



Instructions for Use



INSTRUCTIONS AVAILABLE



TRANSLATION AVAILABLE

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



Product Description

Halo Vents are medical devices that consist of an adhesive hydrogel layer and an adhesive (non-latex) backing layer. Halo Vents do not contain any medicinal substances and are not constructed from animal or human derivatives. Halo Vents are impermeable to liquids and seals the wound. Halo Vents 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 Vents are designed to aid treatment of thoracic wounds by using standard dressing application techniques that aid emergency responders and medical professionals in the pre-hospital setting. Halo Vents are designed to cover and protect wounds. Do not use the dressing as a replacement for sutures and other primary wound closure methods. Halo Vents are a single use product. Attempts to reuse Halo Vents may introduce contamination and infection.

Intended Use/Intended Purpose

Halo Vents allow for the release of air from thoracic wounds. Halo Vents aid in the prevention, and management of a tension pneumothorax, potentially caused by penetrating thoracic trauma.

Patient Profile

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

Application

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

These symptoms may include:

- a. Sharp thoracic pain, increased respiratory rate, shortness of breath, tachycardia, a fast resting heart rate, or low blood pressure.
- b. 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.

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



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



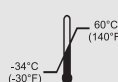
NOT MADE WITH NATURAL RUBBER LATEX



NOT STERILIZED



DO NOT REUSE



STORAGE TEMPERATURE



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Warnings

- Do not obstruct the Halo Vent where it can be occluded by patient's body weight or other emergency products, as this may reduce or stop its ability to function properly.
- Ensure Halo Vent 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 Vent as a replacement for sutures and other primary wound closure methods.
- Attempts to re-use Halo Vent 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 or damage vents.

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.
- Allows air release from the thoracic cavity and is impermeable to liquids, air, and debris that may penetrate the wound from the external environment.

Clinical Benefits

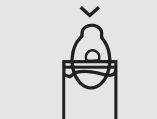
- Reduces risk of ingress of air, liquid, or debris that may contaminate the wound.
- Provides additional time in emergency cases until the patient is transported to a health facility.
- Reduced risk of tension pneumothorax.

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.
- Allows release of air from the thoracic cavity, which in turn reduces the risk of tension pneumothorax.



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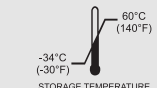
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