

AnchorFast SlimFit™ Oral Endotracheal Tube Fastener

Indication for Use

The oral endotracheal tube fastener is indicated for use by healthcare professionals in securing oral endotracheal tubes ranging in size from 5.0 to 8.0 mm inner diameter. The suitability of the oral endotracheal tube fastener must be assessed for each patient. (See the section below entitled “Precautions” for factors to consider.)

- A – Hook & loop closure (gray tab)
- B – Skin barrier pads
- C – Upper lip foam
- D – Neck strap
- E – Gliding tube shuttle on track
- F – ET tube wrap
- G – One-click security clamp

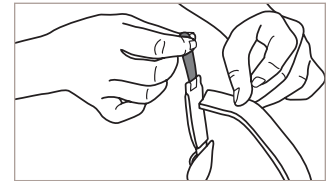
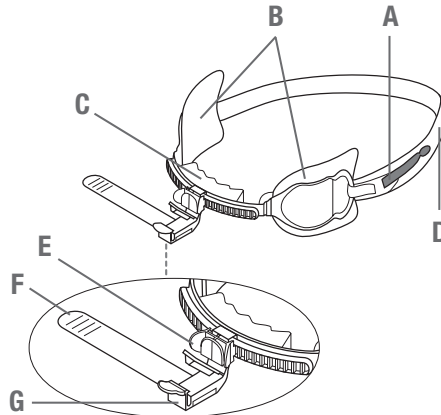


Figure 1

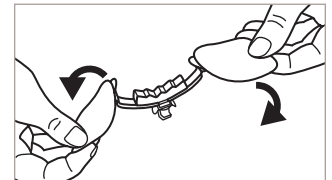


Figure 2

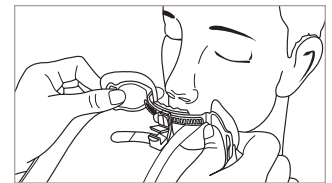


Figure 3

Application

Step 1 - Preparing the Skin

- Before applying the device, the patient’s skin should be clean, dry, and free of oily residue.
- Do not use skin gel wipes or other skin preps with the oral endotracheal tube fastener.

Step 2 - Applying the Oral Endotracheal Tube Fastener (Figures 1, 2, & 3)

- Remove the product from the packaging.
- Separate hook and loop closure (gray tab) of the neck strap.
- Remove the release liners from the two skin barrier pads.
- Pull back gently on the skin barrier pads so they are out of the way, to prepare for application.
- Center the device on the patient’s upper lip, so the non-absorbent upper lip foam lightly touches the skin.
- Press the two skin barrier pads on the patient’s skin and hold in place until they adhere well. This should take approximately 30 seconds.

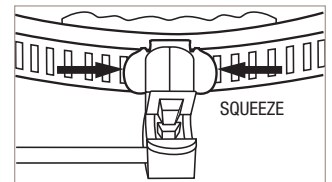


Figure 4

Step 3 - Securing the ET Tube (Figures 4 & 5)

- Squeeze the tabs on the sides of the gliding tube shuttle and move the clamp along the track to a location adjacent to the ET tube.
- Remove the release liner from the “ET tube wrap” [wrap], exposing the adhesive. Before applying the wrap to the ET tube, make sure the ET tube is dry and free of any residue.
- Position the ET tube under the non-slip grippers.
- Loop the wrap tightly around the ET tube; avoid including any other tubes within the wrap.
- Pull the remaining portion of the wrap through the security clamp.
- Secure the wrap by snapping shut the one-click security clamp (an audible click will be heard).

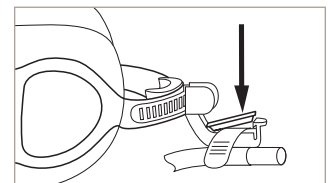


Figure 5

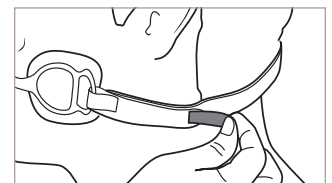


Figure 6A

Step 4 - Adjusting the Neck Strap (Figures 6A & 6B)

- For greater comfort and security, adjust the neck strap at the gray tab. Do not overtighten.
- Allow two fingers width between the strap and the back of the patient’s head.

