TOTAL CONTROL INTRODUCER™

KEEPING PROVIDERS AND PATIENTS SAFE DURING COVID-19 INTUBATIONS

THROUGH THE CORDS
Next-Generation Airway Tools

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COVID-19 INTUBATIONS BY THE NUMBERS

4-6 MILLION
COVID-19 INTUBATIONS IN THE PIPELINE

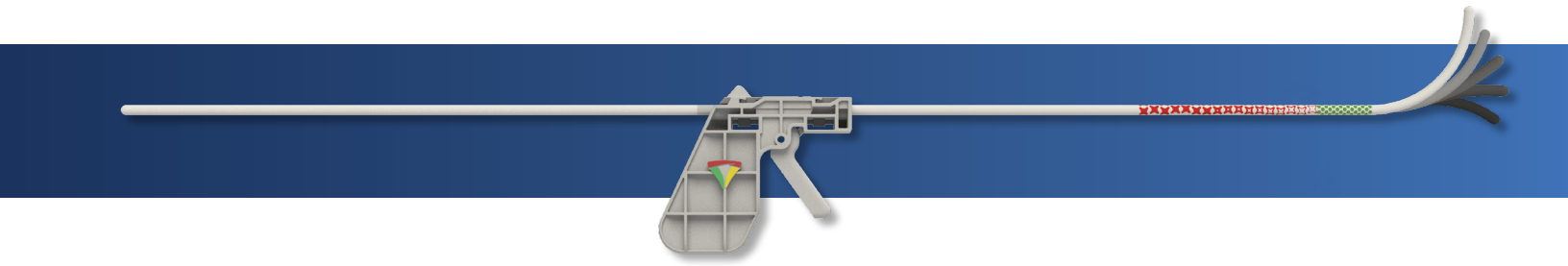
- 40–60% of Americans will be infected (~100M)
- ~5M will need intubation
- ~3-5% will be difficult intubations (150,000–250,000)
- 6-18 month epidemic course (depending on social distancing)
- These numbers are based on 40% infected, may reach 60%

PROTECTING OUR CLINICIANS WITH THE TOTAL CONTROL INTRODUCER™ (TCI)

Total Control Introducer™ (TCI) is the only articulating endotracheal tube introducer that combines a flexible shaft, a dynamically shapeable articulating tip, and intuitive depth control. Designed specifically for video assisted intubation in high risk patients, the Total Control Introducer™ is an immediately available, single use rescue tool in the event of a failed intubation attempt with VL. This is especially important in COVID-19 intubations as rescue with VL can keep your providers risk of COVID-19 exposure as low as possible.

HEALTH AFFAIRS BLOG
American Hospital Capacity And Projected Need for COVID-19 Patient Care
Thomas C. Tsai, Benjamin H. Jacobson, Ashish K. Jha **MARCH 17, 2020**

