Esophageal Variceal Hemorrhage Rescue Device: Var-Ex Tube

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Esophageal Variceal Hemorrhage Rescue Device: Var-Ex Tube

***Abstract*—. Esophageal variceal bleeding is a medical emergency affecting patients of diverse backgrounds worldwide. The need for a medical device for the occlusion of hemorrhagic esophageal variceal rupture in a prehospital setting is one that is unmet, leaving clinicians without tools for effective treatment of these patients. The presence of esophageal variceal bleeding is common in patients with liver disease but is nondiscriminatory in the dangers to patients. The interdisciplinary approach of this project involves rigorous testing, adherence to International Organization for Standardization (ISO) standards, and input from Nationally Registered Paramedics (NRPs). In designing the Var-Ex Tube, the team began with thorough research including a literature review and multiple design concepts were created and then narrowed down to a balloon tamponade style device. The Var-Ex tube was modeled, prototyped, and thoroughly tested. This novel device is able to occlude over 90% of the fluid and remain inflated for over 45 minutes, which exceeds the average transport time of patients treated by Emergency Medical Services in the United States. The Var-Ex tube is under a provisional patent and constitutes advancing efforts to treat patients with esophageal variceal hemorrhaging.**

***Index Terms*—**Esophagus, esophageal varices, hemorrhage, prehospital, pre-hospital, paramedic.

IV. 1.0 INTRODUCTION

THE human body contains many complex systems that interface with each other in delicate balance. One of these systems is the human gastrointestinal (GI) system, responsible for digestion of food, movement of food from mouth to absorption centers in the lower GI system and the excretion of bodily waste [1]. The GI system is both innervated by the central and peripheral nervous systems and is supplied with blood from several arteries. The section of the GI system known as the esophagus, which connects the pharynx and the stomach, is highly venous and can develop varices [2].

Esophageal varices are a common condition, with approximately 30% of patients with cirrhosis of the liver being affected [3]. These dilated veins can cause catastrophic issues if hemorrhaging occurs. The incidence of rupture is dependent on the severity of the condition and survival is heavily dependent on the condition of the patient prior to rupture. Although common in cirrhosis patients, many other conditions can cause portal hypertension, which is the underlying cause of esophageal varices. Some of these conditions include Wilson disease, tuberculosis, and constrictive pericarditis [4]. Due to the prevalence of esophageal variceal bleeding as well as the deadliness of rupture, new devices must be created in order to transition patients from a prehospital environment to a surgical suite. The main scope of this project is critical patients with acute and highly volumetric varices. These patients will also be candidates for intubation as a device inserted into the esophagus has risks of compromising an airway as well as stimulating the gag reflex [5].

Currently, the prehospital treatment by paramedics for ruptured esophageal varices includes fluid resuscitation and vasoactive agents [6]. These therapies are often not effective in cases of acute and emergent bleeding. Current medical device options are almost exclusively developed for use during surgery with tools available in a surgical suite. This leaves a large gap in treatment for patients and providers in the prehospital setting. Many of these issues are compounded by the unequal access to emergency healthcare as well as the affordability of primary care globally and in the United States [7]. For many patients with esophageal varices without primary care access, the first indication of the disease is rupture. In cases of rupture the patient will often go into hemorrhagic shock, followed by death due to blood loss [8].

This project aimed to create a device to treat esophageal variceal bleeding in an emergent prehospital setting. This device was tested rigorously and compared to several relevant ISO standards to ensure it reached all project goals and objectives. The device is modeled through computer simulation and computer aided design (CAD) using SOLIDWORKS. Guided by these models, a prototype was developed for the aforementioned testing. This project is guided by input from Nationally Registered Paramedics (NRPs) through a series of interviews with those having experience with ruptured esophageal varices in a clinical setting as well as public autopsy case studies of those who have experienced these episodes.
Completion of this project resulted in a functional prototype. The Var-Ex tube prevented the flow of liquid through a model version of variceal hemorrhage, maintained constant pressure for over 45 minutes, and can be inserted and deployed in under 30 seconds. These results indicate that this device can apply pressure to prevent variceal bleeding for long enough to transport a patient to a hospital setting.

V. Literature Review

A. 2.1 Anatomy and Physiology

1) 2.1.1 Basics of the Esophagus

The esophagus is the tubular structure that connects the pharynx to the stomach and is an essential part of the body's digestive system. It runs parallel to the trachea and behind the heart and lungs. The esophagus passes through the diaphragm while remaining in front of the spine for its entire length. It is typically 9 to 10 inches (25cm) in adults between the sphincters at each end, and approximately 40 cm from teeth to stomach. The upper esophageal sphincter (UES) is located in the pharynx and the lower esophageal sphincter (LES) is located about 3 cm above the actual stomach. The esophagus is categorized into three different sections, the superior cervical esophagus, thoracic esophagus in the middle, and the inferior abdominal esophagus [9].

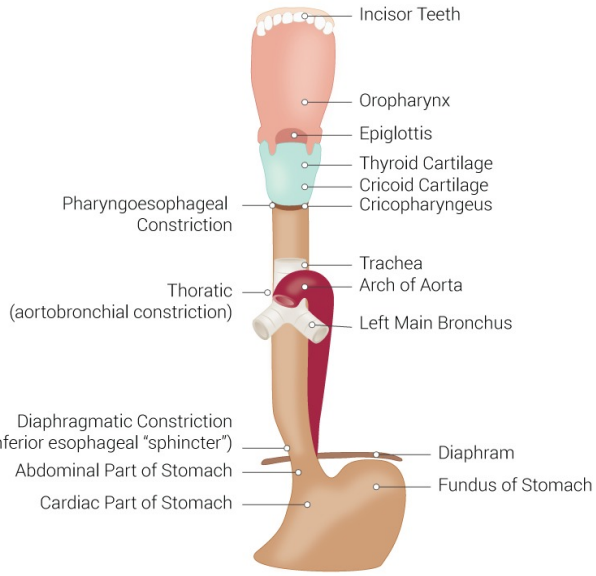


Fig. 1. Diagram of the three sections of the esophagus. The three constrictions, the pharyngoesophageal constriction, the orobranchial constriction and the diaphragmatic constriction are shown and labeled on the left of the drawing. The image shows the path of the esophagus and the terminal anatomy, starting with the incisors (teeth) and ending with the cardiac section of the stomach. The entirety of the image also shows the path food takes through the human body, without the excretory system [9].

2) 2.1.2 Cervical Esophagus

The first section of the esophagus begins at the cricopharyngeal, the muscle located at the junction of the pharynx and the esophagus [9]. This is where the UES resides, which is also the narrowest point in the esophagus being only 14 mm in diameter [10]. It continues down to the suprasternal notch which is the visible external dip between the clavicles at the bottom of the neck. If looking at the body from the back,

the cervical esophagus spans between the sixth and eighth cervical vertebra and sits between the spine and trachea. It is connected to the trachea with loose connective tissue [9].

3) 2.1.3 Thoracic Esophagus

The second section of the esophagus begins at the suprasternal notch and extends to the diaphragm. This section sits between the vertebral column and the trachea [9]. The thoracic esophagus contains the broncho-aortic constriction, which occurs when the esophagus passes behind the tracheal bifurcation and left mainstem bronchus, here the diameter is only 15 -17mm. Between the UES and the broncho-aortic constriction is the superior dilation which expands to a 19 mm diameter. Between the broncho-aortic constriction and diaphragmatic constriction is the inferior dilation, which has a 22 mm diameter [10].

4) 2.1.4 Abdominal Esophagus

The final section of the esophagus is proportionally short, measuring about 35 cm, and is part of the lower thoracic. It begins at the diaphragmatic constriction, where the esophagus passes through the right crus of diaphragm at the level of 10th thoracic vertebra [9]. The diaphragmatic constriction has a diameter of 16 - 19 mm. This section ends at the LES, which is the entrance to the stomach, and the end of the esophagus [10].

5) 2.1.5 Muscles and Esophageal Walls

The outer wall of the esophagus does not have a serosa, which is unlike the other organs of the digestive system. The outer wall, the adventitia, contains collagen and elastin that provide the necessary structure [10]. Under this wall lies the muscularis propria, also known as the muscularis externa, which is a layer of bi-directional muscles. The dominant muscle layer is organized into inner circular and outer longitudinal muscle layers. Both layers are several muscle cells thick, or about 0.75mm thick. The circular muscle is continuous with cricopharyngeal muscle and the inferior pharyngeal constrictor, as well as the LES at the other end. The longitudinal muscles originate from the dorsal, superior, and lateral margins of cricoid cartilage. As the longitudinal fibers extend, they surround the circular muscles entirely until they merge into the circular muscles of the LES. Between the two layers of muscle is a sympathetic and parasympathetic network, known as the myenteric plexus, which resides in the intermuscular septum [11]. Unlike any other organ in the body, the esophagus is made up of skeletal and smooth muscle cells. The upper portion, about 2-4 cm, of the esophagus contains striated skeletal muscle, the middle is a mixture of skeletal and smooth muscles, and the remaining 11 cm is all smooth muscle [11]. Both the LES and UES are formed by layers of muscle that allow the function of opening and closing the esophagus [9]. The UES is composed of all skeletal muscles, and the LES of all smooth. The LES physiology is interesting as there is no consistent thickening of the muscles in autopsy specimens, however in vivo imaging clearly shows a region of thick circular and longitudinal muscles in the LES region. The muscle thickness changes based on the pressure on the LES, so it is likely that the lack of muscle tone in autopsy specimens causes the degradation of the LES [11].Under the muscular layers is the submucosa. The mucous gland, blood vessels, extensive lymphatic network, and Meissner's plexus reside here. Under the submucosa, is the mucosa, also known as the lining of the lumen [10]. The muscularis mucosa that exists as an epithelial protective layer, it is only two or three cells thick, but has multiple roles as they also act mechanically as a reflux barrier within the esophagus [12].

6) 2.1.6 Blood Supply

There are four main suppliers of blood to the esophagus. The cervical section and UES are mainly supplied by the inferior thyroid artery. The subclavian artery, main carotid artery, vertebral arteries, ascendant pharyngeal artery, superficial cervical artery, and cervical trunk also contribute to supplying blood to the cervical esophagus [13].The thoracic section is supplied by aortic esophageal arteries, and the terminal branches of bronchial arteries. The abdominal segment and the LES are supplied by left gastric artery and the left phrenic artery branch [9]. For the transport of deoxygenated blood, the cervical

esophagus blood goes to the inferior thyroid veins. The thoracic section empties into the azygos vein, right brachiocephalic vein and, occasionally vertebral veins on right side. It also empties into the hemiazygos vein, left brachiocephalic vein and vertebral veins on the left side [13]. The abdominal section's blood goes through the left gastric vein. All of which eventually merge to the superior vena cava [10]. Declining flow in esophageal veins can lead to venous dilation and vertices [13]. Typically diagnosed through endoscopy, bleeding in the esophagus can have a variety of causes, but the most significant cause of highly volumetric bleeding is esophageal variceal bleeding [14].

7) 2.1.7 Nervous System

The main nerves that control the esophagus are the vagus nerve, the thoracic chain nerve, and the cervical chain nerve. The vagus nerve is part of the parasympathetic nervous system and controls the parasympathetic functions of the muscles and glands. The thoracic and cervical chain nerves control constriction of blood vessels, the UES, the LES, and muscle wall relaxation. As far as sensations, the vagus nerve can detect pressure, and the chain nerves detect pain [9]. The innervated GI system shares similarities to the central nervous system (CNS) in its web of interneurons, making sensation in the esophagus and GI tract complex and not well understood. Conditions of the esophagus often share symptoms meaning patients can struggle to garner a proper diagnosis efficiently [15].

8) 2.1.8 Physiology of the Esophagus

The main function of the esophagus is to transport food and drink from the mouth to the stomach. This is done through swallowing. There are four stages of swallowing: early oral stage, late oral stage, pharyngeal stage, and the esophageal stage. The early oral stage consists of chewing and lubrication of the bolus with saliva in the mouth. The late oral stage is when the food bolus is moved into the oropharynx. At this point the pharyngeal stage occurs as the food is moved to the hypopharynx due to reflexes [10]. The final stage, the esophageal stage, is the only stage that occurs in the actual esophagus, as the pharynx is connected to but not considered a portion of the esophagus. First, the UES relaxes to allow the bolus to enter the esophagus, then peristaltic movement propels the bolus down the entire esophagus [9]. The peristalsis wave travels down the esophagus at 3 - 5 cm/sec and reaches the stomach in 5 to 10 seconds [10]. At the bottom of the esophagus, the LES is controlled involuntarily due to the peristaltic movement and opens to allow the food to enter the stomach. The striated and smooth muscles contract in normal peristalsis function are controlled primarily by the CNS and the peripheral nervous system (PNS) and the neuronal network of the esophagus. The desired function of the esophagus works this way; however the team must note that matter can travel up the esophagus when a patient vomits or has acid reflux [9].

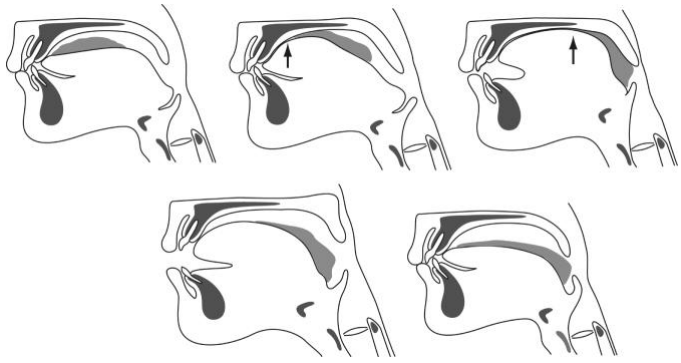


Fig. 2. A bolus travels down through the mouth with peristaltic motion [16]. This image illustrates the coordinated muscular contractions driving the wave-like movement that propels substances through biological passages. Peristalsis, a key physiological process, exemplifies the efficient transport mechanisms within living organisms [16].

B. 2.2 Disease State

1) 2.2.1 Background of the Disease State

Esophageal varices typically originate from the disease state of the liver. The development of varices ultimately comes as a result of damage to the liver due to medical diseases and conditions [6]. Such diseases, including non-alcoholic fatty liver disease and liver cirrhosis/scarring [3] impair the liver's ability to effectively and efficiently filter blood and rid the body of toxins. Other causes of esophageal varices can include gastroesophageal reflux disease (GERD), which can lead to esophageal cancer and thus varices, but liver conditions remain the main cause of varices, primarily due to consequent hypertension of the portal vein [6]. The combination of resistance as well as increased fluid volume causes the blood pressure of the portal vein to rise substantially, forming varices. The walls of the varices are thin, and although capable of expanding in response to portal hypertension, have an upper pressure limit. The hypertension forces the pressure inside the varices to rise, and once a certain threshold is reached (around 12 mmHg), the varices may rupture and cause catastrophic hemorrhage. Unfortunately, children are also victims of esophageal varices due to depressed liver function and consequent portal hypertension [6].

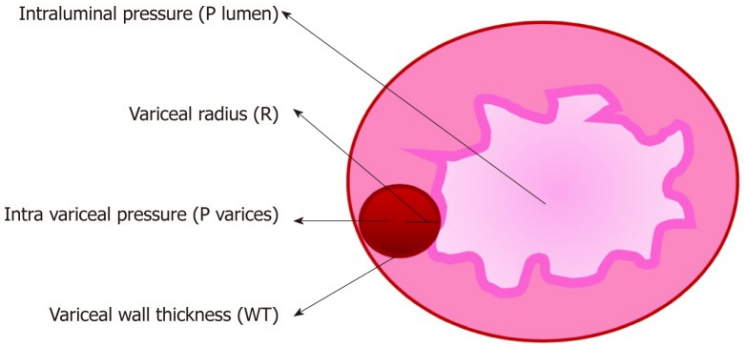


Fig. 3. A cross-sectional view of esophageal varices in the esophageal wall [17]. The image shows the development of esophageal varices within the esophageal wall and the associated intra variceal pressure. The image highlights the tensional component in the development of esophageal varices and the pressure components of the esophagus. This includes the intraluminal pressure applied against the varices and the esophageal wall.

2) 2.2.2 Clinical Significance

Esophageal bleeding is a life-threatening complication, with a limited number of solutions. Although there are devices on the market geared towards the in-hospital treatment of people experiencing esophageal bleeding, there are limited devices for prehospital providers. Some of the main devices being used to treat esophageal variceal bleeds are balloon tamponade systems (Sengstaken-Blakemore tubes), transjugular intrahepatic portosystemic shunts, and various drug treatments. Each of these possible solutions work in some way to stop the bleeding, and are good ways of keeping a patient stabilized until surgery can be performed. In areas without widespread endoscopic opportunities, the screening for varices is often reduced through no fault of the patient or provider, making the space for development of emergent devices important [18].

3) 2.2.3 EMS Providers and Current Protocols

Currently, the paramedic standing orders in the United States are controlled by the operating protocols of the state in which the paramedic is licensed. Because of this, there are slight nuances between paramedic scope of practice and protocols across the country. However, the expected core competencies of graduate paramedics remain relatively the same due to regulation by the National Registry of Emergency Medical Technicians (NREMT). These core requirements include teamwork, communication, many clinical skills, critical thinking and decision making. All Paramedics are required to operate within their scope, regardless of state of treatment [19]. The prehospital treatment for esophageal variceal bleeding includes attempted stabilization of the patient with fluid support and the administration of vasoactive drugs. Once a patient is

received in the hospital, an emergency endoscopic procedure is performed, usually including band litigation or other existing intervention to stop the bleed [20].

C. 2.3 Prior Art and Research

1) 2.3.1 Overview of Prior Art

One of the most important components in the emergency care of esophageal variceal hemorrhage is stopping the bleed. Not only does this prevent fluid loss and consequent hypotension and shock, but this also keeps fluid from occluding the airway and compromising the patient's ability to breathe. Models and devices to prevent bleeding are rather limited for the in-field provider, however, as emergency pre-hospital care initiated by paramedics is pre-endoscopic in scope and endoscopic devices and procedures are typically only available or performed in the hospital setting, including surgical interventions such as a transjugular intrahepatic portosystemic shunt (TIPS) [21].

Emergency prehospital esophageal care is generally overlooked with little to no devices specifically designed to visualize the esophagus. MQP advisor Professor Brenton Faber, NRP, notes that devices such as intubation equipment can help providers visualize the larynx and vocal cords of a patient in respiratory distress, but such visualization does not extend to the esophagus. Emergency pre-hospital care for esophageal varices is thus mostly characterized by transfusion, fluid resuscitation, and pharmaceutical interventions such as vasoactive agents rather than specific medical devices or models [21]. While these methods can attempt to slow bleeding and/or replace lost fluids, the most effective care is administered in the hospital setting.

Devices and models available in the hospital setting are varied, but unfortunately not all are necessarily effective for emergent cases. Band ligation, hemostatic clips, and injection-/sclero-therapy needles are all interventions that are available for purchase from medical device companies such as STERIS Healthcare, but issues have raised from some of these devices. The evidence for the effectiveness of hemostatic clips is not robust [21], and although sclerotherapy used to be considered one of the treatments of choice along with endoscopic band ligation [22], injection-/sclero-therapy needles have been cited as risks for complications [21].

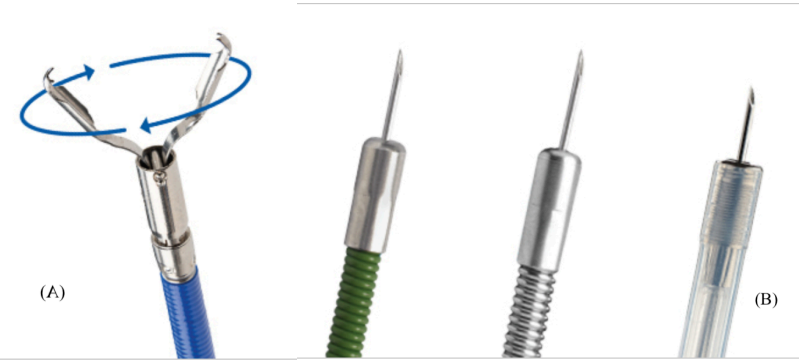


Fig. 4. (A) depicts the Assurance® hemostatic clip sold by STERIS Healthcare. (B) depicts a variety of injection needles used for sclerotherapy, also sold by STERIS Healthcare [23]. Both of these devices can be used in the treatment of esophageal varices, in-hospital.

2) 2.3.2 Esophageal Variceal Band Ligation

Esophageal variceal band ligation is considered one of the standards of in-hospital care for patients with esophageal variceal rupture/bleeding, and for good reason. A study performed on a cohort of 140 portal hypertensive patients looked into the efficacy of endoscopic variceal ligation in terms of acute hemorrhage management, variceal rebleeding and recurrence, and complete and durable varices eradication. The study found that, across 160 emergency variceal ligation procedures and 298 elective procedures, 81% of patients (114 patients) had their varices controlled with index banding, while only 19% of patients (26 patients) experienced complicated and refractory bleeding. In terms of acute variceal bleeding, the study found that

endoscopic variceal ligation controlled acute bleeding in 95.7% of patients (134 patients) during index endoscopic procedure. The remaining 6 patients experienced bleeding that could not be controlled by endoscopic variceal ligation, and 4 of the 134 patients re-bled within 5 days after the index banding procedure, resulting in a total 5-day failure rate of 7.1%. As stated, overall 81% of patients (114 patients) experienced bleeding control after index banding procedure and did not experience further bleeding after repeat variceal banding. The remaining 19% of patients (26 patients) experienced complicated and refractory bleeding, with 4% (6 patients) requiring balloon tamponade during the index procedure due to failure of the band ligation, and the other 15% (20 patients) experiencing rebleeding over varying periods of time following the index banding procedure. The study concluded that band ligation is effective for acute management of variceal hemorrhage with low complication rates [24].

Considering the team's device is meant for use in the pre-hospital environment, long-term insertion/placement of the device is not intended. Instead, the device is meant as a temporary intervention for paramedic application prior to arrival at a hospital or specialized center. The data collected from the study shows that band ligation carries a small chance of failure or rebleeding but is overall very effective for acute esophageal variceal bleeding. However, band ligation devices come with their own complications making them unsuited for pre-hospital applications. The first endoscopic devices that will be analyzed include the two banding devices mentioned in Krige and authors' study: the Saeed Multi-band Ligator [25],[26],[24].

Fig. 5. (A) and **(B)** are images of the Saeed Multi-band Ligator (left) and the Speedband Superview Super 7 Multiple Band Ligator (right) [25], [26] also used in the in-hospital treatment of esophageal varices in a surgical setting.

Band ligation devices come in many shapes and sizes, but the general function remains similar: the device or a component of the device is inserted down the patient's throat into the esophagus and deploys flexible bands around the bleeding varices. By tying off the varices, blood flow no longer reaches the ruptured tissue, slowing or stopping the hemorrhage. Multiple bands can be deployed using multi-band devices. Proper suctioning and visualization using other endoscopic devices may be required in order to locate the ruptured varices and ligate them, or the band ligation device may come with visualization features, such as the Saeed Multi-band Ligator which has suctioning and irrigation functionality [25]. The Saeed Multi-band Ligator comes in many variations depending on features such as the desired outer diameter of the endoscope, trigger cord length, or number of deployable bands [25]. No matter which model is selected, however, the device is only sold with natural rubber latex bands, which, although a biocompatible material [27], would incite allergic reactions among patients with latex allergies. The Speedband Superview Super 7 Multiple Band Ligator, in contrast, is sold with latex-free material [26], which poses a reduced risk for patients with latex allergies. However, the device is restricted to sale by or on the order of a physician according to United States Federal law as seen in Figure 6. Similar esophageal variceal banding devices, such as the SmartBand® multi-band ligation kit sold by STERIS Healthcare, are also restricted to sale by a physician (Figure 7).

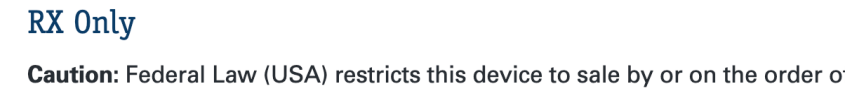


Fig. 6. Figure 6 depicts a section of the Speedband Superview Super 7 Multiple Band Ligator Prescriptive Information manual. The text relays that the device can only be purchased by or on the order of a physician, meaning the device can only be purchased with a medical doctor's prescription, or is being purchased by or on the order of a physician [26]. Currently, this device is not an option for non-physician clinicians, including those working in a prehospital setting according to the device manufacturer.

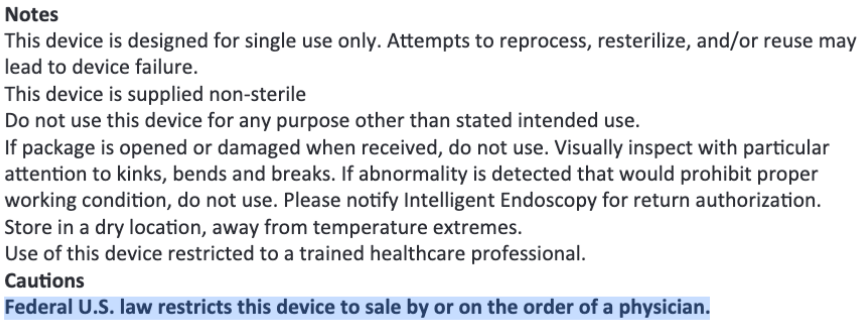


Fig. 7. Figure 7 depicts the Notes section of the SmartBand® multi-band ligation kit Instructions for Use manual. The highlighted text relays that the device can only be purchased by or on the order of a physician, meaning the device can only be purchased with a medical doctor's prescription, [28], or is being purchased by or on the order of a physician. This in turn means the device is currently unusable in a prehospital setting without medical director supervision.

When a device can only be purchased by or on the order of a physician, as stated in Boston Scientific's Prescriptive Information manual [26] and Intelligent Endoscopy's Instructions for Use (IFU) manual [28], United States Federal law restricts the sale of the device unless on the medical prescription of a physician, or the device is being purchased by or on the order of a physician [29]. This labeling clearly specifies that physicians are the intended possessors and/or users of these band ligation devices, excluding paramedics from the audience of intended users. The use of band ligation devices by pre-hospital emergency personnel is thus unadvisable and would be considered unlawful if obtained outside the orders of a physician. Even if the device were to be purchased by or on the order of a medical director or other physician who works closely with paramedics, band ligation is intended for physician implementation and in-hospital use, further evidenced by demonstration videos showing the functionality of the band ligators. The videos demonstrate ideal situations wherein bleeding is not or is no longer active and the physician has adequate visualization of the esophagus and varices. In an emergent situation, the patient would be actively hemorrhaging to a severe degree, necessitating immediate suctioning and stabilization techniques. The pre-hospital environment thus presents a clinical situation and set of unique conditions the band ligation device is not intended to be utilized under.

3) 2.3.3 Sengstaken-Blakemore Tube and Balloon Tamponade

The Sengstaken-Blakemore tube is a balloon tamponade technique that is considered one of the bridges to surgical intervention in the case of refractory hemorrhage [21]. The tube is not a definitive fix, but rather a temporary intervention and a last resort in order to stabilize patients until they can receive the highest level of care from a gastroenterologist and/or surgical intervention such as a transjugular intrahepatic portosystemic shunt [21], [22]. Variations of the tube exist, including the Linton-Nachlas tube and the Minnesota tube; all three tubes are depicted in Figure 8 [30].

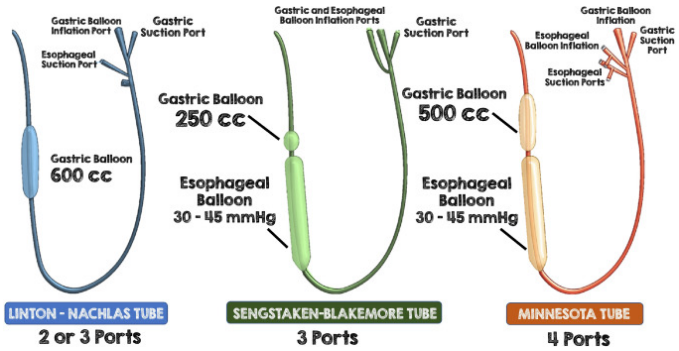


Fig. 8. Figure 8 depicts three variations of the Sengstaken-Blakemore tube. In the classic three-port Sengstaken-Blakemore tube, the gastric balloon sits in the patient's stomach as an anchor and provides traction as the esophageal balloon is inflated. The esophageal balloon then applies pressure against the esophageal walls. The Linton-Nachlas tube only contains a gastric balloon, without an esophageal balloon. The Minnesota tube contains similar components to the Sengstaken-Blakemore tube but involves an additional port for esophageal suctioning [30].

Key differences between the three tubes include the number of external ports as well as the function of each port (either to inflate an internal balloon or suction out internal contents), the pressure at which the balloons are inflated, and the number of balloons [30].Balloon tamponade devices can be efficient rescue devices for uncontrolled variceal esophageal hemorrhage, but they come with their own set of risks. In one study conducted on patients with liver cirrhosis, 66 were treated with a Sengstaken-Blakemore tube to stop uncontrolled variceal hemorrhaging when endoscopic treatment failed [31]. The tube successfully controlled the initial hemorrhage in 75.8% of patients (50 patients), with 11 of those 50 patients experiencing rebleeding after tube insertion [31]. Achieving control of the initial bleed greatly decreased mortality rates over a 30-day period, but risk factors including esophageal perforation if the tube is inserted following endotracheal intubation – such was the case in four patients – is a reason to tread lightly when utilizing balloon tamponade devices [31]. As a result, Sengstaken-Blakemore tubes are typically only deployed as a rescue device when other measures fail.

