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.

The Anchorfast devices do not contain any materials that are magnetic, conductive or metallic and therefore meet the requirements of ASTM F-2503 to be considered "MR Safe."

- A Hook & loop closure (gray tab)
- ${f B}$ 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

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.

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)

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

(Continued)



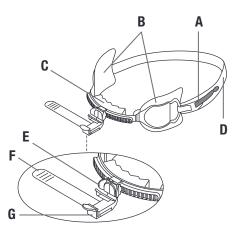












Figure 3

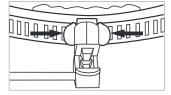


Figure 4

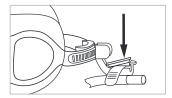


Figure 5



Figure 6a



Figure 6b

AnchorFast SlimFit Oral Endotracheal Tube Fastener

Routine Care

- To reposition the ET tube, squeeze the gliding tube shuttle tabs on the outer edges and move in either direction along the track (Figure 7)
- Reposition the ET tube from side-to-side at least every two hours or more frequently if the patient's condition dictates, to minimise the risk of the injury to the skin and/or lips from unrelieved pressure and shear forces

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

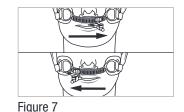
Precautions

- Be sure to frequently assess patient since wear time varies by patient
- To minimise the risk of pressure injury, inspect the patient's lips and skin 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 or skin irritation occurs
- Repeated adjustment of the ET tube in a distal or proximal direction may affect the performance of the "ET tube wrap" [wrap]
- Avoid including all other tubes (e.g. inflation, subglottic) within the wrap
- · After use, handle and dispose of in accordance with institutional protocol and universal precautions for contaminated waste

In case of serious injury (incident) in relation to your use of the product, please contact your local Hollister Territory Manager. Visit www.hollister.com to view video instructions for product application.

* CAUTION: PRIOR TO USE OF THE ANCHORFAST GUARD ORAL ENDOTRACHEAL TUBE FASTENER BE SURE TO READ THE PRODUCT INSTRUCTIONS FOR USE PACKAGE INSERT THAT ACCOMPANIES THE PRODUCT.

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