

Novel Device for Emergency Cricothyroidotomy Procedure

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Every year in the United States over 5,000 people die due to choking. There are only a few precious minutes between loss of the airway and brain death. By creating a simple device which can establish an airway in one step when a blockage (either caused by choking or anaphylaxis) occurs, many of these people could be saved. Crucial to the success of the device is its availability. The device will be low-cost and easy to use, so it can be added to first aid kits and placed in public areas. Unlike current devices on the market, which are difficult to use and contain multiple moving parts, our product aims to be accessible and easy to use when emergencies occur.

At a minimum, most emergency cricothyroidotomy devices on the market are sold as a sterile kit containing a scalpel to create an incision, a cuffed endotracheal tube, and tape or a strap to affix the device. Some devices require complex components, such as a guide-wire and air catheter, to facilitate insertion. All commercially available kits feature a metal instrument to create the stoma. These kits have prices ranging from \$25 to over \$200. This Emergency Cricothyroidotomy Device is a single-component design that punctures the skin and cricothyroid membrane. It is used to establish an emergency airway when a choking related accident occurs. The puncturing component consists of a sharpened beveled edge at the end of a straight, hollow, aluminum tube. The lancet needle point design creates a clean incision and unobstructed lumen. For redundancy, there is an additional hole along the side of the needle shaft which can be used to clear a potential blockage in the needle lumen. Opposite the beveled tip, there is a flange that can securely connect to a bag valve mask (BVM). If a BVM is not available, the user may breathe directly through this opening. The wider diameter of the flange also prevents the device from being inserted too far into the patient and puncturing the backside of the trachea.

The prototype was designed closely to the client requirements. It is made of aluminum, which is a non-ferrous material and sharp enough to pierce a porcine trachea and cricothyroid membrane. The diameter of the tip is nearly twice as large as a 14 gauge needle. CAD simulation testing confirmed that the device is capable of exchanging 500 mL of air every three seconds, which is the average rate of exchange in healthy adult males. Overall, the device is compact, lightweight, and low cost. The device weighs 11.01 grams, which is about the same as a plastic pen. The novel device is carefully designed to create a streamlined and effective tool used to complete a cricothyroidotomy.

After fabrication, the device was meticulously validated through many aspects of testing. CAD simulations of airflow and compression testing confirmed the device can withstand force needed to puncture tissue and deliver adequate ventilation. Testing was performed on porcine larynges and tracheas as well as porcine skin samples. Complete puncture of the porcine tissues was achieved for all participants.

Should testing validate the functionality of the device, this device has the potential to be integrated into every first aid kit across the country. Due to the small size of the device, people should have the ability to keep it in their belongings in the instance that they are a bystander in a choking situation. Since the device remains ergonomically simple, it should be used by any bystander, regardless of training, which opens the market to many diverse consumers. The prototype should be priced competitively, ranging from \$15-\$25, thus creating the commercial opportunity.