Furthermore, Sengstaken-Blakemore tubes are firmly an in-hospital modality and are rarely seen in the field. One exception to this was discussed by one of the team's interviewees, Diana Libby-Billings, NRP, and MQP advisor Professor Brenton Faber, NRP: a rare situation occurred in which a balloon tamponade device was used in the field to treat esophageal variceal hemorrhage, all with the help of a football helmet, as depicted in Figure 9:

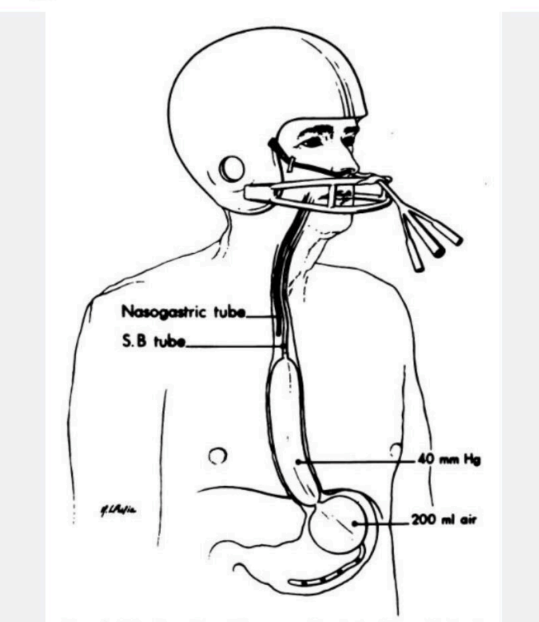


Fig. 9. Rare example of a Sengstaken-Blakemore tube used in the pre-hospital environment. The football helmet provides a securement point and can be used to create tension and exert vertical compression against the esophageal varices. This is a very rare use case of a balloon tamponade device pre-hospital and is not considered the standard of care. Image courtesy of Professor Brenton Faber, NRP and Diana Libby-Billings, NRP

Upon gaining the expert insight of Diana Libby-Billings and Professor Brenton Faber regarding this rare use of a Sengstaken-Blakemore tube in the field, it was evident that this measure was performed by a provider with years of experience and knowledge. Balloon tamponade devices are unheard of in the pre-hospital environment, and paramedic training does not cover the use of such devices for esophageal variceal bleeds. Therefore, the implementation of balloon tamponade devices in the field is territory that has yet to be explored.

D. 2.3.4 Similar Patented Devices and Concepts

Patents for similar devices/ideas have been filed, but none match the design nor the intent of the team's device.

1) 2.3.4.1 Balloon Tamponade

US patent US9888927 dated February 13, 2018 submitted by Belfort et al. is for implantable double-balloon tamponade devices used to occlude hemorrhage in the pelvic cavity, abdominal cavity, vagina or uterus. This patent also uses the idea of direct pressure from a balloon for bleeding cessation. However, this patent is primarily for body cavities and does not include the esophagus in the definition of cavity.

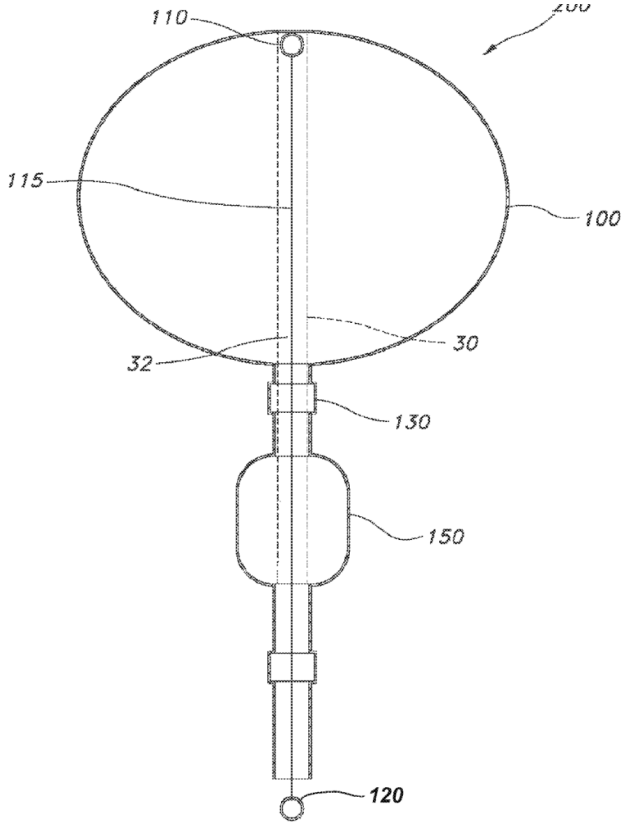


Fig. 10. Shown is the cross-sectional view of the patented double-balloon tamponade device. The drawing includes both the pilot balloon and the occlusion balloon as well as channel representations for inflation and a working line.

2) 2.3.4.2 Device for Controlling Bleeding from a Ballistic or Penetrating Wound

US patent US10918838 dated February 16, 2021 submitted by Ramsey III covers a device for internal compression tamponade in the form of a catheter system. Although this patent does not relate to esophageal rupture the concept of tamponade is used. This system is specifically related to blood occlusion in deep tissue spaces in organs specifically damaged by penetrating or ballistic wounds.

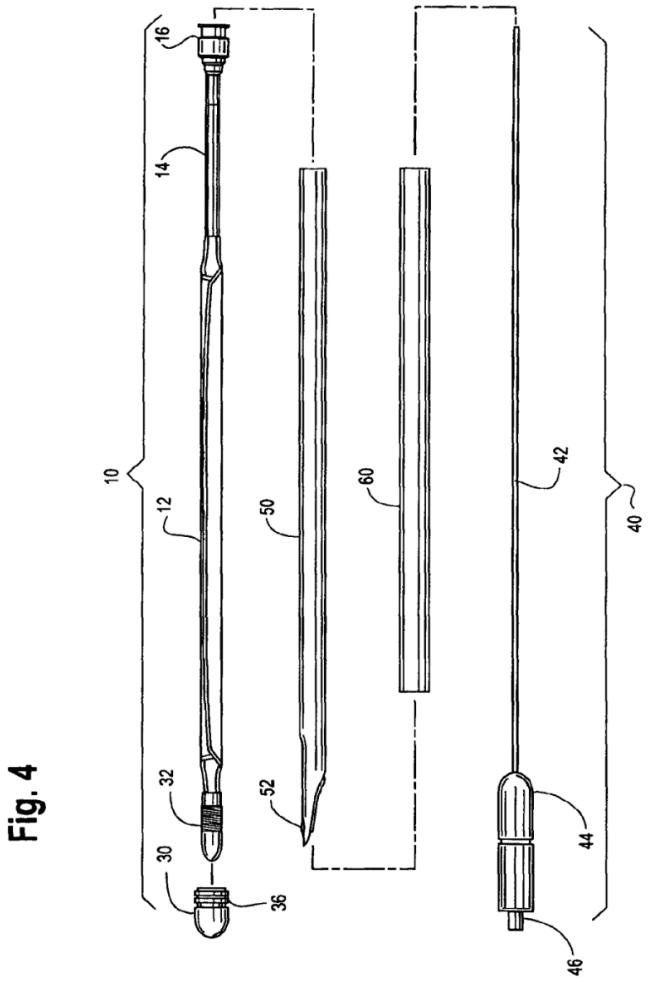


Fig. 11. This figure shows the proposed device for an inserted catheter for bleeding occlusion. The patented device operates on the principle of applied tamponade pressure. The figure shows the device sheaths and inflation points, as well as the connection points for the device.

3) 2.3.4.3 Intra-Esophageal Balloon

United States patent number US 10,661,060 B2 dated May 26, 2020 by Niazai is a similar device as it is an intra-esophageal balloon, as seen in Figure 12, but it is not used as a balloon tamponade. Rather, it is used to move the esophagus away from the heart to prevent damage to the esophagus during atrial fibrillation ablation. This device involves an esophageal balloon, but it inflates asymmetrically and necessitates the pumping of pressurized, cooled liquid into the balloon to inflate it.

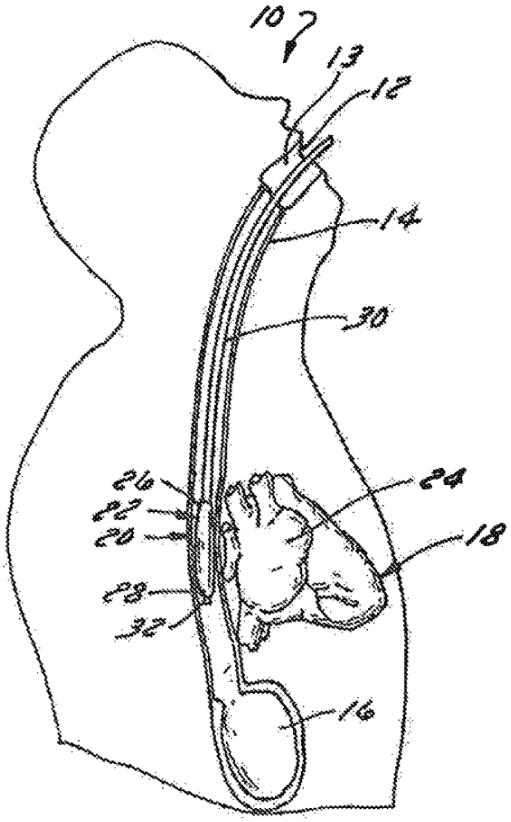


Fig. 12. A schematic illustration of the intra-esophageal balloon invention inserted in the preferred manner into a patient's esophagus. The device includes an anchor balloon, labeled 16 on the figure.

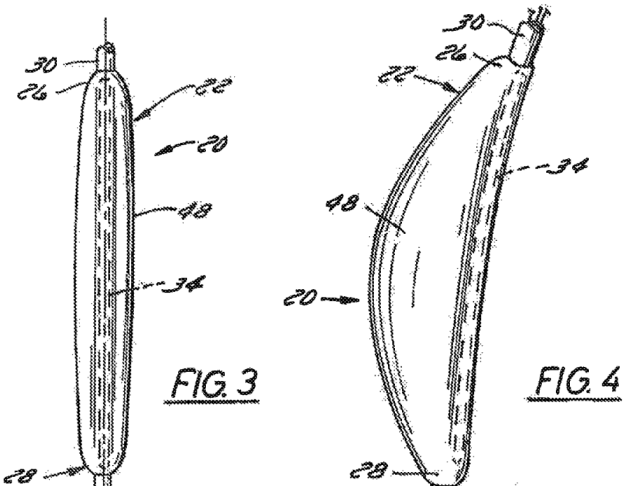


Fig. 13. Side elevation views of the balloon of the intra-esophageal balloon invention, both in a deflated state (left) and in an inflated state (right)

4) 2.3.4.4 Methods for Permanent Occlusion of a Hollow Anatomical Structure

United States patent number US 7.402,320 B2 dated July 22, 2008 by Mirizzi, et. al. is similar in intent to the team's device as it aims to occlude bleeding blood vessels. The patent involves inserting a device or material into a hollow anatomical structure, or its surrounding tissue, to occlude the hollow structure. Although the patent directly refers to esophageal varices as one of the possible use cases, the patent refers to the occlusion of the blood vessels themselves; for example, the patent mentions various ways to occlude blood vessels such as by decreasing the cross-sectional area of the blood vessel prior to applying occlusive

material. None of the patent methods referred to balloon tamponade, as they mainly focused on occlusive materials, the use of sclerosants, etc.

5) 2.3.4.6 Uterine Hemorrhage Controlling System and Method

United States patent number US 11,291,473 B2 is similar in intent to the team's device as it temporarily controls a hemorrhaging blood vessel. This patent uses the concept of inserting a device into the uterus and using a pump to suction out the blood. It is intended to be used in the occurrence of a hemorrhaging uterus after birth. Although this device is used to reduce the amount of blood from a hemorrhage, it is only to be used in the uterus. This device has no correlation to esophageal varices or the hemorrhaging episode of esophageal varices.

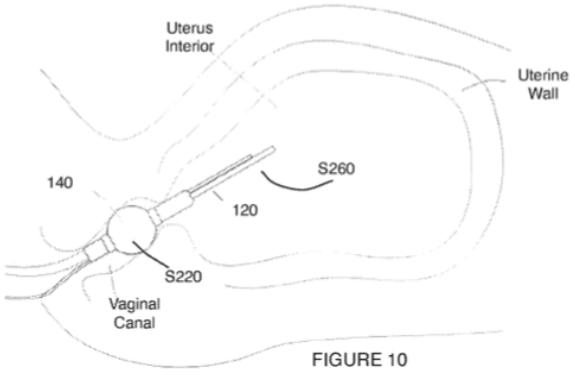


FIGURE 10

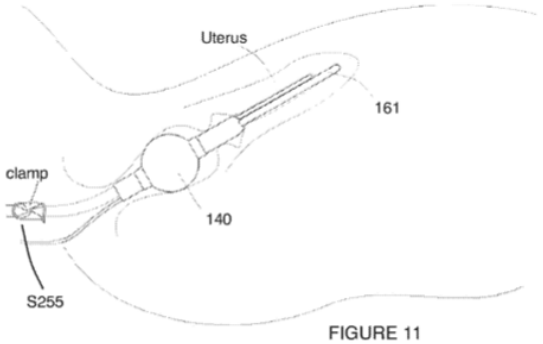


FIGURE 11

Fig. 14. This figure shows the patented uterine hemorrhage control device. The device operates by placing flexible tubing within the uterus, and a vacuum pump controls the level of bleeding. This figure depicts an embodiment of the uterine hemorrhage controlling method.

6) 2.3.4.6 Devices and Methods for Intrahepatic Shunts

Another patent that relates to treatment of esophageal varices is US 11,369,346 B2. This patent is for a device that aids in creating a shunt between a portal vein and a hepatic vein, in order to divert some of the blood away from the portal vein. This lowers the risk of a hemorrhaging esophageal varix. This device has a pressure sensor, catheter, and balloon components, which are somewhat similar to the team's design. This device however is a proactive solution, the team's device is a reactive solution. The team's device is also meant to be used in a pre-hospital setting and this patented device is only to be used in a surgical setting.

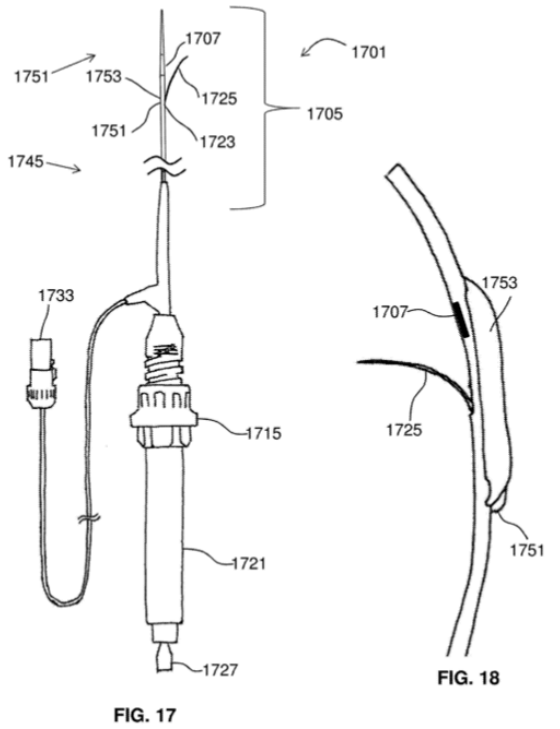


Fig. 15. This figure depicts the device used to create intrahepatic shunts. This figure shows both the shunt creating apparatus on the left, as well as the device with both balloons inflated on the right.

7) 2.3.4.7 Implantable Luminal Devices

United States patent number US10,441,290 is a device which allows for the occlusion of blood vessels during bleeding. It consists of the ability to selectively target an area, and is similar, in regard to its shape, to a stent. While not entirely similar to the team's device, this patent's device still seeks to limit the amount of bleeding in the location where it is placed and can obstruct the vessel to limit blood loss.

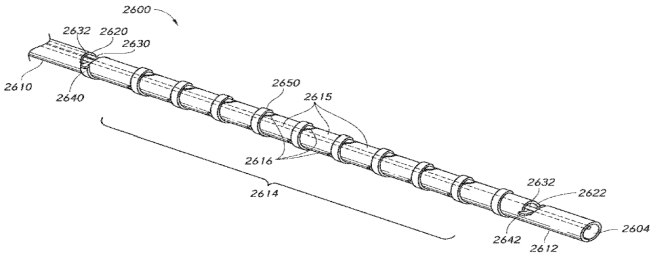


Fig. 16. The figure shows the implantable luminal device. It depicts the physical features on the device such as the bands, vent in the tube, and the tube itself.

8) 2.3.4.8 Prosthesis Development System for vascular Repair

European patent number 2,640,322 is similar to the team's device in the intention of achieving hemostasis of blood vessels during an emergency. Like the team's device, while not specifically made for the esophagus, this patent's device aims to prevent the hemorrhaging of blood vessels. The device of this patent is largely intended for medical professionals and physicians, whereas the team's device is mainly focused on pre-hospital care.

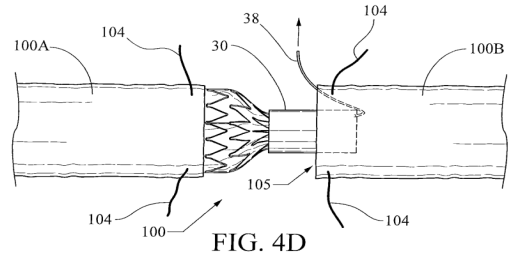


FIG. 4D

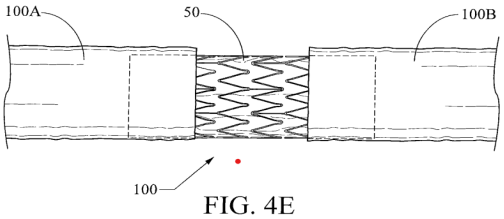


FIG. 4E

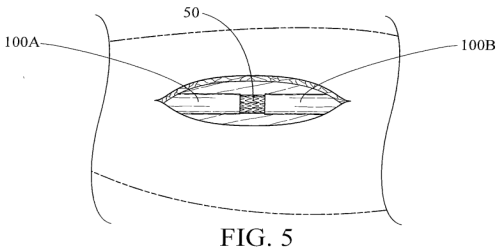


FIG. 5

Fig. 17. The figure depicts partial views of the prosthesis deployment system for vascular repair. Detailing the deployment and operation of the system, by showing the device being placed into the body, and the separation of the device pieces.

VI. 3.0 Project Strategy

A. 3.1 Client Statement

Design a rescue device for paramedics to use in the field for patients with life-threatening esophageal varices rupture as a temporary bridge to surgical intervention.

B. 3.2 Technical Design Requirements

In order to ensure the device meets ISO standards, and will benefit the patient, design standards were created. They fall into the main categories of not hindering standard care, maintaining provider safety and logistical standards, and effectively functioning. The first category covers topics such as transportation time, airway access, patient harm, and speed of care. The second discusses provider harm, safe device deployment in an ambulatory setting, ability to use the device without hospital technologies, and keeping the cost of the device low. Lastly, the final category addresses hemorrhage reduction, fitting the esophagus, and biocompatibility. Table I below goes into more detail for each of these specifications.

Table I: Qualitative and quantitative design specifications the novel device must meet.

Must Not Hinder Standard Care:	**Quantitative Specs for Testing**	**Maintain Provider Safety and Logistical Standards:**	**Quantitative Specs for Testing**	**Must Function Effectively:**	**Quantitative Specs for Testing**
Device or model shall not increase transportation time by a significant amount	Device or model shall not increase transportation time by greater than 2 minutes.	Device or model should not cause harm to the provider or compromise the provider body substance isolation procedure.	Device deployment shall not cause glove ripping or bodily injury to the provider in greater than 99% of deployments.	Device or model should stop or significantly reduce the active bleeding of the hemorrhaging esophageal varices before arrival at the hospital (< 10 minutes).	Device or model shall reduce blood loss by 80% within 10 minutes of deployment, measured via collection of hemorrhaged blood during trials.
Device or model shall not compromise airway access for the paramedic.	Device or model shall not occlude the airway or prevent intubation or access to the lungs in greater than 99% of trials	Device shall be safely deployed without danger to a standard ambulance environment.	Device shall not spark or deploy without provider trigger in greater than 95% of storage trials.	Must be able to be applied in a prehospital setting.	Device or model shall be successfully deployed in greater than 95% of in-field trials and in greater than 95% of trials conducted at 40 mph.
Device or model shall not harm the patient in any significant manner before, during or after deployment.	Device or model shall not result in excessive bleeding in more than 99% of deployments.	Device or model shall be safely deployed and placed without assistance from x-ray or ultrasound technology	Device shall be confirmed and placed correctly in greater than 99% of trials.	Must fit the functional anatomy of the target audience.	Device or model shall not exceed 13'' long. (Standard adult male esophagus size) (*Esophagus*, n.d.)
Device or model shall not slow the continuity of patient care.	Device or model shall be able to be deployed in less than 1 minute.	Device or Model must not cause undue financial burden to purchasing clients.	Device or model shall not exceed the price points set by competitive devices or models ($150)	Device or model shall be compatible with the body.	Materials that come in contact with the bodily tissues shall not cause harmful reactions or permanent damage to the bodily tissues in greater than 99% of trials
		Device or model must fit in a standard ambulance without the displacement of other medical tools and functional equipment.	Device or model shall not exceed 27.25'' x 25.25'', the standard ambulance cabinet size.		

		Training of the device or model use shall not increase the training time required of professional paramedic licenses.	Device or model training shall not exceed 6 hours and shall allow for proper insertion in a realistic scenario greater than 95% of times.		

1) 3.2.1 Objectives

To fulfill the client statement, this project had the following objectives:

1. Understand the mechanisms of disease, anatomy and causes of esophageal varices and the issues incurred from the rupture of these varices.
2. Create a device for esophageal variceal bleeding that did not hinder standard care for prehospital providers, maintained provider safety and logistical standards and functioned effectively at hemorrhage reduction.
3. Design and test this device in a realistic human anatomical model using an intubation dummy with associated esophageal access.
4. Analyze the data from trials and testing using the expert opinions of NRPs aånd physicians in the associated fields to understand the efficacy of the device for its intended purpose.

2) 3.2.2 Constraints

The underlying constraints of this project have varying limitations including, time, expenses and the design specifications of the client statement. The team will have 28 school-year weeks to design, prototype and test the product which provides a time constraint. Compared to the traditional 3-5 year medical device timeline in industry, this product development was expedited [32]. Although the end goal was not to bring a complete device to market, the design was required to be feasible as a model to effectively treat esophageal variceal hemorrhaging. Because of this requirement, extensive testing is required of the device. Test design, verification and validation are required of the test methodologies as well as the actual device, both lengthy processes that indicate the direction of test design and model design.

The team will also need to design a model for test trials to be conducted. Purchase of these devices can be expensive for dual models (including both airway and esophagus) and, as this model would be department owned, the team may need to split time with other researchers and development efforts requiring the model in the department. Price of prototyping equipment is also an important consideration as hemostatic test materials and biocompatible materials need to be trialed and purchased. The team must carefully consider each purchase in order to remain within the appropriate budget.

3) 3.2.3 Functions

The main function of this device is to stop or significantly reduce the amount of hemorrhaging as a result of the esophageal variceal bleeding. In order to do this, the device must be compatible with both airway integrity and esophageal intubation. It should accurately fit into the esophagus to reduce the bleeding. These two aspects of the device are among the most important and are implemented into the design. Another significant design consideration is safety, for both patient and provider. The device must be safe for the healthcare provider using it; if it causes a risk to the provider, the patient will not get the care that they need. The device should also not be a safety concern for the patient. Biocompatibility will play a large role in this, as the device will be used inside the body and therefore must be safe in the event of ingestion.

4) 3.2.4 Material Use Details

The device shall not be used by untrained prehospital providers with recognized certifications, the following operating specifications apply exclusively to licensed use. The device main tube body is made of

medical grade plasticized Polyvinyl Chloride (PVC) and maintains the operational ranges of medical PVC . The device shall not be used outside of the range of -45 degrees to 60 degrees Celsius. The PVC will maintain average material properties for the industry standard including a typical elongation percent of 375%, a tensile strength of 1700 psi and a passable brittleness temperature of -40 degrees celsius, values per ASTM testing methods D2240, D412 and D7462 [33].

C. 3.3 Design Requirements (Standards)

1) 3.3.1 Engineering Standards

The medical device industry is heavily regulated, primarily by the International Organization for Standardization, more commonly called the ISO [34]. The primary applicable standards for medical devices include ISO standards 14971, 62304, 13485 and 10993.

Table II: The regulating standards applied to medical devices [34].

ISO 14971	ISO 62304	ISO 13485	ISO 10993
Discusses risk management that occurs with normal use of a medical device.	Discusses medical device software, including software in medical devices or devices that are software.	Discusses quality systems in terms of medical devices, throughout the design and lifespan of the device.	Discusses the biocompatibility of medical devices and the risk of harmful interactions.

2) 3.3.2 CAD Industry Standards

The Computer Aided Design (CAD) software used for this project is Dassault Systemes Solidworks. The primary regulatory concern associated with CAD design is drawing standards. The drawings associated with the device follow American Society of Mechanical Engineers (ASME) standards, specifically ASME Y14.100. CAD drawing must contain the required drawing views, typically front, back, side, and isotropic, in order to dimension the assembly without redundant or omitted dimensions. The associated lists and tables must contain the relevant project information; usually the primary engineer and one who has checked the drawing, proprietary statements, unit considerations, title, revision number and where the drawing ranks in the full drawing set. Individual parts of the assembly may be assigned separate drawing numbers in the set for greater clarity in the assembly drawing dimensions or for ease of manufacturability. The drawings associated with the final rescue device assembly and its components adhere to the ASME standards using ANSI style A paper style in Solidworks Draw. This development was done in stages following the selection of a leading concept as outlined below. These iterations allowed for the production of the final CAD drawings and dimensions that guided the prototype creation.

D. 3.4 Ethical Standards

1) 3.4.1 Consent for Emergency Medical Providers

Having set standards for medical device use and design decreases the risk of ethical violations. However well-intentioned the research and development path of a medical device is, there are always unintended consequences. Regulatory bodies exist to ensure ethical boundaries are crossed less often in the name of reduced production costs, profit or bringing a device to market [35]. In terms of device development for variceal bleeding, because there is not a current supplier or market, nor external funding, the potential for a conflict of interest is much lower. Ethical considerations must be discussed in terms of providing a benefit to the patient without harm. A risk-benefit to the patient must be considered before the application of any medical device, regardless or level of invasion to the patient [35]. This device can improve the quality of life for patients and their families by offering an option for those in acute esophageal variceal bleeding episodes as a life saving measure. Through interviews with a registered paramedic, it was explained that the current

procedures do not offer adequate survival rates (D. Libby-Billings, personal communication, October 5th, 2023). This device offers an increased chance of survival by offering another treatment avenue for critical patients.

As with unconscious patients or patients who are unable to respond to first responders verbally, implied consent is considered to be given to the responding paramedics. This would be the space in which the consent for this device would be applied, as an intubated patient is not able to speak (Ogilvie et al., 2023). Regardless of profession, touching a patient without some form of consent, expressed or implied, is considered battery or assault. Transporting a patient without their consent can also be considered kidnapping or wrongful imprisonment, if the person has declined treatment [36]. To avoid these cases, the consent of use of the rescue device would also be garnered with the general consent to treat a patient. No separate consent shall be obtained, as this device would be considered only for critical patients as a lifesaving maneuver in which the benefits of application outweigh the risks and complications of not applying the device or managing the hemorrhaging in other ways.

2) 3.4.2 The Four Types of Ethics

There are four main types of ethics the team considered during preliminary development and conceptualization of the device, social, economic, environmental, and global ethics (Worcester Polytechnic Institute Biomedical Engineering Department, 2023). According to the Worcester Polytechnic Institute Biomedical Engineering Department's guidelines for Major Qualifying Project (MQP) students, social factors to consider include education, social supports, wealth, demographics, cultural influences, and politics. Economic factors include economic growth, inflation, and foreign legislature or regulations. Environmental factors include resource availability, pollutants, and impacted organisms and their habitats. Finally, global factors consider social, environmental, and economic factors on a global rather than local scale and the interaction of global societies with one another (Worcester Polytechnic Institute Biomedical Engineering Department, 2023).

Since the team is developing a medical device for treating patients, further questions needed to be considered while devising the team's approach to each ethical problem, as seen in Figure 18.

