*Runnels Steerable Introducer™ previously known as TCI™

The Runnels Steerable Introducer™

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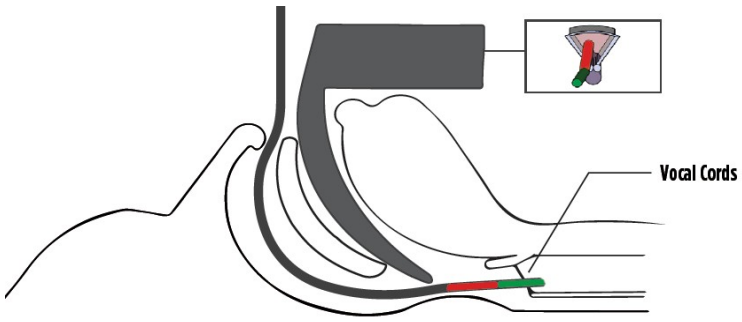
About Us

Through the Cords is an ambitious project with the goal of improving access to life changing and curable surgeries by developing safe, inexpensive, durable, and easy to master methods and equipment for managing difficult airways. Founded in 2016 by DR. Sean Runnels, Through the Cords is based in Salt Lake City with National Representation through Specialty Distributor Partners and select, highly experienced Sales Representatives in strategic markets.

The Runnels Steerable Introducer™

NEXT-GENERATION AIRWAY TOOLS-DESIGNED WITH THE VIDEO LARYNGOSCOPE IN MIND

Airway tools designed to take full advantage of the superior view provided by video laryngoscopes. The Through-The-Cords Articulating Introducer allows precise tip control. Designed to make the most difficult airways easy. Once in the trachea, an intuitive depth control system allows precise tip depth control throughout the intubation.



If you can see the cords, you can intubate the cords. Green at the cords, tip mid-trachea. **Simple as that**.

THROUGH THE CORDS
Next-Generation Airway Tools

TOOLS DESIGNED TO REDUCE FIRST PASS FAILURE AND POOR DEPTH CONTROL

Intubation: The Fastest Way to Save a Life (or End It)

– We can only live for **3-5 minutes without oxygen**

– **40M intubations** per year in the USA (4M ED and ICU intubations)

FIRST ATTEMPT FAILURE, POOR DEPTH CONTROL AND THE COST OF CURRENT COMPLICATIONS

600K → $20B → 120K

Major Complications | Complications Cost | Deaths

Product Name	Description	Quantity	Product Code
Runnels Steerable Introducer™	Articulating Introducer with detachable handle, intuitive depth system, 70 CM, 15 Fr, latex free, single use, sterile, fits 6.0 and larger ID tubes	5/Box 20/Case	001031

Product Description

The Runnels Steerable Introducer™ is a novel articulating endotracheal tube introducer featuring a fully articulating tip, a flexible shaft, a removable pistol grip handle, and an intuitive color zone depth control system. The Runnels Steerable Introducer™ articulating tip allows active and precise maneuverability while navigating the upper airway into the trachea. Once precision tracheal access is achieved, the intuitive color band depth control system allows precise tracheal depth without looking away from the video laryngoscope screen.

The Runnels Steerable Introducer™ is designed especially for use with any video laryngoscope but can be used with any direct laryngoscopes as well.

Typically, this Runnels Steerable Introducer™ is used in conjunction with a video laryngoscope but may be used with a direct laryngoscope as well. The laryngoscope is used to provide visualization and the Runnels Steerable Introducer™ is used for precise access to the trachea during difficult intubations.

A video laryngoscope is placed into the patient's mouth and advanced until a view of the vocal cords is obtained. The laryngoscope is used with the left hand.

The Runnels Steerable Introducer™ is then inserted into the mouth alongside of the laryngoscope blade until the tip appears in the field of view of the video laryngoscope. The Runnels Steerable Introducer™ is held and controlled with the right hand.

The pistol grip handle of the Runnels Steerable Introducer™ is then used to precisely articulate the tip anteriorly, as needed, to reach the vocal cords, and then posteriorly, as needed, to advance into the trachea.

Once in the trachea, the Runnels Steerable Introducer™ is advanced into the trachea until the green zone printed on the shaft of the introducer lies next to the vocal cords indicating safe placement of the tip in the mid trachea. If the red zone is next to the vocal cords, this signals the introducer is too deep in the trachea placing the introducer should be withdrawn until the green zone is next to the vocal cords.

Once safely placed into the trachea, the pistol grip handle is released and removed using the right thumb leaving the shaft of the introducer in place in the trachea.

Once the handle is removed, an endotracheal threaded over the introducer shaft and advanced into the trachea.

Once the endotracheal tube is well placed into the trachea, the introducer shaft is removed out the back of the endotracheal tube leaving the endotracheal tube in place.

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.

Intended Use

TTC Runnels Steerable Introducer™ 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).

DEVICE DESCRIPTION

The TTC Runnels Steerable Introducer™ is a 15 FR, 70 cm long catheter. It has a rounded-tip with centimeter markings as well as color zonal markings to facilitate placement and use. The distal end of the catheter is curved with a tip that articulates and can be passed with visualization into the trachea.

INTENDED USE

The TTC Runnels Steerable Introducer™ is intended to facilitate endotracheal intubation. The introducer has been designed for placement of a single lumen endotracheal tube whose inner diameter is 6 mm or larger. **NOTE:** Do not use the TTC Runnels Steerable Introducer™ with double lumen endotracheal or endobronchial tubes.

