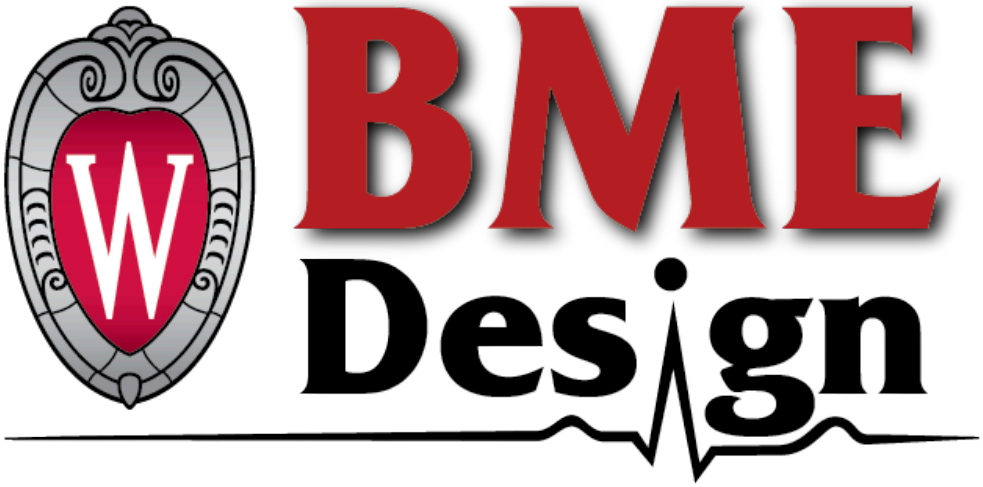

Emergency Cricothyroidotomy Device

Preliminary Product Design Specifications

Team: Katerina Smereka, Annika Rossebo, Mateo Silver, Megan Finell, Zac Mayhew

Client: Dr. Lenard Markman

Advisor: Dr. Darilis Suarez-Gonzalez

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Function:

Each year over 5,000 deaths occur in the United States related to choking. Choking is the leading cause of death for infants and fourth leading cause of unintentional death [1]. Severe damage from upper airway obstruction, leading to no proper oxygen flow, can cause brain damage within 4 to 6 minutes [2]. In a choking emergency, the first response is to deliver a repeated cycle of 5 back blows and 5 abdominal thrusts. If the person falls unconscious, cardiopulmonary resuscitation should be performed immediately [3]. In hospital settings, emergency airway puncture can be performed to place an airway below the obstruction through the cricothyroid membrane [4]. However, there is no suitable device on the market that creates an emergency airway, as an alternative rescue measure, that is accessible to the general public. Death can occur in situations if oxygen flow is not restored in time [5]. This device aims to be a novel choking rescue tool to create an emergency airway to replenish oxygen for an unconscious choking victim.

Client requirements:

- The device must be made out of a non-ferrous material.
- It should not be bulky, it should be easy to carry with someone.
- The tip of the device should be fabricated with plastic or ceramic material.
- The device must come sterile upon first use.
- It should be a single-use device.
- The tip must be sharp enough to piece the skin and the cricothyroid membrane.
- The width of the tip should be more than 14 gauges thick.
- The handle end of the device should be adaptable to a bag valve mask and/or facilitate a person breathing into it.
- Once the airway is created, the device should be capable of exchanging 5000mL of air every 3 seconds.
- The device should be marked to indicate the depth inserted.
- The overall cost of the device must remain inexpensive.
- The device should be 3.25 inch in length.

Design requirements:

1. Physical and Operational Characteristics

a. Performance requirements:

This device must be able to puncture through the skin and the cricothyroid membrane in a single attempt. The handle end of the device must be adaptable to a bag-valve mask or facilitate rescue breaths delivered by the user. There must be marks indicating the relative depth on the device. For the average male, the device should puncture at a depth of 4.53 ± 0.92 mm in order to successfully go through the cricothyroid membrane. For females, this depth should be 2.89 ± 0.22 mm [6].

The device is single use and should be discarded upon usage. It also should come with instructions in order to make it accessible to a wider population, regardless of medical training.

b. Safety:

This device should be sterile upon initial use. It should be immediately discarded once removed from a patient. It will not be used in conjunction with any anesthetics. If the device is incorrectly inserted, it could lead to a false passage or potentially pneumothorax. Further damage to the trachea and larynx could possibly occur, such as esophageal perforation, aspiration, vocal cord injury. Long term complications include but are not limited to airway stenosis, dysphonia, infections, hematoma, scarring, tracheoesophageal fistula [7].

c. Accuracy and Reliability:

This device should be able to puncture swiftly through the skin and the cricothyroid membrane. As this device will be used for a diverse population, it is expected for the device to puncture at various depths. For the average adult, the device is expected to puncture at a depth of 4.53 ± 0.92 mm for males and 2.89 ± 0.22 mm for females [6]. Upon successful creation of the airway, it should maintain an airway until first responders are on the scene and during the evaluation and care provided by emergency medical services. It should at least maintain an airway for 7 ± 4 minutes for first responders to respond in urban settings and 30 ± 10 minutes for rural areas [8]. As the average scene time for first responders is 14.2 minutes and transport time is 17.5 minutes, the device should maintain an airway for an estimated total time of 38.7 ± 4 minutes in urban areas and 61.7 ± 10 minutes in rural areas [9].

d. Life in Service:

This device will be single use and therefore not require resterilization. It will be in use for up to ten minutes while in interaction with bodily fluids such as blood, saliva, mucus, and acid.