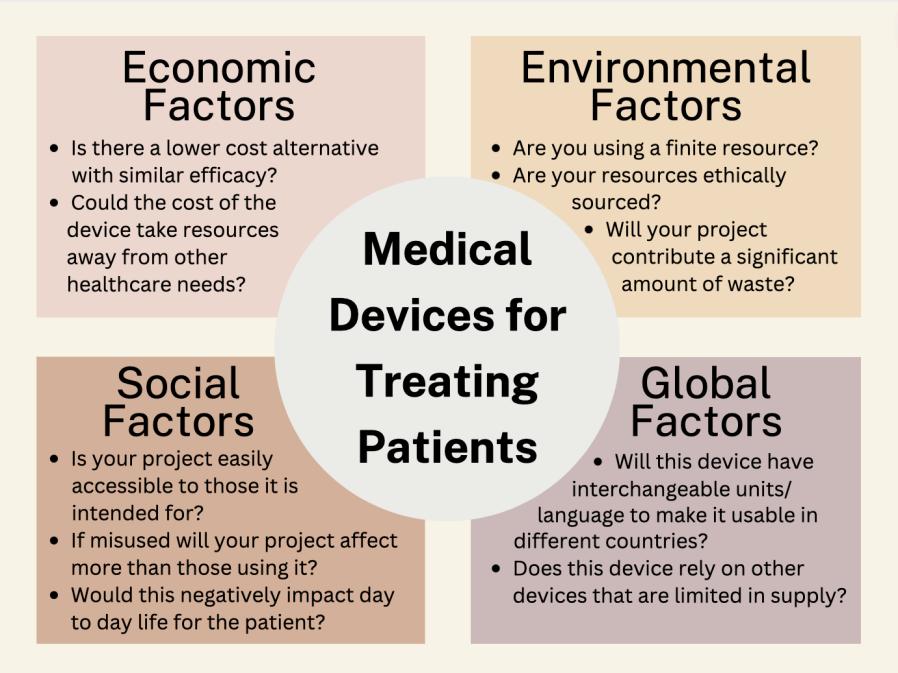


Fig. 18. Further ethical questions the team considered, specific to medical devices. This graphic shows the four main components of the ethical considerations for the creation and use of medical devices. These categories include consideration of global factors, social factors, environmental factors and economic factors (Worcester Polytechnic Institute Biomedical Engineering Department, 2023).

a) 3.4.2.1 Social Ethics Statement

The major social ethics problem arising from our device is rooted in healthcare disparities and access to immediate and effective medical attention. Our device would be carried on ambulances, which will lead to some patients getting the prompt attention they need, whereas other communities would not. For example, in a United States national cross-sectional study of over 63,000 patients who suffered out-of-hospital cardiac arrests, emergency medical service (EMS) response times were 10% longer in the poorest communities, while patients of wealthier communities were more likely to receive EMS care that met national benchmarks of 8 or 15 minutes [37]. The differences observed in EMS response, on-scene time, and transport time in low-income communities compared to high-income ones is one example of how healthcare disparities proliferate even in emergency situations. Furthermore, lower-income communities are more likely to suffer worse patient outcomes due to higher rates of disease and structural healthcare disparities experienced in these communities [37]. In terms of the team's device, those of lower socio-economic status would likely not be receiving the same caliber of emergency treatment for esophageal variceal rupture, perhaps due to elongated EMS response times. Those of lower socio-economic status would also likely have higher rates of rupture as healthcare disparities in their communities would make it more difficult for them to receive effective treatment, or any treatment at all, thus leading to lethal patient outcomes. Without prompt access to emergency care or easy access to medical attention, these patients would be overlooked and would not benefit from the team's device.

To remedy this, the team's device could be made available to mobile health clinics in areas of healthcare disparity in order to relieve this social ethical problem. Mobile health clinics can be an effective way of delivering medical attention to underserved communities. For example, a study was conducted on 5,900 patients who visited an urban mobile health clinic called "The Family Van" in Massachusetts [38]. The study found that repeated visits to the clinic and monitoring of hypertension over time resulted in the reduction of systolic and diastolic blood pressures, as well as reduced risks for heart attack and stroke. Since mobile health clinics can provide a range of services, including cost-effective preventive care, they can be an asset to underserved communities in which poor health status is prevalent, and disease prevention and management is necessary [38]. The issue the team may face is not all mobile clinics can have the capacity to provide urgent or emergency care, which is the intended use of the team's device. Thus, the team should consider providing the device to health clinics that are capable of providing emergency care to underserved communities and are staffed by emergency medical professionals, such as paramedics, emergency room physicians, etc., who work in these communities.

Due to the one-size-fits-all device design, some groups of people may have anatomical abnormalities that would make it difficult to insert the device, such as children. In the future, the team should consider various iterations of the device in an effort to conform the device to the individual. Since esophageal variceal rupture typically occurs in adults, however, the team aims to focus on the largest affected group possible. The benefits of developing the device, even though it may not reach certain groups of people, outweigh the costs as there is at least one population whom the device could benefit. Furthermore, focusing on the device at hand and ensuring its individual success is essential as it will provide a key foundation for future versions of the device.

b) 3.4.2.2 Environmental Ethics Statement

The primary environmental ethics problem to consider is whether the team's device can be reused, or if it must be single-use. Due to the invasive nature of the device and many of its component parts needing to be inserted directly into the body, the device must be single-use. Even the components not being directly inserted into the esophagus, such as the balloon pump and pressure gauge, would most likely be considered biohazardous waste as the sheer volume of blood ejected from the patient's esophagus (as confirmed by Diana Libby-Billings, NRP and Esther Gruesz, NRP, personal communications, 2023) would contaminate the entire device.

As a result of the invasive implementation of the device and its single-use case, it would have to be produced in a sterile facility, stored in sterile packaging, be assigned a set expiration date, and be considered biohazardous waste and disposed of appropriately after use. This would result in medical waste that, if not handled properly, could cause harm to organisms, animals, and their habitats due to pollution and contamination by man made waste. To combat this issue, the team should clearly convey the importance of careful handling of the product and proper disposal in biohazardous waste containers on the packaging and on the product itself. The team should also be sure to use medical-grade materials and equipment that will pose little to no harm to humans, and ideally little to no harm to animals or other organisms. If such materials cannot be obtained, the team must clearly convey the hazards of the materials on the packaging and highlight the importance of prompt and proper disposal of the device after use.

Despite these environmental factors, the benefits of the device being produced and stored in a sterile environment, expiring over time, and being single-use far outweigh the costs of potentially infecting patients or harming patients due to an expired/inefficient device. The additional medical waste produced by the device should not deter its production as long as the waste is not unnecessary, the materials used are medical-grade, any and all hazards are identified and conveyed, and instructions for proper handling and bio-hazardous disposal are made clear to users. Ultimately, the benefit of the device saving a life, or at least prolonging patient survivability until arrival at the hospital, outweighs the cost of not having a device available to paramedics at all during an esophageal variceal rupture.

c) 3.4.2.3 Economic Ethics Statement

The current economic ethics problem is the willingness of services to purchase the device. Ambulances currently do not carry specific devices for esophageal variceal rupture, so the device may be seen as a sunk cost and an unnecessary purchase. Furthermore, considering the device is single-use, the economic strain of the device may not be considered worthwhile. Ensuring the device is made out of quality, yet relatively easy-to-obtain materials would keep costs down and allow the team to price the device competitively. Ultimately, however, the benefits of developing the device outweigh the costs since the device could help save a life. It is important to note the financial burden on the patient would be quite hefty, especially for those who would have to cover emergency treatment without insurance. This could cause additional healthcare disparities in lower-income communities due to the sheer financial burden of calling an ambulance and receiving life-saving treatment. Therefore, providing the device to health clinics capable of providing urgent or emergency medical care and are staffed by trained emergency medical professionals, could help relieve the financial burden on lower-income communities while still ensuring prompt life-saving medical attention is rendered.

d) 3.4.2.4 Global Ethics Statement

The current global ethics problem is the availability of materials across the globe. For example, if one region of the globe does not have access to the same quality of medical-grade materials that the team is using to build their device, some patients may not be able to obtain the same quality of treatment. Furthermore, global tensions may make it difficult to obtain or send materials to other countries depending on where the materials are being produced. Unfortunately, the team cannot do much to alleviate global restrictions or foreign regulations on the transport of materials, but the team can do its best to produce the device using materials that are relatively affordable, can be found in most areas of the globe, and are not subject to international restrictions. Depending on the global region, the materials may not be the exact same, but as long as the device is high-quality, functional, and resilient, comparable devices are able to be manufactured.

The problem of healthcare disparity remains prevalent on a global scale. The team could provide the device or comparable devices to healthcare professionals, clinics, organizations, etc. who provide urgent or emergency medical care specifically in underserved areas of the globe suffering from healthcare disparities. This would be an additional cost to such organizations and clinics, but the benefits of ensuring our device

can be manufactured and utilized worldwide ultimately outweigh the costs of not sharing the team's solution on a global scale. Comparable materials or models of the device would be able to be produced and implemented across the globe if the same ones cannot be provided; as long as such materials and models are selected carefully, tested to the same rigor as the original device, and are not subject to international regulations or restrictions.

E. 3.5 Management Approach

1) 3.5.1 Overview

The basic structure for a device design MQP is to follow the engineering design process throughout the year. The first term of the year is devoted to research and brainstorming. This encompasses everyone contributing ideas of possible solutions, through research into existing solutions, interviewing experts in the field, and going through the design process to end the term with a leading design concept. The second half of the fall semester was spent confirming if the leading design concept is capable of meeting the design requirements. CAD programming was used to create a digital model of the device, then physical modeling based off of these digital drawings. Initial proof of concept testing was also completed by the end of the semester. The first half of the second semester is entirely dedicated to verification and validation. A functional prototype and test methodologies should be completed a few weeks into the semester. Then all of the tests should be run, results recorded, and statistics calculated, and the data analyzed. The final few weeks of the semester will be dedicated to perfecting the report and presentation of the project and product.

2) 3.5.2 A Term

Fig. 19. The A Term Gantt Chart. The background writing will be completed from weeks 1-7. The client statement will be identified and written during weeks 1 & 2. The need statement and preliminary objectives will be identified and written during weeks 1, 2 and 3. Interviews will also be conducted during weeks 1-7. Competition reverse engineering will be conducted during weeks 5-7 and concept brainstorming will start in week 4 and continue through week 7.

In A term, the primary focus was research. In order to create a device, prior knowledge of anatomy, physiology, and existing treatment protocol was required. To gain this knowledge, the team began with the literature review. This provided the team with knowledge on the anatomy and physiology of the esophagus as well as the disease itself. Understanding the space our device will be used as well as the cause and states of the condition are essential to developing a useful device. Also from the literature review, the team gained a basic knowledge of current treatment options in use. Almost all of the current treatment options are surgical, so there is a very limited range of competition for an infield device. Due to this lack of in field

options, the team interviewed multiple paramedics in order to better understand how they would temporarily stop the hemorrhaging in order to transport the patient to the hospital. Their input combined with our research allowed us to create multiple potential design concepts. By the end of the term, the team had settled on a leading concept design to begin prototyping in B term.

3) 3.5.3 B Term

Fig. 20. The B Term Gantt Chart. Interviews will continue through week 3. The computer aided design (CAD) will be iterated through all 7 weeks as well as writing updates. Modeling will be conducted through week 7 starting week 3. Test method writing will be conducted weeks 1-5. Acquiring the test model will occur in weeks 5-7 and testing will start week 3 and continue through week 7.

Throughout B Term, the main priorities consisted of developing a proof of concept, modeling of the device (both CAD and physical) and continuing to write the report. To start off the term, the team began gathering the materials needed to develop a basic proof of concept. The initial proof of concept included a bucket of water, lumen tubing, a PVC pipe, and a balloon. A small hole was drilled in the pipe, in which one end of the lumen tubing was inserted, with the other end being placed in the bucket of water. This allowed for water to flow from the bucket through the lumen tubing, through the pipe, and into an empty bucket underneath. Once there was a steady flow of water, the team placed the balloon into the top of the PVC pipe and inflated it. Within several seconds of this, the water stopped flowing through the pipe. When the balloon was deflated, the water started to flow once more. Below is an image of the setup of the initial proof of concept test.

Fig. 21. Initial proof of concept testing. A siphon system was set up to run water through a small tube, representing a ruptured esophageal varix. The large white tube represents the esophageal wall. A balloon was inflated in the white to show cessation of water out of the bottom of the tube, representing cessation of bleeding.

Although this initial proof of concept worked well, the team decided to run another iteration with a few changes. A King Tube replaced the balloon, and the water was colored red, in order to better visualize the flow of the water. The outcomes of this experiment were the same, with the King Tube stopping the flow of water when inflated.

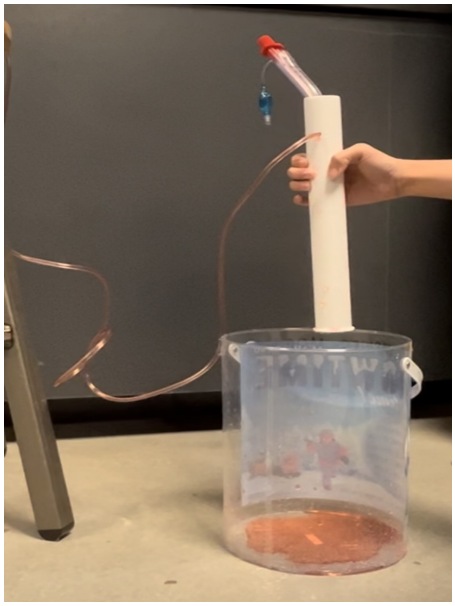


Fig. 22. A second proof of concept. A siphon system was set up again to run water through a small tube, representing a ruptured esophageal varix, filled with red water for better visualization. The large white tube represents the esophageal wall. A endotracheal tube was inflated in the white to show cessation of water out of the bottom of the tube, representing cessation of bleeding.

The next step was to move on to modeling and mechanism testing. The team developed a semi-functioning model, using an endotracheal tube, a balloon animal balloon, and a syringe. The balloon was cut on both ends and placed onto the endotracheal tube, and the syringe was used to inflate and deflate the balloon. The model was then inserted into a life-sized esophagus tube, and was successfully able to stop the water moving through the tube. Another important accomplishment of B Term was working on the CAD models of the device. The team attempted to make the CAD design as realistic as possible compared to the end-goal design. This consisted of detailed images of the design, including labels and dimensions. CAD

was a significant part of the work done throughout the term, as that is what allowed the team to start visualizing the device and begin determining the specifications to make it safe and effective.

4) 3.5.4 C Term

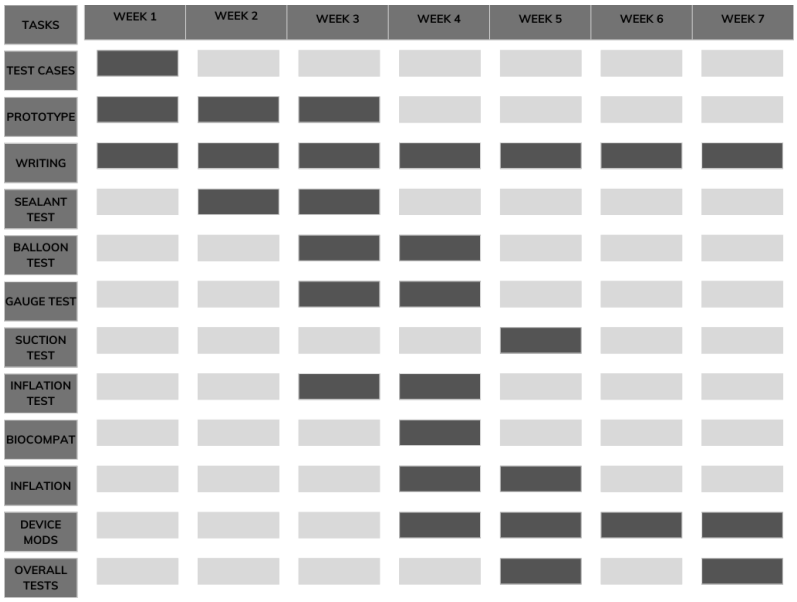


Fig. 23. The C Term Gantt Chart. C Term was mostly dedicated to testing, beginning with writing the test cases in week one and building the prototype in the first few weeks. In the following weeks, the team distributed their time between each of the different tests and writing the report.

The start of the spring semester was devoted to testing. The team identified 11 categories of testing that needed to be completed, and developed through test methodologies for them. These categories included: proof of concept, biocompatibility, sealant, pressure gauge, volume occlusion, inflation bulb, leakage, balloon strength, deployment and insertion, and finally main body suction testing. A schedule for completing these tests was created and followed, which can be seen above in Figure 23, the C Term Gantt Chart. For more in depth explanation of the testing see chapters 5 and 6, or refer to appendix A for test methodologies.

5) 3.5.5 D Term

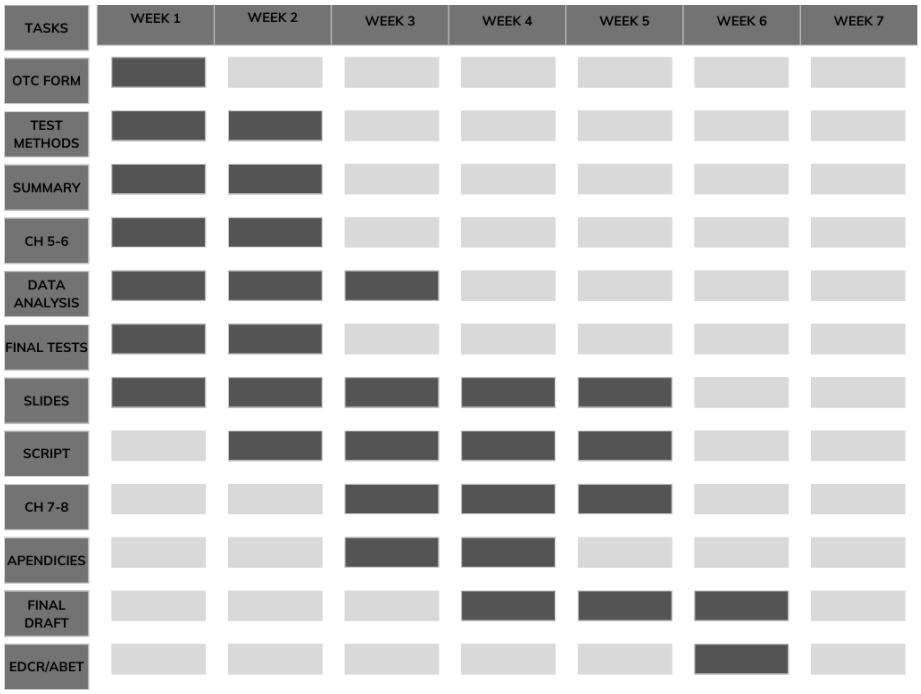


Fig. 24. The D term Gantt Chart. The majority of D term was spent working on the presentation and report writing. All of the final tests and data analysis was completed by week 3. The OTC form to apply for a patent was completed in the first week. The report writing and presentation slides were worked on throughout the remaining weeks of the term.

The remaining weeks of the second semester were filled by finishing testing, report writing, and presentation practices. A few of the tests needed additional trials or to be redone for more accurate results, these tests were completed at the beginning of D term. The team began weekly presentation run throughs with the advisors, in order to prepare for the upcoming Undergraduate Research Projects Showcase, on April 19th. This report was also continuously being written and edited throughout the term. Another important note for D term was the approval by the WPI Office of Technology Commercialization, approving the Var-Ex Tube for a Provisional US Patent.

VII. 4.0 Design Process

A. 4.1 Needs Analysis

1) 4.1.1 Need Statement

Develop a device or model that allows emergency medical professionals to treat hemorrhagic esophageal varices in a prehospital setting.

2) 4.1.2 Statement of Design Problem

In-field, emergency esophageal bleeding is considered a surgical emergency with a mortality rate of 30%-50% during a patient's first episode [39]. Lack of effective treatment for ruptured esophageal varices are detrimental to the patient and provider.

3) 4.1.3 Need Statement Summary - Population and Outcome

As the prehospital care system develops with increasing scope and demand, new developments are needed to support paramedic providers' ability to treat patients. When treating ruptured esophageal varices, it is important to consider the target population and the outcomes for these patients. As discussed, esophageal variceal bleeding is an emergent surgical condition, meaning the role of the EMS system is to bridge the gap between the onset of rupture and when patients arrive at a hospital able to perform surgery. As previously discussed, transportation times within the EMS vary tremendously with many factors including hospital location in relation to the patient as well as provider and surgical team availability [40].

Due to this and nuanced differences in patient case severity and anatomy, the outcomes of esophageal variceal bleeding for patients is varied, often ending poorly. The ideal of this device would be to stabilize the patient pre-surgery to allow for patient survival. In order to account for these differences, the device must be robust to support varying transport times and allow patient survival rate increases.

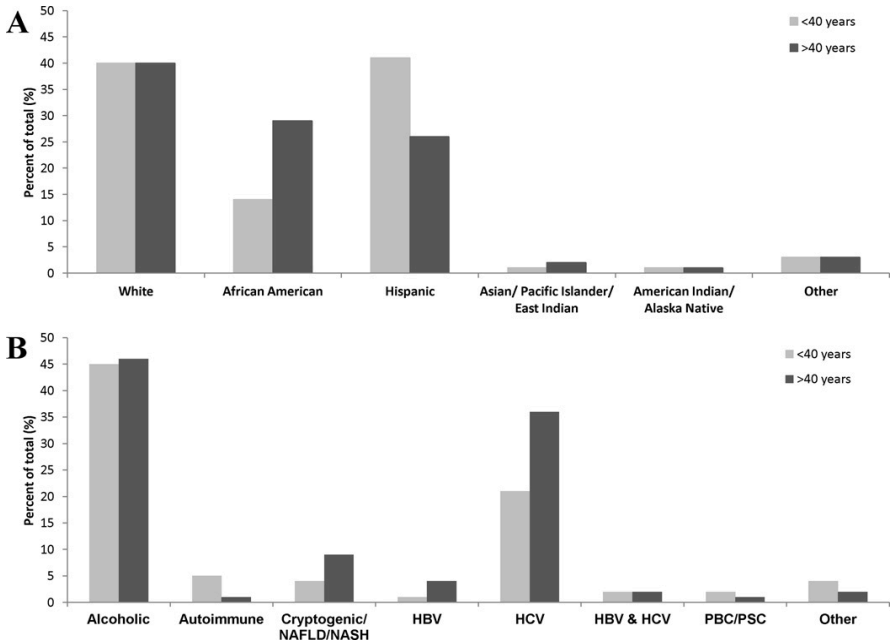


Fig. 25. Graph showing a correlation between the development of liver disease and ethnicities. The darker bars represent individuals above 40 years old and the lighter bars represent individuals below 40 years old. (**A)** shows the correlation between six ethnicities, White, African American, Hispanic, Asian/Pacific Islander/East Indian, American Indian (more commonly referred to as Native American)/ Alaska Native and those falling under several ethnicities or "other", and the total percent of the population affected by cirrhosis. **(B)** shows the usual underlying causes for cirrhosis and the affected population in a percentage. Liver cirrhosis is the most common cause of esophageal varices [41].

The main candidates in the United States for the development of esophageal varices are those with severe liver disease, regardless of the underlying cause. 58.8% of compensated cirrhosis cases and 60.3% of decompensated cirrhosis cases occurred in those polled of the self-identifying male gender, across all underlying causes. Additionally, those with other compounding medical conditions such as obesity or diabetes were at higher risk for the development of esophageal varices [42].

Individuals over the age of 40 were also at increased risk. Studies also suggest a correlation between certain ethnic groups and the development of liver disease [41]. Between 2011 and 2018, there were 322,761 admissions to hospitals for esophageal varices. Of these, 236,802 patients (73.6%) experienced bleeding esophageal varices, while 85,959 patients (26.4%) experienced nonbleeding esophageal varices according to the National Inpatient Sample (NIS) database in the United States [43].

Although certain population groups are at an increased risk of esophageal varices, they are diagnosed across demographics. It is important to consider the most common patient without completely disqualifying the presence of other potential patient applications. This need statement aims to encourage the development of a device or model that encompasses the largest variety of patients commonly afflicted by this emergent event, without compromising device efficacy.

4) 4.1.4 Design Decision Process

To begin the design process, each team member developed two potential device concepts. In order to determine which concept was the most suitable, the design specifications in Table I were put into a pairwise comparison chart. This allowed the team to determine the importance of each design specification in order to direct the focus during the concept brainstorming. Once the most important design specifications

were selected, they were compared against each of the team members' design concepts. Through this process, the leading design concept was selected.

a) 4.1.4.1 Band Ligation

Band ligation is a procedure involving rubber bands that are placed around varices to prevent blood flow and bleeding. This procedure is often referred to as the gold standard for treating esophageal variceal ruptures. This treatment was used as the baseline for the Pugh design matrices.

b) 4.1.4.2 Balloon Tamponade

The balloon tamponade design idea featured aspects of traditional balloon tamponade scaled for application to the esophageal varices. Balloon tamponade is traditionally used for the control of refractory bleeding. The initial concept and example of this idea are shown below.

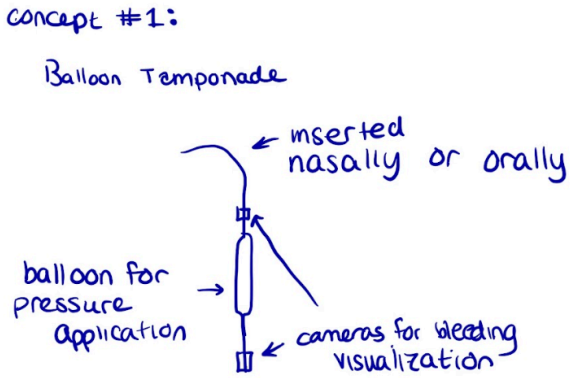


Fig. 26. The balloon tamponade design idea. This design includes a balloon that is inflated for pressure application against the esophageal walls. A camera for visualization of balloon application and patient bleeding was also included in the preliminary concepts.

c) 4.1.4.3 Clamps

The clamp concept was designed with inspiration from band ligation, meaning the clamp would target individual ruptured varices for bleeding cessation.

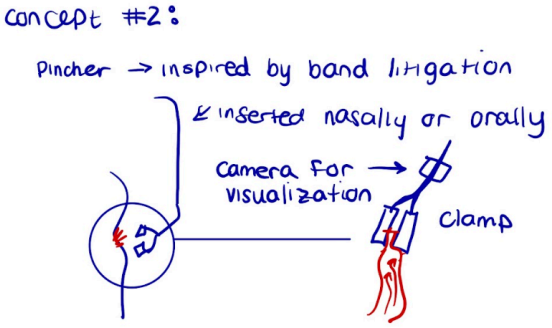


Fig. 27. The clamp design idea. This design includes a set of mechanical pinchers inserted into the esophagus by the providers to clamp varices to prevent patient bleeding. Included in this design idea was a camera for the provider to visualize the esophageal varices.

d) 4.1.4.4 Hemostatic Dressing

Hemostatic dressings are topical treatments used to reduce bleeding. They are a gauze material, often coated in powder. They are commonly used in the medical field, and due to this, were considered as a potential concept. Although hemostatic dressings are commonly used on the exterior of the body and can accurately stop blood flow, they are rarely used inside the body, as they are not safe to digest and therefore could be considered not biocompatible when inside the body.

Fig. 28. A hemostatic dressing gauze used to stop blood flow.

e) 4.1.4.5 Stent Style Polymer Tube

The stent style polymer tube was modeled after a coronary artery stent. Stents are designed to expand and hold open an artery that has decreased in diameter due to formation of build up. However, for a hemorrhaging varix the cage like nature of the stent would not be enough constant and even pressure to temporarily prevent the bleeding. Thus a flexible polymer tube that could be expanded using the same mechanism as a stent, replaced the cage style.

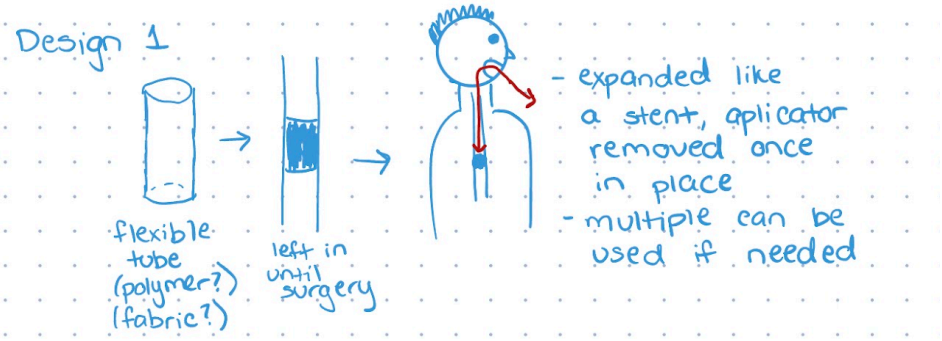


Fig. 29. The stent style polymer tube idea. This design includes a couple inch tall polymer tube that can be extended by inflating a small balloon sitting inside it, much like the balloons they use to insert stents. The tube would be placed directly over the hemorrhaging location to apply pressure to the area and stop the bleed.

f) 4.1.4.6 Rigid Plastic Tube

The rigid polymer tube idea came from the tubes that run between a patient and a ventilator. They have a more stiff structure with rings that resemble the natural tracheal rings. This design idea was to insert one of those tubes while it was flat or shrunken onto a smaller tube, then expand the tube to its full diameter. The ring structure of the tube would provide the mechanical stability needed to hold the walls of the esophagus open and apply pressure to the hemorrhaging location. The application line could then be removed, leaving the tube in place but allowing the mouth of the patient to not be occluded during intubation.

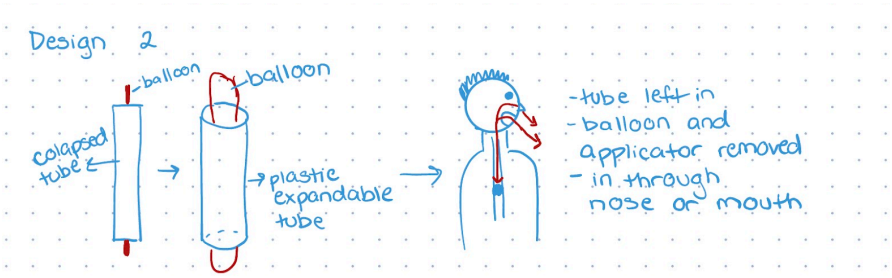


Fig. 30. The rigid plastic tube idea. This design includes a rigid plastic tube with ringlet structure that spans the majority of the esophagus. The tube would be expanded by a balloon to apply pressure to the esophagus walls and prevent the bleeding.

g) 4.1.4.7 Hemostatic Balloon

The hemostatic balloon concept was based on the design of the Sengstaken-Blakemore balloons currently used in-hospital to help mitigate esophageal variceal bleeding. An endoscope consisting of a flexible tube containing an internal light, camera lens, and suction port would be inserted into the esophagus. The endoscope would be connected to a pressure gauge, suction container, and an ergonomic control handle which would all remain external from the body. The ergonomic control handle would allow providers to control the endoscope tube inside the esophagus. The balloon would be inflated in the esophagus using the control handle, and the balloon itself made out of hemostatic dressing or covered in hemostatic coating to help further control esophageal variceal bleeding.