CONTRAINDICATIONS

- Do not use if the 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
- Pediatric patients
- Adults with abnormal lower airway anatomy
- Inability to visualize the color-depth-zone system throughout the procedure

WARNINGS

- The color-depth-zone system is sized for normal adult tracheal anatomy.
- To avoid trauma to the lungs, bronchial injury, or pneumothorax, examine the patient's anatomy to help determine the optimal placement for the TTC Runnels Steerable Introducer™.
- Ensure the introducer is in the clinician-preferred location relative to the carina by referencing its centimeter markings or color-zoned-tip.
- Care must be taken not to provoke injury to the epiglottis and glottis, perforation of the sinus pyriformis, bronchus, or trachea.
- Do not use the TTC Runnels Steerable Introducer™ with double lumen endotracheal or endobronchial tubes.
- Lubricate the catheter introducer and endotracheal tube before use.
- Ensure proper sizing of the endotracheal tube to be used in combination with the TTC Runnels Steerable Introducer™.
- Care must be taken when introducing/removing the catheter introducer from the endotracheal tube; contact with sharp edges on the internal surface of the endotracheal tube may cause small fragments to be shaved off the catheter introducer during introduction/removal.
- Possible allergic reactions should be considered.

- Do not reattach the handle to the introducer after it has been removed

PRECAUTIONS

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

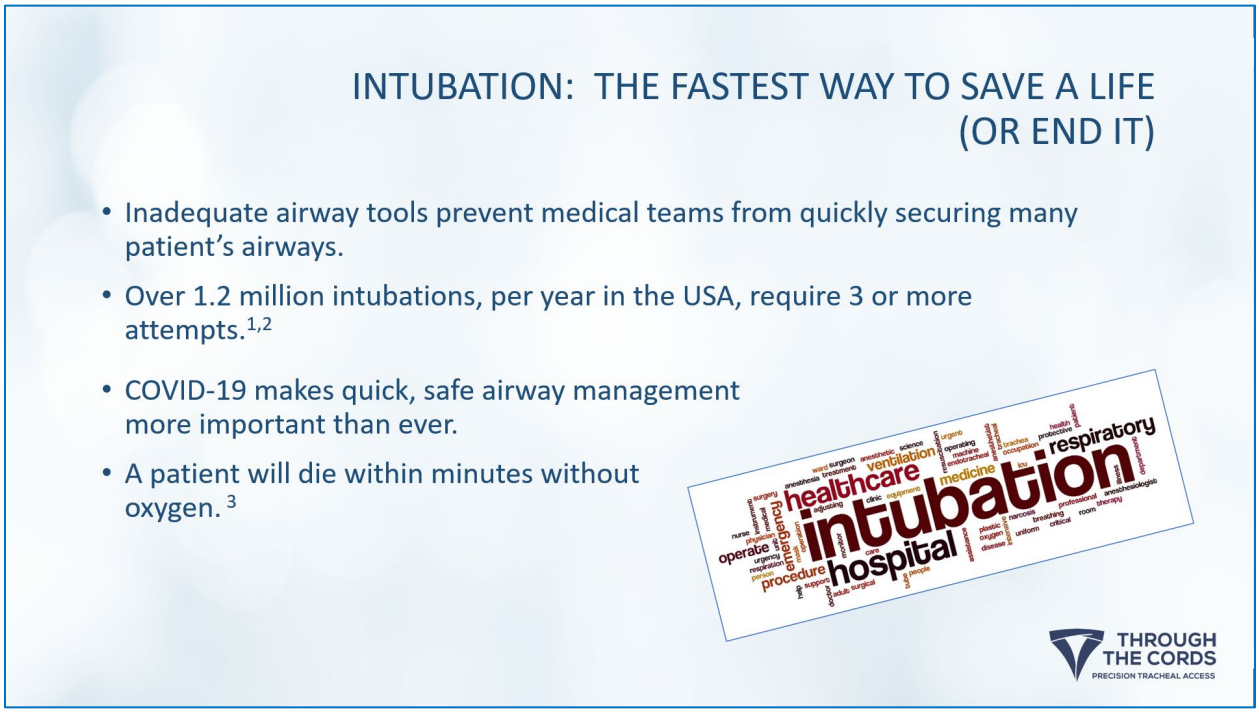
INSTRUCTIONS FOR USE

1. Place video laryngoscope (VLS) to visualize cords
2. Straighten tip by squeezing trigger
3. While inserting into mouth, directly visualize the tip of the introducer until it is no longer directly visible
4. Once the tip appears in the laryngoscope view, release the trigger to bring the tip up
5. Move tip towards the entrance to the trachea
6. Use the trigger and rotate the handle to adjust tip to enter the trachea
7. Once the tip is in the trachea, squeeze the trigger to articulate the tip to facilitate passage down the trachea
8. If resistance is encountered, do not force the introducer
9. Insert the device into the trachea until the green zone of the color-depth-zone system is at the entrance to the trachea
10. Remove fingers from the trigger entirely
11. Release handle by pushing thumb-release forward until it stops, and then down to open the cover
12. Remove the handle from the introducer
13. Pass control of the VLS to an assistant to maintain the view of the relationship between introducer shaft and the vocal cords
14. While maintaining the green zone of the color-depth-zone system at the vocal cords, pass tube over introducer into the trachea
15. While leaving ET tube in place, remove introducer
16. Remove VLS
17. Inflate the cuff of the ET tube (if present)
18. Ventilate patient

HOW SUPPLIED

Supplied sterilized by Ethylene Oxide 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.

