



SUREGLIDE PRO - INSTRUCTIONS FOR USE

CAUTION: U.S. Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

INTENDED USE

The Sureglide Pro is intended to facilitate endotracheal intubation with a video laryngoscope.

DEVICE DESCRIPTION

The Sureglide Pro is a tracheal tube delivery stylet capable of advancing the endotracheal tube along the tracheal serpentine to facilitate endotracheal tube placement during tracheal intubation. The device has a rigid stainless steel stylet with rounded tip, secured by a housing in the shape of an ergonomic grip, which houses a slide that articulates to facilitate the advancement of an endotracheal tube into the trachea under visualization with a video laryngoscope. Intended for one-time use. The devices are supplied sterilized by Gamma Radiation (R) in peel-open packages.

One size of the Sureglide Pro is available to facilitate single lumen endotracheal tubes in adults. The single size Sureglide Pro should be used only with endotracheal tube sizes 7.0mm – 8.0mm ID on patients >16yrs of age.

CONTRAINDICATIONS

- Entrance to the trachea cannot be visualized when performing laryngoscopy, i.e., Grade III or Grade IV Cormack & Lehane laryngoscopy classification.
- Inability to place a laryngoscope into patient's airway
- Patients with abnormal tracheal anatomy
- Patients with existing or potential tracheal trauma.

WARNINGS

- CAUTION: U.S. Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).
- The Sureglide Pro is only intended to be used with the inverted load of the endotracheal tube.
- Only use the Sureglide Pro provided tube connector that comes pre-attached to the Sureglide Pro.
- Remove any non-Sureglide tube connectors from an endotracheal tube before use.
- Do not use the Sureglide Pro with Flex-Tip® endotracheal tubes.
- For best results, use the Sureglide Pro only with video laryngoscopes.
- The Sureglide Pro is supplied sterile for single use only. It should be discarded after use and must not be re-used. Reuse may cause cross infection and reduce product reliability and functionality.
- Store devices in an environment that avoids direct sunlight and extreme temperatures.
- Excessive force must be avoided at all times.
- Care must be taken not to provoke injury to the epiglottis, glottis, or trachea.
- Possible allergic reactions should be considered.

PRECAUTIONS

- The product is intended for use by clinicians trained and experienced in airway management.
- If intubation cannot be completed, the endotracheal tube and the Sureglide Pro should be removed.

INSTRUCTIONS FOR USE

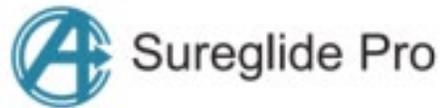
1. Confirm the Sureglide Pro package is unopened and undamaged. Note: Do not use product if there is doubt as to whether the product is sterile. Upon removal from the package, inspect the product to ensure no damage has occurred.
2. Remove tube connector included with the endotracheal tube.
3. Using a firm grip holding the endotracheal tube in a position rotated 180 degrees longitudinally from its natural position so that its curvature is opposite that of the stylet, slide the endotracheal tube over the distal tip of the Sureglide Pro until the proximal end of

the tube is slid over the white tube connector, which is supplied pre-attached to the Sureglide Pro, with moderate force to secure the tube on the connector. Note: This may be referred to as the “inverted load” of an endotracheal tube.

4. Confirm the slide of the Sureglide Pro is in contracted position. Adjust if necessary.
5. Confirm the endotracheal tube is properly loaded in the inverted fashion. By holding the Sureglide Pro with the right hand on the pistol grip, the Inverted load of the endotracheal tube is validated by the Murphy’s eye of the endotracheal tube at the distal tip of the tube facing left. *If not, the tube may be adjusted by rotating longitudinally along the stylet on the white tube connector.
6. Advance the video laryngoscope into the patient's mouth and position it for a view of the vocal cords.
7. Using the right hand to hold and control the Sureglide Pro with inverted loaded tube, insert the distal tip of the stylet and tube into the patient's mouth following the video laryngoscope blade and then through the vocal cords until the proximal end of the endotracheal tube cuff is in line with the vocal cords.
8. Using the right thumb, press the button on the back of the Sureglide Pro to advance the endotracheal tube into the desired position in the trachea. Note : the maximum amount of tube advancement the device is capable of is 2.5”. Note: If significant resistance is encountered, do not force the tube to advance further. Do not use any more than half the strength that one thumb can provide.
9. Using the thumb and index finger of the left to hold the endotracheal the tube in place, remove the Sureglide Pro from the endotracheal tube and patient by rotating it forward.
10. Remove the video laryngoscope from the patient.
11. Confirm the tube connector is secured in the endotracheal tube.
12. Confirm the endotracheal intubation with end tidal CO₂.

HOW SUPPLIED

Supplied sterilized by Gamma Radiation (R) in peel-open packages. Intended for one-time use. Sterile if package is unopened and undamaged. Do not use the product if there is doubt as to whether the product is sterile. Store in a dark, dry, cool place. Avoid extended exposure to direct sunlight. Upon removal from the package, inspect the product to ensure no damage has occurred.



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