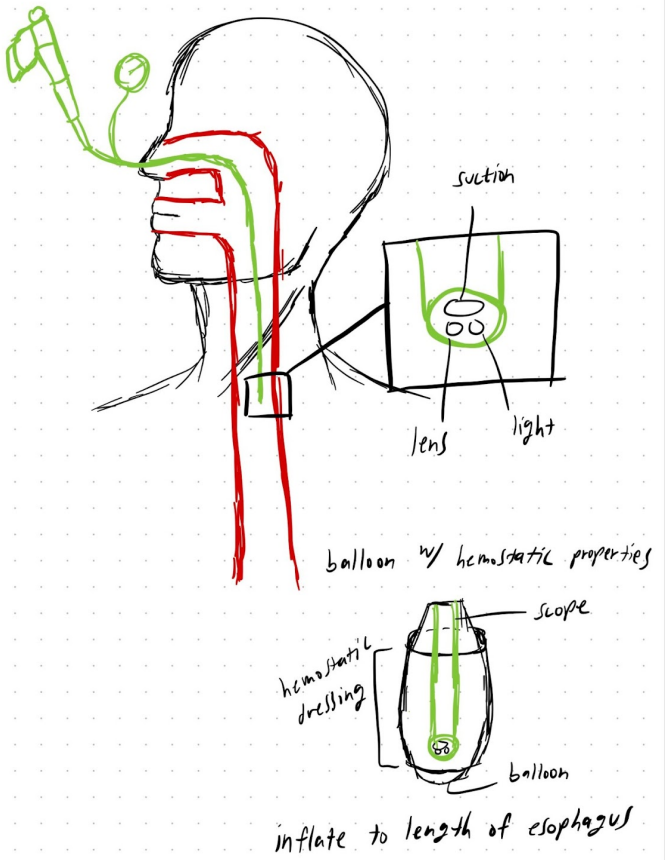


Fig. 31. Drawing of the hemostatic balloon design idea. An endoscope would be inserted into the esophagus and would contain an internal light, camera lens, and suction port as well as be connected to the hemostatic balloon. The endoscope would be connected to an external pressure gauge, suction container (not shown), and control handle. The balloon would either be made out of hemostatic dressing or covered in hemostatic coating to give the balloon hemostatic properties.

h) 4.1.4.8 Expandable Cage

The expandable cage concept was based on the design of collapsible tubes that are able to be inserted in their collapsed orientation, then expanded up to their full diameter. An endoscope consisting of a flexible tube containing an internal light, camera lens, and suction port would be inserted into the esophagus. The endoscope would be connected to a pressure gauge, suction container, and an ergonomic control handle which would all remain external from the body. The ergonomic control handle would allow providers to control the endoscope tube inside the esophagus. The cage would be able to be expanded within the esophagus using the control handle, and the cage covered in a hemostatic dressing to help further control esophageal variceal bleeding.

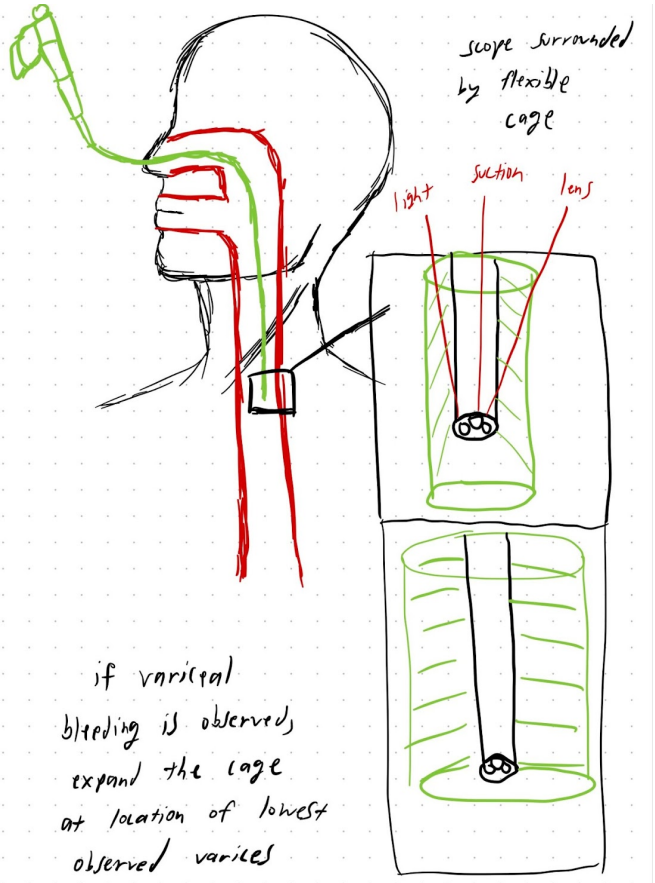


Fig. 32. Drawing of the expandable cage design idea. An endoscope would be inserted into the esophagus and would contain an internal light, camera lens, and suction port as well as be connected to the expandable cage. The endoscope would be connected to an external pressure gauge (not shown), suction container (not shown), and control handle. The cage would be covered in hemostatic dressing to give the cage hemostatic properties.

5) 4.1.5 Pugh Design Decision Matrix

In order to determine the leading concept for the device design, a Pugh design decision matrix was implemented. All of the design specifications from Table I were compared against one another, shown in the pairwise comparison chart in Fig. 33. The team implemented the following comparison strategy: if the design specification listed in the vertical column was deemed more important than that of the horizontal row, a 1 was assigned to the column specification; if the specifications were equally as important, a 0.5 was assigned to the column specification; if the horizontal row specification was considered more important than that of the column, a 0 was assigned. The numerical values of each column were then summed to determine the ranking of each specification.

Objective	Transport Time	Airway Access	Paitent Harm	Deployment Time	Provider Harm	Intentional Deployment	Need for Xray	Price	Compact Size	Hemoarrhage Reduction	Pre-hosptial Setting	Fits Esophagus	Biocompatability
Transport Time		1	1	0	1	0	0	0	0	1	0.5	1	1
Airway Access	0		0.5	0	0.5	0	0	0	0	0.5	0	0.5	0.5
Paitent Harm	0	0.5		0	0.5	0	0	0	0	0.5	0	0.5	0.5
Deployment Time	1	1	1		1	0.5	0	0	0	1	0.5	1	1
Provider Harm	0	0.5	0.5	0		0	0	0	0	0.5	0	0.5	0.5
Intentional Deployment	0	1	1	0	1		0	0	0	1	0	1	1
Need for Xray	1	1	1	1	1	1		0	0.5	1	0.5	1	1
Price	1	1	1	1	1	1	1		0.5	1	0	1	1
Compact Size	1	1	1	1	1	1	0.5	0.5		1	0.5	1	1
Hemoarrhage Reduction	0	0.5	0.5	0	0.5	0	0	0	0		0	0.5	0.5
Pre-hosptial Setting	0.5	1	1	0.5	1	1	0.5	1	0.5	1		1	1
Fits Esophagus	0	0.5	0.5	0	0.5	0	0	0	0	0.5	0		0.5
Biocompatability	0	0.5	0.5	0	0.5	0	0	0	0	0.5	0	0.5	

Fig. 33. Pairwise comparison chart comparing the design specifications listed in Table I. The leftmost criteria were compared to the criteria they intersected. The team decided which specifications were more, less or equally important to each other as shown above.

Since there were six specifications that had the same score, a second pairwise comparison chart was produced to further compare. The six top specifications could be narrowed down to determine the most essential components of the device. Fig. 34 depicts the second pairwise comparison chart. The six specifications were compared using the same system implemented during the first comparison: specifications listed in the column that were deemed more important than those listed in the row scored a 1, specifications of equal importance scored a 0.5, and column specifications deemed less important than those listed in the row scored a 0. The numerical values of each of the columns were then summed, and the top design specifications were then ranked from most important to least important based on their scores:

1. Provider Harm
2. Patient Harm
3. Airway Access
4. Hemorrhage Reduction
5. Biocompatibility
6. Fits Esophagus

Objective	Airway Access	Paitent Harm	Provider Harm	Hemoarrhage Reduction	Fits Esophagus	Biocompatability
Airway Access		0.5	1	0.5	0	0
Paitent Harm	0.5		1	0	0	0
Provider Harm	0	0		0	0	0
Hemoarrhage Reduction	0.5	1	1		0	0
Fits Esophagus	1	1	1	1		1
Biocompatability	1	1	1	1	0	
Total	3	3.5	5	2.5	0	1

Fig. 34. The secondary pairwise comparison chart compares the top six specifications from the first pairwise comparison, shown in Fig. 16. The same procedure for comparison was used in this pairwise chart. The final ranking was, in descending order: provider harm, patient harm, airway access, hemorrhage reduction, biocompatibility and fits esophagus.

Once the ranking of the top six design specifications was completed, the weights were able to be used in the Pugh analysis, wherein each team member's design concepts were compared against one another based on the most important design specifications. As shown below in Fig. 35, each design specification is listed in the first column of the Pugh matrix, with weights assigned based on ranking. The second column is the current gold standard, the "baseline", which is band ligation. Although band ligation is not a pre-hospital modality, it is commonly used to treat esophageal varices and provided the team with a physical device to compare the conceptual designs to. Each column of the Pugh matrix correlates to a design concept previously discussed. Each concept was compared to the baseline and assigned a score. If the proposed concept was considered better at meeting the design specification than the baseline, it received a 1; if the proposed concept and baseline device were equally as good at meeting the specification, the concept received a 0; if the concept was worse at meeting the specification, it received a -1. Once scoring was complete, each score was multiplied by the "weight" value listed in the score's row. Finally, the columns were summed to determine the team's leading concept. The concept with the highest score, and the team's current leading concept, is a balloon tamponade-style device, with a stent-style polymer tube and a hemostatic version of a balloon tamponade device coming in second as potential alternative designs.

Objective	Weight	Baseline = Band Ligation	Balloon Tamponade	Clamps	Hemostatic Dressing	Stent Style Polymer Tube	Rigid Plastic Tube	Hemostatic Balloon	Expandable Cage with Camera
Airway Access	4	0	1(4)	0	0	1(4)	1(4)	1(4)	-1(4)
Patient Harm	5	0	0	0	-1(5)	0	0	0	0
Provider Harm	6	0	0	0	0	0	0	0	0
Hemorrhage Reduction	3	0	1(3)	-1(3)	1(3)	1(3)	0	1(3)	-1(3)
Fits Esophagus	1	0	0	-1(1)	0	-1(1)	1(1)	0	-1(1)
Biocompatibility	2	0	1(2)	0	-1(2)	0	0	-1(2)	0
Totals			9	-4	-4	6	5	6	-8

Fig. 35. The Pugh design selection matrix. This matrix combined the weight of the specifications with the design concepts. All concepts were compared to the baseline of band ligation, listed in column 3. The associated weights were informed by the previous pairwise comparison charts. After the pairwise comparison chart, the rankings were, in descending order: balloon tamponade, stent style polymer tube & hemostatic balloon, rigid plastic tube, clamps & hemostatic dressing, and expandable cage with camera.

B. 4.2 Design Concepts

1) 4.2.1 Means of Insertion

This device must be inserted into the esophagus by the provider as a quick and effective maneuver. The device will be inserted orally using tubing similar to esophageal endoscope tubing. Suction can also be used at this stage to ensure accurate placement of the device.

2) 4.2.2 Means of Inflation

The balloon on the device will be inflated manually using an inflation mechanism similar to that of a manual blood pressure inflation. This will be controlled by the provider to provide more control in varying patient anatomy, age and sex where the esophagus may require more or less pressure to stop the bleeding.

3) 4.2.3 Means of Retraction

The device will be retracted as the patient is brought to a hospital for a permanent or more advanced maneuver, such as cauterization. At this stage the provider will deflate the balloon and remove it from the esophagus in a gentle pulling motion. With the balloon deflated, the device condenses into a smaller diameter that can easily be removed from the body.

4) 4.2.4 CAD Modeling

The final model contains three main components. The first is the main body of the tube. Encompassed in this component are two main channels with a third y-split section of the external tube piece. These Y-connection ports will be the inflation balloon connected to the inflation line and the pressure gauge for the main balloon body, allowing for more provider control as seen in Fig. 36 . Within the working channel of

the main body tube, there is a stabilization support so as to not compromise or compress the trachea. The end 250mm of the working channel is the location of the balloon.

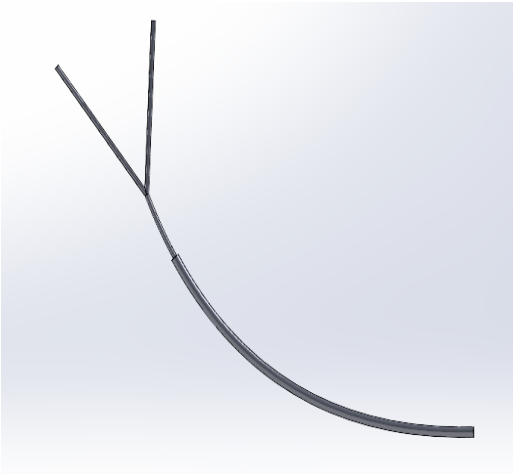


Fig. 36. The main body component of the full rescue device assembly. This component features the ports for inflation and the pressure gauge. The bottom section of the main body is the rigid section that houses the balloon. The hollow center of the device allows for suctioning by the provider down the tubing.

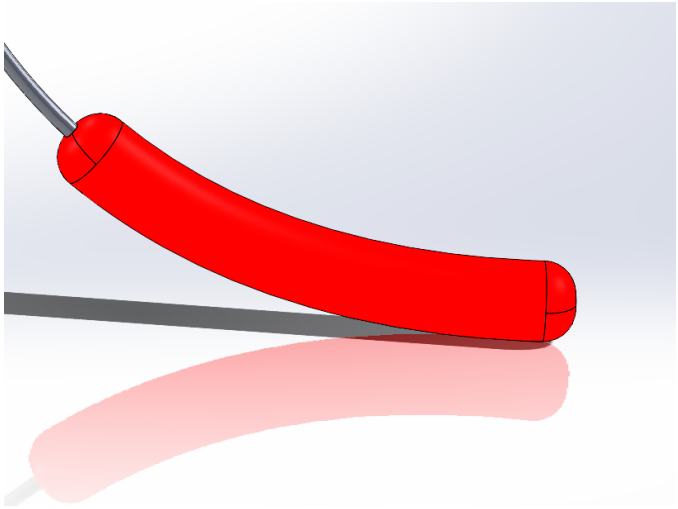


Fig. 37. The esophageal balloon body is shown. This balloon attaches to the main body tubing and applies pressure to the esophageal wall, inflated by the inflation bulb, through the inflation line of the main body tube. The hollowed center of this tubular balloon allows for suction down the length of the balloon, while maintaining pressure and inflation capabilities.

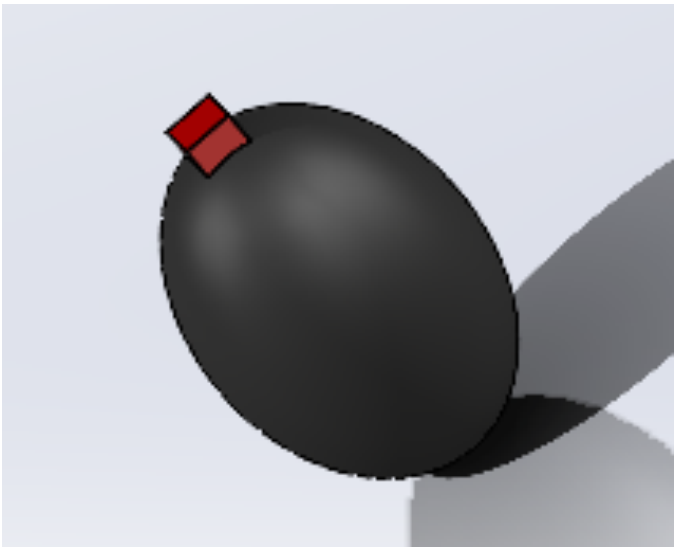


Fig. 38. The balloon inflation bulb. This bulb attaches to the inflation line and is used by the provider to inflate the balloon body, found on the main body component. This bulb contains a pressure valve that opens and closes for both inflation and deflation of the balloon, similar to the mechanism of a blood pressure cuff bulb.

The second component is the balloon body. This is a thin-ringed balloon design able to inflate to apply pressure to the inside of the walls of the esophagus. The balloon is attached to the end of the main body tubing through medical adhesive sealant. The balloon is 250 mm, designed to span the length of a majority of the 400 mm human esophagus. The main balloon body is inflated by the pressure balloon, attached to one end of the Y-Connection port on the main tube body. This will allow the provider to inflate and deflate the balloon manually. The top piece functionality is inspired by a blood pressure cuff inflation balloon, where the deflation is initiated by the turning of the knob, modeled in red. The full assembly, shown in Fig. 39, shows the device in entirety with all components. Each component will be connected via biocompatible medical adhesive, commonly used in endotracheal tubes or King tubes. The full assembly as shown in Fig. 39 contains all the components, as they interact with each other. For visibility ease, the balloon components are shown in opaque black, which may not reflect the final manufacturing color. The dimensions of the product are shown in Fig. 40 conforming to ASME standards.

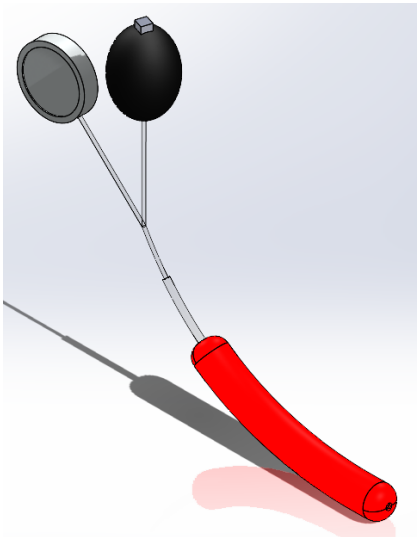


Fig. 39. An isometric view of the complete rescue device assembly. The main body tubing, the balloon body,the inflation bulb and a pre-purchased pressure gauge are shown. The device will be assembled using medical grade UV sealant.

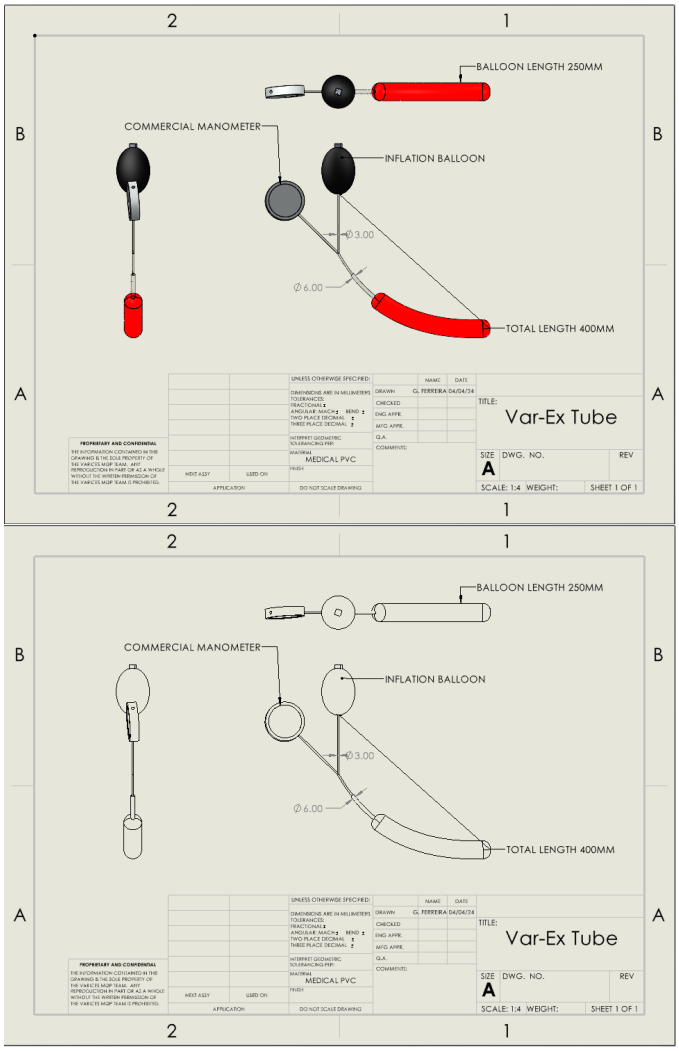


Fig. 40. The rescue device assembly drawing. This drawing shows the critical dimensions of the full device. The scale of the drawing is 1:8 and contains the critical drawing views as well as the isometric view. All of the dimensions of the device are listed in mm, with the associated +/- 0.1 mm tolerances. This is drawing 1:1 for the complete device assembly and is on drawing size A.

5) 4.2.5 Minimum Viable Product

In order to begin prototyping from our CAD designs, the team first created a minimum viable product to gather an idea of how the team could create our device. The main body of the model is an animal endotracheal tube. This shows the basic concept of the balloon while deflated, and then the ability to have a provider inflate the balloon once it is properly placed. A piece of lumen tubing was attached, and the blood pressure cuff pressure gauge was attached to the tube. The blood pressure cuff bulb was attached to the inflation line of the endotracheal tube. This model can be seen below in Fig. 41.

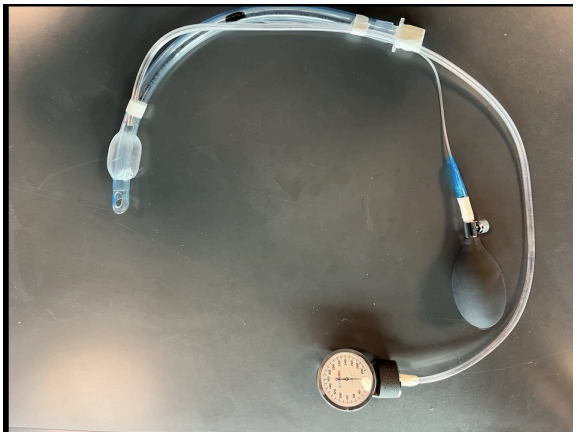


Fig. 41. The minimum viable product. This model was assembled for dimensionalities as well as visualization purposes. Due to the assembly style, the balloon was not inflated by the inflation bulb or line, meaning it is not a working model, but represents the approximate size and assembly of the final device.

This model is nonfunctional since the bulb and the pressure gauge are not actually connected to the balloon. The lumen tubing is simply taped to the endotracheal tube, blub, and pressure gauge. Physical visualization of our concept was the main focus of this model, so functionality was not of high importance. The balloon of the endotracheal tube can be inflated and deflated by the small built in inflation tube for visualization purposes.

6) 4.2.6 Semi-Functional Prototype One

Moving along in the prototyping process, the next step was to create a semi-functional model. The small PVC balloon was cut off of a human 6.5mm endotracheal tube so the built-in airline could be utilized. A balloon animal party balloon was cut at both ends, and stretched over the endotracheal tube, covering the inflation point from the original balloon. The ends of the balloons were sealed to the tube with duct tape. The syringe that comes with the endotracheal tube was used to inflate and deflate the balloon. The inflated balloon can be seen in Fig. 42.

Fig. 42. Inflated balloon on the human endotracheal tube. This model used previously-installed aspects of the endotracheal tube, such as the built-in inflation line to show proof-of-concept for the inflation of a larger and longer balloon on a similar size medical tubing.

This is the first iteration of functional models. The next steps in the prototyping process are to refine the materials the team will be using, and assemble the model based off of the CAD design. This will require adding the inflation bulb and pressure gauge to the endotracheal tube and extending the balloon to the correct dimensions. As well as changing all of the pieces to the desired biocompatible materials.

7) 4.2.7 Feasibility Studies

Following the development of a working prototype, several tests must be conducted in order to determine the feasibility of the design. Each determination has an associated test method to be performed. The following chart shows the tests to be performed to determine if the device design is feasible before more advanced prototyping and assembly occurs:

Table III: Test procedures that will be used to determine functionality of the device.

Determination	Relevant Experiment
Ability of the balloon to apply pressure in a tube.	The balloon will be inflated into a small tube to determine the amount of force that can be applied to gauge applicability of pressure application.
Ability of the balloon to inflate.	The balloon will be inflated manually to ensure it is feasible by a provider without popping or increasing time of deployment by too much.
Ability of a balloon to be inserted into an esophageal sized tube.	The balloon will be attached to an insertion model and inserted into a similarly sized tube.

Determination	Relevant Experiment
Ability of the balloon to apply pressure in a tube.	The balloon will be inflated into a small tube to determine the amount of force that can be applied to gauge applicability of pressure application.
Ability of the balloon to inflate.	The balloon will be inflated manually to ensure it is feasible by a provider without popping or increasing time of deployment by too much.
Ability of a balloon to be inserted into an esophageal sized tube.	The balloon will be attached to an insertion model and inserted into a similarly sized tube.

To test the concept of the balloon as listed above, a very basic proof of concept model was created. The first piece of this model was the esophagus, a 40mm diameter PVC pipe, with a hole drilled into the side and a section of lumen tube inserted. This lumen tubing was used as a siphon to run water dyed red, the blood in this scenario, through the pipe, acting as the hemorrhaging vein. This test was run two different times, once with a simple party balloon, and again with a king tube. In both cases, when the balloon was inflated the pressure it exerted on the walls of the PVC pipe was enough to stop the flow of the water through the pipe. Thus validating that the balloon can apply pressure in a tube, inflate properly in the tube. A visual of this test with the king tube can be seen below in Figure 43. See Appendix A for the full testing procedure.

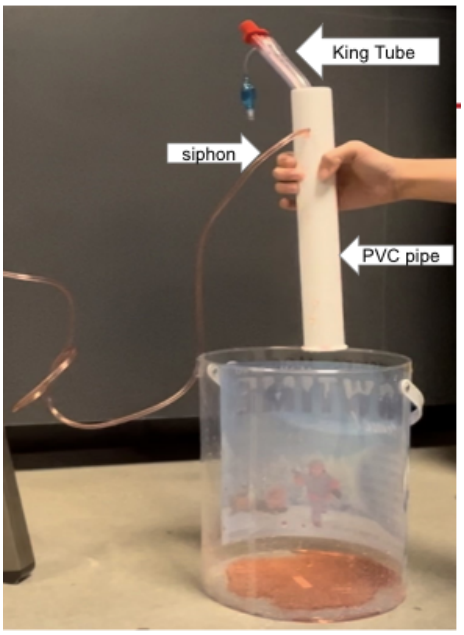


Fig. 43. The King tube with balloon inflated in the 40mm PVC pipe, preventing the flow of the water through the tube. This test served to represent that the balloon could occlude a flowing liquid source. This meant that the concept of balloon-applied pressure for bleeding cessation was viable.

To test the second specification in Table III, the first prototype was created. This prototype is described above in section 4.2.6. Using the syringe to pump air through the inflation line of the endotracheal tube, the longer balloon was able to be fully inflated and deflated multiple times. See Appendix A for full test protocol.

In order to test the third specification in Table III, the ability of the balloon to be inserted into an esophageal sized tube, a to scale model was needed. The team acquired an intubation mannequin, which has an anatomically correct size trachea and esophagus. The esophagus tube was removed from the mannequin and brought to a sink in the lab. Using the semi-functional prototype, which is described in detail in the Semi-functional Prototype 1 section, the device was inserted into the bottom of the tube while water from the sink was running through the tube. The balloon on the model was then inflated and was able to prohibit the water from flowing all the way through the tube, the water pooled on top of the balloon since it was coming from the top of the esophagus tube. Thus confirming that the inflated balloon on the model is able to be inserted and inflated within an esophageal sized tube.

C. 4.3 Alternative Designs

The designs shown below show the iterative process needed to finalize the design through CAD modeling.

1) 4.3.1 Alternate Design 1

The first design proposed by the team was a simple, single-tubed balloon support with an associated, multi-port top portion for multiple suction lines and for inflation. The balloon in this design was 125mm, significantly smaller than the final design. Additionally, the port piece was determined to be unnecessary if the working line was large enough.

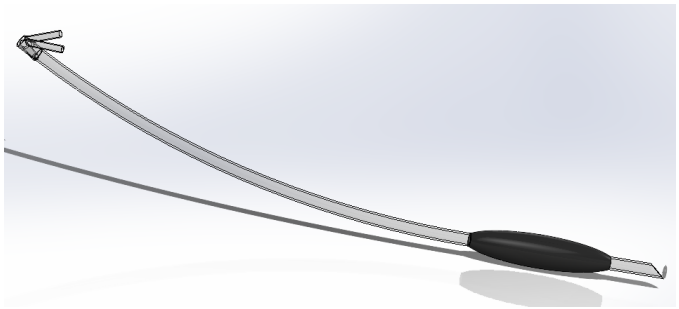


Fig. 44. The first alternative design of the rescue device. This design included an additional port piece for more lines to be run through the main body tubing. This was deemed unnecessary as the working channel could accommodate a suction line without the need for an additional port. Additionally, the balloon was sized at 125 mm, smaller than the final design.

2) 4.3.2 Alternate Design 2

In the second iteration of the rescue device design, a second, external and attached inflation line was added to reduce the risk of inflation line failure through a separate chamber. The inflation balloon was also modeled as attached to the line for operator ease. Additionally, blood drains were added to aid in provider understanding of variceal location when suctioning.

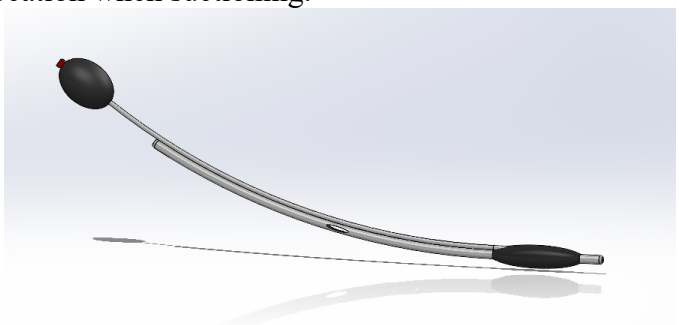


Fig. 45. The second alternative design of the rescue device. This design did not include a pressure gauge, but did introduce blood ports to the main body tube for drainage to allow the provider to suction along the length of the esophagus and determine the potential location of the varix based on bleeding patterns. The 3-port adapter was removed and the main body tube was lengthened for ease of insertion.