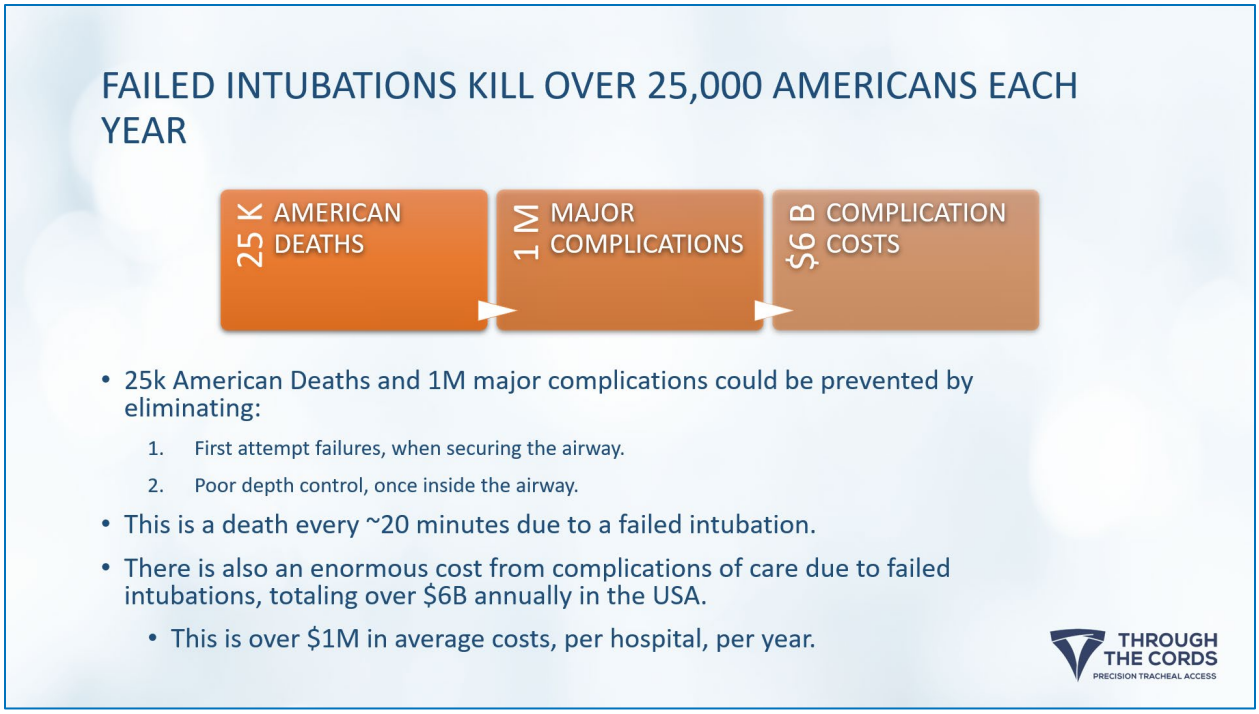
Clinical Impact



- Intubation is the fastest way to save a life (or to end it)
- Inadequate airway tools prevent medical teams from quickly securing many patient's airways
- Over 1.2 million intubations, per year in the USA, require 3 or more attempts in the Operating Room Setting. This becomes even more complicated with emergent intubations in the ED and ICU (of which there are over 3M per year in the USA).
- It is often difficult to predict which patients will have a difficult airway before an intubation (especially emergent intubations). Therefore having proper airway tools available to medical providers is key to ensuring patient safety.
- Multiple failed intubation attempts increase the risk of injury or death to patients.
- COVID-19 makes quick, safe airway management more important than ever.
- As you know, a patient will die within minutes without oxygen.

References:

- Frerk C, Mitchell VS, Mcnarry AF, et al. Difficult Airway Society 2015 guidelines for management of unanticipated difficult intubation in adults. 2015;115(November):827-848. doi:10.1093/bja/aev371
- Sgalambro F, Sorbello M. Videolaryngoscopy and the search for the Holy Grail. Published online 2016:471-472. doi:10.1093/bja/aex020
- Sakles JC, Chiu S, Mosier J, Walker C, Stolz U. The Importance of First Pass Success When Performing Orotracheal Intubation in the Emergency Department. doi:10.1111/acem.12055



ED and ICU Emergency Intubation

- When you look at the best statistics from peer reviewed journals, the number of complications and deaths due to failed intubations is tragic, even when using low-end estimates.
- Over 25k American Deaths and 1M major complications could be prevented by eliminating a couple major issues with Intubations. These include:
  - First attempt failures, when securing the airway.
  - Poor depth control, once inside the airway.
- This is a death every ~20 minutes in the USA due to a failed intubation.
- Additionally, the breakdown of these 1M complications is very grim, with respect to their morbidity and mortality. They include:
  - 4,000 Cardiac arrests
  - 16,000 Aspiration events
  - 300,000 major hypoxemia patient injuries
  - 700,000 cases of hypotension
- It should also be noted that failed first pass intubation complications directly lead to a 400% increase in mortality, associated with ICU stays.
- There are also enormous costs directly associated with complications of care due to failed intubations, totaling over $6B annually in the USA.
- This is over $1M in annual costs, per hospital, per year (as there ~6,000 hospitals in the USA).