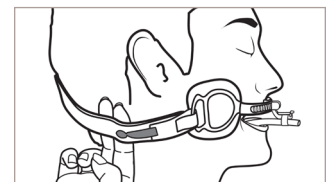


Figure 6B

USA: RX ONLY

* CAUTION: FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN OR OTHER HEALTHCARE PRACTITIONER LICENSED UNDER STATE LAW TO ORDER THIS PRODUCT.

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Routine Care (Figure7)

- To reposition the ET tube, squeeze the gliding tube shuttle tabs on the outer edges and move in either direction along the track.
- Reposition the ET tube from side-to-side at least every two hours or more frequently if the patient's condition dictates, to minimize the risk of injury to the skin and/or lips from unrelieved pressure and shear forces.

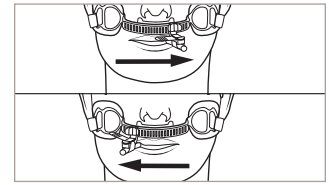


Figure 7

Removal

- Release the security clamp holding the wrap in place.
- Carefully remove the wrap from around the ET tube.
- Release the neck strap by unfastening the hook and loop closure at the gray tab.
- Remove the skin barrier pads by gently peeling them away from the patient's skin.

Warnings

- The oral endotracheal tube fastener is indicated for single use. To help ensure proper adhesion, do not reuse.
- As with any fixation device, excessive pressure introduced by the device and/or patient's head and/or body position (e.g. prone or side-lying) may cause dermal injury, tissue ischemia, or necrosis.
- Improper assembly and/or attachment of the device may increase the risk of hypoventilation or aspiration.

Precautions

- Store, handle, and dispose in accordance with institutional protocol and universal precautions.
- Be sure to frequently assess patient since wear time varies by patient.
- To minimize the risk of pressure injury, inspect the patient's lips, skin and oral cavity at least every two hours or more frequently if the patient's condition dictates (e.g. vulnerable to fluid shifts and/or edema).
- After application of the oral endotracheal tube fastener, check the patient frequently to ensure that both the oral endotracheal tube fastener and the ET tube are secure and correctly positioned.
- Use caution in patients with full or swollen lips, facial swelling, dental appliances, restorative implants, and/or loose or protruding teeth.
- Patients without front upper teeth or unable to wear upper dentures may lack the maxillary support required to use the oral endotracheal tube fastener.
- Patients with facial hair may lack the necessary support to anchor the skin barrier pads.
- Reconfirm position, depth of intubation, and patency of the ET tube or other airway device during and after any change in the patient's head, neck, or body position, or any change in the location of the fixation device.
- Use caution during patient movement and/or repositioning to avoid dislodging the ET tube.
- To ensure proper fixation of the device, exercise caution with the use of other devices and/or instruments (i.e., feeding tubes, fiberoptic (fibre optic) scopes) within the oral cavity during endotracheal intubation.
- Discontinue use of the device if redness, skin irritation or pressure injury occurs.
- Repeated adjustment of the ET tube in a distal or proximal direction may affect the performance of the "ET tube wrap" [wrap].
- Avoid aligning the inflation lumen directly under the non-slip grippers when securing the ET tube, and including all other tubes (e.g. inflation, subglottic) within the wrap.

In case of serious injury (incident) in relation to your use of the product, please contact your local distributor or manufacturer, and your local competent authority. For more information, see www.Hollister.com/authority or contact EC Rep or local distributor.

Prior to use, be sure to read the Instructions for Use for information regarding Intended Use, Contraindications, Warnings, Precautions, and Instructions.

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