THE PRODUCT

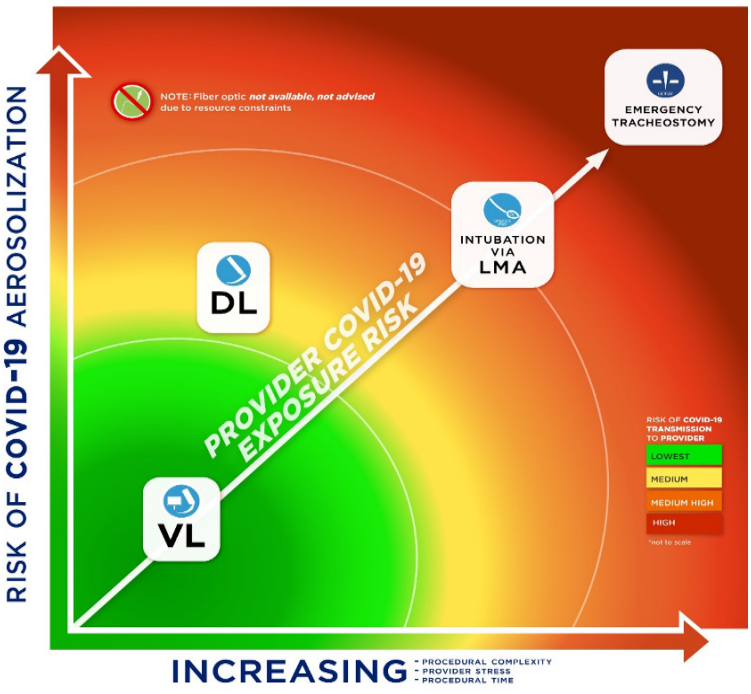


VALUE PROPOSITION FOR COVID-19 INTUBATIONS

KEEPING PROVIDERS AND PATIENTS SAFE DURING COVID-19 INTUBATIONS

The TCI enables providers to rescue failed intubation attempts with a lower exposure risk profile than traditional rescue techniques. The TCI fills an important exposure risk gap that exists in COVID-19 Intubation protocols.

The TCI is designed to reduce the skills and complexity needed to achieve smooth endotracheal tube delivery and rapid intubation with video laryngoscopy. By giving the provider the ability to dynamically shape the tip of the introducer, navigation in the trachea is easy and intuitive. Making intubation faster and less complex in COVID-19 intubation, lowers the risk of COVID-19 exposure for the provider and can reduce complications for the patient.

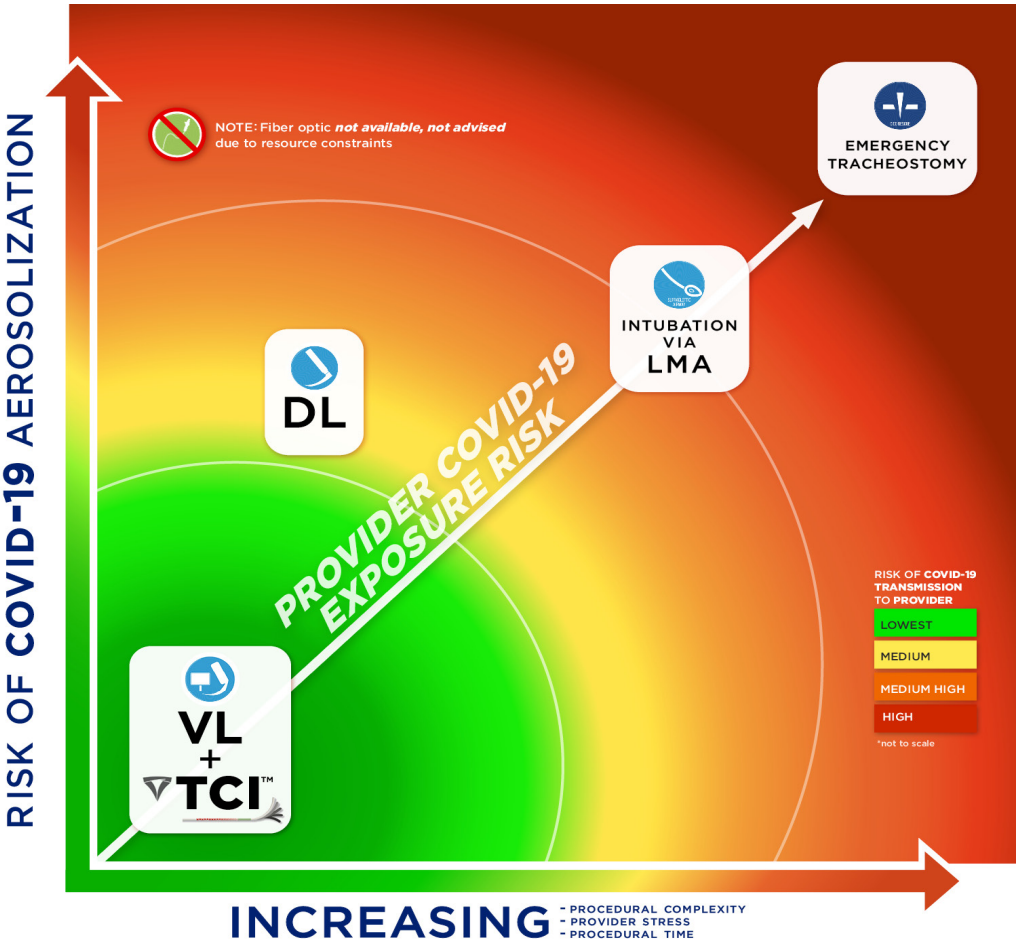


INTUBATION IS A HIGH-RISK PROCEDURE FOR COVID-19 PROVIDER EXPOSURE

- Virus can be aerosolized...Shortage of PPE equipment!
- Heavy mental task load...Easy to make sterile protocol mistakes!
- Provider fatigue and stress...Easy to make sterile protocol mistakes!