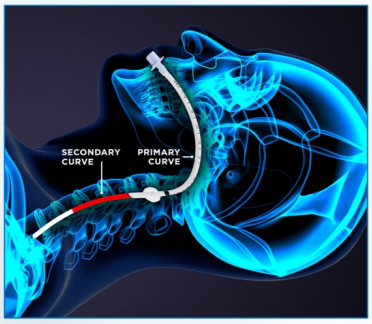
References:

- Schilling AL. Estimating the Economic and Absolute Number of Complications Associated with Emergency Intubations Performed Outside the Operating Room ; A Methodology for Estimating the Burden in the US.; 2019.
- Frerk C, Mitchell VS, Mcnarry AF, et al. Difficult Airway Society 2015 guidelines for management of unanticipated difficult intubation in adults. 2015;115(November):827-848. doi:10.1093/bja/aev371
- Sgalambro F, Sorbello M. Videolaryngoscopy and the search for the Holy Grail. Published online 2016:471-472. doi:10.1093/bja/aex020
- Sakles JC, Chiu S, Mosier J, Walker C, Stolz U. The Importance of First Pass Success When Performing Orotracheal Intubation in the Emergency Department. doi:10.1111/acem.12055

- Cook TM, Woodall N, Frerk C. Major complications of airway management in the UK: results of the Fourth National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society. Part 1: Anaesthesia 2020; Br J Anaesth. 2011;106(5):617-631. doi:10.1093/bja/aer058
- Schilling AL, Runnels S, Hollenbeak CS, S U. National Costs of Complications Associated with Emergent Tracheal Intubations. In: Academy Heath Research Meeting. ; 2019. https://academyhealth.confex.com/academyhealth/2019arm/meetingapp.cgi/Paper/33893
- Spaite DW, Bobrow BJ, Keim SM, et al. Association of Statewide Implementation of the Prehospital Traumatic Brain Injury Treatment Guidelines With Patient Survival Following Traumatic Brain Injury The Excellence in Prehospital Injury Care (EPIC) Study. 2020;85724. doi:10.1001/jamasurg.2019.1152
- Spaite DW, Hu C, Bobrow BJ, Adelson PD, Keim SM, Viscusi C. HHS Public Access. 2018;70(4):522-530. doi:10.1016/j.annemergmed.2017.03.027.Association
- Lee LA, Cheney FW, D M. Management of the Difficult Airway ASA Closed Claims 2005. 2005;(1):33-39.
- Intubation T, Posner KL, Ph D, Duggan L V, Mincer SL, Domino KB. Management of Difficult ASA Closed Claims 2019. 2019;(4):818-829. doi:10.1097/ALN.0000000000002815
- Bhatti NI, Mohyuddin A, Reaven N, et al. Cost analysis of intubation-related tracheal injury using a national database. Otolaryngol - Head Neck Surg. 2010;143(1):31-36. doi:10.1016/j.otohns.2009.11.004
- States U, Survey AHAA. Fast Facts on US Hospitals. 2020;(312).

CURRENT AIRWAY TOOLS ARE A BIG PART OF THE PROBLEM

- **Direct Laryngoscopy (DL)** – The "old" standard for intubations
  - Poor visualization of the airway
  - Antiquated design requires extensive training, with no guaranteed result
  - Rigid airway tools (stylets and introducers) cannot "steer" around anatomy
  - Proximity to COVID patient airways is risky for providers
  - Failed intubations require escalation to "rescue tools"



- Direct Laryngoscopy (DL) – This is currently the standard for intubating patients and it has many issues including:
  - Visualization of the airway is not good, making it difficult to secure the airway and ensure proper depth control
    - This is because of antiquated airway tools that were designed over 50 years ago. They require extensive training and practice by medical providers, to achieve even modest results – and this is no guarantee of patient safety, even by trained airway experts.
  - Rigid airway tools (such as stylets and introducers) cannot "steer" around the 2 natural curves of the airway (*as you can see in the image, there are 2 directionally opposed curves, known as Greenland's theory*).
    - None of these airway tools are dynamically shapeable while attempting to secure the airway, making multiple intubation attempts inevitable in many patients.
  - Additionally, proximity to COVID patient airways, when using DL, puts medical providers at elevated risk for contracting COVID-19
  - Failed intubations require escalation to "rescue tools", after a few failed attempts.

References:

- Frerk C, Mitchell VS, Mcnarry AF, et al. Difficult Airway Society 2015 guidelines for management of unanticipated difficult intubation in adults. 2015;115(November):827-848. doi:10.1093/bja/aev371
- Al-Qahtani AS, Messahel FM, Ouda WOA. Inadvertent endobronchial intubation: A sentinel event. Saudi J Anaesth. 2012;6(3):259-262. doi:10.4103/1658-354X.101218

CURRENT "RESCUE TOOLS" FOR DIFFICULT AIRWAYS ALSO HAVE ISSUES

- **Fiber Optic Bronchoscopes and Difficult Airway Carts**
  - Very expensive
  - 4 handed operation - Requires multiple medical providers
  - Requires in-depth training for safe and effective use
  - Not immediately available in the OR, requiring 5 - 10 minutes for delivery (patient safety risk)
  - Disrupts hospital workflow, with escalation to crisis atmosphere

THROUGH THE CORDS
PRECISION TRACHEAL ACCESS

- Fiber Optic Bronchoscopes and Difficult Airway Carts – These are the most common "Rescue Tools" and have many issues:
  - They are very expensive at ~$300 - $400 per procedure.
  - Require multiple medical providers (4 handed operation) and in-depth training, for safe and effective use
  - Not immediately available in the OR, requiring a special request that involves 5-10 minutes in delays (during which the patient is "bag ventilated" with less safety and reliability), putting patients at further risk of major complications or death
  - Using these tools disrupts hospital workflow and efficiency, delaying other procedures.
  - Getting to this point in an intubation leads to a "crisis atmosphere". This causes further disruptions in efficiency and a detriment to the mental health of medical providers. That much cortisol is not good for anyone ;)

