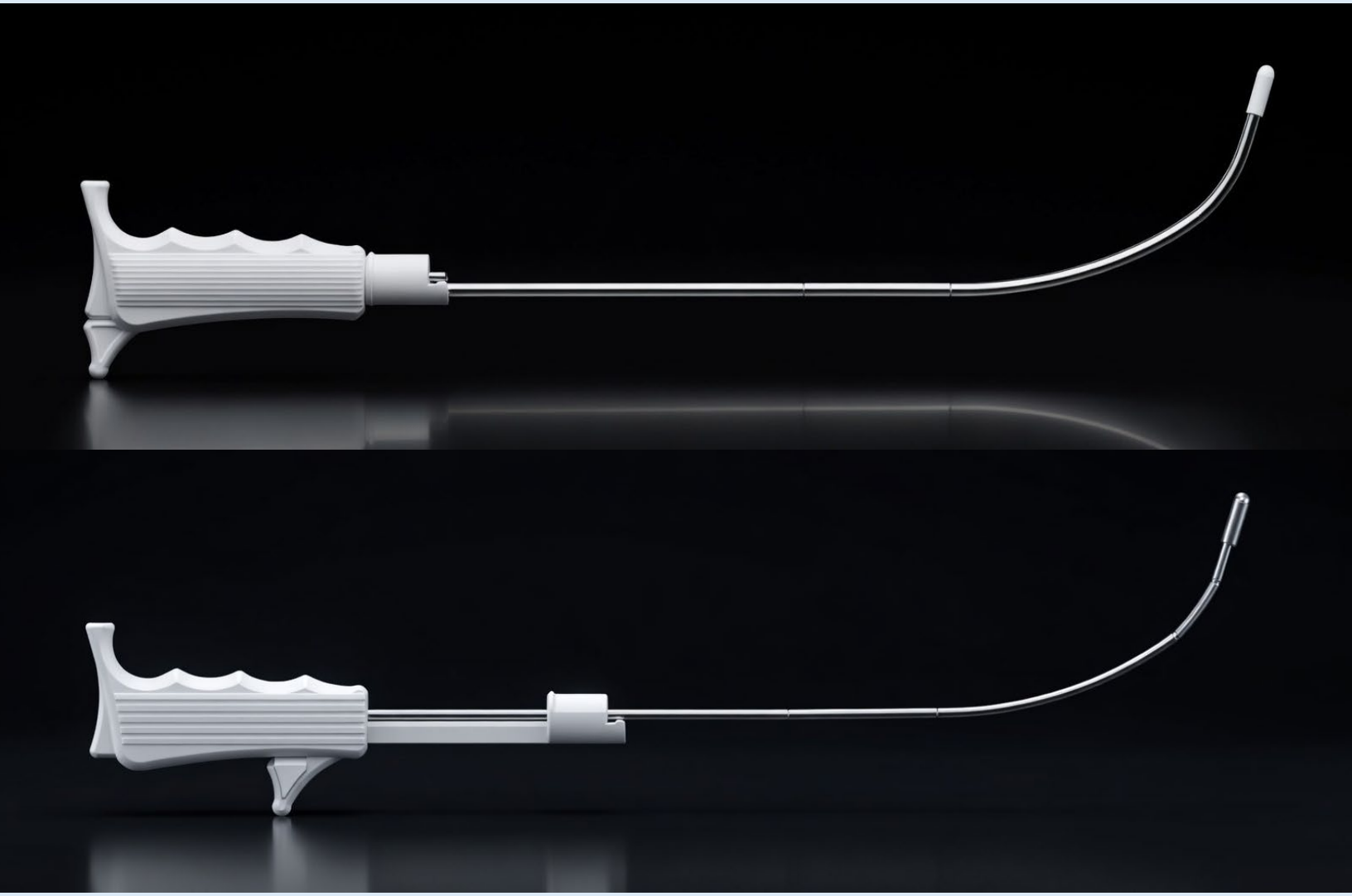
SUREGLIDE PRO

TUBE ADVANCING INTUBATION STYLET



Innovative technology for both difficult and every day endotracheal tube intubation

Improves patient safety and quality of care by mitigating the cost of intubation complications

Allows for reliable and consistent single-operator securement of the airway

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THE SUREGLIDE PRO ADVANCING STYLET

The future of endotracheal tube intubation was built around the often overlooked, second curve of the airway - unlocking the full potential of the video laryngoscope. The ergonomic grip and rigid stylet of the Sureglide allow for full control of the endotracheal tube to direct it to the vocal cords. Then with the press of a thumb, the slide assembly securely guides the tube down with the serpentine shape of the airway into the trachea. Aim and deliver.