The device should be able to undergo travel without concerns of compromising mechanics and material properties, including reaching up to an elevation of 42,000 feet, as planes often fly between 36,000 and 42,000 feet [10]. In addition, the device needs to withstand these conditions for up to 10,000 miles whilst being delivered worldwide [10].

e. Shelf Life:

The device must remain fully functional in storage for 5 years without any deterioration in accordance with the shelf life of a first aid kit. It should be packaged and kept in a sterile and hygienic environment. In addition, the packaging needs to be dust and moisture resistant. Storage conditions include temperatures from 65℉ to 80℉ to comply with standard room temperatures between 68℉ and 77℉ [11]. The device must withstand a humidity of up to 65% in storage [11]. Appropriate storage pressures range from 740-780 mmHg [12].

f. Operating Environment:

The device will need to withstand the force used to puncture the skin, which is dependent on the surface area, the velocity, and the sharpness of the object making contact. In addition, the force of blowing through the device must not cause any damage to the mechanical integrity. The device must withstand humidity levels from 10% to 95% as well as temperature levels between -20℉ to 110℉ [13]. It will be used primarily by physicians and trained medical personnel, but should be adaptable to be used by the general public as well. If the device is placed in a first aid kit, friction against other tools should not jeopardize the integrity of the device.

g. Ergonomics:

The device must be comfortably used in one hand by an average adult. In addition, the grip area on the device should allow for comfortable wrist placement for the user. To ensure no misalignment of the cut, the grip should have an anti-slip surface for contact with the hand.

h. Size:

The device should be as compact as possible, while not compromising on providing adequate ventilation. The size of the airway created should allow for 500mL of air to pass every 3 seconds. Current procedures for a needle cricothyroidotomy call for the usage of a 12-14 gauge needle [14]. Competing devices have a penetrating depth of approximately 15 to 20mm into the trachea [15]. Based on images of competing designs, the dimensions of the entire device can be approximated to 12.5 cm x 5 cm x 2.5 cm [15]. This device is intended to be carried by medical personnel and civilians who aim to be prepared in emergency situations. Therefore, it is important that the device be portable and easy to store. Additionally, the device should be small and light enough to be added to a first aid kit easily.

i. Weight:

The device should weigh as little as possible, for portability and material cost reasons. However, it should not be too light as to reduce the durability of the product. Based on the weight of a 10mL syringe often used in competing designs, the device will weigh approximately 25 g [16]. The weight distribution is an important consideration, as deliberate design could make the placement of the device more natural for an inexperienced user. A lighter weight would also facilitate the addition of the device into first aid kits.

j. Materials:

The material used must be biocompatible, and cause no adverse effects during extended contact with the body. As the device is single use, it does not need to be sterilized in between uses, just when produced. The client prefers a ceramic or plastic material, as opposed to metal construction, to aid in portability. The device should not set off a metal detector, for example, in an airport. The tip of the device should be able to hold a sharp point for the shelf life of the device.

k. Aesthetics, Appearance, and Finish:

The device should have a function-focused appearance, with markings to facilitate proper usage and placement of the device. The proper depth of insertion will be marked obviously on the device. An anti-slip texture should be used on the areas of the device in contact with the user's hand, to aid in placement.

2. Production Characteristics

a. Quantity:

This device would be used once per patient. Once it has been touched or taken outside of the sterile wrapping, it can no longer be used. One unit of this product consists of one device. One unit would be placed in every first-aid kit.

b. Target Product Cost:

The client expressed that the target cost to sell this device would be less than $60.00. Pediatric emergency cricothyroidotomy devices retail for roughly $30.00 [17], [18]. Adult emergency cricothyroidotomy devices retail anywhere from $30.00 to over $200.00 [19]–[21]. If the present device were to retail for less than $60.00, it should cost roughly $20.00 to manufacture to ensure profit.

3. Miscellaneous

a. Standards and Specifications:

This device falls under two categories in the Code of Federal Regulations Title 21 set by the U.S Food and Drug Administration (FDA): Emergency airway needle and Retrograde intubation device [22]. Both regulations state that this device is classified as a Class II medical device. In addition, the Retrograde intubation device controls disclose that this device must pass special controls set by the FDA. This device must have valid testing that proves that the device functions as predicted under foreseeable conditions**,** such as compatibility of components that interact, accuracy testing of markings, validation of the maximum airway pressure. This device must also prove its shelf life, ability to remain sterile and functional over the specified shelf life and clear labeling [23].

As this device does not fall under any exemptions set by the FDA, a 510(k) must be filed before the device reaches the market. A 510(k) illustrates that the device is safe, effective and must compare the novel device with a current, legal device on the market in order to substantiate the claims made [24].