References:

- Sgalambro F, Sorbello M. Videolaryngoscopy and the search for the Holy Grail. Published online 2016:471-472. doi:10.1093/bja/aex020
- Sakles JC, Chiu S, Mosier J, Walker C, Stolz U. The Importance of First Pass Success When Performing Orotracheal Intubation in the Emergency Department. doi:10.1111/acem.12055
- Aziz MF, Abrons RO, Cattano D, et al. First-Attempt Intubation Success of Video Laryngoscopy in Patients with Anticipated Difficult Direct Laryngoscopy: A Multicenter Randomized Controlled Trial Comparing the C-MAC D-Blade Versus the GlideScope in a Mixed Provider and Diverse Patient Population. 2016;122(3):740-750. doi:10.1213/ANE.0000000000001084
- Mouritsen JM, Ehlers L, Kovaleva J, Ahmad I. A systematic review and cost effectiveness analysis of reusable vs. single-use flexible bronchoscopes. Published online 2020:529-540. doi:10.1111/anae.14891

VIDEO ASSISTED INTUBATION (VL) HELPS INTUBATION SUCCESS, BUT STILL HAS PROBLEMS

- Video Laryngoscopy (VL) – The "new" standard
  - Excellent visualization, providing a view around the airway curves
  - Provides further distance from COVID patient airways
  - Optimized design for usability, requiring less training
- However, static airway tools cannot "steer" around the multiple curves of difficult airway anatomy
  - Tracheal access is now the main intubation fail point, with over 50% of VL failures being 'failure to access the trachea despite an adequate view!'
- Improved visualization is less effective without next-generation airway tools to use with VL!

THROUGH THE CORDS
PRECISION TRACHEAL ACCESS

- Video Laryngoscopy (VL) helps improve intubation success and is the way of the future, with many practitioners already utilizing these tools. COVID-19 has accelerated this conversion.
- VL provides:
  - Improved visualization, allowing the practitioner to see around the curves of the airway.
  - Further distance from COVID patient airways, reducing risk to the medical team
  - Newer designs that are optimized for usability, requiring less training
- However, as previously discussed, rigid airway tools (such as stylets and introducers) cannot "steer" around 2 curves, found in typical airway anatomy.
  - VL actually exacerbates this issue, making access into the trachea more difficult.
  - Tracheal access is now the main intubation fail point, with over 50% of VL failures being *'failure to access the trachea despite an adequate view!'*
  - The situation become even more complicated when you have difficult airway anatomy and higher BMIs.
  - This is a major problem, causing consistently failed intubations, patient complications, and deaths!
- The improved visualization is not as effective as it could be, without next-generation airway tools designed for use with VL!

References:

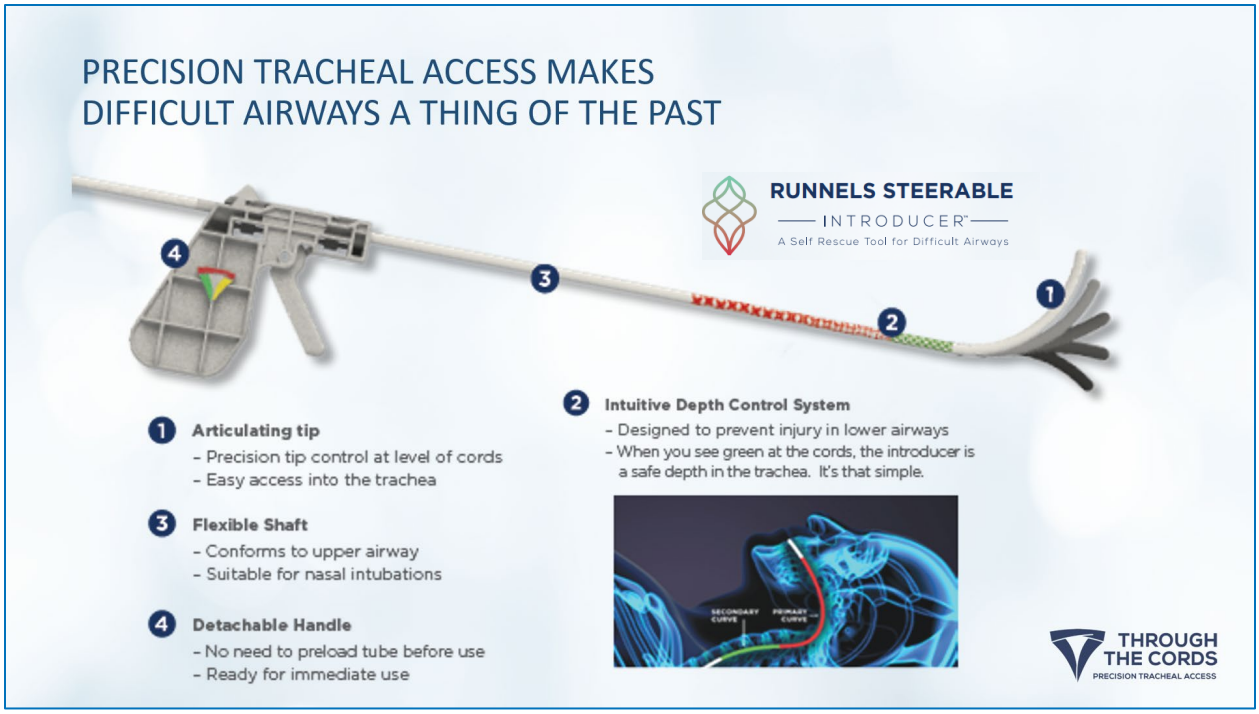
- Cook TM, Boniface NJ, Seller C, et al. Universal videolaryngoscopy : a structured approach to conversion to videolaryngoscopy for all intubations in an anaesthetic and intensive care department. *Br J Anaesth*. 2018;120(1):173-180. doi:10.1016/j.bja.2017.11.014
- Cook TM, El-Boghdadly K, McGuire B, McNarry AF, Patel A, Higgs A. Consensus guidelines for managing the airway in patients with COVID-19: Guidelines from the Difficult Airway Society, the Association of Anaesthetists the Intensive Care Society, the Faculty of Intensive Care Medicine and the Royal College of Anaesthetists. *Anaesthesia*. 2020;75(6):785-799. doi:10.1111/anae.15054
- Willett AW, Shanks A, PhD, et al. Success of Intubation Rescue Techniques after Failed Direct Laryngoscopy in Adults. 2016;(4):656-666.

