The HORSESHOE™

Endotracheal Tube Securement Device

USAGE GUIDE

INDICATIONS FOR USE

The HORSESHOE™ Endotracheal (ET) Tube Securement Device is indicated for securing oral single-lumen endotracheal tubes in patients undergoing mechanical ventilation. The device is intended for use across a broad patient population, including adults in acute and subacute clinical settings such as ICUs, EDs, operating rooms, burn units, transport environments, and long-term ventilator care settings.

INTENDED PERFORMANCE

- Minimize the risk of unplanned extubation
- Reduce the incidence of medical device-related pressure injuries (MDRPIs)
- Facilitate routine oral care procedures without compromising tube stability

DEVICE INTRODUCTION

The HORSESHOE™ is a healthcare professionals securing endotracheal tubes.

- The device is for single-lumen ET tubes ranging in size from 6.5 to 10.0mm.
- The device is intended for single-patient use only. Do not reuse the device.

The following provides direction for device pre-application, application and removal, as well as repositioning of the ET Tube when using the device.

DEVICE PRE-APPLICATION

Always intubate the patient prior to device application.

Confirm that the oral cavity is of sufficient size to accommodate the device and identify that there is at least one – upper or lower – back molar on both sides of the patient's mouth prior to device application. See warnings and precautions for additional patient selection and pre-application requirements.

DEVICE APPLICATION

Stabilize the ET tube with one hand during device application.

Figure 1

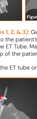

Figure 2

Figure 3

Step 1 (Figures 1, 2, & 3): Gently compress the sides of the device while inserting it into the patient's mouth, passing it between the patient's tongue and the ET Tube. Make sure the red arrow is visible and pointing toward the top of the patient's head.

Step 2: Keep the ET tube on top of the gliding track with the red line.

Figure 4

Figure 4a

Step 3 (Figure 4 & 4a): Maneuver the device into the oral cavity until you can feel that the molar props on both sides of the device are positioned between the upper and lower back molars.

Figure 5

Step 4 (Figure 5): Once the device is placed on the molars, slip the ET tube into the clamp and squeeze the sides of the clamp until it fits snugly around the ET tube. Check that the pilot balloon line and any feeding tubes or temp probes are not caught in the clamp lumen before securing the clamp around the tube.

Do not overtighten or dent the tube with the clamp.

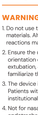

Figure 6

Step 5 (Figure 6): Once the clamp is locked, pull the free end of the red tab and place the first open slot over the end of the clamp arm.

Figure 7

Step 6 (Figure 7): Ensure that the clamp is locked on the gliding track by rotating the locking cam 180 degrees clockwise (following the direction of the arrow) until you hear and feel it click into place.

When properly locked, the red arrow on the locking arm should point toward the patient's head, and the red line on the locking arm should align with the red line on the gliding track.

ET TUBE REPOSITIONING USING THE DEVICE

Figure 8

Step 1 (Figure 8): To reposition the ET tube, ensure that the device is in the "unlocked" position (lever arm perpendicular to the track) or the clamp will not slide along the track.

Figure 9

Figure 10

Step 2 (Figures 9 & 10): Slide the ET tube clamp along the gliding track to the desired position, then rotate the lock arm 90 degrees clockwise to lock it in place.

The red arrow on the locking arm should be pointing toward the patient's head, and the red line on the locking arm should align with the red line on the gliding track when the device is locked properly.

Step 3: Once the device is in the locked position, the pilot balloon line and the NG/OG tubing can be organized in the ancillary tubing bracket.

If indicated by your institution's protocol, attach a strap to the device via the D-rings on the inside of the frame of the device.

In patients missing one or more back molars, the HORSESHOE™ may still be used at the clinician's discretion. For additional security, a strap or tie may be applied using the D-Rings on the frame. In cases where the device contacts mucosal tissue directly rather than teeth, clinicians should use best judgement, as patient sensitivity may vary.

DEVICE REMOVAL

The device can be removed either while the ET tube remains clamped in place or after it has been removed, in accordance with institutional protocols for ET tube removal.