In terms of standards needed to acquire for the device, there are several necessary. ISO 10993 is an important standard needed for this device. This standard evaluates the biocompatibility of the device in order to determine and manage the biological harms. There are 24 parts to this standard, but only 10 parts are needed. ISO 10993-1, 3, 4, 5, 11, 13, 18, 19, 20 and 23 are the main parts of the overall standard required for this device [25, p. 10]. ISO 4135:2022 is another prominent standard expected of the device. This standard discloses the vocabulary and the meanings used for respiratory equipment and related devices [26]. Because this device is considered an intubation device, ISO 5366:2016 is necessary. Typically for tracheostomy tubes, this standard specifies the requirements for tracheostomy tubes and other devices that create artificial ventilation or assist ventilation in other ways [27]. Another standard in relation to general airway equipment that is necessary is the ISO 18190:2016, which discloses the requirements of airway and respiratory equipment [28].

In relation to the sterilization and shelf life of the product, the ISO 11607 must be held. There, specifications for requirements and testing methods for sterile materials and their packaging systems [29].

b. Customer:

As this device should be designed with accessibility and inclusivity, the customer should not only be limited to medical professionals, but the average population. Therefore, it is imperative to include clear, concise directions with the device in order to encourage a normal civilian to use this device in an emergency. Because this should be used with one hand, it should accommodate both left and right handed people. As the client would like the device to be sterile upon initial use, it should be able to withstand an autoclave, carried out at 134°C for 5 minutes [30]. Since this device not only creates an emergency airway but is adaptable to deliver manual or bag-valve rescue breaths, the handle must be adaptable to external attachments.

c. Patient-related concerns:

This device must be sterilized after the manufacturing process. Sterilization ensures that no infection will be conferred to the patient due to the device itself. In order to perform an emergency cricothyroidotomy, an incision must be made in the patient's neck. Any time the skin barrier is broken, the chance of infection increases. Ideally, the skin could be sanitized with an alcohol prep pad or sterilized with chloraprep before any incision is made. However, the client expressed that this device will be quick to use and would only be sold as a single device.

This device has the potential to puncture the dorsal side of the trachea and even puncture into the esophagus. Puncturing the esophagus can lead to aspiration of stomach contents into the respiratory system. This can be fatal. The device should include a clear line of demarkation to illustrate where the device should meet the patient's skin. This line of demarkation will show the provider where to not insert the device past to mediate chances of puncturing the dorsal side of the trachea.

d. Competition:

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 hold the emergency cricothyroidotomy device in place. Some devices require a system of tool insertions, such as a guide-wire and air catheter. All of the commercially available kits feature a metal tool (scalpel or catheter) to create the stoma. This likely leads to the high prices per device. Listed below are devices commonly sold for emergency responders.

Rusch QuickTrach Cricothyroidotomy Kit

This product is a pre-assembled emergency cricothyroidotomy device that features a 10 mm syringe with a stainless steel needle attached to a flexible tube and tube holder [21]. Notably, this product features a 'safety stop' feature on the tube holder that aims at preventing puncture of the back of the trachea. It retails for $212.95.

STATForce Adult Deluxe and Pediatric Field Cric Kit

This commercially available kit features a #10 sterile scalpel, as opposed to a needle, and a trach tube holder [19]. It also contains a 6.0 cuffed endotracheal tube and syringe to inflate the endotracheal tube balloon. Notably, this kit includes an iodine prep pad, face shield for the provider performing the procedure, and a trach hook. It is sold for $29.95. A pediatric version of this kit is available with a 2.5 cuffed endotracheal tube and retails for the same price of $29.95 [18].

The Quick Fix Adult Cric Kit and The Quick Fix Jr.

This kit includes a scalpel, cuffed tube, syringe, forceps, and tape [20]. Notably, the kit contains photo directions for easy review and states the kit comes in a sterile package that takes up “very little space” (5’’x8’’). It retails for $60.95. A pediatric version of this kit includes only a 1.25’’ large bore IV catheter, syringe, and 15mm endotracheal tube adapter. The pediatric Quick Fix Jr. is sold for $23.95 [17].

US Patent US4677978A- Emergency Cricothyrotomy System and Cricothyrotomy Kit

This patent describes a device that can be inserted into the trachea through an incision. It does not include a method by which to create an incision . This patent features an over-the-needle catheter that is removed after insertion of a guide-wire [31]. From there, the cricothyroid membrane is dilated and an air passage catheter is inserted along the guide-wire. The guide-wire is then removed and the air passage catheter is secured.

US Patent US4438768A- Emergency Cricothyroidotomy Instrument

This patent is a single elongated needle with a sharp point and an accompanying needle holder [32]. The needle features an adapted outer shaft designed to abut the needle holder. The needle holder features ridges designed to hold the device in place. The needle and needle holder are connected by a hinge that allows for pivotal movement of each section to open and close the needle holder.

US Patent US4291690A- Means for Performing an Emergency Cricothyrotomy

This device is a trocar assembly featuring an outer cannula and cutting stylet [33]. Once inserted, it is designed to be inserted two-thirds of the length of the cannula. The device maintains its position in the neck by the flaring distal end of the device.

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