- This is where Through the Cords Next-Generation Airway tools solve the problem with intubations.
- SECURE THE AIRWAY THE FIRST TIME, EVERY TIME with the Runnels Steerable Introducer™
  - The Runnels Steerable Introducer™ is a self-rescue tool for difficult airways.
  - Its next-generation design is specifically geared towards use with the Video Laryngoscope
- When used in conjunction, these tools ensure first pass success on every intubation
- In addition to improved patient safety, the Runnels Steerable Introducer™ helps save money for your hospital, reducing the cost of expensive airway rescue tools and mitigating the direct cost of complications of care

References:

- Shah A, Durnford K, Knecht L, Jacobson C, Runnels S. Capability and Effectiveness the TCI™, a Dynamically Controllable Introducer, in the Context of Rescue after Failed Video Laryngoscopy and Direct Laryngoscopy. Pre-publication whitepaper. 11 October 2020.

*The Runnels Steerable Introducer™ does not mitigate the inherent risk of intubations. However, clinical studies show that with workable airway anatomy, a trained medical professional has a substantially improved chance of first pass success rate. In the above study, 100% of patients were able to be intubated on the first attempt, when the Runnels Steerable Introducer™ was used in conjunction with VL.



- Difficult airways are a thing of the past with the Runnels Steerable Introducer.
- The Runnels Steerable Introducer™ Provides precision tracheal access, in a self-rescue tool.
- The next-generation design of the Runnels Steerable Introducer™ unique in the market. A few of the key aspects of the design include:
  - An articulating tip, which allows the introducer to be steered around difficult anatomy encountered during many intubations. This provides easy access into the trachea and helps ensure you secure the airway the first time, every time. The tip is controlled by the direct-drive trigger, allowing medical professionals to use 1 hand for the VL and 1 hand for the Runnels Steerable Introducer™. Only 1 practitioner is required to secure the airway, making it a true self-rescue tool.
  - An intuitive depth control system is imprinted along the shaft, helping prevent injury to the lower airway and vocal cords. The color-coding system is very simple. When you see green at the cords, the introducer is a safe depth in the trachea. It's that simple.
  - The flexible shaft is suitable for both traditional and nasal intubations, providing medical teams with the options they need to ensure the safety of the patient.
  - A quick-release, detachable handle means you do not have to pre-load an endotracheal tube before use. You can instantly do this on the fly, as you are intubating the patient. Again, this ensures it is only a "2 handed operation" and does not require additional practitioners to secure the airway.
  - In addition to the functional and patient safety features of the Runnels Steerable Introducer™, the Runnels Steerable Introducer™ will improve your hospitals financial health. It will minimize the costs associated with complications of care, additional personnel, disruptions to work-flow, and the costly use of fiber optic scopes or airway carts.
  - The use of the Runnels Steerable Introducer™ is very simple, due to its intuitive design.
    - Insert the Runnels Steerable Introducer™ into the upper airway and visualize the tip with a VL.
    - Pull the trigger on the Runnels Steerable Introducer™ to dynamically shape and steer the Runnels Steerable Introducer™ into the lower airway.
    - When you see the green portion of the shaft at the cords, the tip of the introducer is perfectly placed mid-trachea and you are ready to insert your Endo Tracheal (ET) tube.
    - When you're done, simply discard the Runnels Steerable Introducer™ – they're single use, ensuring your team is always ready for the next intubation in no time.

Clinical Data

PEER REVIEWED 1. Kumar A, Gupta N, Kumar V,Bhargava T, Total control introducer-aided nasotracheal intubation using a videolaryngoscope in an anticipated difficult airway: a novel technique

2. Navarro G, Allori R, Alvarez Rosario C, Knecht L, First reported use of a Runnels Steerable Introducer™ with Video Laryngoscopy in Patients with Cervical Spine Immobility due to Instability of fusion. Three Successful First Pass Intubations.

PEER REVIEWED 3. Pollard J, Runnels S, Warrick C. First Case Report of Intubation With a Runnels Steerable Introducer™ and a Hyperangulated Video Laryngoscope. A A Pract. 2020 Sep;14(11):e01310. doi:10.1213/XAA.0000000000001310. PMID: 32985849.