Product Name	Description	Quantity	Price
Sureglide Pro	Endotracheal intubation stylet with user activated 2.5" tube advancement, inverted load capable, ergonomic handle, single use, sterile, latex free, fits size 7.0 - 8.0 tubes	10/Box 50/Case	$54.00/Unit

Sureglide Pro – Product Description

Using a firm grip holding the endotracheal tube, rotated 180 degrees longitudinally from its natural position so that its curvature is opposite that of the stylet, the proximal end of the endotracheal tube slides over the distal tip of the Sureglide Pro until the proximal end of the tube is slid over the white tube connector, included on the Sureglide Pro assembly

Holding the Sureglide Pro with the right hand on the pistol grip, the Inverted load of the endotracheal tube is validated by verifying the Murphey's eye at the distal tip of the tube is facing left.

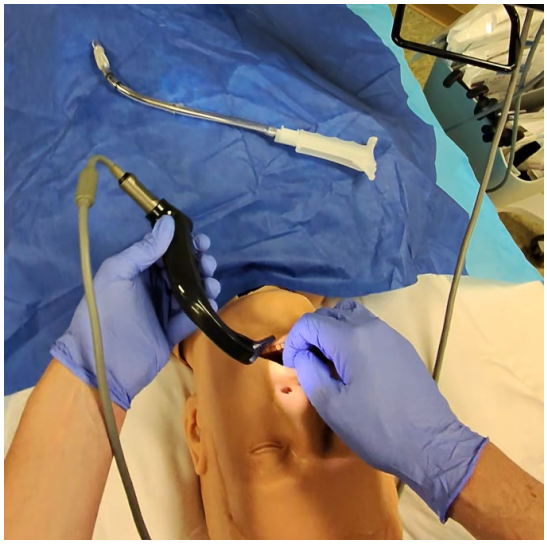
With the left hand, a video laryngoscope is advanced into the patient's mouth and is positioned for a view of the vocal cords

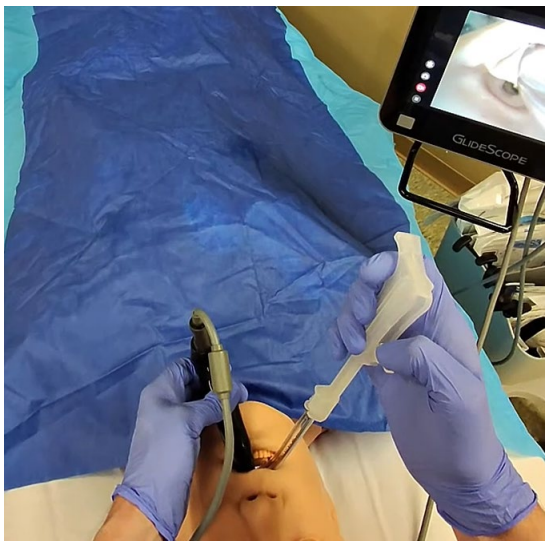
With the Sureglide Pro held and controlled by the right hand around its pistol grip, the distal tip of the stylet, with loaded endotracheal tube, is inserted into the patient's mouth following the video laryngoscope blade and then through the vocal cords until the proximal end of the endotracheal tube cuff is in line with the vocal cords.

Using the right thumb, the button on the back of the Sureglide Pro housing is pressed to advance the endotracheal tube into the trachea limited at 2.5"

By using the thumb and index finger of the left to hold the endotracheal the tube in place, the Sureglide Pro is removed from the patient and endotracheal tube by rotating it forward.

