



TOTAL CONTROL INTRODUCER PRODUCT INFORMATION KIT



**THROUGH
THE CORDS**
Next-Generation Airway Tools

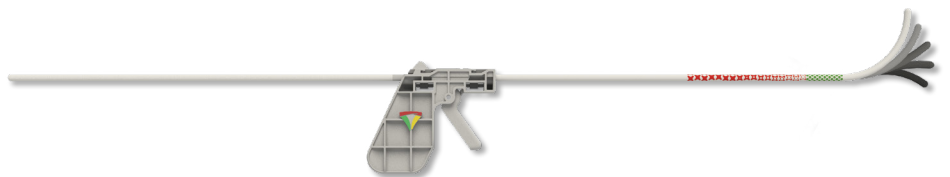


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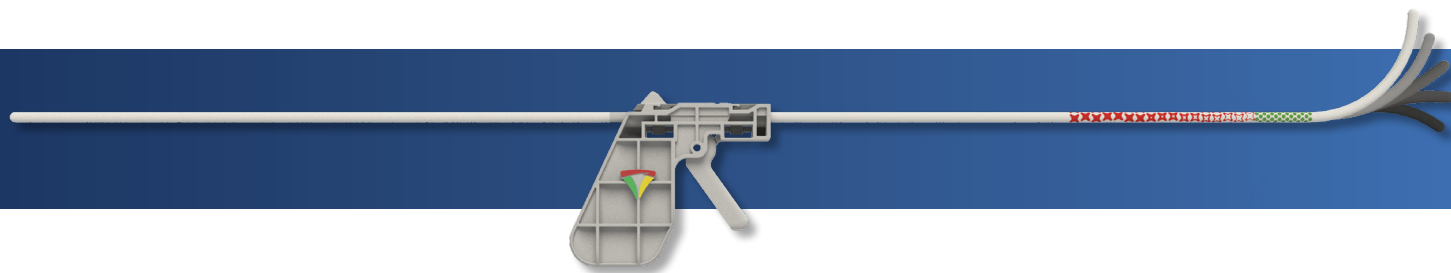
MAJOR COMPLICATIONS
INCREASE BY
400%
OR MORE DUE TO FIRST
PASS FAILURE IN
EMERGENCY INTUBATIONS





THE PRODUCT

Total Control Introducer™ (TCI) is the only articulating endotracheal tube introducer that combines a flexible shaft, a tip that articulates both up and down, and the intuitive depth control system. Designed specifically for video assisted intubation in high risk patients, the Total Control Introducer™ is an immediately available, cost effective rescue tool in the event of failed intubation or anticipated difficult airway.



VALUE PROPOSITION

CLINICAL VALUE

- **Designed to reduce the risk of first pass intubation failure in emergency airways** - The introducers flexible shaft and articulating tip are designed to reduce the risk of first pass intubation failure by giving the provider precise introducer tip control at the level of the vocal cords.
- **Proven superior rescue technique** - Video assisted laryngoscopy + introducer articulation is RTC proven superior to video assisted + rigid stylet as a rescue technique after 2 failed laryngoscopy attempts. (Lenhardt 2017)
- **Proven superior depth control in the trachea** - Once placed in the trachea, a proven intuitive depth control system allows intuitive and accurate introducer tip depth control throughout the intubation. (Runnels 2018)
- **Single operator rescue technique**

DIRECT SUPPLY COST SAVINGS

- **\$150-\$200 less than fiber optic bronchoscope per use**
- **Reduced need for on-call coverage and emergency cart deployment** - Intubating becomes safer with less experience and with less frequent need to deploy difficult airway carts.

OPERATIONAL VALUE

- **Immediately available for unanticipated difficult airways** - Disposable product can be easily stored in potential high risk areas.
- **No pre-loading of endotracheal tube required** - Removable pistol-grip handle allows for the tube to be placed over the introducer once it is in place in the trachea.
- **Reduced need for fiber optic bronchoscope towers and difficult airway carts** - Reduce wasted movement, delays, equipment storage and maintenance needs



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

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

The TCI provides improved clinical outcomes as well as cost savings. It increases the ability to provide care efficiently, and to a greater number of patients. Less-highly trained providers may be utilized to achieve consistent results.



PAYERS

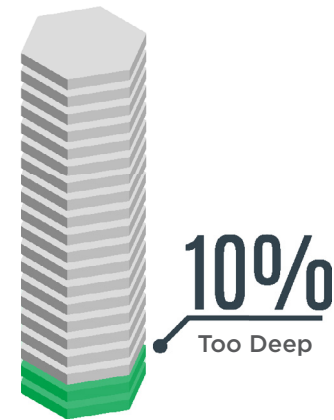
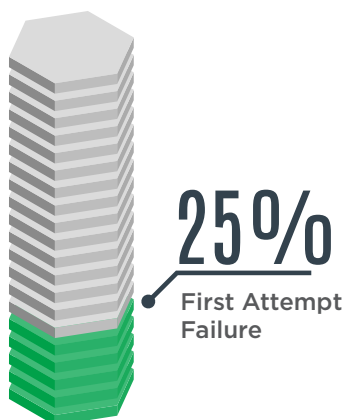
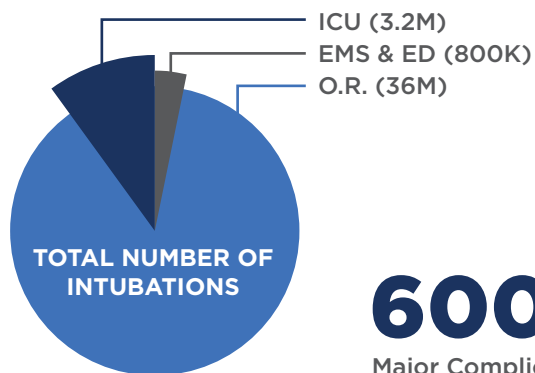
Efficient and effective solutions to persistent airway management problems limits complication and risk as well as minimizes the need for multiple airway devices, lowering the total cost of care.