4. Shah A, Durnford K,Knecht L, Jacobson C, Runnels S, Capability and Effectiveness the TCI™, a Dynamically Controllable Introducer, in the Context of Rescue after Failed Video Laryngoscopy and Direct Laryngoscopy

5. Behrens M, Runnels S, Report of the Successful Use of a Total Control Introducer™ in Combination with a Hyperangulated Video Laryngoscope for Intubation of a Patient with a Supraglottic Tumor; A Modified, Combined-Intubation Technique

6. Bodine G, Gnadinger P, Successful Use of TCI™ in Predicted Difficult Intubation

PEER REVIEWED 7. Keefe K, Cannon R, Runnels S, Successful intubation of a patient with a supraglottic tumor using a novel articulating introducer for precision tracheal access

PEER REVIEWED 8. Shah, Ashka MD; Durnford, Katryn MS; Knecht, Lauren MD; Jacobson, Cameron MS; Runnels, Sean Torin MD A Consecutive Case Series of Rescue Intubations With the Articulating Total Control Introducer for Precision Tracheal Access, A & A Practice: March 2021 - Volume 15 - Issue 3 - p e01418 doi: 10.1213/XAA.0000000000001418

Referenced Documents

PEER REVIEWED 1. Al-Qahtani AS, Messahel FM, Ouda WOA, Inadvertent Edobronchial Inubation: A sentinel event

PEER REVIEWED 2. Aziz MF, Abrons RO, Cattano D, First-Attempt Intubation Success of Video Laryngoscopy in Patients with Anticipated Difficult Direct Laryngoscopy: A Multicenter Randomized Controlled Trial Comparing the C-MAC D-Blade Versus the GlideScope in a Mixed Provider and Diverse Patient Population

PEER REVIEWED 3. Bhatti NI, Moyuddin A, Reavan N, Cost analysis of intubation-related tracheal injury using a national database

PEER REVIEWED 4. Cook TM, Boniface NJ, Seller C, Universal videolaryngoscopy: a structured approach to conversion to videolaryngoscopy for all intubations in an anaesthetic and intensive care department

PEER REVIEWED 5. Cook TM, El-Boghdadly K, McGuire B, Patel A, Higgs A, Consensus guidelines for managing the airway in patients with COVID-19

PEER REVIEWED 6. Cook TM, Woodall N, Frerk C, Major complications of airway management in the UK: results of the Fourth National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society. Part 1: Anaesthesia

PEER REVIEWED 7. Frek C, Mitchell VS,Mcnarry AF, Difficult Airway Society 2015 guidelines for management of unanticipated difficult intubation in adults

PEER REVIEWED 8. Intubation T, Posner KL, Duggan LV, Mincer SL, Domino SL, Management of Difficult Tracheal Intubation: A Closed Claims Analysis

PEER REVIEWED 9. Lee LA, Cheney FW, Management of Difficult Tracheal Intubation: A Closed Claims Analysis

PEER REVIEWED 10. Mouritsen JM, Ehlers L, Kovaleva J, Ahmad I, A systematic review and cost effectiveness analysis of reusable vs. single-use flexible bronchoscopes

PEER REVIEWED 11. Sakles JC, Chiu S, Mosier J, Walker C, Stolz U, The Importance of First Pass Success When Performing Orotracheal Intubation in the Emergency Department

PEER REVIEWED 12. Sgalambro F, Sorbello M, Videolaryngoscopy: the more I practice, the luckier I get

13. Shah A, Dunford K, Jacobson C, Runnels S, Capability and Effectiveness the TCI™, a Dynamically Controllable Introducer, in the Context of Rescue after Failed Video Laryngoscopy and Direct Laryngoscopy

PEER REVIEWED 14. Spaite DW, Bobrow BJ, Keim SM, Association of Statewide Implementation of the Prehospital Traumatic Brain Injury Treatment Guidelines With Patient Survival Following Traumatic Brain Injury

15. States U, Survey AHAA, Fast Facts on US Hospitals, Willet AW,Shanks A, Success of Intubation Rescue Techniques after Failed Direct Laryngoscopy in Adults

PEER REVIEWED 16. Willet AW, Shanks A, Success of Intubation Rescue Techniques after Failed Direct Laryngoscopy in Adults

17. Schilling AL, Estimating the Economic and Absolute Number of Complications Associated with Emergency Intubations Performed Outside the Operating Room; A Methodology for Estimating the Burden in the United States.

PEER REVIEWED 18. Schilling AL, Runnels S, Hollenbeak CS, National Costs of Complications with Emergent Tracheal Intubations

PEER REVIEWED 19. Spaite DW, Hu C, Bobrow BJ ,Adelson PD, Keim SM, Viscusi C, The Bougie and First-Pass Success in the Emergency Department