The video laryngoscope is removed from the patient. The endotracheal tube cuff is then inflated and connected to a breathing circuit. ET CO_2 and a stethoscope should be used to confirm proper endotracheal tube placement.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INNOVATORS OF AIRWAY MANAGEMENT

SUREGLIDE PRO – INTENDED 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 CO_2.

Endotracheal Tube Intubation – The Most Critical Routine Procedure in Medicine

Successful intubation on the first attempt is crucial to minimize the risk of complications such as hypoxia (low oxygen levels), aspiration, and cardiac arrest, which often occur with repeated attempts.
After just one minute without ventilation, patients will become hypoxic and brain cells will begin to die, by minute 2.5 - extensive neuron damage, by minute 3 - irreversible brain damage. By minute five – Death.

25,000 Americans die every year from failed intubation

- 4,000,000 Intubations occur annually in United States Emergency Departments and ICUs
- The Emergency Department was shown to experience a 23.2% failure rate of intubation attempts
- The ICU was shown to experience a 18.3% failure rate of first pass intubation attempts
- Every year, these failed attempts lead to 4,000 Cardiac arrests,16,000 Aspiration events, 300,000 major hypoxemia patient injuries and 700,000 cases of hypotension - costing billions between 6,000 hospitals.

Endotracheal Tube Cuff Pressures in the Operating Room of a Pediatric Hospital: A Quality Improvement Initiative : Kelly M Moon [*,†,✉], Sherry Donaworth [*], Molly S Hagele [†], Stephani S Kim [†], Brittany L Willer [†,‡], Joseph D Tobias [†,‡]

Video Laryngoscopy Is Associated With First-Pass Success in Emergency Department Intubations for Trauma Patients: A Propensity Score Matched Analysis of the National Emergency Airway Registry : Stacy A. Trent MD, MPH a b , Amy H. Kaji MD, PhD c d, Jestin N. Carlson MD e, Taylor McCormick MD a b , Jason S. Haukoos MD, MSc a b f, Calvin A. Brown III MD g h, National Emergency Airway Registry Investigators

Difficult Airway Characteristics Associated with First-Attempt Failure at Intubation Using Video Laryngoscopy in the Intensive Care Unit : Raj Joshi 1,2, Cameron D. Hypes 1,2, Jeremy Greenberg 1,2, Linda Snyder 1, Josh Malo 1, John W. Bloom 1,3, Harsharon Chopra 3, John C. Sakles 2, and ORCID IconJarrod M. Mosier 1,2

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The Video Laryngoscope

Video laryngoscope usage has grown rapidly since its introduction to the world just twenty-five years ago and is now considered **the standard of endotracheal tube intubation**. Its popularity grew because it provides superior visualization of the vocal cords when compared to direct laryngoscopy. Despite the superior view, better patient care, and significant improvements to first pass success rates, the video laryngoscope **increases the difficulty of tracheal access.** Studies show that 50% of failed VL FP attempts occur from inability to direct tube even with adequate view. The increased difficulty in tracheal access comes from modern airway tools not being able to direct the tube around the two curves of the airway. These tools may be able to always get the tube up to the cords, but not always through the cords and down to the trachea. This is the problem the Sureglide Pro was built to solve - unlocking the full potential of the video laryngoscope.

Difficult Airway Characteristics Associated with First-Attempt Failure at Intubation Using Video Laryngoscopy in the Intensive Care Unit (2016) PubMed: 27983871

Evaluation of six video laryngoscopes in 720 patients with a simulated difficult airway: a multicentre randomized controlled trial – British Journal of Anesthesia (2016)