3) 4.3.3 Alternate Design 3

The third iteration of the design included a wider working chamber for suctioning purposes as well as a balloon that was increased in size to 400 mm to better cover the entire length of the esophagus. Additionally, the decision was made for the external portion of the device to be reduced for ease of management outside of the body.

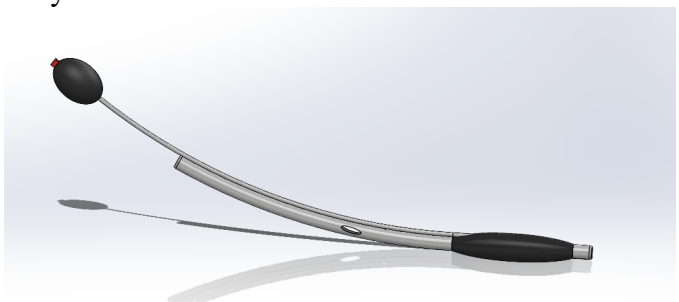


Fig. 46. The third alternative design of the rescue device. This design included an increased balloon size for more esophageal length coverage. This design did not include the pressure gauge aspect of the final design. The length of tubing extending out of the body was shortened for ease of line management for the provider.

D. 4.4 Final Design Selection

1) 4.4.1 Dimensions of Main Body Tube

In order for the device to properly fit the esophagus of the average adult, the main body tube needs to run from the mouth to the lower esophageal sphincter. This is a distance of about 40 cm from the incisors to the

LES [44]. Thus, the distance of the main tube is 400mm so the base of the balloon will reach the lower esophageal sphincter and the other end of the tub rests in the patient's mouth to prevent the tube from slipping too low.

2) 4.4.2 Dimensions of Balloon

The final device features a balloon 250 mm in length so the balloon can more easily cover the majority of the 400mm length of the esophagus. The device is designed so that the balloon meets the lower esophageal sphincter and can be moved up the esophagus in situations where varices would appear in the upper esophagus rather than the lower esophagus. The balloon should be able to exert 40 mmHg of pressure against the varices/esophagus, as referenced in Figure 9.

3) 4.4.3 Closed Tube

The final device features a closed tube design to allow the provider to run a lumen suction line down the device to suction blood in the lower esophagus or stomach. As esophageal varices typically develop in the lower third of the esophagus [45], distal to the incisors, this device was designed to not occlude the trachea with a thin diameter tube (Figure 40 references the design dimensions). In the rare chance the varices rupture in the upper portion of the esophagus, where it parallels the trachea, the provider will be able to visualize the bleeding and manually move the balloon to a higher position to apply the pressure to the upper esophagus.

4) 4.4.4 Pressure gauge and single built-in inflation line and pressure bulb

The final device also includes a pressure gauge, a pressure bulb, and a single built-in inflation line. These three aspects of the design were significant in the overall functionality of the device. The built-in inflation line is what allows the device’s balloon to inflate to the needed size. The pressure gauge and pressure bulb are used to help control the inflation rate of the balloon.

VIII. 5.0 Final Design Verification

A. 5.1 Overview of Testing

The testing of the Var-Ex Tube was performed in stages and at the individual sub-system level. Each test targeted an aspect of functionality or a design specification integral for device use. The device was tested rigorously to ensure statistical significance of results and applicability in use. The main subsystem tests that were performed were primary proof of concept testing, biocompatibility testing for the materials used, sealant and balloon tensile strength testing and pressure gauge calibration. The entire device was tested to ensure it was able to occlude fluid flow and that it could successfully be inserted into a mannequin esophagus. The balloon of the device was also tested to ensure it would hold pressure for an extended period of time and finally that the device would not hinder suctioning through the esophagus.

B. 5.2 Proof of Concept Testing

1) 5.2.1 Prevention of Water flow by Inflation of Balloon

Using a PVC pipe to represent the esophagus, water was run into the pipe through a siphon, and a balloon was inflated inside to prevent the flow of water. The results of this test are qualitative, see images below. See Appendix A for full test methodology.

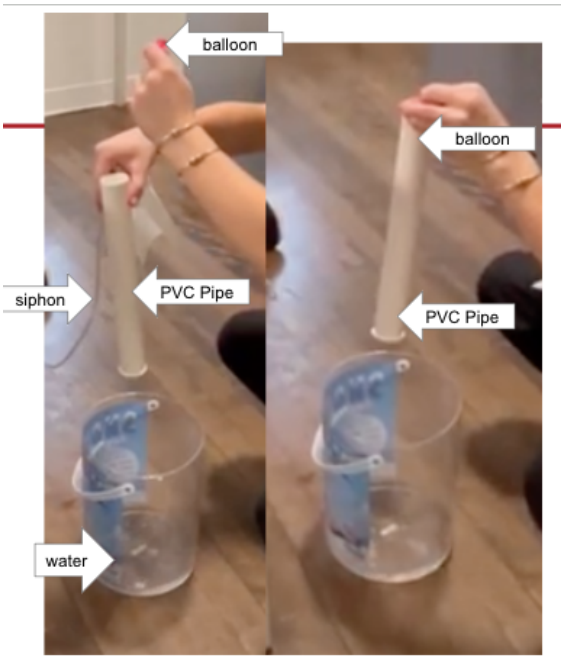


Fig. 47. This figure depicts the flow of water with and without the balloon inflated in the PVC pipe. The left image shows motion in the water at the bottom of the bucket, as the water is running through the PVC pipe and into the bucket because nothing is in the tube preventing it. The balloon is still in the team member's hand in the left image. The right image shows no flow through the tube, as the balloon is inflated in the top of the PVC pipe and thus preventing the flow of water through the pipe.

2) 5.2.2 Prevention of Water Flow with a King Tube

Using a PVC pipe to represent the esophagus, water was flowing through it from a siphon in the side of the pipe, and a king tube was inserted and inflated within the pipe. The results of this test are qualitative, see images below. See Appendix B for full test methodology.

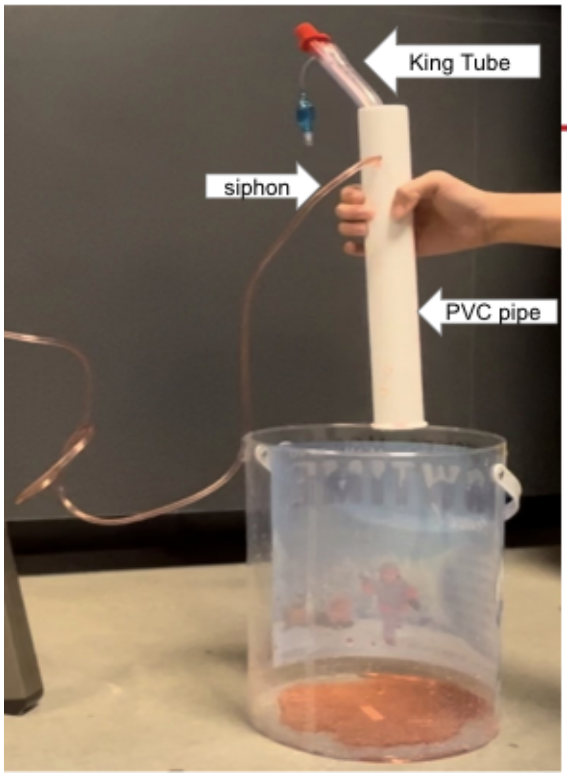


Fig. 48. The King tube is in the PVC pipe and the balloon is inflated, preventing the flow of the water through the tube. This test served to represent that the balloon could occlude a flowing liquid source. This meant that the concept of balloon-applied pressure for bleeding cessation was viable.

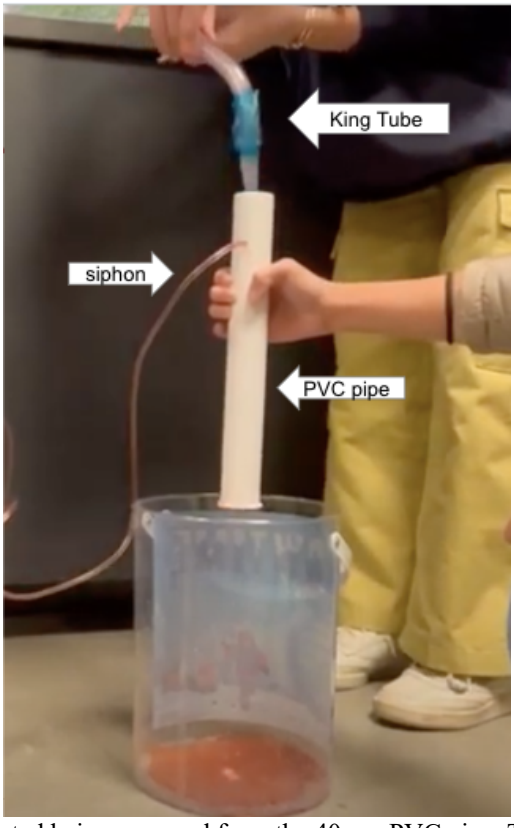


Fig. 49. The king tube with balloon deflated being removed from the 40mm PVC pipe. There is more red water at the bottom of the bucket than in Figure 48 because it begins to flow through the pipe again once the balloon is deflated.

3) 5.2.3 Ability to Inflate Larger Balloon with Endotracheal Tube Inflation Line

The small balloon on an endotracheal tube was removed, a 6 inch party balloon was then put over the endotracheal tube and sealed with duct tape. The results of this test are qualitative, see images below. See Appendix C for full test methodology.

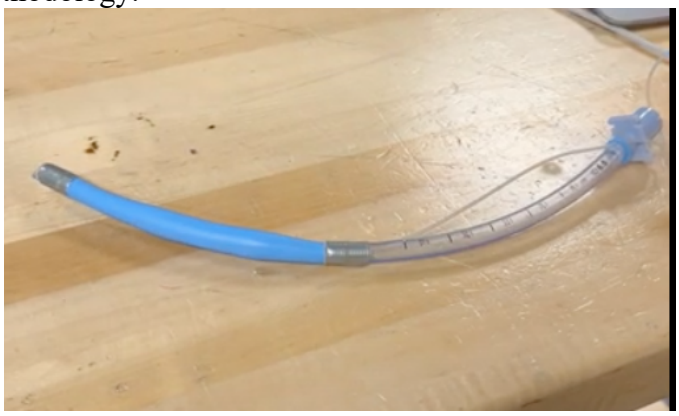


Fig. 50. A longer party balloon was installed on a human endotracheal tube. The ends of the balloon were sealed with duct tape. This figure shows the balloon deflated, but it can be inflated using the inflation line of the endotracheal tube.

Fig. 51. The same party balloon installed on a human endotracheal tube as the previous figure. This figure shows the balloon fully inflated, it was inflated through the manufactured inflation line of the human endotracheal tube.

4) 5.2.4 Larger Balloon on Endotracheal Tube, Prevention of Fluid Flow

A 15mm diameter tube was attached to a sink and the water was running through it. The modified endotracheal tube from the last test was inserted into the bottom of the tube and then the balloon was inflated. The results of this test are qualitative, see images below. See Appendix D for full test methodology.

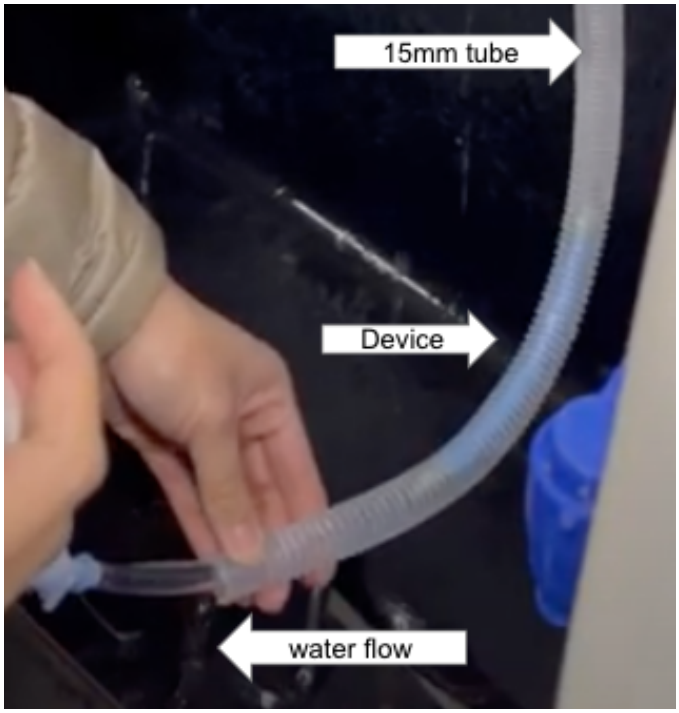


Fig. 52. The tube is connected to the sink, with water flowing through it. The endotracheal tube with the party balloon from the previous figure is inserted into the bottom of the tube. The balloon is not inflated, allowing the water to flow through the tube, and run out of the bottom of the tube as shown here.

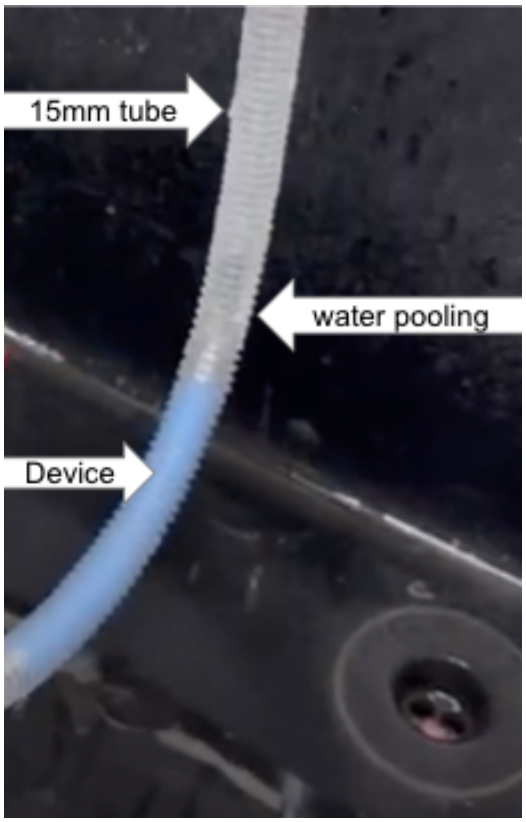


Fig. 53. The tube is connected to the sink and has water flowing through it. The endotracheal tube with a longer balloon has been inserted into the tube. The balloon has been inflated and is preventing the flow of water through the tube. The water can be seen pooling at the top of the tube, above the inflated balloon.

C. 5.3 Biocompatibility Testing

Trial 1 was conducted with 6 separate 25mm tissue culture plates of P7 HLM-vec cells seeded at 150,000 cells per ml. The cells were given 24 hours to attach before being introduced to materials. Trial 2 was conducted with a 6 well plates seeded at 100,000 cells per ml with P9 HLM-vec cells. The cells were given 24 hours to attach before being introduced to materials. Trial 3 was conducted with a 6 well plate seeded at 60,000 cells per ml, and left for 48 hours to allow the cells to attach, with P9 HLM-vec cells. See Appendix E for full test methodology.

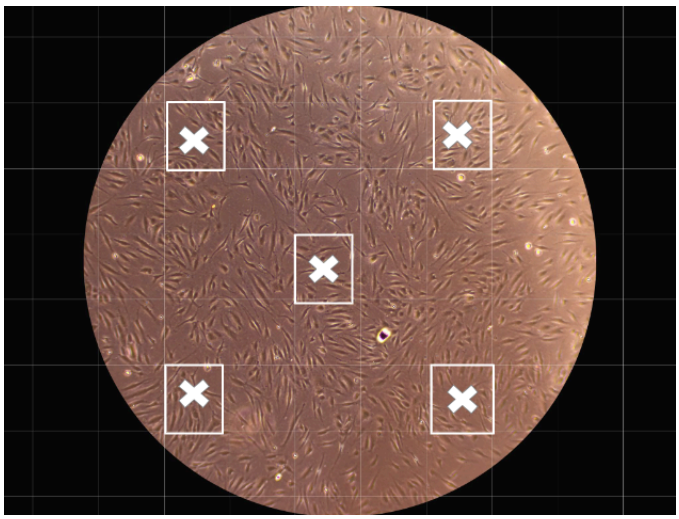


Fig. 54. This image shows the grid applied over the image of the cells, with the counted boxes clearly outlined and marked with an X. Each box was counted and then all five were added together to get the count for one photo. This same process was used for all wells.

1) 5.3.1 Tubing Material

Table IV: A grid was placed on top of each image in ImageJ and five of the boxes in the grid were counted. There were two wells with tubing pieces placed in them for each trial. The difference was calculated by subtracting the before count from the after count. Any major cell loss was due to surface scratching or physical damage, not to cytotoxicity.

Tubing Matieral	Before 1	After 1	Difference 1	Before 2	After 2	Difference
Trial 1	80	65	-15	84	94	10
Trial 2	124	110	-14	115	127	12
Trial 3	126	96	-30	102	89	-13

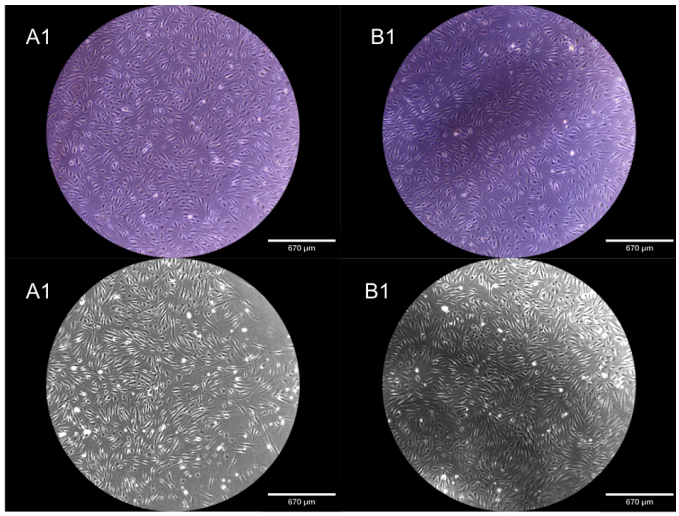


Fig. 55. This figure shows the wells of cells that were exposed to the tubing material in trial one. The top row images were taken before the materials were added into the wells. The bottom row images were taken after the cells had been exposed to the materials for 24 hours.

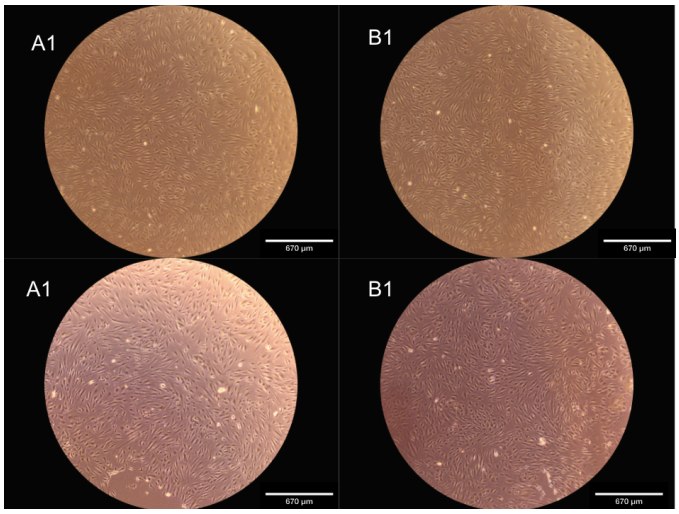


Fig. 56. This figure shows the wells of cells that were exposed to the tubing material in trial two. The top row images were taken before the materials were added into the wells. The bottom row images were taken after the cells had been exposed to the materials for 24 hours.

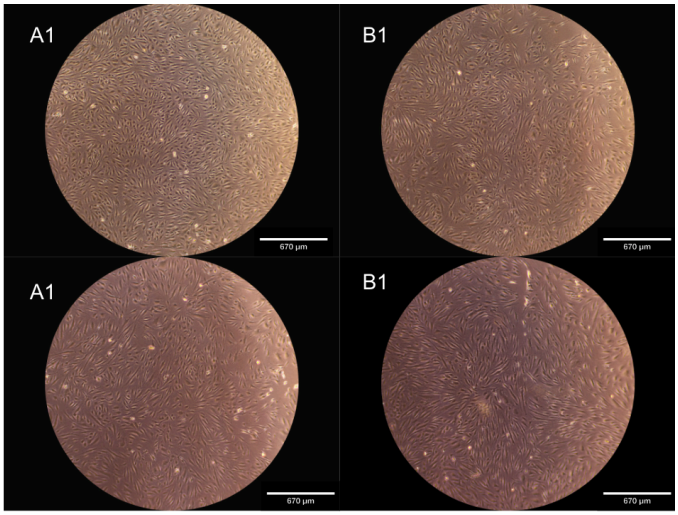


Fig. 57. This figure shows the wells of cells that were exposed to the tubing material in trial three. The top row images were taken before the materials were added into the wells. The bottom row images were taken after the cells had been exposed to the materials for 24 hours.

2) 5.3.2 Balloon Material

Table V: A grid was placed on top of each image in ImageJ and five of the boxes in the grid were counted. There were two wells with balloon pieces placed in them for each trial. The difference was calculated by subtracting the before count from the after count. Any major cell loss was due to surface scratching or physical damage, not to cytotoxicity.

Balloon Matieral	Before 1	After 1	Difference 1	Before 2	After 2	Difference
Trial 1	103	102	-1	99	100	1
Trial 2	128	151	23	167	105	-62
Trial 3	114	124	10	103	137	34

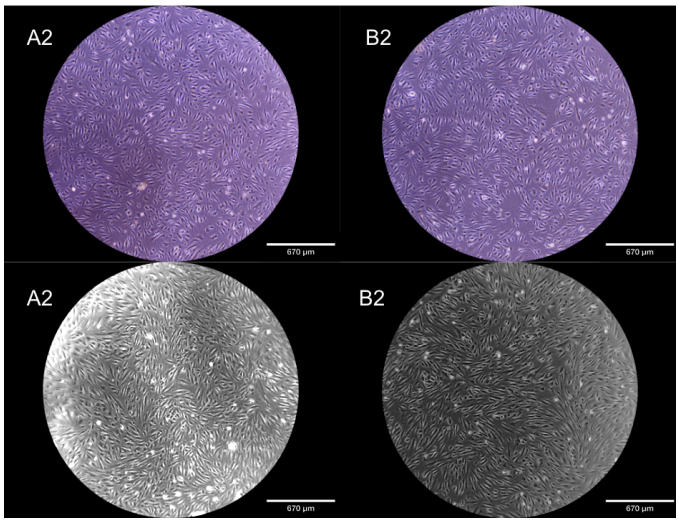


Fig. 58. This figure shows the wells of cells that were exposed to the balloon material in trial one. The top row images were taken before the materials were added into the wells. The bottom row images were taken after the cells had been exposed to the materials for 24 hours.

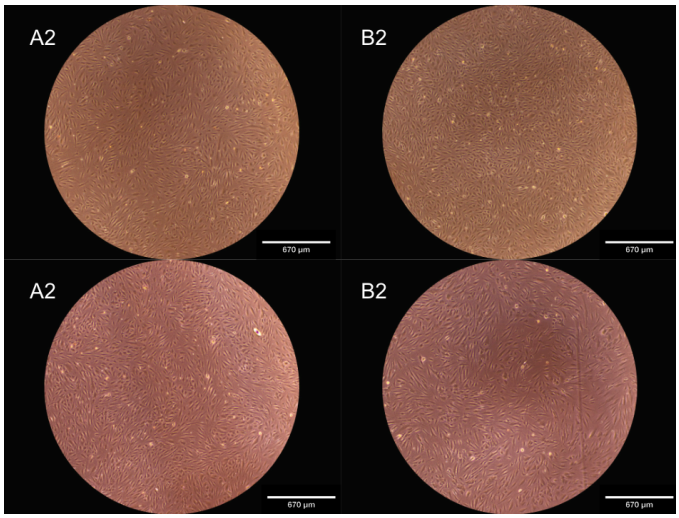


Fig. 59. This figure shows the wells of cells that were exposed to the balloon material in trial two. The top row images were taken before the materials were added into the wells. The bottom row images were taken after the cells had been exposed to the materials for 24 hours.

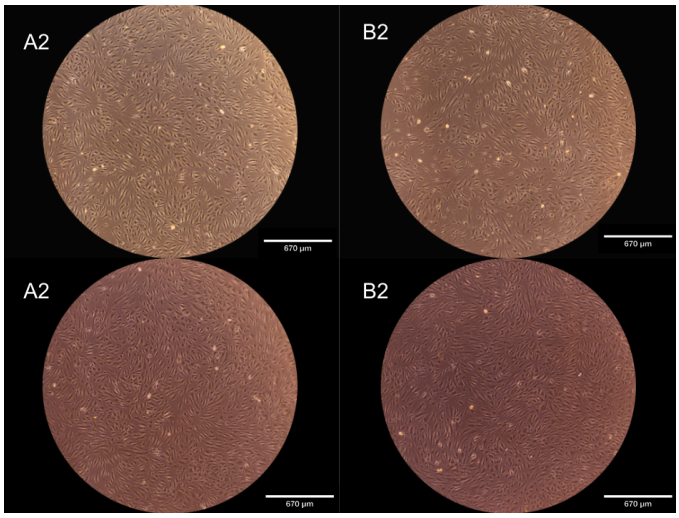


Fig. 60. This figure shows the wells of cells that were exposed to the balloon material in trial three. The top row images were taken before the materials were added into the wells. The bottom row images were taken after the cells had been exposed to the materials for 24 hours.

3) 5.3.3 Control Wells

Table VI: A grid was placed on top of each image in ImageJ and five of the boxes in the grid were counted. There were two wells with no pieces placed in them for each trial, these acted as our control wells. The difference was calculated by subtracting the before count from the after count. Any major cell loss was due to surface scratching or physical damage, not to cytotoxicity.

Controls	Before 1	After 1	Difference 1	Before 2	After 2	Difference
Trial 1	85	106	21	86	89	3
Trial 2	98	116	18	106	117	11
Trial 3	88	104	16	82	111	29

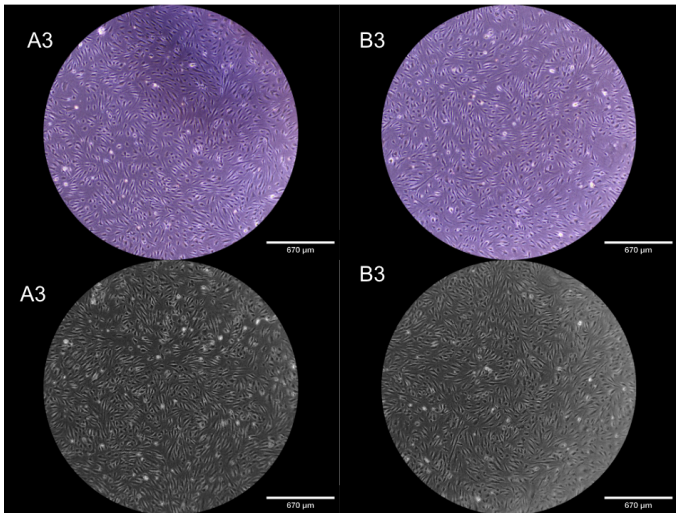


Fig. 61. This figure shows the wells of cells that were in the control wells in trial one. The top row images were taken before the materials were added into the non-control wells. The bottom row images were taken after 24 hours. These images were taken in the same time frame as the wells that were exposed to materials.

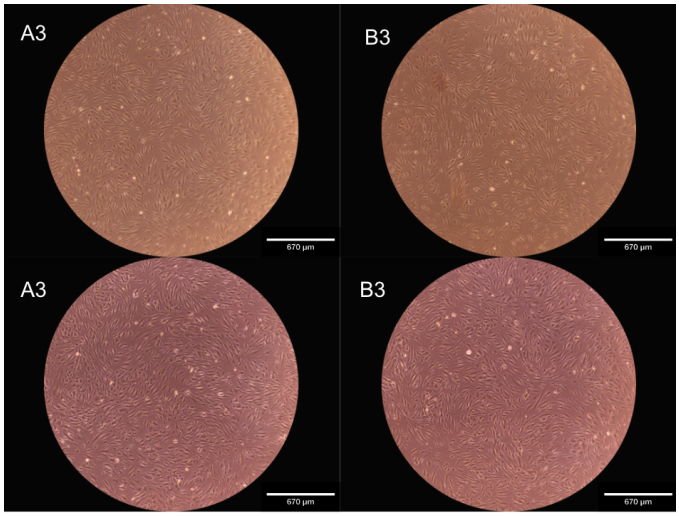


Fig. 62. This figure shows the wells of cells that were in the control wells in trial two. The top row images were taken before the materials were added into the non-control wells. The bottom row images were taken after 24 hours. These images were taken in the same time frame as the wells that were exposed to materials.

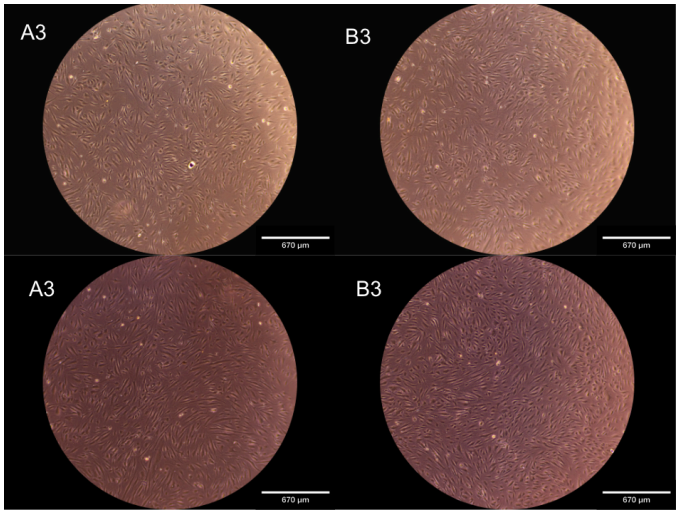


Fig. 63. This figure shows the wells of cells that were in the control wells in trial three. The top row images were taken before the materials were added into the non-control wells. The bottom row images were taken after 24 hours. These images were taken in the same time frame as the wells that were exposed to materials.

