

ABOUT THE CANTRELL DUAL-BLADE LARYNGOSCOPE (C-DBL)



The Cantrell Dual-blade Laryngoscope (C-DBL), prototype shown at right, was invented by emergency physician, Elroy T. Cantrell, D.O., Ph.D. to improve the speed and accuracy of routine intubations in the field, in the ER, and in the operating room. There are roughly 17 million intubations performed in the U.S. per year outside of the operating room, and published studies have shown that 5 - 20% of intubations were "missed." The

primary cause of a missed intubation was misplacement of the endotracheal tube into the esophagus. This device will help prevent that disturbingly prevalent medical error.



The C-DBL is used to assist in the placement of an endotracheal ("ET") tube into the trachea of a patient which maintains a patent airway and assists in proper airway management. It consists of two opposing blades, with a ramp at the distal end of the lower blade. A handle and lever at the proximal ends of the blades allow vertical



separation of blade tips to create the C-channel seen in the picture above right. (See picture at left for most recent design of the upper blade, which is removable and may be used alone or with the handle and lower blade.) The entire device can be disposable, reusable, or a combination of both (e.g., disposable blades with a detachable and reusable handle). The C-DBL does not remain in the airway or mouth after the endotracheal tube is positioned and secured, but easily slides laterally off the tube (see picture at right). In use, the blades are inserted into the mouth and are then separated with the lever to reveal the vocal cords and trachea.

The ramp at the tip of the bottom blade will block or partially block the esophagus, preventing misplacement of the endotracheal tube, as well as deflect the tube up into the trachea. The device also includes integrated suction and a removable light to illuminate the throat (removable key-fob LED—visible or infrared). The key-fob is the black piece in the two pictures above left, and its targeted lighting capabilities are demonstrated in the picture above right. These features all contribute to the ease, speed, and accuracy of intubation using the C-DBL.



In summary, the features and benefits of the C-DBL include.

1. Decreased risk of missed intubation and injury caused by intubation efforts,
2. Increased speed of intubation,
3. More complete visualization of vocal cords during intubation,
4. Inclusion of suction ports and channel in blade, accelerating intubation when emesis or mucus are present,
5. Removable key fob LED lamp (visible or infrared) to ensure adequate visibility in multiple environments,
6. Upper blade with tongue deflector, and tip configured for epiglottic elevation,
7. Lower (palatal) blade configured to decrease likelihood of injury to teeth,
8. Lower blade tip which serves as an esophageal obturator,
9. Lower blade tip with a ramp to plug and restrict esophageal entry,

10. Configuration of the ramp to deflect an inserted ET tube into the trachea,
11. Single hinge with right side open, allowing lateral blade removal without disturbing the ET tube,
12. Ease of use, and rapid learning by EMT's and military medics,
13. Inexpensive to use, employing standard ET tubes (the "gold standard" for airway management), and
14. Disposability, if desired.

COMPARISON TO THE LMA/ILMA

A Laryngeal Mask Airway (LMA) is a device that is blindly inserted into the pharynx and guided by the operator's finger to be seated over the glottic opening at the level of the epiglottis and arytenoid cartilages. This device does not prevent emesis from entering the trachea during vomiting and can be easily dislodged during movement of the patient (such as during airlift). The airways are poorly suitable for long-term use with a ventilator, and ET intubation is usually required later if resuscitation is successful. Multiple sizes must be kept in stock at a cost greater than ET tubes. An intubating LMA (ILMA) is also available, but its use implies a need for "twice-intubation"—first inserting the LMA, and then inserting the ET tube. Studies show that it takes 15-18 seconds to insert the LMA and ventilate the patient, and an additional 17-60 seconds for intubation (Levitan, 1999 and Martel, 2001). Since intubation with an ILMA is still a blind intubation, it is estimated that "[t]he incidence of esophageal placement is probably about 5%." (Martel, 2001) It is believed that the C-DBL will typically facilitate intubation in 10-15 seconds and result in negligible, if any, esophageal placement.

RESEARCH EFFORTS

Throughout the development of the current C-DBL, the design concepts have been validated in manikins proving speed and accuracy. Several prototypes have been built and intubations performed on various intubation manikins (e.g., Ambu, Nasco, and Laerdal). These tests indicate that the device could cut in half the time required for ET intubation (see associated video clips) and substantially reduce the occurrence of missed intubations, especially by lesser-trained persons. This information was also confirmed by a Focus Group held in December 2005 with physicians, EMT's, CRNA's, and EMT-Paramedic Trainers in Roanoke, VA (see picture at right).



Dr. Cantrell has applied for IRB approval from his employing institution (Carilion Clinic - Roanoke, VA) to conduct cadaver and additional manikin studies with EMT students using the most recent design of the device. Manikin studies could also be conducted with military medic students to determine their ease in learning to use the device, and speed in intubating with the device compared to an ILMA, for example. Upon approval by the IRB, he will submit a grant application to Carilion Clinic for up to \$20,000 to fund the completion of these studies. Once preliminary data is collected, it will be submitted to the FDA in an Investigational Device Exemption (IDE) application, and following approval and the securing of funds for the research, clinical studies will begin to validate these claims in humans.

INTELLECTUAL PROPERTY

The C-DBL was issued U.S. Patent # 6,991,604 on January 31, 2006, with a priority date of September 4, 2003. There are several other claims pending in Continuation Application #11/292,828, which was filed on December 2, 2005. Application #PCT/US2004/028714 was filed under the Patent Cooperation Treaty on September 3, 2004 with a priority date of September 4, 2003. The EPO issued European application #04783076.5 on January 20, 2006. National filings were made in March 2006 in the following countries: Canada, Australia, the EU, and Japan.

REGULATORY

We believe this device falls within the U.S. FDA medical device classification of "Laryngoscope, Rigid," and will be regulated under 21 CFR § 868.5540. The classification code will be: CCW. Upon completion of pre-clinical studies, an IDE will be filed with the FDA before commencing clinical trials. Ultimately, clearance for marketing will be sought via a 510(k) application (as confirmed telephonically with the FDA).