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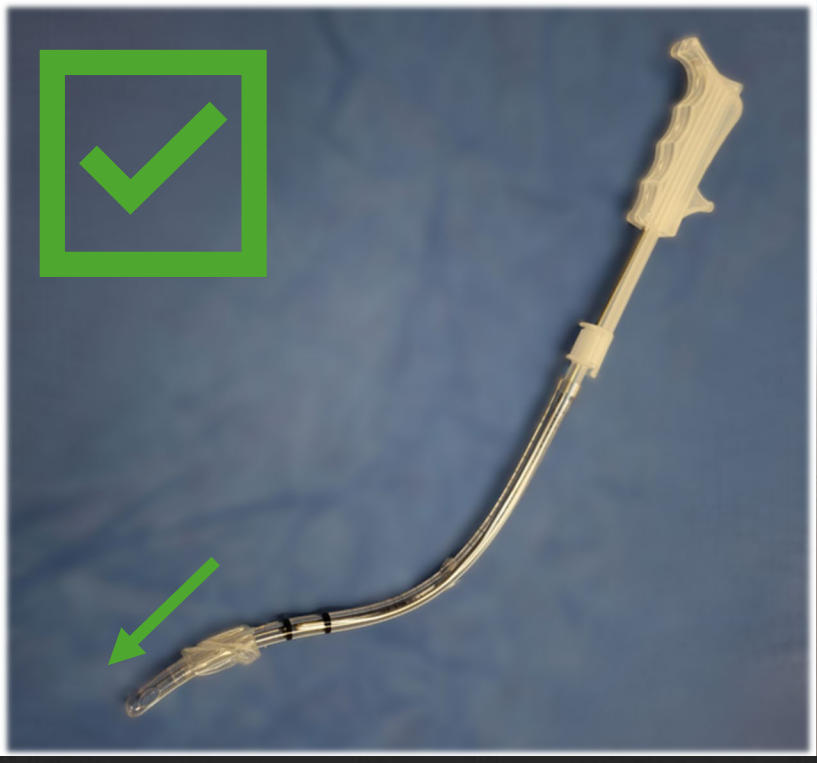
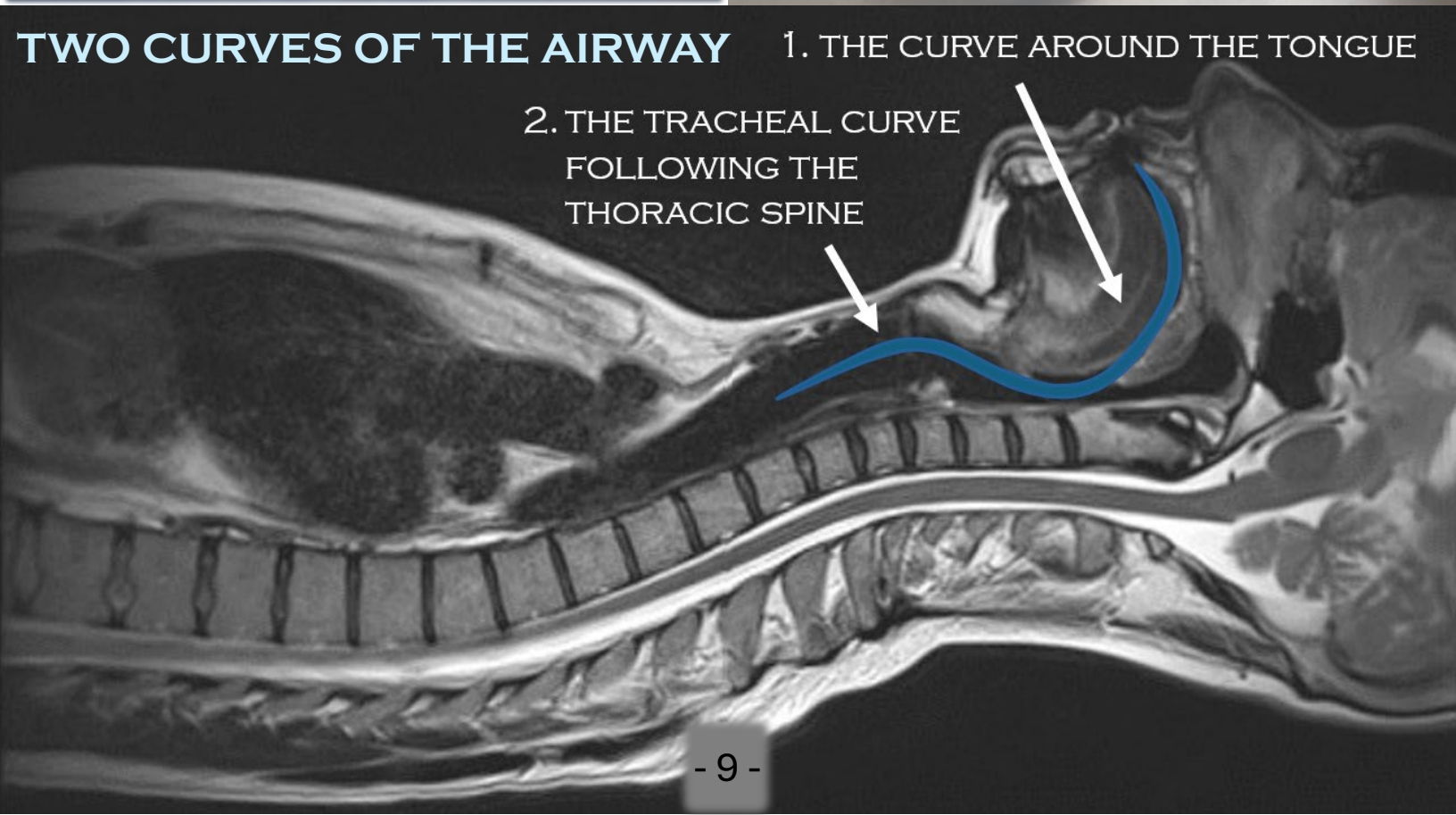
SUREGLIDE PRO