D. 5.4 Sealant Testing

The following data was collected per the sealant test methodology protocol. The composition of medical cyanoacrylate is almost identical to superglue, so for cost savings, generic superglue (non-medical cyanoacrylate) was used in testing. A Y-connector and device tubing, cut into 2-inch strips, was used as the subject of the trials for tensile testing.

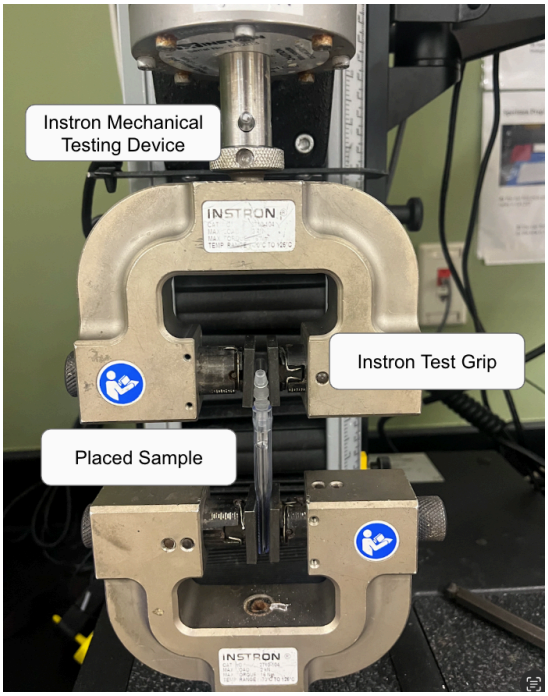


Fig. 64. The Y-Connector and tube, bonded with superglue, inserted into the Instron testing grips.

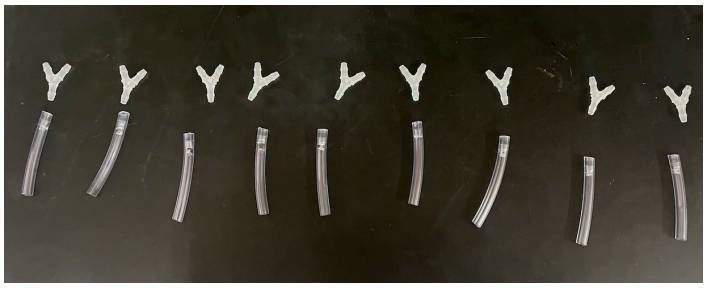


Fig. 65. The nine sealant samples, after the Instron tensile testing. The y-connector pieces are disconnected from the tubing at various force amounts, recorded by the Instron Bluehill Software.

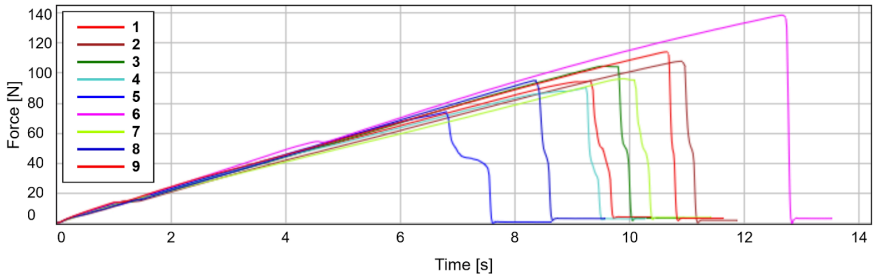


Fig. 66. The forces at which each of the nine samples, bonded using superglue sealant disconnected from the main tubing.

Table VII: This table shows the results in Newtons and mm of the force at tensile strength and displacement at tensile strength of each of the tested specimens, listed on the left of the table. Automatic statistical calculations completed by the Instron Bluehill Software are shown below.

	Specimen number (included)	Maximum Force [N]	Tensile stress at Maximum Force [MPa]
1	1	95.02	1.89
2	2	107.94	2.15
3	3	104.65	2.08
4	4	90.36	1.80
5	5	74.19	1.48
6	6	138.66	2.76
7	7	96.26	1.92
8	8	95.18	1.89
9	9	114.14	2.27
Mean	5	101.82	2.03
Maximum	9	138.66	2.76
Median	5	96.26	1.92
Minimum	1	74.19	1.48
Range	8	64.47	1.28
Standard deviation	2.74	17.92	0.36

Please see Appendix F for the complete sealant test methodology.

E. 5.5 Pressure Gauge Testing

1) 5.5.1 Pressure Loss Testing

The following data was obtained from the pressure loss testing protocol (please refer to Appendix G for detailed test methodology and protocol). A pressure sensor was connected to the open end of the Y-connector through a line, and the bulb was pumped until the pressure read 60 mmHg. The purpose of this test was to identify the amount of pressure lost from the point of inflation (inflation bulb) to the point at which the inflation line is attached to the pressure gauge and inflation bulb (Y-connection piece).

Table VIII: The table displays the readings from the pressure gauge and sensor, as well as the percent error of the gauge.

Trial	Pressure Reading - Gauge (mmHg)	Pressure Reading - Sensor (inHg)	Pressure Reading - Sensor (mmHg conversion)	Percent Error of Pressure Gauge*
1	60	2.31 +/- 0.02	58.674 +/- 0.508	2.26%
2	60	2.27 +/- 0.02	57.658 +/- 0.508	4.06%
3	60	2.27 +/- 0.02	57.658 +/- 0.508	4.06%
4	60	2.29 +/- 0.02	58.166 +/- 0.508	3.15%
5	60	2.31 +/- 0.02	58.674 +/- 0.508	2.26%

2) 5.5.2 Pressure Sensor Verification

The following data was obtained from the pressure gauge testing protocol (please refer to Appendix H for detailed test methodology and protocol). Due to limited available calibration machines/tools, the team was not able to calibrate the device's pressure gauge directly. To solve this problem, a pressure sensor was calibrated and the device gauge assumed to be pre-calibrated. The purpose of this test was to apply pressure directly to the pressure sensor and ensure the sensor was able to reach a target pressure of approximately 60 mmHg. The device pressure gauge was assumed to be pre-calibrated prior to use as the pressure gauge's original intent was for use in blood pressure cuffs to take blood pressure readings and would not be calibrated between uses. This test thus ensured the pressure sensor could be calibrated to the target pressure and assumed the device pressure gauge was pre-calibrated, thus indicating the results from the pressure loss

testing were not due to pressure sensor error, but due to true pressure loss observed during pressure loss testing.

Table IX: The table displays the readings obtained from the pressure sensor upon applying pressure directly to the sensor using the pressure inflation bulb.

Pressure Sensor Value (inHg)	Pressure Sensor Value (mmHg)
-3.14	-79.76
-9.80	-248.92
-6.80	-172.72
-5.96	-151.38
-2.45	-62.23
-3.77	-95.76
-2.02	-51.31
-2.24*	-56.90

F. 5.6 Volume Occlusion Testing

The following data was obtained per the volume testing protocol where a pipe representing the esophagus and a tube representing a varix were used as a model for hemorrhage reduction with and without the Var-Ex Tube Present. The purpose of this test was to determine the device's ability to occlude liquid in an esophageal model. Please see Appendix I for the complete test methodology.

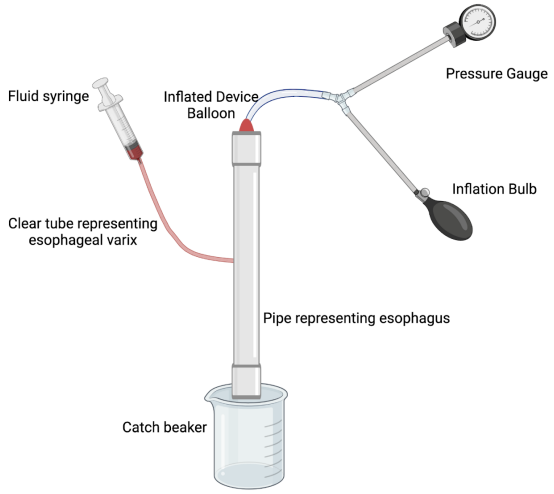


Fig. 67. The experimental setup used to obtain the values of the volume occlusion trials. The fluid entering the tube and the fluid measured after the trial in the discharge catch beaker was recorded with and without the device in place in the pipe.

Table X: The percent of fluid that was occluded and the volumetric amount, in mL, of fluid occluded without the device present in the model.

Trial Number	Fluid Entering Tube (mL)	Fluid Measured After in Discharge Container (mL)	Volume Difference (mL)	Percentage of Fluid Occluded
1	60	58	2	0.03333333333
2	60	59	1	0.01666666667
3	60	57	3	0.05
4	60	58	2	0.03333333333
5	60	60	0	0

Trial Number	Fluid Entering Tube (mL)	Fluid Measured After in Discharge Container (mL)	Volume Difference (mL)	Percentage of Fluid Occluded
1	60	7	53	0.8833333333
2	60	5	55	0.9166666667
3	60	4.5	55.5	0.925
4	60	5	55	0.9166666667
5	60	4	56	0.9333333333

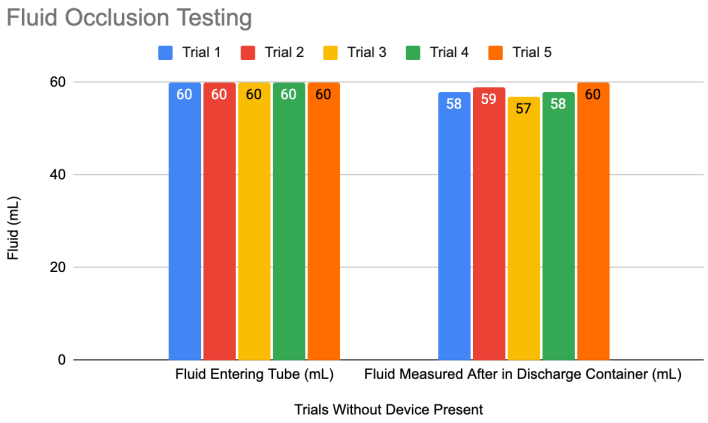


Fig. 68. The fluid occlusion testing results without the device present, comparing the fluid entering the tube and the fluid measured in the discharge container after testing.

Table XI: The percent of fluid that was occluded and the volumetric amount, in mL, of fluid occluded with the device present in the model.

Trial Number	Fluid Entering Tube (mL)	Fluid Measured After in Discharge Container (mL)	Volume Difference (mL)	Percentage of Fluid Occluded
1	60	58	2	0.03333333333
2	60	59	1	0.01666666667
3	60	57	3	0.05
4	60	58	2	0.03333333333
5	60	60	0	0

Trial Number	Fluid Entering Tube (mL)	Fluid Measured After in Discharge Container (mL)	Volume Difference (mL)	Percentage of Fluid Occluded
1	60	7	53	0.8833333333
2	60	5	55	0.9166666667
3	60	4.5	55.5	0.925
4	60	5	55	0.9166666667
5	60	4	56	0.9333333333

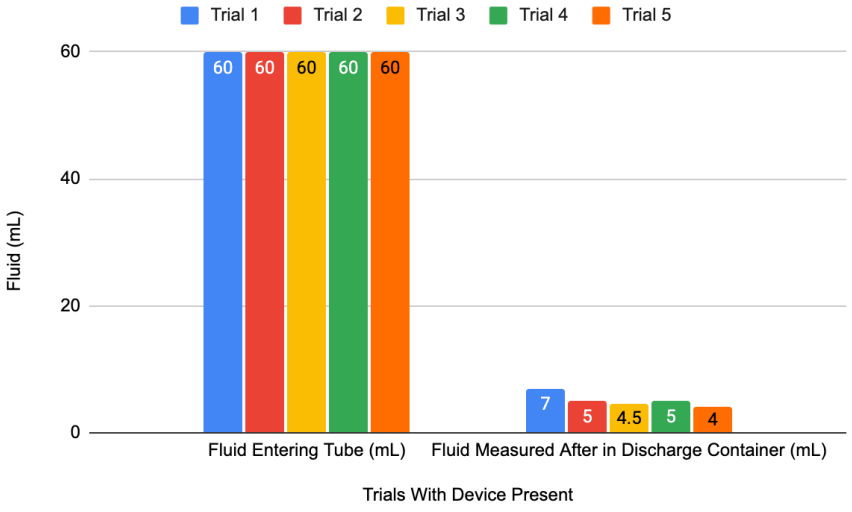


Fig. 69. The fluid occlusion testing results with the device present, comparing the fluid entering the tube and the fluid measured in the discharge container after testing.

G. 5.7 Inflation Bulb Testing

The purpose of this test was to evaluate the inflation bulb's ability to accurately inflate the balloon to the desired pressure. The results of this test are qualitative, see the image below. See Appendix J for full test methodology.

Fig. 70. The device is able to inflate to a particular pressure and can maintain that pressure for an extended period of time. This image shows the device with the balloon inflated by the inflation bulb, holding air, and the bulb and pressure gauge are also visible.

H. 5.8 Leakage Testing

The Var-Ex tube was sprayed down with soapy water, and then inflated to check for any air leaks. The results of this test are qualitative, see images below. See Appendix K for full test methodology.

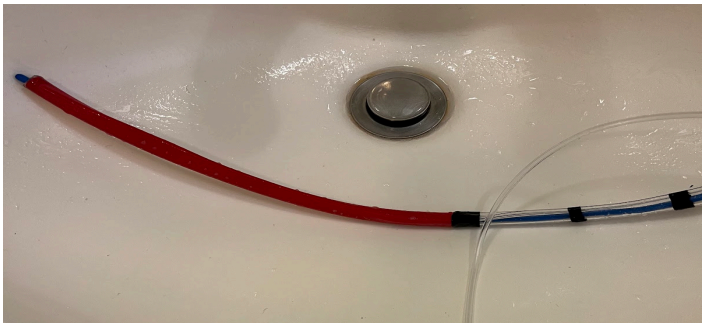


Fig. 71. The device is in the sink, and has been sprayed down with soapy water. This figure shows the balloon before inflation, at the beginning of the test protocol.

Fig. 72. The device is in the sink, and has been sprayed down with soapy water. The balloon has been fully inflated. There are no visible soap bubbles.

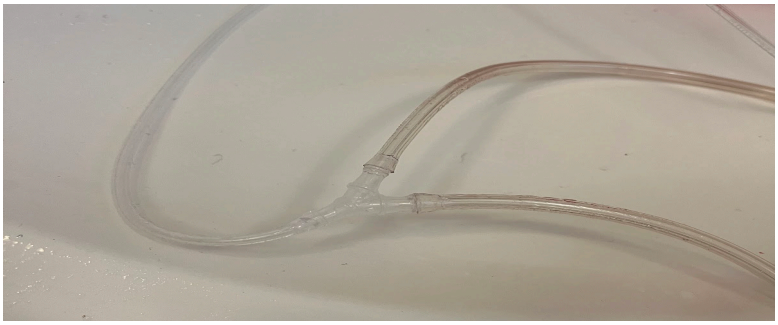


Fig. 73. The device is in the sink, and the Y connector has been sprayed down with soapy water. The balloon is inflated, and no bubbles formed on or near the Y connector.

I. 5.9 Balloon Strength Testing

The following results were obtained per the Balloon Strength Testing test methodology. The purpose of this testing was to determine the force the prototype's balloon material was able to withstand in tension. Please see Appendix L for the associated test methodology.

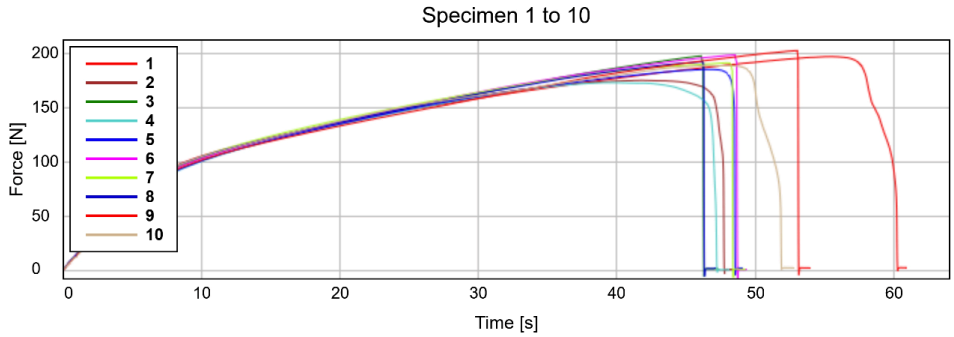


Fig. 74. The forces at which each of the nine cut 2-inch samples broke.

Table XII: This table shows the results in Newtons and mm of the force at tensile strength and displacement at tensile strength of each of the tested specimens, as well as the maximum force withstood in Newtons. Automatic statistical calculations completed by the Instron Bluehill Software are shown below.

	Specimen number (included)	Modulus (Automatic Young's) [MPa]	Displacement at Maximum Force [mm]
1	1	7.02	184.67
2	2	7.23	139.41
3	3	7.26	153.74
4	4	7.40	132.07
5	5	7.08	155.34
6	6	7.42	161.81
7	7	7.29	159.67
8	8	7.16	153.81
9	9	6.96	176.54
10	10	7.37	155.41
Maximum	10	7.42	184.67
Mean	6	7.22	157.25
Median	6	7.24	155.37
Minimum	1	6.96	132.07
Range	9	0.46	52.60
Standard deviation	3.03	0.16	15.40

	Maximum Force [N]	Data point at Maximum Force	Tensile stress at Maximum Force [MPa]
1	196.87	2771	3.92
2	175.05	2092	3.48
3	197.47	2307	3.93
4	172.99	1982	3.44

5	185.08	2331	3.68
6	198.31	2428	3.95
7	191.16	2396	3.80
8	192.10	2308	3.82
9	202.37	2649	4.03
10	188.75	2332	3.76
Maximum	202.37	2771	4.03
Mean	190.01	2360	3.78
Median	191.63	2332	3.81
Minimum	172.99	1982	3.44
Range	29.39	789	0.58
Standard deviation	9.83	230.99	0.20

J. 5.10 Deployment and Insertion of the Device Testing

Using an intubation mannequin, and inserting, inflating, deflating, and removing the device following the procedure outlined in the test methodology as seen in Appendix M, the following data was obtained.

Table XIII: The total time in seconds to insert the device into the esophagus and inflate the balloon to desired pressure and the associated trial number. As seen in Fig. 65, the team inserted the device into the mannequin's esophagus and inflated it, timing this process appropriately.

Trial #	Total Time to Deploy (seconds)
1	11.38
2	12.34
3	12.79
4	10.23
5	12.33
6	11.47
7	12.35
8	12.22
9	9.85
10	11.75

Fig. 75. This image shows the device being placed into the intubation mannequin, with the help of a laryngoscope to guide it. The device was easily able to be inserted and removed without damage.

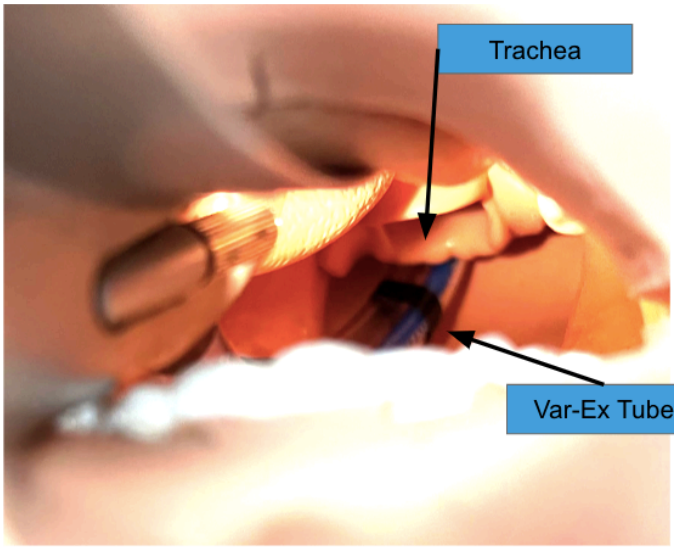


Fig. 76. This image shows the inside of the mouth of the intubation mannequin. The device is properly placed in the esophagus, and the opening of the trachea can be clearly seen. The device is not occluding the airway.

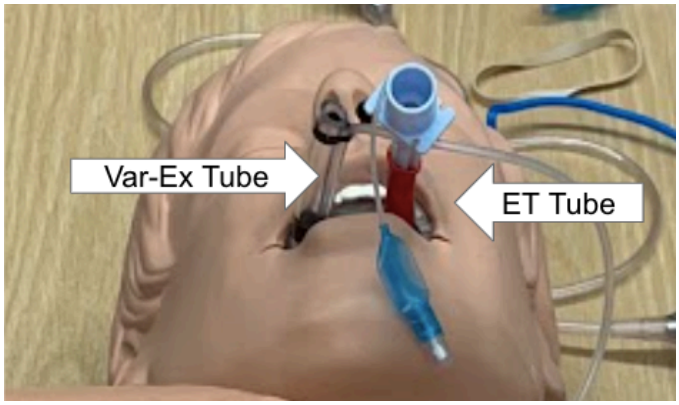


Fig. 77. This image shows the device and an endotracheal tube within the intubation mannequin. Thus demonstrating that the device does not prohibit intubation.

K. 5.11 Main Body Suction Testing

The following data was obtained per the Main Body Suction Test Methodology (Appendix N). The purpose of this testing was to ensure suction could still occur through the main body tubing of the device.

Table XIV: The table shows the volume of fluid suctioned through the main body tubing as well as not through the main body tubing, in milliliters.

X	Group A	Group B
Trial	Without Device (mL)	With Device (mL)
X	Y	Y
1	28.0	29.0
2	27.5	28.0
3	26.5	28.0
4	27.0	29.5
5	30.0	30.0
6	29.0	31.0
7	29.5	26.0
8	30.5	27.0
9	28.0	30.0
10	27.0	29.5

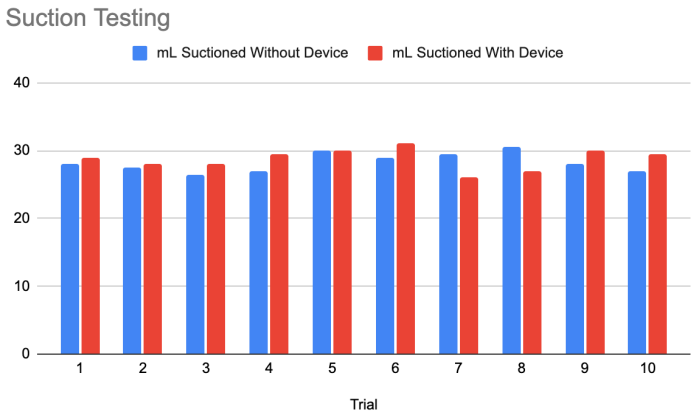


Fig. 78. The chart shows the volume of fluid suctioned from the catch beaker with and without the device present.

IX. 6.0 Final Design Validation

A. 6.1 Summary of Experimental Methods

The testing process began with general proof of concept of the prototype. This includes the primary inflation for occlusion test method where the concept of applied balloon pressure against a fluid leak was tested. During this test method, a pipe representing the human esophagus had a small hole drilled into it and a line containing red food dye and water was run into it, representing esophageal hemorrhage. An ET Tube was used for concept representation and the balloon was inflated against the modeled hemorrhage. In addition to this, biocompatibility testing was performed to determine if balloon application in the body was feasible, without cellular toxicity. Three trials were performed with 2 different balloon samples and a control for a total of nine plates of endothelial cells.

Following the success of these tests, the individual systems of the device prototype were tested. Firstly, the junction and sealant strengths of the prototype were tented using an Instron and tensile testing to ensure the forces routinely encountered the device would not cause these junctions to break. This test was followed by a similar one to determine the balloon strength for the same purpose. After successful completion of these tests, the pressure system was tested. This included pressure values lost in the line, the calibration of the pressure gauge and the accuracy of applied pressure in the balloon. These tests were conducted to ensure successful and predictable use of the balloon tamponade system. Finally, the entire

prototype was tested in deployment tests to ensure device efficacy. Also performed at this stage was suctioning and main body tests to ensure the device did not inhibit other clinical maneuvers, such as suctioning down the main body tube and the simultaneous tracheal intubation of a patient.

B. 6.2 Summary of Data Analysis

Sealant Testing:

Table XV: This table shows the results of a one sample t-test against a theoretical mean of 59.9 Newtons. This value was selected due to previous experimental data of the mean strength of a human finger pull [46].

One sample t and Wilcoxon test		A
		Max Force (N)
		Y
1	Theoretical mean	59.50
2	Actual mean	101.8
3	Number of values	9
4		
5	**One sample t test**	
6	t, df	t=7.083, df=8
7	P value (two tailed)	0.0001
8	P value summary	***
9	Significant (alpha=0.05)?	Yes
10		
11	**How big is the discrepancy?**	
12	Discrepancy	42.32
13	SD of discrepancy	17.92
14	SEM of discrepancy	5.975
15	95% confidence interval	28.54 to 56.10
16	R squared (partial eta squared)	0.8625

Balloon Strength Testing:

Table XVI: This table shows the results of a one sample t-test against a theoretical mean of 59.9 Newtons. This value was selected due to previous experimental data of the mean strength of a human finger pull [46].

One sample t and Wilcoxon test		A
		Max Force (N)
		Y
1	Theoretical mean	59.50
2	Actual mean	189.0
3	Number of values	10
4		
5	**One sample t test**	
6	t, df	t=34.63, df=9
7	P value (two tailed)	<0.0001
8	P value summary	****
9	Significant (alpha=0.05)?	Yes
10		
11	**How big is the discrepancy?**	
12	Discrepancy	129.5
13	SD of discrepancy	11.83
14	SEM of discrepancy	3.740
15	95% confidence interval	121.1 to 138.0
16	R squared (partial eta squared)	0.9926

Volume/Occlusion Testing:

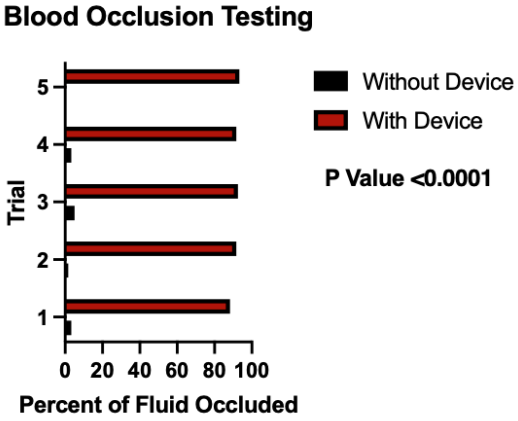


Fig. 79. This bar graph shows individual fluid occlusion trials and the percent of fluid occluded with and without the Var-Ex Tube in place. The p-value result is <0.0001.

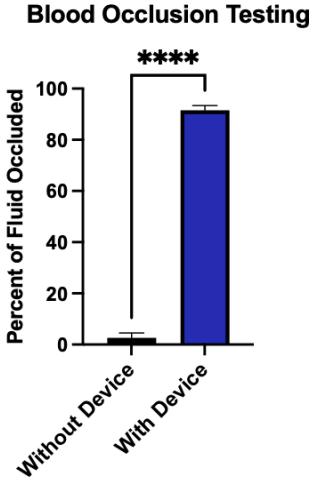


Fig. 80. This bar graph shows the percent of fluid occluded with and without the Var-Ex Tube in place. The p-value result is <0.0001.

Table XVII: This table shows the results of a two-tailed, unpaired t-test between the volume occluded with and without the device. The p-value result is <0.0001.

1	Table Analyzed	Data 1
2		
3	Column B	With Device
4	vs.	vs.
5	Column A	Without Device
6		
7	**Unpaired t test**	
8	P value	<0.0001
9	P value summary	****
10	Significantly different (P < 0.05)?	Yes
11	One- or two-tailed P value?	Two-tailed
12	t, df	t=73.91, df=8
13		
14	**How big is the difference?**	
15	Mean of column A	2.667
16	Mean of column B	91.50
17	Difference between means (B - A) ± SEM	88.83 ± 1.202
18	95% confidence interval	86.06 to 91.60
19	R squared (eta squared)	0.9985
20		
21	**F test to compare variances**	
22	F, DFn, Dfd	1.000, 4, 4
23	P value	>0.9999
24	P value summary	ns
25	Significantly different (P < 0.05)?	No
26		
27	**Data analyzed**	
28	Sample size, column A	5
29	Sample size, column B	5

Suction Testing:

Table XVIII: This table shows the results of a two-tailed, unpaired t-test between the volume suctioned through the main body tubing with and without the device. The p-value result is 0.4528.

1	Table Analyzed	Data 1
2		
3	Column B	With Device
4	vs.	vs.
5	Column A	Without Device
6		
7	**Unpaired t test**	
8	P value	0.4528
9	P value summary	ns
10	Significantly different (P < 0.05)?	No
11	One- or two-tailed P value?	Two-tailed
12	t, df	t=0.7675, df=18
13		
14	**How big is the difference?**	
15	Mean of column A	28.30
16	Mean of column B	28.80
17	Difference between means (B - A) ± SEM	0.5000 ± 0.6515
18	95% confidence interval	-0.8687 to 1.869
19	R squared (eta squared)	0.03169
20		
21	**F test to compare variances**	
22	F, DFn, Dfd	1.234, 9, 9
23	P value	0.7593
24	P value summary	ns
25	Significantly different (P < 0.05)?	No
26		
27	**Data analyzed**	
28	Sample size, column A	10
29	Sample size, column B	10

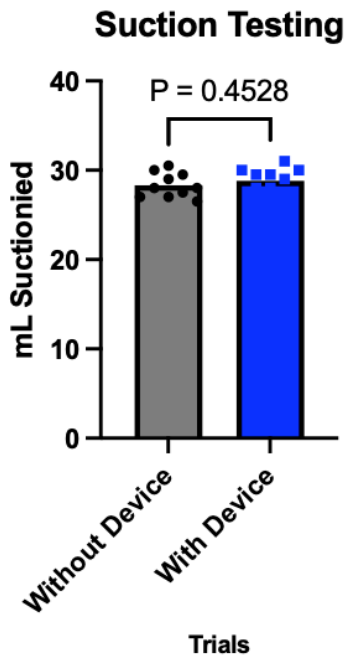


Fig. 81. This figure shows the results of a two-tailed, unpaired t-test between the volume occluded with and without the device. The p-value result is 0.4528.