STAY IN THE GREEEN ZONE. Video laryngoscopy is the safest way to intubate COVID-19 patients.

TCI HELPS KEEP YOU IN THE GREEN



HOW DOES THE TCI FIT INTO THE NEW COVID-19 INTUBATION PROTOCOLS?

Intubation protocols for COVID-19 call for video laryngoscopy to be used for visualization, as it keeps the providers face out of the path of the airway in case the patient coughs..

Most intubation attempt failures with video laryngoscopy are failures to maneuver the endotracheal tube through the upper airway and into the trachea despite an adequate view.

Standard rescue techniques after a failed a video laryngoscope attempt involve a higher COVID-19 exposure risk profile due to:

1. **Elevated risk of aerosolization and direct contamination**
2. **Increasing complexity and mental task load resulting in contamination mistakes**
3. **Longer procedure times and hence longer overall time risk exposure**

The TCI is specifically to designed for use with a video laryngoscope. The TCI offers an intuitive, quick and low risk option for the provider to self-rescue after a failed video laryngoscope attempt. Rescue with TCI keeps the operator in the green zone.

KEY FEATURES

DEVICE FEATURES VALUABLE IN THE COVID-19 CRISIS

AVAILABILITY
Made in the USA. In stock and availability now. Valuable.

PORTABILITY
Light weight, one piece that can be hung on cart or delivered bedside whenever needed.
Availability, and portability. Valuable.

INFECTION CONTROL
Cleaning airway carts and fiberoptic towers will quickly become an overwhelming burden for exhausted staff. The risk of cross contamination will only increase. *Single use and disposability. Valuable.*

DEPLETION OF DISPOSABLE FIBEROPTIC BRONCHOSCOPES
Fiberoptic bronchoscopy is a cornerstone technique for managing difficult airways. When a fiberoptic bronchoscope is used to intubate, it is no longer available for diagnosis and treatment. Minimizing use of fiberoptic scopes for difficult airway management will be critical. *Equipment that can displace the use of fiberoptic scopes for intubation. Valuable.*

REMOTE TRAINING WITH SHORT PROGRESSION TO MASTERY
Aggregate airway management skills will go down as the COVID crisis unfolds. Intubation will take place where and when it is needed. The availability of providers highly skilled in airway management is limited. As these providers will be called to the front line early in the crisis, we can anticipate that their availability will go down as the crisis unfolds due to exhaustion, exposure, and quarantine. As demands escalate and skilled personnel are stretched, the task of intubation must partially shift to those with less skills and training. The ability to quickly train providers will be key. Achieving consistent intubation out comes in difficult settings, with shorter training times, while consuming fewer resources will save lives. *Online training for the easy to use Through the Cords Articulating Introducer is available now. No in-hospital training needed. Very Valuable.*

STAKEHOLDER BENEFITS

PATIENTS

Improved first-pass intubation and depth control means fewer airway management complications and better outcomes for patients and their loved ones.

PROVIDERS

Providers are the heart of any medical system. COVID-19 transmission risk increases with PPE shortages! The TCI is designed to lower exposure risk for your providers during intubation. Minimizing their COVID-19 infection risk can be the difference between collapse or survival of our medical systems. The Total Control Introducer™ (TCI) is intuitive and easy to use which means less mental and emotional stress before, during and after managing high-risk airways.