Value Proposition

- The Runnels Steerable Introducer™ fully articulating introducer gives providers **dynamic navigational capabilities** and **intuitive depth control** while accessing the trachea when placing endotracheal tubes when combined with any video laryngoscope.
- Precision navigation and precision depth control **enables faster, safer, and less expensive intubation** in a wider variety of anatomy with shorter training times.
- **Faster:** Studies show that difficult intubations managed with Runnels Steerable Introducer™ are significantly **faster** than those managed other advanced airway techniques. On average, 'in room to intubated' times was 21.0 mins when managed with a fiberoptic bronchoscope vs 13.2 mins when managed with a video laryngoscope and Runnels Steerable Introducer™.
- **Predictable:** Studies show that the 'in room to intubation" time is more **predictable** with a lower standard deviation when using a Runnels Steerable Introducer™ when compared to other advanced airway techniques. The standard deviation with FOB management was 11.4 mins vs 5.3 mins when managed with a video laryngoscope and Runnels Steerable Introducer™.
- **Effective**: Studies show superior **first pass intubation success** rates in the settings of rescue intubations and primary management of difficult intubations when compared to other advanced airway techniques. The Runnels Steerable Introducer™ successfully rescued **97%** of cases after failed attempts with standard techniques of VL an DL. Published rescue success rates range from 85-89% for other advanced airway techniques. The Runnels Steerable Introducer™ had significantly **higher first pass success rates** when used to manage predicted difficult intubations achieving a first pass success rate of **90%** compared to first pass success rates of 67% to 88% of other more expensive and time-consuming advanced intubation techniques.
- **Safer**: Studies show improved introducer tip **depth control** in the trachea when our patented **Color Zoned Depth Control System** was used during endotracheal tube exchanges. Introducer tip travel below the carina (danger for pneumothorax and bronchial injury) was **eliminated** when a color zone depth system was used vs standard, incremental measurements at the teeth.
- **Patient Satisfaction**: Hoarseness and transient loss of voice in outpatient surgery is **significantly lower** when a Runnels Steerable Introducer™ is used to intubated Vs all other intubation techniques. In a large retrospective review of self-reported hoarseness and loss of voice at post-operative day one in outpatient surgeries. Hoarseness for any intubation technique was found to be 15% and transient loss of voice 3%. When a Runnels Steerable Introducer™ was used for intubation hoarseness was found to be **5% and there was no loss of voice.**
- Extends the range of patient's that can be intubated with a standard video laryngoscope.
- Designed for single operator use.
- Each QR code linking to quick and effective training videos for on-the-fly training or refreshing.
- Live training via Web or in person if requested.

- QR code with airway management pearl of the month.
- Quarterly Current topics in Airway management (CME).
- Packaging with a tab allows for storage via video laryngoscope tower making it readily available.
- Eliminates the need for disinfection and cleaning of bronchoscopes and other equipment.

The fully loaded costs of care include the Direct Medical Costs, the Indirect Care Costs, Self-Care Costs, and Lost Productivity Costs at the workplace
Cost savings in the delivery of care can be best understood in the operating room setting and in the ICU or ED setting.

Operating Room Setting:

Savings in equipment costs
Fiber Optic Bronchoscopes and Difficult Airway Carts – These are the most common "Rescue Tools" and have many issues:

- They are very expensive at ~$300 - $400 per procedure.
- Require multiple medical providers (4 handed operation) and in-depth training, for safe and effective use.
- Not immediately available in the OR, requiring a special request that involves 5-10 minutes in delays (during which the patient is "bag ventilated" with less safety and reliability), putting patients at further risk of major complications or death.
- Using these tools disrupts hospital workflow and efficiency, delaying other procedures.
- Getting to this point in an intubation leads to a "crisis atmosphere". This causes further disruptions in efficiency and a detriment to the mental health of medical providers. That much cortisol is not good for anyone.

Time Cost savings:

Time in the OR has two important aspects. Speed, and predictability. Each is valuable in different ways. Speed is valuable in the strict sense of cost per minute. That is a very easy calculation, what is an OR minute worth? How much time is saved performing a procedure with different equipment?
Predictability is important as well. It is difficult to plan and manage an operation room if there is a great deal of variability around procedure times. The cost savings in predictability is real, but much harder to measure.
The Runnels Steerable Introducer™ offers cost saving in both speed and predictability.

- **Faster:**
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Difficult intubations are reported to make up between 2-5 % of intubations in the operating room.
We have developed a cost saving calculator based on the number of difficult intubations that allow a prediction of total time saved when using the Runnels Steerable Introducer™.

ED and ICU emergency intubation

Burdon of first pass failure in emergency intubations in terms of number of major complications and costs of those complications.

- Multiple intubation attempts have been directly linked to sharp increases in complications and increasing mortality.
  - Approximately 3 million emergency intubations are performed a year in the US.
  - First pass success in critically ill patients is important.
  - Current first pass success rates in these setting is published to be 85%.
  - The annual US national burden of tracheal intubation morbidity and cost to be at least 1,161,316 major complications costing $5,937,615,900.
  - The current burden attributable to first-pass intubation failure to be at least 167,594 major complications costing $890,415,900.
  - Each intubation carries a complication cost burden of $1,979.
  - Eliminating first pass failure could save $300 per intubation.

Equipment Cost Savings:

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Indirect Care Cost Savings:

Malpractice
Airway management remains the most common cause of major mortality and morbidity in Anesthesia care.
Median legal payout in the US is between 271,205 and 305,000 with a range of $49,050 – $854,000.
Peterson 2005

Major vocal cord injury legal payout average $7699 The cost of complications is unknown; however each cord injury is associated with 1 extra day intubated in the ICU and most require additional procedures such as vocal cord injections or surgery.

Lost Productivity Savings:

- The Runnels Steerable Introducer™ can reduce the risk of COVID 19 exposure during intubation.
- Single use devices reduce handling and cleaning post use, for support staff and increased provider to patient distancing during intubation potentially reduces exposure risk during intubation. Not aware of current clinical data published regarding this issue. There are ongoing monitoring systems looking at this problem. (COVID Intubate Data Base, Penn State)

Care Facility Operational Savings:

What non-clinical operational savings does your product deliver to care facilities, for instance, does the product reduce expenditures on other products or create savings in some other way? What is the economic advantage of using your product? (Be sure to include the cost of conversion from another and the cost of integration into the facilities' operation.) What evidence do you have to support these savings?

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Reduced OR Time:

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References

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