Pressure Loss Testing:

Table XIX: This table shows the results of a two-tailed, unpaired t-test, between the loss of pressure in the inflation bulb and Y connector. The p-value is less than 0.0001.

Table Analyzed	Data 3
Column B	Pressure Sensor Reading
vs.	vs.
Column A	Gauge Reading
Unpaired t test	
P value	<0.0001
P value summary	****
Significantly different (P < 0.05)?	Yes
One- or two-tailed P value?	Two-tailed
t, df	t=8.121, df=8
How big is the difference?	
Mean of column A	60.00
Mean of column B	58.17
Difference between means (B - A) ± SEM	-1.834 ± 0.2258
95% confidence interval	-2.355 to -1.313
R squared (eta squared)	0.8918
F test to compare variances	
F, DFn, Dfd	Infinity, 4, 4
P value	<0.0001
P value summary	****
Significantly different (P < 0.05)?	Yes
Data analyzed	
Sample size, column A	5
Sample size, column B	5

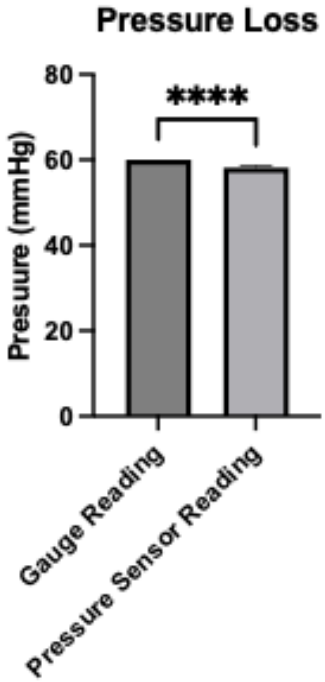


Fig. 82. This figure shows the results of the two-tailed, unpaired t-test of the pressure readings. The p-value is <0.0001.

Pressure Gauge Testing:

Table XX: The table shows the results of a two-tailed T-test. The p-value is 0.1127.

Column B	Pressure Sensor Value
vs.	vs.
Column A	Gauge Reading
Unpaired t test	
P value	0.1127
P value summary	ns
Significantly different (P < 0.05)?	No
One- or two-tailed P value?	Two-tailed
t, df	t=1.692, df=14
How big is the difference?	
Mean of column A	60.00
Mean of column B	107.4
Difference between means (B - A) ± SEM	47.37 ± 27.99
95% confidence interval	-12.67 to 107.4
R squared (eta squared)	0.1698
F test to compare variances	
F, DFn, Dfd	Infinity, 7, 7
P value	<0.0001
P value summary	****
Significantly different (P < 0.05)?	Yes
Data analyzed	
Sample size, column A	8
Sample size, column B	8

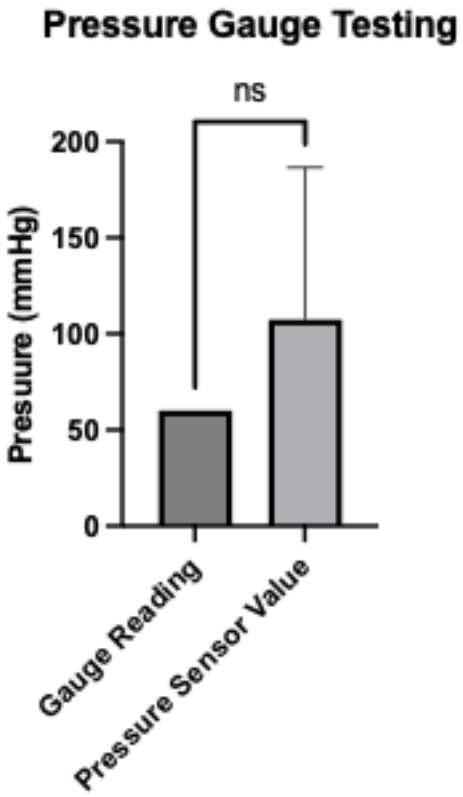


Fig. 83. The figure depicts the results of the one sample test of the pressure gauge readings. The p-value is 0.1127, indicating statistical insignificance.

Biocompatibility Testing:

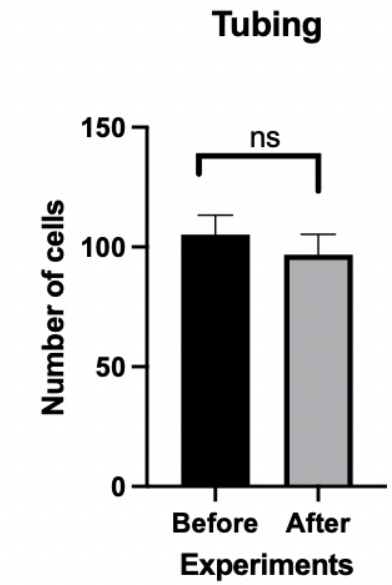


Fig. 84. This figure compares the average cell count before and after 24 hours of exposure to the tubing material. The P value was 0.4945 which is greater than 0.05 making these results statistically insignificant.

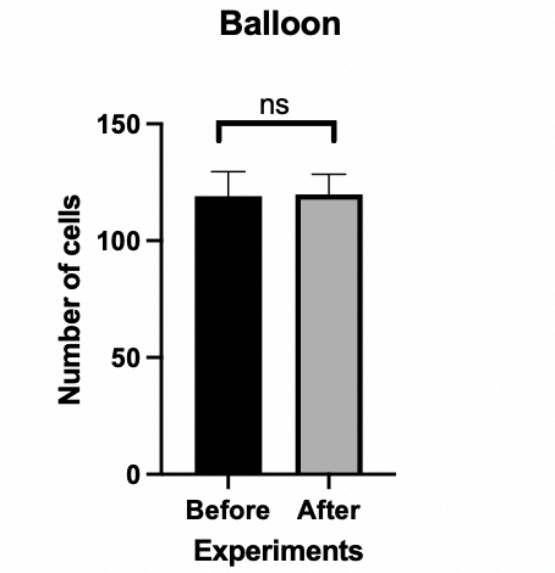


Fig. 85. This figure compares the average cell count before and after 24 hours of exposure to the balloon material. The P value was 0.9523 which is greater than 0.05 making these results statistically insignificant.

Deployment and Insertion Testing:

Table XXI: This table shows the results of a one sample t-test against a theoretical mean of 300 seconds (5 minutes). This value was selected due to previously determined technical specifications defined in the device requirements for timely insertion.

One sample t and Wilcoxon test		A
		Insertion Time (sec)
		Y
1	Theoretical mean	300.0
2	Actual mean	11.67
3	Number of values	10
4		
5	**One sample t test**	
6	t, df	t=942.6, df=9
7	P value (two tailed)	<0.0001
8	P value summary	****
9	Significant (alpha=0.05)?	Yes
10		
11	**How big is the discrepancy?**	
12	Discrepancy	-288.3
13	SD of discrepancy	0.9673
14	SEM of discrepancy	0.3059
15	95% confidence interval	-289.0 to -287.6
16	R squared (partial eta squared)	1.000

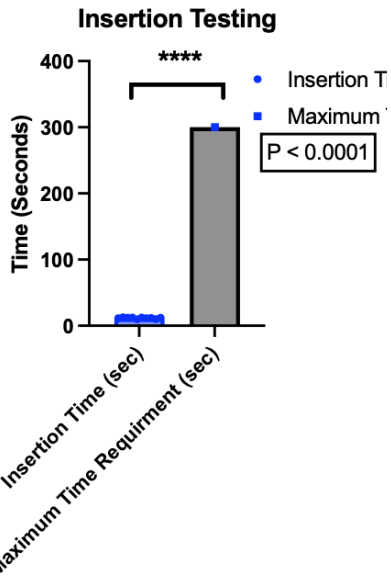


Fig. 86. The insertion testing times compared on a column graph including the calculated p-value of <0.0001.

C. 6.3 Final Design Standards

Due to the nature of the device, several standards were required to ensure its safety and efficacy. The International Organization for Standardization (ISO), as well as the American Society for Testing and Materials (ASTM), are responsible for many of the standards that regulate medical devices, and many of these standards relate directly to this device. ISO 14971 refers to the risk management associated with the normal use of a device. In order for this device to be deemed safe for use, it was necessary to design it in such a way that would adhere to the design requirements and safety specifications. ISO 13485 relates to the overall quality of the device, particularly regarding the device's design and lifespan. Verification and validation methods were used to determine the quality of the device. ASTM F1980 is a standard that evaluates the aging of medical devices. This standard would need to be incorporated when in the industry

and would be used to determine the length of time in which the device is considered usable. ISO 10993 refers to the device's biocompatibility. A similar standard is ASTM F813, which evaluates the cytotoxic potential of materials used in medical devices. These standards were heavily incorporated into the device's design, as extensive biocompatibility testing was done throughout the course of its development. After determining that all materials of the device are biocompatible, this standard was satisfied.

D. 6.4 Economics

The device would not affect the activities of daily living of the average person as it would not be marketed towards nor used on the average person. However, it would affect establishments who would purchase and use the device, most prominently ambulance services whose paramedics would use the device and potential other establishments that provide emergency medical care such as hospitals/emergency rooms, mobile health clinics, etc. In addition, it would affect those responsible for the healthcare costs of implementing the device, such as insurance companies. Unfortunately, the financial burden of implementing the device would be placed on the patient or the patient's family if they do not have insurance and would have to pay out of pocket. The aim would be to keep the device cost low and about the same price as an endotracheal tube at $3-10. This would be significantly less costly than the Sengstaken-Blakemore balloons used in-hospital which range from $250-350 in cost. The financial burden would not be substantial on establishments purchasing the device as the device is relatively affordable. Unfortunately, the financial cost expected to be paid by the patient's insurance or by the patient themselves would still be very high as it would include ambulance costs and other emergency medical care provided by paramedics outside of the use of the device itself.

Ideally, the device would increase patient survivability so that patients would survive long enough to make it to the hospital and surgical intervention. Once the patients are stable, however, they have a long road to recovery from such a traumatic event, including inpatient monitoring until the patient is stable enough to return home. This would render the patient unable to continue working, which would prove detrimental if the patient was the main or only source of income for themselves and/or their families. If the patient needed extended time off in order to receive treatment, the patient may not be offered sick leave or paid time off from work, forcing other family members to work longer hours or obtain jobs in order to support themselves, especially if the patient/patient's family does not have health insurance. In the greater schema, not only would the patient and their family suffer from a potential loss of income, but corporations would lose revenue due to their loss of an employee for an extended period of time. This would reduce productivity in the workplace and result in losses for the company if they are not able to hire another employee, even temporarily. Ultimately, patient survivability is the goal, but the long recovery time may be considered a consequence due to the sheer trauma sustained from an esophageal variceal hemorrhage.

E. 6.5 Environmental Impact

The device is single-use and would be considered a biohazard after implementation due to its direct insertion into the esophagus and the very high volume of blood expected from an esophageal variceal hemorrhage. Thus, the device would create medical waste which could cause potential harm to the environment if it is not disposed of appropriately. If the device were not disposed of in an appropriate medical waste bin, it could potentially kill wildlife or animals that may come in contact with the device. Furthermore, the device could contaminate the environment or contaminate people other than the patient, leading to the potential spread of communicable diseases including bloodborne, airborne, or droplet-borne. It is assumed paramedics would be taking appropriate body substance isolation precautions including personal protective equipment such as gloves, goggles, and masks, but it's likely the patient and any bystanders, witnesses, and/or family would not be. The spread of disease outside the scene to the environment or the general public could potentially lead to a public health concern such as an epidemic. If the personal protective equipment donned by paramedics does not get disposed of correctly, this could lead to the same environmental impacts/concerns. It should be made clear on the packaging and/or on the device

itself as well as in protocols related to use of the device that biohazard disposal protocols should be followed after using the device.

F. 6.6 Societal Influence

The device will not have an impact on the activities of daily living of the average person as the device would not be marketed towards the average person; it would only be marketed towards medical professionals. The device is not intended for home use and thus would not be sold to those who do not hold a medical license or to establishments that are not officially recognized by appropriate governing bodies or authoritative establishments, including but not limited to the emergency medical service division of the state, province, and/or country in which the establishment is located. The device could potentially be made available to the general public through illegal means, including the black market or individuals who purchase the device and resell it through online means. It would be the responsibility of the bodies manufacturing and selling the device to ensure the device is only marketed and sold to medical professionals, to ensure the device is not being marketed or sold to the general public, and to contact the appropriate authorities if the device is found in the hands of those it shouldn't be.

G. 6.7 Political Ramifications

The device may not be immediately accessible globally depending on the body manufacturing and/or selling the device. Global tensions including restrictions placed on medical devices and/or medical-grade materials, tariffs, and trade disputes/barriers may cause supply chain issues and prohibit the shipment and/or use of the device in certain countries, or the materials needed to assemble the device may be prohibited from being manufactured in or sold to other countries. This would put some countries at an advantage over others, resulting in higher survival rates in those countries. Advocating for the device's recognition globally by emphasizing the need for a novel prehospital intervention would be key so patients across the world would be able to benefit from the device. In some instances, it may be necessary to acquire and use alternative materials if the preferred ones are found to be inaccessible in some countries. It will be the responsibility of the body manufacturing and/or selling the device to research alternative materials and assemble and test the alternate device to ensure it is still effective and functional. Ensuring compatibility of alternate devices with the availability of materials and adjusting as necessary in order to accommodate the rules and regulations of other countries/nations may also help alleviate global disparities in emergency care. This can be done by obtaining the emergency medical care protocols recognized by other countries and ensuring the device is compatible with the protocols.

H. 6.8 Ethical Concerns

The device will attempt to address a good and satisfying life by assuring autonomy (patient consent and freedom of choice), beneficence (doing the most good for the most amount of people), doing no harm to the patient nor provider, and assuring justice (implementation of the device is justified).

The device is intended to increase the rate of survival of those suffering from esophageal variceal hemorrhaging, which will ultimately ensure the patient remains alive and capable of recovery and returning to their daily lives. However, their life may look different following a variceal hemorrhage depending on the amount of blood lost, comorbidities, etc. If an extreme amount of blood is lost prior to paramedic arrival, the patient may suffer a cardiac arrest or a stroke, resulting in potential future heart disease or a permanently altered mental status. In some cases, a medically-induced coma may be warranted. If the blood loss is not as severe prior to paramedic arrival, the patient may require invasive devices to be placed and may be required to start new medications and pharmaceutical interventions. It is impossible to say how exactly a patient's life may look different after implementing the device as each patient is different and has a different medical history. However, at the least, the device is meant to maintain patient survivability would ensure the patient's family does not suffer the loss of a family member, and if the patient holds a job, also ensures the patient's family does not suffer a potentially catastrophic loss of income and quality of life. The device cannot ensure the patient will be able to make a full recovery and return to normal life

following use of the device as this can only be achieved through treatment and ongoing medical care as well as supportive care, including emotional support from those close to the patient. The device is instead intended to keep the patient alive and stable from paramedic arrival to transport to a hospital, limiting the amount of blood loss until more permanent interventions can be implemented. This will reduce the amount of damage done to the body and help the patient recover quicker and more fully. Following an event as traumatic as a variceal hemorrhage, the patient will hopefully be more aware of the dangers of their condition and will hopefully make lifestyle changes and/or seek ongoing medical care and monitoring so they never have to go through the same event again.

However, not all patients may want medical intervention during an esophageal variceal hemorrhage. When using the device, patient rights are essential and acknowledged. The patient has full autonomy and can choose whether they want paramedics to implement the device or not, assuming the patient is of sound mind and able to clearly communicate their decision. The patient has the right to refuse the device at any point in time. However, if the patient has an altered mental status away from their baseline or is unable to clearly communicate their autonomy (i.e. due to unconsciousness), implied consent is applied and ensures the patient will receive quality medical intervention. It is more likely the patient would not be of sound mind and would not be able to make a treatment decision, especially since variceal hemorrhage patients would be candidates for intubation, so any medical/advance directives related to use of the device would need to be retrieved and followed in order to maintain the patient's wishes. If no such documentation is found and the patient is unable to refuse care/treatment, then implied consent is acknowledge and the device is implemented.

Observing autonomy in turn observes beneficence as the device does the most good for the most people. The patient is able to refuse if they are of sound mind, but if they do consent whether through clear visual or verbal means or implied, the device will be implemented to give the patient the best chance of survival and to do the best good for the patient and the patient's family. Without implementation of the device, the alternative is fatal and the patient would likely die within minutes, leaving the family with the loss of a family member and their associated income, etc.

The device is designed to be safe for both the provider and the patient as these were the two most important factors the team kept in mind while developing the device. Doing no harm to the provider entailed ensuring the device was easily usable without any sharp/particularly heavy components. Doing no harm to the patient entailed the other essential factors of the device, which included fitting the length of the average adult esophagus, occluding hemorrhaging blood, biocompatibility with human tissue, and ensuring the airway would be accessible during device use so the patient would be able to be intubated if necessary. In order to ensure the device was safe for both patient and provider, the team conducted rigorous testing of the device prototype and ensured the prototype met the quantitative benchmarks set by the team. Not all of the benchmarks could be tested due to a lack of advanced/sophisticated testing and calibration devices and mechanisms (such as testing the device efficiency within a simulated vehicle moving at 40 miles per hour or faster), but the design specifications identified and set by the team to ensure patient and provider safety were tested and passed the team's benchmarks.

Finally, assuring justice involved making sure design and implementation of the device was justified. The team found that there are no pre-hospital devices available for esophageal variceal hemorrhage, indicating a clear need for a device as esophageal variceal ruptures are fatal within minutes without intervention. The team followed a design similar to that of a Sengstaken-Blakemore balloon as it met all of the team's required design specifications, but altered the design so that the team's device would be able to be inserted blind in the field without risk of rupture or injury (in contrast, Sengstaken-Blakemore balloons can only be implemented in-hospital as they involved gastric balloon anchors that require imaging to be placed accurately and safely). Furthermore, there are no current patents that the team's device can be compared to. The device design was justified as it met all of the team's design specifications as evidenced by testing of the device prototype. Finally, implementation of the device is justified as it aims to increase patient survivability and stabilization en route to the hospital so they make it to surgical intervention and are able to recover more fully from an esophageal variceal rupture.

I. 6.9 Health and Safety Issues

The device will not affect the health and safety of the average person. The device actively attempts to increase the survival of a patient suffering from esophageal variceal hemorrhaging, so it is built to be safe for patient and provider in an emergency situation. The device is not intended to be a preventive or long-term measure, but rather an acute, temporary intervention, so it would not be considered safe outside of emergency medical care or for extended periods of time. The device is also not intended to better the health of the patient as that can only be achieved through healthy lifestyle changes, regular healthcare visits, and specialized physician monitoring and consultation.

J. 6.10 Manufacturability

The Var-Ex tube was designed in order to be very easily produced, as it is not a complex design, having only the tubing, balloon, pressure gauge, and inflation bulb. The Var-Ex tube would fall into the same category as other emergency rescue devices such as a king tube or an endotracheal tube, since the materials overlap and they are simple tubing based devices. Overall, these devices are relatively cheap to purchase, typically $30 to $50, and if they are purchased in bulk, the price per unit decreases [47]. Since all of the materials are off the shelf parts, it would not cause manufacturers any financial burden to create this device. Table XXII below breaks down the cost of manufacturing the device more specifically. Overall, the Var-Ex tube can be very easily manufactured and widely distributed.

Table XXII: Displays the bill of materials for one Var-Ex Tube, including associated parts, quantities, and calculations of total cost for one device based on the prices of component parts per unit.

Bill of Materials: Var-Ex Tube			
Part Name	**Cost per Unit**	**Quantity**	**Cost per Device (1 Var-Ex Tube)**
Plastic Tubing	$0.10 /cm	65 cm	$6.50
Pressure Bulb	$3.00	1	$3.00
Rubber Balloon	$0.55	1	$0.55
Y-Connector	$0.05	1	$0.05
Pressure Gauge	$5.55	1	$5.55
Total Device Cost		**$15.65**	

K. 6.11 Sustainability

Due to the Var-Ex tube being a single use device, it unfortunately is not as sustainable as other medical devices. Each patient would need their own sterile device, much like a king tube or an endotracheal tube, so it would also need to be individually packaged. However, this is for the greater safety of the patient, as it greatly decreases the risk of spreading infections or any other type of biohazard between patients. It is not uncommon for there to be lots of disposable products in the medical industry, as it ensures no cross contamination. There is potential to decrease medical waste overall, however with emergency medical devices they will likely remain disposable for patient and provider safety.

X. 7.0 Discussion

A. 7.1 Summarize Findings

After the extensive amount of work done for this device, several key findings were uncovered. The main and most significant outcome of this device is that it works. Through the various testing procedures that were completed, it was found that this device can successfully and effectively occlude the bleeding from esophageal hemorrhaging. Due to this, this device is the first of its kind to be able to accurately stop hemorrhaging prior to receiving in-hospital care.

B. 7.2 Interpretation of Results

Proof of Concept Testing:

There were four separate proof of concept tests performed. The first test was used to determine if a regular balloon could exert enough force on the walls of a tube to prevent the flow of a liquid. The team created a model of the esophagus with a ruptured varix and inflated a party balloon inside of it. The balloon was able to prevent the flow of the liquid when inflated against the esophagus walls. The second test was using the same esophagus and varix model but replacing the party balloon with a king tube. A king tube is used in emergency situations to keep the airway open, so it has a small balloon built into it. The king tube balloon was also able to prevent the flow of fluid through the esophagus model. Next, the team needed to investigate the use of a larger balloon, as the esophagus is 25mm between the UES and the LES, and a varix can rupture at any height or in multiple places along the esophagus [9]. To access this, the team removed the balloon from an endotracheal tube, and replaced it with a 6 inch party balloon. The built-in inflation line of the endotracheal tube was able to inflate the larger balloon. This model was then put through a fluid occlusion test, but with a tube more similarly sized to the esophagus, and with a larger volume of liquid. The model was able to prevent the flow of liquid through the tube. All of these tests demonstrated that a balloon tamponade style device could temporarily stop variceal hemorrhaging.

Biocompatibility Testing:

Three trials of the biocompatibility testing were run, with two samples of each material and two controls every time. The HLM-vec cells, P7 for trial 1 and P9 for trials 2 and 3. Were given at least 24 hours to attach to the plates before the materials were added. The materials were left in the plates for 24 hours, this amount of time is shorter than typical biocompatibility tests, however the device would not be in contact with the patient for more than a couple of hours. Due to the setup of adding in the materials after the cells have settled, the addition and removal of the materials caused some of the cells to get scratches off of the surface of the plates. The majority of the cell loss between addition and removal of the materials was due to this. In order to fully verify that the amount of cell death was not related to the materials, the images were uploaded to ImageJ, and had a grid applied; five boxes of the grid were counted in each image, see Figure 54. A student's *T* test was performed between the tubing pieces cell count before and after material exposure, which resulted in a statistically insignificant p-value. Another student's *T* test was performed between the balloon pieces cell count before and after material exposure, which also resulted in a statistically insignificant p-value. In this case, an insignificant p-value meant that there was not a large enough difference in the cell count before the materials versus after the materials, thus verifying the biocompatibility of the materials, and that the cell loss was only due to the physical damage.

Sealant Testing:

The purpose of sealant tensile testing was to ensure that routine contact forces encountered by the device junction points would not cause damage or render the device non-functional. These included the connections between the pressure gauge and inflation bulbs and the y-connector The average maximum force prior to disconnection of the junction points was 101.8 N. A study by Cort & Potvin [46] results indicating that an average applied finger force in the pressing configuration was 59.5 N. A single tailed T-Test was performed with an alpha value of 5% to compare this theoretical mean with the sealant maximum force to ensure they were statistically largely different. The results were a P value of less than 0.0001

indicating statistical significance of the testing. This test confirmed that the device junction points could withstand intended use.

Pressure Gauge Testing:

Two separate pressure gauge tests were performed. The first of this set of tests measured the amount of air loss in the tubes between the point at which pressure was applied (the inflation bulb) to the point at which pressure would be delivered to the balloon (the connection from the inflation bulb to the inflation line). The inflation line was disconnected from the Y-connector, leaving the inflation bulb and device pressure gauge still connected to the Y-connector. A digital pressure sensor was connected to the open port of the Y-connector where the inflation line was previously connected. The inflation bulb was squeezed until a pressure of 60 mmHg was read on the device pressure gauge. The value read on the digital pressure sensor was compared to the value on the analog device pressure gauge. The results from the two-tailed *T*-Test were statistically significant, with a p value of less than 0.0001. This indicates there was pressure being lost from the lines, as expected since pressure was not being delivered directly to the pressure sensor, but rather had to travel through the lines first in order to reach the sensor.

The second of this set of tests calibrated the digital pressure sensor as well as the device pressure gauge. The team assumed the device's analog pressure gauge was pre-calibrated prior to use as the gauge's original intent was for use in blood pressure cuffs to take blood pressure readings and would thus not be calibrated in between uses. The team calibrated the pressure sensor by directly connecting the sensor to the pressure inflation bulb and squeezing the bulb. A pressure of around 60 mmHg (around 2.36 inHg) was targeted, but the team found the digital pressure sensor could reach pressures both below and well above the target. This indicated the pressure sensor was capable of reaching the desired pressure, and since the device pressure gauge was assumed pre-calibrated, this indicated to the team that the pressure sensor readings obtained from pressure loss testing were not due to error, but rather to true pressure loss within the device lines. A two-tailed *T*-Test was performed, resulting in a p-value of 0.1127. This p-value indicates statistical insignificance, signifying only a small amount of pressure loss from the bulb to the pressure sensor. This means that the bulb was able to increase the pressure in the gauge reliably above and below the targeted 60 mmHg without statistically significant pressure loss skewing the result.

Volume Occlusion Testing:

Volume occlusion testing was performed using an esophageal model including a ruptured varix with and without the device present. Without the device in place, the fluid that was occluded was less than 1% (0.93). With the device in place 91.5% of the fluid was occluded. This is a 32 fold difference, meaning a large numerical difference in fluid occlusion was seen throughout the trials. The trial values were compared in a Student's *T*-Test with an alpha value of 5%. The results were very significant with a P-value of less than 0.0001. This means that the device is effective at occluding blood flow in an esophageal model, well exceeding the important criteria of efficacy and cessation of fluid flow originally proposed as a specification by the team.

Inflation Bulb and Leakage Testing:

Since variceal hemorrhaging is a fatal condition, it is imperative that the balloon can be inflated evenly and quickly, and maintain enough pressure to prevent the flow of blood. In order to test this, the balloon was inflated and deflated multiple times, proving that the device can do that consistently. The device was also able to remain inflated for up to 45 minutes, ensuring that paramedics would have enough time to safely transport the patient to the hospital. Without this time, the patient would be dead upon arrival to the hospital.

In order to ensure that the device would not lose pressure on accident, it was also tested for any leakage. The device was placed into a sink and thoroughly sprayed down with soapy water. The balloon was then inflated and deflated many times to watch for formation of any soap bubbles. No soap bubbles formed anywhere on the device, thus showing no leakage. This goes along with the device's ability to remain

inflated, if it was leaking it would not live up to the result of the inflation test, and the patient would have a chance of beginning to hemorrhage yet again during transport.

Balloon Strength Testing:

The purpose of the balloon strength tensile testing was to ensure that routine contact forces encountered by the balloon on the device would not cause damage or render the balloon non-functional. The average maximum force prior to breakage of the PVC balloon material was 189.0 N. A study by Cort & Potvin [46]. included results indicating that an average applied finger force in the pressing configuration was 59.5 N. A Student's *T*-Test was performed with an alpha value of 5% to compare this theoretical mean with the balloon's maximum force to ensure they were statistically different. The results were a P value of less than 0.0001 indicating statistical significance of the testing. This test confirmed that the device balloon could withstand intended use.

Deployment and Insertion Testing:

There were two main goals of the deployment and insertion testing. The first goal of this testing was to ensure that the device does not occlude the airway, so the patient can still breathe on their own or be safely intubated while the device is in place. The second was to ensure that the device can be inserted and deployed quickly, since a patient can bleed out in a matter of minutes. Using the intubation mannequin, both of these functions were tested. The first was tested by placing the device into the esophagus, and then intubating the mannequin with an endotracheal tube. The endotracheal tube was able to be inserted and removed without difficulty, and the lungs of the mannequin were still able to inflate with the Var-Ex Tube in place. The second goal of this testing was measured by inserting and inflating the Var-Ex tube and measuring the amount of time that entire process took. In every trial the device was able to be inserted and inflated in under 30 seconds. This value is statistically significant because it is much longer than the baseline of 5 minutes that it would take for a patient to bleed out. This proves that the device would be able to be used by paramedics to perform life saving procedures, and ensure the patient would survive the trip to the hospital.