HEALTH SYSTEMS

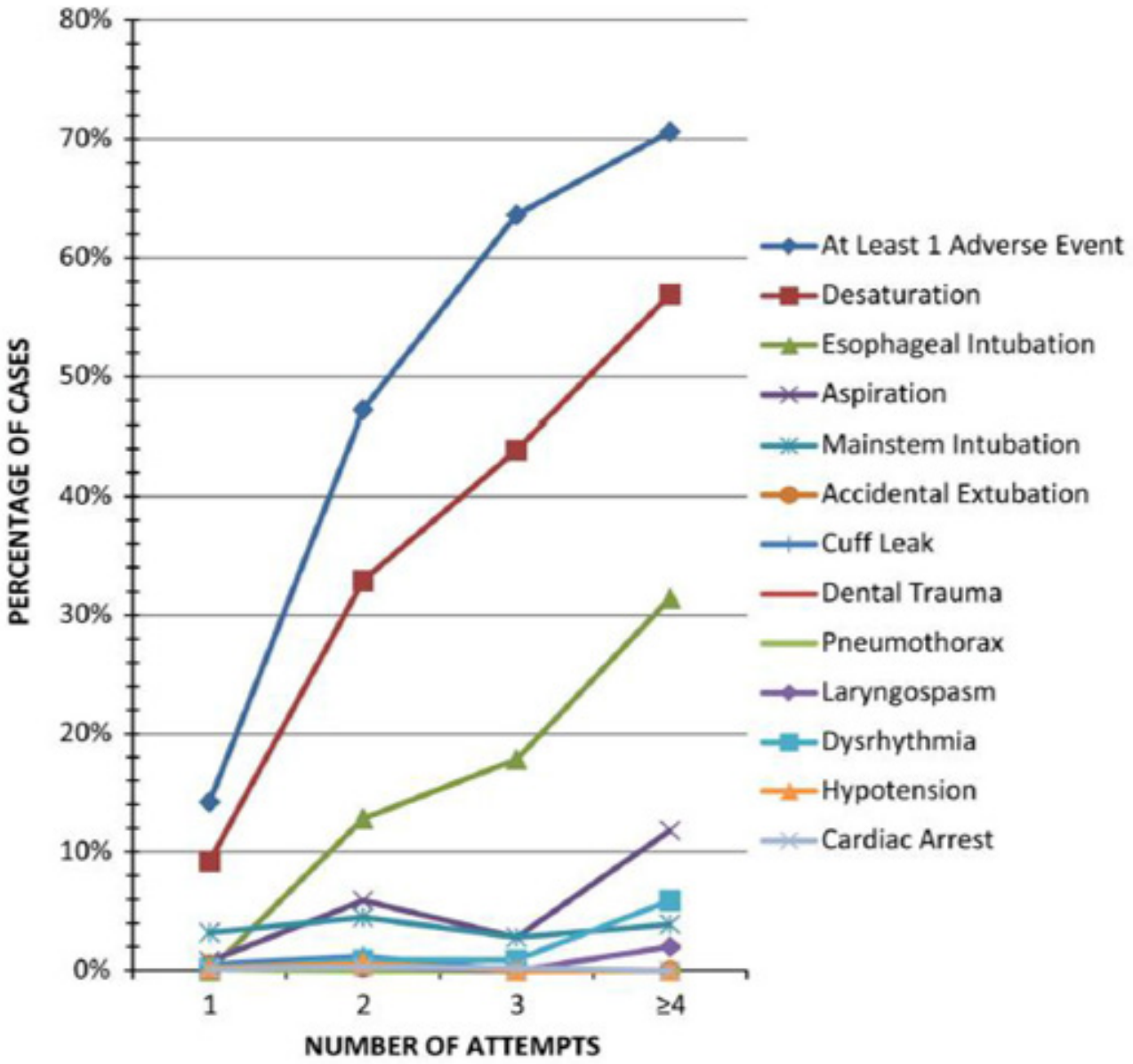
4.5M potential COVID positive patients in the pipeline, making it critical to keep staff safe and complications low. The TCI is easy to master, disposable and portable. TCI can make intubation safer for providers and patients. Single use eliminates cross-contamination risk and eliminates handling and cleaning. Made in America lowers risk of supply chain disruption.

PAYERS

Efficient and effective solutions to COVID-19 airway management problems limits complication and risk as well as minimizes the need for multiple airway devices, lowering the total cost of care.

