumothorax.

Clinical Claims

- Effectively seals the wound's perimeter, if applied as directed by the manufacturer.
- Impermeable to liquid, air, and debris that may contaminate the wound.
- Seals the thoracic cavity, which in turn reduces the risk of tension pneumothorax.

CLEAN AND DRY AREA

REMOVE PRODUCT FROM PACKAGING. REMOVE CLEAR LINER

APPLY PRODUCT WITH LIGHT PRESSURE. DO NOT STRETCH PRODUCT

TRANSPORT PATIENT TO EMERGENCY CARE FACILITY FOR POST TREATMENT

DO NOT USE IF PACKAGE IS DAMAGED OR OPEN

LATEX
NOT MADE WITH NATURAL RUBBER LATEX

NON STERILE
NOT STERILIZED

DO NOT REUSE

60°C (140°F)
-34°C (-30°F)
STORAGE TEMPERATURE

MD
MEDICAL DEVICE

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