Built to make the inverted load of an endotracheal tube a reality – allowing for the tube to turn down with the secondary curve of the airway as the tube is advanced with the press of a thumb.

Current Standard Rigid Stylet

As the stylet is retracted through either a second provider or a very difficult-to-learn technique, the distal tip of the tube turns up, often getting caught in the laryngeal notch – which prevents the tube from advancing





Sureglide Pro – Value Proposition

The Sureglide Pro Advancing Stylet gives providers **serpentine tube advancement** and **full control of the intubation to a single operator** when delivering endotracheal tubes paired with video laryngoscopes.

A single provider having full control of the intubation combined with serpentine tube advancement results in a safer, more efficient, risk reduced, and less expensive intubation.

A single provider having full control of the intubation reduces risk, as it removes the need for a second provider, typically a nurse, anesthesia tech, or surgical assistant, which are the most inexperienced providers in the room.

Serpentine advancement of the endotracheal tube with the second curve of the airway eliminates the tube delivery difficulties that video laryngoscopes create.

Existing Options for Difficult Airways

Rigid Stylet

- Standard requires two operators
- Increased risk as 2nd operator is often the most inexperienced person in the room
- No depth control
- **Does not deliver tube with the second curve of the airway** – often resulting in physicians twisting the tube (in a corkscrew fashion) to obtain proper depth – damaging the vocal cords trachea.

When this fails you are left with the options below

Fiber Optic Bronchoscope

- $300-$400 Per Use
- Not immediately available in the OR
- Five minutes to retrieve (Hospitals spend roughly $50 per minute in an operating OR)
- Requires two operators
- Significant training required
- Requires costly sterilization after use

Cricothyrotomy

- Extremely Invasive
- Used because intubation attempts failed and time is running short
- Additional cost and care required after cutting the neck
- Increased patient recovery time
- Significant risk
- $200 per single use Cric Kit

Sureglide Pro

- Easy to use
- Non-invasive
- Requires only one operator
- Solves the issue of operator's inability to deliver tube
- If you see the vocal cords, you can intubate
- Solves the tube delivery difficulties video laryngoscopes create
- Solves depth issues of Bougies
- Prevents damage to the vocal cords and trachea
- Utilizes existing endotracheal tube inventory
- Carried on the GlideScope cart for easy access
- Provides depth control
- Single use
- Supplied sterile in peel open packaging
- Manages risk, the most experienced person in the room now has total control
- The most efficient per result method of intubation on market
- Aim and deliver – easy as that

$49 Per use.