KEY FACTS WHY THIS IS IMPORTANT

THE COST OF FAILED EMERGENCY INTUBATIONS (NON COVID-19)



KEY FACTS WHY THIS IS IMPORTANT

10% OF INTUBATIONS ARE HIGH RISK FOR POOR OUTCOMES. (*Mort 2004*)

- **Emergency intubations**
- **Pre-hospital, Emergency Room and ICU**
- **Difficult airways in the OR**

25% FIRST PASS INTUBATION FAILURE IN EMERGENCY INTUBATIONS (*Sakles 2013, Mort 2004*)
First pass failure in the emergency setting increases major complications 4–5 fold

55% OF FIRST PASS FAILURES IN THE EMERGENCY SETTING ARE DUE TO INABILITY TO DIRECT THE ENDOTRACHEAL TUBE INTO THE TRACHEA DESPITE VISUALIZING THE VOCAL CORDS. (*Sakles 2013*)

POOR CONTROL OF DEPTH IN THE TRACHEA IS COMMON DURING HIGH-RISK INTUBATIONS LEADING TO LOWER AIRWAY INJURY AND PNEUMOTHORAX

- **10.7%** - Endobronchial intubation injury rate in the emergency setting. (*Timmermann 2007*)
- **66%** - Endobronchial intrusion rate documented when using an airway introducer. (*Runnels 2018*)
- Endobronchial intubations make up **2% of adult malpractice claims** and **4% of pediatric claims** against anesthesiologists. (*Caplan 1990, ASA Closed claims*)
- **18.7%** - Mortality rate for iatrogenic pneumothorax (*Health Grades 2004*)

COST OF AIRWAY COMPLICATIONS

- $10,000 - Average cost of an airway complication (*CMS Grand Rounds: Achieving Safer Airway Management August 4, 2014*)
- $17,000 - $45,000 - Cost of an intragenic pneumothorax. (Health Grades 2004)
- $143,250 - Average cost of a malpractice settlements for airway management complications (*Caplan 1990, ASA Closed Claims*)

PROBLEMS WITH FIBEROPTIC BRONCHOSCOPES

- **3%** Cross contamination rate (*Terjesen 2017*)
- **$300** per use (*Perbet 2017*)

DETAILED PRODUCT OVERVIEW

STERILE SINGLE USE

Ready to use out of package, no handling
after used and no cross-contamination risk

1 ARTICULATING TIP
- Higher first pass intubation success
- Precise tip articulation control

2 INTUITIVE DEPTH CONTROL SYSTEM
- Improved device depth control in the trachea
- Proprietary color-coded heads up markings improve depth awareness

3 FLEXIBLE SHAFT
- Conforms to a wide variety of upper airways
- Isolates tip control from shaft configuration

4 REMOVABLE PISTOL GRIP HANDLE
- Single handed use allows single operator intubations
- Easy overall device control
- Thumb release removable handle eliminates need to preload tube on device before use allowing immediate rescue capability.

PRODUCT SPECIFICATIONS AND INDICATIONS

- For use in adults only
- Suitable for use with any non-channeled video laryngoscope and blade.
- Intuitive colored depth system
- 70 CM, 15 Fr
- Fits 6.0 and larger ID endotracheal tube
- Not made with natural rubber latex
- Single use
- Packaged sterile

SUPPORTING REFERENCES

Mort TC. The incidence and risk factors for cardiac arrest during emergency tracheal intubation: a justification for incorporating the ASA Guidelines in the remote location. J Clin Anesth. 2004 Nov;16(7):508-16

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Caplan RA. Adverse respiratory events in anesthesia: a closed claims analysis. Anesthesiology.1990 May;72(5):828-33. PMID: 2339799

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Lenhardt R. Is Video Laryngoscope-Assisted Flexible Tracheoscope Intubation Feasible for Patients with Predicted Difficult Airway? A Prospective, Randomized Clinical Trial. Anesth Analg 2014;118:1259–65

Practice Guidelines for Management of the Difficult Airway

Cost analysis of a single use (aScope™) and reusable bronchoscopes in the ICU
Perbet et al. Ann. Intensive Care (2017) 7:3 DOI 10.1186/s13613-016-0228-3

Quantifying the complications and impact of persistent intubation problems. A White Paper.
Sean T Runnels, MD, Associate Professor, University of Utah SOM, 2018

CONTACT INFORMATION

THROUGH THE CORDS
Next-Generation Airway Tools

Through The Cords, LLC
Phone: 1 (801) 917-3851
www.TTCmed.com

FDA RECORDS

FDA Reg Number: 3015152450
FDA Listing Number: D332359
FDA Product Code: BSR
Product Name: Stylet, Tracheal Tube
FDA Class I, 510(k) exempt

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