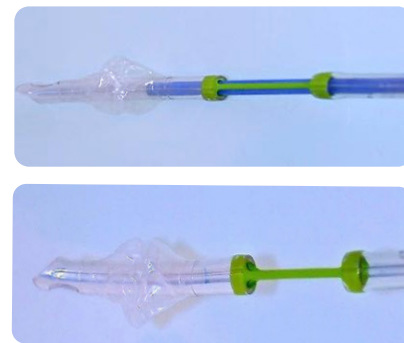


Improved Endotracheal Tube to Prevent Intubation-Related Complications Related to Airway Edema (Swelling)

The improved endotracheal tube (ET Tube) helps diagnose airway edema, preventing premature extubation and emergency re-intubation. Re-intubation can cause significant tissue damage in up to 30% of patients. The improved ET Tube also helps reduce ventilator duration by confirming airway readiness for extubation. The ET Tube has a blue hollow stent inside the ET Tube that can be removed to reveal an open section held by two green bridges that allow a swollen trachea to be easily viewed (see Figures to the right and Figures A-C below and video at <https://youtu.be/17jb1oTSOic>). This ET Tube is simple and easy to use, with a short learning curve. Moreover, this ET Tube can help reduce hospital expenses, patient costs and physician lawsuits.

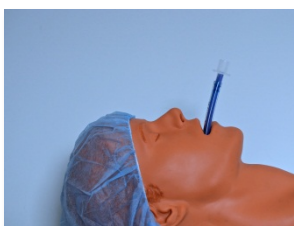


COMMERCIAL OPPORTUNITY

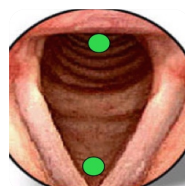
- 25 million intubations are performed in the US per year, and 50 million worldwide with a projected annual growth rate of 5%. Medical literature shows a complication rate of 4-30% in intubated patients, with the patients at highest risk for complications including those with trauma, burns, obesity, pregnancy, a history of difficult airways, prior heart failure, long duration surgeries and prolonged intubations in the I.C.U.
- Re-intubation causes a 4-fold increase in mortality, prolonged ICU course and high costs (\$8-10K per day). Failed re-intubation is associated with permanent brain injury or death from hypoxia resulting in physician and hospital lawsuits.
- Only one improved ET tube would be needed until the patient is safely extubated. Additional airway devices including laryngoscopes, a new ET tube, airway exchange catheters, additional medications, etc. are unnecessary. Our tube requires minimal training, ensuring a quick adaptability of this new technology.
- A unique advantage is that patients can speak while intubated, which is not possible with the common ET tubes. For example, this feature can accurately diagnose vocal cord nerve injury while the patient is still in the O.R after a neck surgery. Also, as opposed to using gestures, a clearly interacting patient will have less anxiety, lowering the need for medications.
- A prototype device has been developed (see Figures above). Regulatory analysis suggests the device falls under the FDA Class II 510(k) exempt device category (clinical trials and pre-market testing not required), indicating a low regulatory barrier to market entry.

TECHNOLOGY

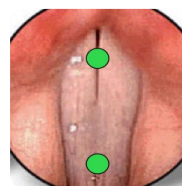
Inserted into the modified E.T tube is a blue hollow stent (see Figures above). To evaluate airway readiness, the blue stent is pulled back 2-3 inches removing the stenting effect of the ET tube which exposes the two narrow profile green bridges across the vocal cords, the area most prone to intubation related changes (see Figures A-C below). If the patient continues to breathe comfortably, then the ET tube can safely be removed. Patients showing signs of respiratory distress continue on mechanical ventilation.



A



B



C

A: E.T Tube in the airway.
B: Patient breathing comfortably, airway ready for extubation.
C: Swollen airway, patient in respiratory distress, continue ventilator

PUBLICATION/PATENT

U.S. patent application filed 9/13/2016 and European patent application filed 10/13/2016 for Dr. Chaudhry

CONTACT

Haskell Adler PhD MBA
Senior Licensing Manager
Haskell.Adler@Moffitt.org
(813) 745-6596

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