Step 1: Detach any ancillary tubing (e.g., OG/NG tubes, pilot balloon lines) from the accessory clip and unfasten the back-up strap, if applied.

Figure 11

Step 2 (Figure 11): Compress the sides of the device while slowly retracting the tube from the patient's airway.

WARNINGS

1. Do not use the device in patients with known allergies to any of its materials. Although materials are biocompatible, hypersensitivity reactions may occur.
2. Ensure the device is correctly oriented during insertion; improper orientation or securement of the device may lead to unplanned extubation, airway compromise, or patient harm. Clinicians should familiarize themselves with the device usage guide before application.
3. The device is not a substitute for continuous clinical monitoring. Patients with secured endotracheal tubes should be monitored per institutional protocols.
4. Not for nasal intubation. The device is designed exclusively for oral endotracheal tubes.
5. Confirm that the ET tube matches the indicated range (6.5 to 10.0 mm) before use; incorrect tube size may result in improper securement and ventilation failure.
6. Do not reuse the device. Reuse may lead to cross-contamination, infection, and mechanical failure.
7. Carefully monitor the locking mechanism after repositioning. Failure to fully engage the locking arm may result in tube slippage or extubation.
8. Exercise caution when using the device in patients with:
   - Severe facial trauma
   - Recent oral or maxillofacial surgery
   - Poor dentition or absences of molars (use with D-rings/straps if applicable)
   - Small oral cavities or abnormal anatomy
   - Temporomandibular joint (TMJ) dysfunction or instability. Use caution in patients with known TMJ dysfunction, prior dislocations, limited mouth opening, or connective tissue disorders. Forced mouth opening may exacerbate TMJ injury risk.
9. Extended use beyond the intended period may result in material degradation and reduced securement effectiveness.
10. Avoid overtightening the ET tube clamp or securing strap, as this may compress the ET tube (risking occlusion), impair tube patency, or cause localized tissue injury.
11. Excessive saliva, blood, vomitus, or secretion buildup may reduce device securement effectiveness. Ensure frequent inspection and maintenance per institutional protocol.
12. If gag reflex is triggered during placement or adjustment, assess risk of aspiration and manage per institutional airway protection protocols.

PRECAUTIONS

1. Visually inspect the device and its packaging before use. Do not use if packaging is damaged, device appears deformed, incomplete, or compromised.
2. Ensure the molar props are properly seated between upper and lower molars to optimize securement and minimize risk of tube occlusion or biting.
3. Follow institutional protocols for endotracheal tube repositioning and securement checks. Periodically reassess ET tube position and device fit, especially after patient repositioning, agitation, or secretion accumulation.
4. Limit device use to patients with compatible oral anatomy. In patients with abnormal inter-molar spacing or missing molars, use additional securing measures (e.g., the arm straps via D-rings) as per clinical judgement. If mouth opening is limited (<3 cm), use extra caution of consider alternative airway management strategies, as limited mobility may predispose to TMJ injury.
5. Prolonged device placement on mucosa, especially in patients with compromised oral hygiene, may increase risk of mucosal injury or pressure ulceration. Perform regular skin/oral cavity assessments.
6. Environmental extremes, including excessive humidity or temperature, may affect material performance. Store and use the device within the recommended environmental conditions: 15–30°C (59–86°F), which corresponds to standard room temperature.
7. Removal of the device while the patient is intubated may result in tube instability and possible extubation.
8. This device is intended for use only by trained healthcare professionals familiar with airway management protocols.

SYMBOLS GLOSSARY

The following symbols may appear on the product labeling, packaging, or Instructions for Use:

SYMBOL	TITLE
	Consult instructions for use
	Do not reuse
	Manufacturer
	Date of manufacture
REF	Catalog number (REF)
LOT	Lot number
	Caution
UDI	Unique device identifier (UDI)
Rx ONLY	Caution: Federal law restricts this device to sale by or on the order of a physician.
MR	MR Safe
	Not made with natural rubber latex
	Scan for usage guide

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For more information on the HORSESHOE™ ET Tube Securement Device, please visit www.surgicaretech.com.

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