KEY FACTS WHY THIS IS IMPORTANT

40M INTUBATIONS ARE PERFORMED PER YEAR IN THE US, 4M OF WHICH ARE EMERGENCIES

THE COST OF FAILED EMERGENCY INTUBATIONS

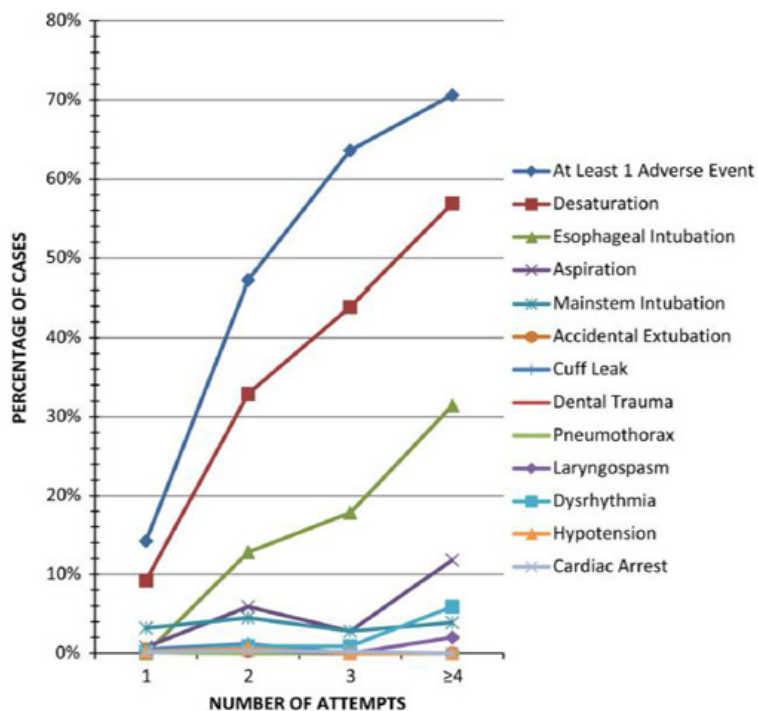


600K
Major Complications

\$15B
Complications Cost

165
Deaths a Day

120K
Deaths





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*)

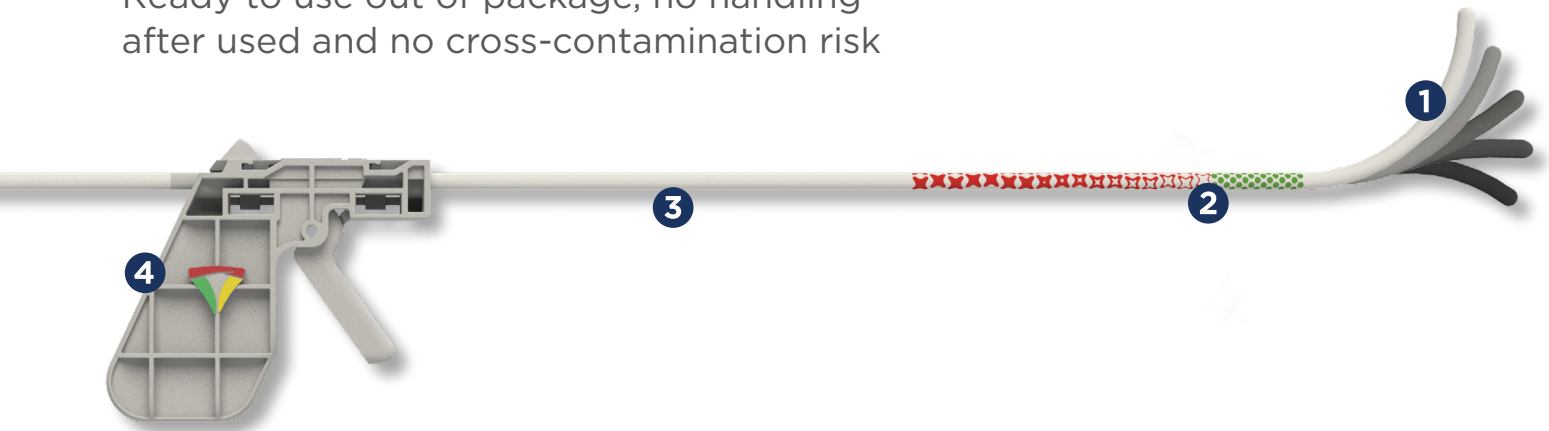




DETAILED PRODUCT OVERVIEW

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

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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](#)

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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

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