Main Body Suction Testing:

In a clinical setting, the ability to suction fluids from the body is critical especially in cases of hemorrhaging. The Var-Ex Tube's hollow design allows the provider to suction down the main body tubing to visualize blood loss and help prevent blood pooling in the stomach that could lead to the patient vomiting. To ensure the use of suctioning was still available to clinicians, the device was tested to ensure it did not occlude suctioning. Water was suctioned from a catch beaker through the device using a 60 mL syringe and with just a 60 mL syringe. The results of this testing showed no significant difference in the amount of water that was able to be suctioned. A two tailed, 2 specimen T-Test was performed with both trials using an alpha value of 5%. The results were a P-value of 0.453, making the difference statistically insignificant. This proves there is no measurable difference in suctioning ability with and without the device. This proves that the device does not inhibit the provider's ability to suction the esophagus after the device is in place and actively preventing the flow of blood.

C. 7.3 Address Implications

The broad and decentralized nature of the EMS system in the United States has made the implementation of new research and patient care into practice a variable process. Largely, trauma protocol, standardization of the industry and opinion of patient management varies based on location need as well as the individual service providers. There is no "one-size" solution for critical care nor trauma management in the United States, but every effort should be made to implement theory into better practices. This starts at an individual provider level but a lot of the burden rests on the system itself to advocate for providers and patients to get the most current devices, protocols and training opportunities to their clinicians. The Var-Ex

tube, although in preliminary stages of development, represents a commitment to patients who have been overlooked due to historically poor outcomes. These outcomes cannot be changed without updates to medical device technology and commitments by providers and agencies to implement these devices.

Technological advancements are only effective with the cooperation of clinicians who are using them. In order for successful implementation of the Var-Ex tube training is necessary. This could potentially be in the form of continuing education for previously certified providers or as a discussion during the certification process of new paramedics in classroom and practical settings. This involves an alteration in the current NRP training protocols which would have to be recognized by the National Registry Service and continuing education material must be developed for agencies and services that implement this device into their protocols. The Var-Ex Tube is part of a larger effort to advance critical care treatments and to support providers working in this space.

D. 7.4 Previous Research

Because this is a novel prehospital device, there are no prehospital devices that can provide a standard to which to directly compare the team's device. However, the device can be compared to balloon tamponade-style devices meant to reduce or occlude esophageal variceal bleeding in the hospital such as the Sengstaken-Blakemore tube (please refer to section *2.3.3 Sengstaken-Blakemore Tube and Balloon Tamponades* for more information). To compare the team's findings against existing studies and research on the Sengstaken-Blakemore tube, the team's design requirements will be set as the points of comparison: (1) the devices do not occlude the airway, (2) the devices fit the esophagus, (3) the devices significantly reduce hemorrhaging, (4) the devices are biocompatible, (5) the devices do not harm the patient nor provider.

One key difference that should first be noted between the Var-Ex tube and the Sengstaken-Blakemore tube is that the Sengstaken-Blakemore involves a gastric balloon anchor that can only be placed safely and accurately in a hospital with appropriate imaging (Brenton Faber, NRP; verbal communication, February 21, 2024). If the Sengstaken-Blakemore were to be implemented in the field, paramedics would not have access to imaging and would run the risk of rupturing the soft tissue of the esophagus if the gastric balloon were not accurately placed into the stomach (Brenton Faber, NRP; verbal communication, February 21, 2024).

The Devices Do Not Occlude the Airway

Upon testing of the device prototype, the team found the Var-Ex tube can be inserted into the esophagus of an intubate-able manikin at the same time an endotracheal tube is inserted into the trachea of the same manikin. Furthermore, the lungs can be inflated upon blowing into the endotracheal tube, indicating the device does not occlude the airway and breathing passages remain open and patent when both an endotracheal tube and the Var-Ex tube are inserted into the body. Sengstaken-Blakemore tubes are not intended to occlude the airway, but it is possible for migration of the gastric balloon to cause such an occlusion. This complication was demonstrated in one case in the United Kingdom: a 66-year old male was treated with a Sengstaken-Blakemore tube, which was correctly placed [48]. However, approximately 16 hours following admission, the patient started going into respiratory failure. It was found the gastric balloon had migrated up into the esophagus behind the trachea, obstructing the patient's ability to breathe. An important piece of information to note is that the Sengstaken-Blakemore tube caused an upper airway obstruction *while the patient was intubated with an endotracheal tube*. The endotracheal tube was found above the level of the gastric balloon according to X-ray imaging, indicating the gastric balloon caused extrinsic tracheal compression below the endotracheal tube [48].

It is likely the endotracheal balloon did not cause an obstruction whereas the gastric balloon did due to the wider diameter of the gastric balloon which measures above 5 cm [49]. Compared to the much smaller diameter of the esophagus which measures 22 mm at its widest point in the thoracic esophagus (please refer to section *2.1 Anatomy and Physiology* for more information), it is clear how a fully-inflated gastric balloon could cause damage to surrounding structures and passageways outside of the esophagus if the balloon

were to migrate up into the esophagus. Because the Var-Ex tube does not involve a gastric balloon, and testing did not indicate airway occlusion, prior research suggests the Sengstaken-Blakemore balloon is more likely to cause an airway occlusion than the team's Var-Ex tube.

The Devices Fit the Esophagus

The Var-Ex tube is intended to fit the average length of an adult esophagus (400 mm), while Sengstaken-Blakemore tubes come in various sizes, measured in "French" (aka FR), such as those sold by Cantel Medical [50] Because the Sengstaken-Blakemore tube is available in various sizes whereas the Var-Ex tube is currently a one-size design, the Sengstaken-Blakemore is more likely to provide a good fit of the esophagus compared to the Var-Ex tube. However, it is important to note the Var-Ex tube is in its prototype stage and various sizes would likely be manufactured upon commercialization of the device.

The Devices Significantly Reduce Hemorrhaging

Choi and colleagues found that the Sengstaken-Blakemore tube may be a beneficial rescue therapy for uncontrolled variceal esophageal hemorrhage if emergency transjugular intrahepatic portosystemic shunt (TIPS) is not available [31]. In their study, conducted on patients with liver cirrhosis, 66 were treated with a Sengstaken-Blakemore tube to stop uncontrolled variceal hemorrhaging when endoscopic treatment failed. The tube successfully controlled the initial hemorrhage in 75.8% of patients (50 patients), with 11 of those 50 patients experiencing rebleeding after tube insertion. Achieving control of the initial bleed using the Sengstaken-Blakemore balloon greatly decreased mortality rates over a 30-day period [31]. This provides evidence to suggest the Sengstaken-Blakemore tube can significantly reduce hemorrhaging esophageal varices and control the volume of blood loss. Some patients experienced rebleeding upon implementation of the device, and not all of the patients whose initial bleeds were controlled survived, but many of the patients were saved upon successful use of the Sengstaken-Blakemore tube [31].

Upon the team's testing of the prototype Var-Ex tube, it was found the team's device could achieve almost 100% fluid occlusion in a simulated test. This suggests the team's device would also be able to significantly reduce hemorrhaging esophageal varices and control the volume of blood loss. It is not clear if rebleeding would occur or what complications may arise from the Var-Ex tube in a true emergency situation with an actual patient, but testing suggests successful use of the device would also significantly reduce blood loss and save many lives. However, the Var-Ex tube would need to be appropriately manufactured for commercialization and subjected to further, more sophisticated/rigorous testing in order to confirm the device's capabilities compared to the Sengstaken-Blakemore tube.

The Devices Are Biocompatible

Sengstaken-Blakemore balloons may cause tissue necrosis if left in the body for longer than 24 hours, thus leading to a greater risk of fatal esophageal rupture [49]. As a temporary measure, however, Sengstaken-Blakemore tubes are biocompatible and can be left in the body for short periods of time.

Upon the team's testing of the Var-Ex tube prototype, the team found the device materials are biocompatible and will not cause death of human tissue/cells. However, the device is only designed for prehospital use and is intended to be removed upon arrival at the hospital and a surgical suite. Thus, the Var-Ex tube is not intended to be left in the body for longer than 24 hours. Testing did not confirm at what period of time the device materials become necrotic, and would require further testing, but the device should be assumed toxic after 24 hours have passed.

The Devices Do Not Harm the Patient Nor Provider

Sengstaken-Blakemore balloons when placed and used accurately can be beneficial as rescue devices. However, they can also lead to fatal complications, appearing to center mostly around device misplacement and the gastric balloon. A previous study conducted by Nielsen and Charles confirms this: in their 10-year study, conducted in Denmark during a period from 2001 to 2010, out of a total 4490 cases, six cases of Sengstaken-Blakemore tube use resulted in lethal esophageal rupture, representing 0.13% of all autopsy

cases [49]. The study suggests gastric balloon inflation within the esophageal wall (due to the balloon's large diameter) or leaving a correctly-placed Sengstaken-Blakemore within the body for longer than 24 hours (due to risk of tissue necrosis) may lead to fatal esophageal rupture. In five of the six cases, it was confirmed the gastric balloon was inflated in the esophagus. Because the gastric balloon diameter is above 5 cm, this may cause the esophagus to rupture. In all six cases, the Sensgtaken-Blakemore was deflated and placed correctly, but the misguided placement of the tubes proved fatal regardless [49].

In Choi and colleagues' study, esophageal perforation occurred in four patients due to misplacement of the Sengstaken-Blakemore tube [31]. In all four cases, the Sengstaken-Blakemore was placed after intubation with an endotracheal tube. This provides evidence to suggest the Sengstaken-Blakemore may be incompatible with endotracheal intubation if not placed correctly. It is not clear in the study why the esophageal perforations occurred, whether due to a specific component of the Sengstaken-Blakemore tube or otherwise, but it is clear that accurate placement of the tube is necessary in order to "do no harm" to the patient [31].

The team's simulated tests were not able to accurately detect esophageal perforation or esophageal rupture; however, because the team's device does not involve a gastric balloon, placement of the device is less risky as the chance of esophageal rupture is much smaller since the esophageal balloon does not have a significantly greater diameter than the esophagus. Furthermore, the device was designed to leave room for endotracheal intubation, allowing appropriate access to the airway and breathing passages. Testing indicated no airway obstruction, but more sophisticated testing would be required in order to accurately determine the risk of rupturing the esophagus with a Var-Ex tube, especially in combination with an endotracheal tube.

E. 7.5 Limitations

One of the biggest constraints the team had was access to medical grade materials. Single use balloon devices are often made from heat molded PVC, which means that the balloons on similar devices are created around each individual tube. Since the team did not have the ability to heat mold the device, the prototype used non-medical grade balloons. The tubing of single use balloon devices are also often made from heat molded plastic. This meant that the prototype inflation line was run along the tube and under the balloon, instead of being integrated with the main body tubing. For future development of the device, getting it properly manufactured with disposable, medical grade materials, and performing the validation tests would be ideal.

Another limitation the team faced was time constraints. Typically, medical devices are developed over the course of 3-5 years, however the team only had one academic year to work on this device. Due to this time restriction, the team was limited on how many iterations of the CAD and physical models could be made. There was also limited time to test. Thus, this device would need more prototyping, testing, and development before it could even be considered for manufacturing or regulatory approval.

In addition, the team had limited funds to work with. There was not enough budget to purchase human epithelial cells, so the biocompatibility testing was done with human endothelial cells instead. Medical grade molded PVC, the typical balloon material used on medical devices, can only be produced with a specific machine. The team did not have access to this because the budget was too small to afford proper manufacturing. With a larger budget, more time, and thus more access to material the team would have gotten further in the device development process.

F. 7.6 Future Directions

Based on what has been accomplished with this device throughout its development, there is more that can be explored regarding its future, beginning with more testing. Continuation of the verification and validation testing, along with additional testing for things such as the lifespan of the device, would be a pivotal step to ensure its ongoing improvement. The completion and in-depth analysis of these tests would then enable the device to be considered for regulatory approval to be professionally developed. If this approval were to be granted, the device could be used on primates in initial clinical trials. Primates are an

ideal model for the testing of new medical technologies due to their many anatomical similarities to humans. Once the device can be determined safe based on these primate trials, the findings and results gathered can then be adapted and used for human patient trials. Although testing the team's prototype of the device with the intubation mannequin provided the team with much needed information regarding its functionality, the ability to use the device on human patients would be crucial in ensuring that the device would still work effectively and safely in a real-life scenario. An end-goal for this device, having now been granted a provisional patent, would include having a company professionally manufacture this device and put it on the market for official use within the field.

XI. 8.0 Conclusion and Recommendations

A. 8.1 Conclusions

The team has designed a device and produced a prototype they believe is essential and beneficial to prehospital care. The device is a balloon-tamponade style invention that can be implemented by paramedics in the field without imaging (blind), and in tandem with airway access devices such as endotracheal tubes. The Var-Ex tube is biocompatible for the amount of time it would take to transport a patient to the hospital, and the lack of a gastric balloon awards a less risky placement as the lack of the balloon reduces the risk of rupturing or injuring the esophagus. Testing of the Var-Ex tube suggests that with proper placement and use, almost 100% of bleeding from esophageal varices can be occluded and controlled. One drawback is that the Var-Ex tube may not provide a good fit of the esophagus for every patient as it is currently designed at one size to fit the average adult esophagus.

The Var-Ex tube can be easily and quickly inserted into the esophagus following endotracheal tube intubation, and its components parts, including the inflatable balloon and sealant, are strong. There is a minimal amount of pressure loss throughout the tubing of the device, and when inflated the device has an airtight seal with no air leakage and can maintain a relatively constant pressure for at least 45 minutes. Furthermore, the Var-Ex tube's hollow main body frame allows blood and fluid to be suctioned out of the esophagus and through the tube for evacuation out of the body.

This novel device fills a need in prehospital care where interventions are limited for the in-field provider. The team's device attempts to make stabilization of the patient and bleeding control possible with a design that has been appropriately put to the test. With the Var-Ex tube, lives lost to esophageal variceal hemorrhage can instead become lives saved.

B. 8.2 Recommendations

The future of the Var-Ex Tube is dependent on manufacturability, widespread implementation into paramedicine systems and training opportunities. Prior to implementation the team would consider more testing with the manufactured products. This could include future biocompatibility studies as well as artificial aging studies to determine the expiration of sterility or a reduction in device performance. The team also recommends approval by the ISO and other standardization bodies prior to introduction in the EMS System as regulatory compliance is essential for device implementation. Additionally, future feedback studies should be conducted to improve device use and clinician experience.

Determining the most appropriate manufacturing processes would also be integral in future testing and implementation. This could be done through the expert knowledge of an established medical device manufacturer and an appropriate material supplier. Using other single-use medical device supply chains as a model, such as the king tube or endotracheal tube, the team may determine the most appropriate packaging and sterility processes as well. Additionally, making the labeling of the packaging conform to standards in the United States or anywhere the device is sold is an important step in ensuring compliance to expiration dates and usage expectations.

The team believes this device has the potential to be used in the EMS system as an additional tool to be used by in-hospital clinicians and supports future efforts in bringing the Var-Ex Tube into widespread paramedical use.

APPENDICES

APPENDIX A

Proof of Concept: Prevention of Water flow by Inflation of Balloon
Date Performed: November 6, 2023

Scope

This test method will encompass the ability of the balloon being inflated to prevent the flow of blood from the hemorrhaging spot.

Materials Table

Material	Quantity	Description
Drill	1	Used to create a hole in the side of the PVC pipe.
40mm PVC Pipe	1	This is the "esophagus" in this scenario.
Small tubing line	1	Carries water from the bucket to the PVC pipe, essentially the vein.
Bucket	2	One to hold water for the top of the siphon, one to place under the PVC pipe to catch the water.
Balloon	1	To stop the flow of water through the pipe.

Significance and Intended Use

The purpose of this first test is to see if a balloon can prevent the flow of liquid when inflated inside of a tube. This test method is only for proof of concept and does not represent the device's biocompatibility.

Procedure

1. Drill a small hole in the 40mm PVC pipe.
2. Fill a bucket with water and place on a table or similar height surface.
3. Take a piece of tubing, put one end in the bucket of water.
4. Take the other end of the tube, holding it lower than the end in the bucket at all times. Create suction on this end of the tube to get the water flowing down the tube like a siphon.
5. Insert lower end of siphon tube into the hole in the PVC pipe.
6. Insert balloon into top of PVC pipe, low enough to cover the hole in the side of the tube.
7. Inflate the balloon until it stops the water.
8. Deflate the balloon.
9. Remove the balloon from the pipe and stop the siphon.

Safety Considerations

Although all apparatus involved contain a low damage risk to humans, ensure proper lab etiquette, PPE use and document any injury or damage to the device or the operator and report per the WPI Standard Operating Procedure.

Data Collection

All of the data collected from this test method is qualitative. Photo and video proof will act as the measurements of the results.

Results

The inflation of the balloon was able to successfully prevent the water from continuing to flow into the pipe from the siphon.

Photos and Videos

https://drive.google.com/file/d/1KK3f4dwphBydy3Zii48apH85RMSN3Zq3/view?usp=drive_link

APPENDIX B

Proof of Concept: Prevention of water flow with a king tube balloon
Date Performed: November 14, 2023

Scope

This test method will encompass the ability of the inflation of the smaller king tube balloon to prevent the flow of the water from the siphon.

Materials Table

Material	Quantity	Description
Drill	1	Used to create a hole in the side of the PVC pipe.
40 mm PVC Pipe	1	This is the “esophagus” in this scenario.
Bucket	2	One to hold water for the top of the siphon, one to place under the PVC pipe to catch the water.
Red Food Coloring	1	To color the water for better visualization in documentation.
King Tube	1	To be inserted into the pipe and inflated.
Large Syringe	1	Used to inflate and deflate the balloon on the king tube.

Significance and Intended Use

The purpose of this first test is to see if a king tube balloon can prevent the flow of liquid when inflated inside of a tube. This test method is only for proof of concept and does not represent the device's biocompatibility.

Procedure

1. Drill a small hole in the 40mm PVC pipe.
2. Fill a bucket with water, add red food coloring to the water, place the bucket on a table or similar height surface.
3. Take a piece of tubing, the team used lumen tubing, place one end into the bucket of water.
4. Take the other end of the tube, holding it lower than the end in the bucket at all times, create suction on this end of the tube to create a siphon of flowing water.
5. Insert lower end of the siphon tube into the hole in the PVC pipe.
6. Insert king tube into the top of the PVC, aligning the balloon to cover the hole in the side of the PVC pipe with the water flowing through it.
7. Inflate the balloon on the king tube until the flow of water through the pipe stops.
8. Deflate the balloon.
9. Remove the king tube from the pipe and stop the siphon.

Safety Considerations

Although all apparatus involved contain a low damage risk to humans, ensure proper lab etiquette, PPE use and document any injury or damage to the device or the operator and report per the WPI Standard Operating Procedure.

Data Collection

All data collected from this test method is qualitative. Photo and video proof will act as the measurements of the results.

Results

The balloon on the king tube was able to inflate enough to prevent the flow of water through the PVC pipe. The red food coloring did make the water much easier to see in the video.

Photos and Videos

https://drive.google.com/file/d/1NDE6UOc2Cb3DX5oXvGWqsZDcYoeQI7Ic/view?usp=sharing

APPENDIX C

Proof of Concept: Larger balloon ability to inflate with endotracheal tube inflation line
Date Performed: November 30, 2023

Scope

This test method encompasses if the party balloon installed onto the human endotracheal tube is able to be inflated using the built-in inflation line and if the duct tape sealed the ends of the balloon enough to allow the balloon to hold air.

Materials Table

Material	Quantity	Description
Human endotracheal tube	1	Representative of the device body.
Party animal balloon	2	To put on the endotracheal tube.
Exacto knife	1	To remove the original balloon on the tube and cut the new balloon to size.
Duct tape	1	To seal the party balloon ends to the tube, allowing the balloon to hold air.
Large syringe	1	Used to inflate the balloon through the endotracheal tube inflation port.

Significance and Intended Use

The purpose of this first test is to see if a larger balloon can be inflated by the same mechanism provided in an existing endotracheal tube. This test method is only for proof of concept and does not represent the device's biocompatibility.

Procedure

1. Remove the balloon that comes on the endotracheal tube using an Exacto knife.
2. Cut the rubber band and a few inches off the other end of a balloon animal balloon. Leaving roughly 5 or 6 inches of the balloon intact.
3. Slide balloon over the endotracheal tube, covering the inflation hole on the endotracheal tube.
4. Seal the ends of the balloon onto the tube with duct tape.
5. Using the syringe provided with the endotracheal tube, inflate the balloon.
6. Keep the balloon inflated for a minute.
7. Using the syringe again, remove the air from the balloon.

Safety Considerations

Although all apparatus involved contain a low damage risk to humans, ensure proper lab etiquette, PPE use and document any injury or damage to the device or the operator and report per the WPI Standard Operating Procedure.

Data Collection

All of the data collected from this test method is qualitative. Photo and video proof will act as the measurements of the results.

Results

The balloon was able to be inflated using the inflation line of the endotracheal tube. The balloon was also able to hold air and be deflated using the inflation line of the endotracheal tube.

Photos and Videos: https://drive.google.com/file/d/1D3tKCGn25uU5SESr7UauIxeCwCP-TjRG/view?usp=sharing

APPENDIX D

Proof of Concept: Larger balloon on endotracheal tube, prevention of fluid flow
Date Performed: November 30, 2023

Scope

This test method will encompass if the party balloon is able to be inflated and prevent the flow of water through a tube that is roughly the size of the human esophagus.

Materials Table

Material	Quantity	Description
15 mm diameter esophagus tube of intubation mannequin	1	The removable esophagus tube from an intubation mannequin.
Human Endotracheal tube with larger balloon installed	1	The modified endotracheal tube, with the six inch party animal balloon installed onto it, created in the previous test methodology.
Sink	1	To have a constant flow of water through the tube, without drilling a hole in the mannequin tube.
Large Syringe	1	To inflate the balloon using the inflation line of the endotracheal tube.

Significance and Intended Use

The purpose of this first test is to see if a larger balloon on an endotracheal tube can prevent the flow of liquid when inflated inside of a tube. This test method is only for proof of concept and does not represent the device's biocompatibility.

Procedure

1. Remove the esophagus tube from the dummy.
2. Place the tube in the sink and get water running through it.
3. Insert the endotracheal tube with the balloon into the other end of the esophagus tube.
4. Inflate the balloon inside the esophagus tube until it prevents the flow of the water down the tube.
5. Allow the water to pool for a few seconds to get a good visualization of it.
6. Turn off the water, deflate the balloon, and remove the device from the dummy esophagus tube.
7. Dry everything off and put the tube back into the dummy.

Safety Considerations

Although all apparatus involved contain a low damage risk to humans, ensure proper lab etiquette, PPE use and document any injury or damage to the device or the operator and report per the WPI Standard Operating Procedure.

Data Collection

All of the data collected from this test method is qualitative. Photo and video proof will act as the measurements of the results.

Results

The device fit within the model esophagus tube. The balloon was able to be inflated, prevent the flow of water, and the device was able to be safely removed.

Photos and Videos:
https://drive.google.com/file/d/14WgknHY2ibXV5IOrVOqT4-KeICiGD8pF/view?usp=sharing

APPENDIX E

Biocompatibility of Balloon: Test Methodology

Scope:

This test method will encompass testing the biocompatibility of the balloon material with human endothelial cells.

Materials Table

Material	Quantity	Description
HLM-VEC endothelial cells (human)	1 flasks	These cells are present in the esophageal lining so they will be interacting with the material.
Complete cell culture medium	50 mL	The cell culture medium includes DMEM basal medium, penicillin, glutimax, and 10% fetal bovine serum. Will be used to suspend cells and prevent them from drying in the incubation period.
0.25% trypsin-edta	15 mL	This protein aids in lifting the cells from the original plate in order.
70% ethanol	1 bottle	The ethanol will be used to sterilize the forceps and anything else within the biosafety cabinet.
Pieces of balloon material	10	These pieces of material will be placed in the tissue culture plates with the cells to test if they are biocompatible.
Pieces of tube material.	10	These pieces of material will be placed in the tissue culture plates with the cells to test if they are biocompatible.
15ml conical centrifuge tube	3	The centrifuge tube will hold the cell suspension in between plates as well as.
Serological pipette and tip	10	The serological pipettes will be used to measure and

		transport cell medium and trypsin.
Pasteur Pipettes	10	The pasteur pipettes will be used with the vacuum pump for aspiration.
25mm Nunclon Delta Coated tissue culture plates	6	The tissue culture plates will hold the balloon material, tube material, and cells.
Forceps	1	The forceps will be used to add the balloon material into the tissue culture plates.
Scalpel and/or Scissors	1	These will be used to cut the balloon and tube pieces.
100 µL pipette and tips	1	The pipette will be used to take the aliquot for the cell count.
Hemocytometer	1	The hemocytometer will be used to count the cells in suspension.

Significance and Intended Use

The significance of this test is to ensure that the balloon material will not cause a biological reaction when it is in contact with the patient's esophagus. This method will address the required design specifications and will allow for the analysis of qualitative specifications for testing.

Apparatus Table

Apparatus	**Purpose**
Incubator	Provide an environment of 37℃ and 5% CO_2 for idea cell growth.
Biosafety Cabinet	Maintain a sterile environment when working with cells.
Aspiration vacuum Pump	Removal of used fluids.
Microscope	Visualization of the cells.

Procedure

1. All participants should have proper PPE and spray their gloves with 70% ethanol before moving to the next step.

2. Open the biosafety cabinet, turn on the light and air circulation.
3. Using the 70% ethanol and paper towels, spray and wipe down all materials and surfaces within the biosafety cabinet.
4. Sterilize the packaging of the endotracheal tube with 70% ethanol spray, then bring into the hood.
5. Bring the new 25 mm tissue culture plates into the hood. Label them accordingly with the date, and team or your name, and material being tested in that plate.
    1. Labeling used: Date, Varices MQP, T1, T2, B1, B2, C1, and C2
6. Open the sterile endotracheal tube, using a sterile scalpel, cut the balloon off of the tube.
7. Split the balloon into many small pieces. Place all balloon places into a labeled sterile 60mm tissue culture plate.
8. Using the scalpel or sterilized scissors, cut many small pieces of the tubing. Place all pieces of tubing into a labeled 60mm tissue culture plate.
9. Dispose of the remaining portion of the endotracheal tube.
10. Before bringing the plate into the hood, observe the cells under the microscope to check for health of cells and absence of contamination.
11. Bring the 75cm plate of endothelial cells into the hood, label the 15 mL conical centrifuge tube with the necessary information.
12. Taking a sterile pasteur pipette, attach it to the tube of the vacuum pump. Then aspirate the medium from the cell culture plate.
13. Using a serological pipette, add 2 mL of 0.25% trypsin-edta to the plate, gently rinse the cells by tilting the plate.
14. Aspirate the 0.25% trypsin-edta from the plate.
15. Using a serological pipette, gently add 5 mL of 0.25% trypsin-EDTA solution to the plate. Close the lid.
16. Watch the cells under the microscope to make sure cells are detached, rounded, and floating. If the cells look rounded, they are ready to be processed. Return the plate to the hood.
17. Using a new serological pipette, add 15 mL of complete medium to the place. Your total volume should now be 10 mL.
18. Using the same serological pipette, wash the cells off the plate by repeated pipetting, doing your best to avoid air bubbles.
19. Transfer the cell suspension into the 15 mL conical tube.
20. Using a 100 µL pipette, take a 50 µL aliquot of cell suspension for the cell count.
21. Centrifuge the 15 mL conical tube at 200 RCF for 5 minutes.
22. While the centrifuge is running, bring the 100 µL pipette and a hemocytometer to the microscope. Fill both sides of the hemocytometer, about 10 µL each side, with the aliquot and perform a cell count. Be sure to clean the hemocytometer after use.
23. Remove the 15 mL tube from the centrifuge, sterilize, and bring it back into the hood.
24. Taking a new aspiration tip, carefully aspirate the media from the tube, without disturbing the pellet.
25. Resuspend the pellet in 13.33 mL of media, using repeat pipetting with the 25 mL serological pipette.
26. Size down to a 10 mL serological pipette and do more repeat pipetting to fully break up the cell pellet.
27. Open all 6 of the 25 mm labeled plates, add 2 mL of the cell suspension to each.
28. Recover the plates and remove bubbles by gently shaking them, this prevents shear stress on the cells during growth.
29. Place the plates in the incubator and incubate at 37°C and 5% CO_2 for 12 to 18 hours.
30. After incubation, bring the plates back into the hood. Aspirate the media and add 1.5 mL of fresh media to each plate.
31. Using the microscope, take 3 images of each plate in different locations on the plate.

    1. Brightness 55% and Contrast 50%
32. Bring the plates back into the hood. Using the forceps, introduce one piece of balloon into each of the B plates and one piece of the tubing into each of the T plates. Do not add anything to the C plates as they are controls.
33. Return the plates to the incubator and incubate at 37°C and 5% CO_2 for 24 hours.
34. After 24 hours, take the plates from the incubator, and bring them into the hood. Using the forceps carefully remove the pieces from the B and T plates, being careful not to scratch the surface of the plate with the forceps.
35. Using the microscope check the confluency, the distance between the cells and the material location, and also pay attention to any lack of cells in either plate. This would indicate cell death.
36. Using the microscope, take 3 images of each plate in different locations on the plate.
    1. Brightness 55% and Contrast 50%
37. Once satisfied with your images, bring the plates back into the hood and aspirate the remaining cell medium. Dispose of the plates properly.
38. Repeat all steps for two more trials.

Safety Considerations

Although all materials involved contain a low toxicity or damage risk to humans, ensure proper lab etiquette, PPE use and document any injury or damage to the device or the operator and report per the WPI Standard Operating Procedure.

Data Collection

The majority of the data from this test is qualitative. The images taken right after the cells are plated will be compared to those taken after the 24 hour incubation period. If there is much lower confluency, lots of dead cells, or even the cells moving away from the material it is considered to be non-biocompatible or possibly even cytotoxic. If the cells are still on top of or around the material and generally look like they are doing well, the material can be deemed biocompatible.

APPENDIX F

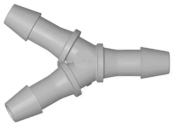
Sealant (Connection point): Test Methodology

Scope:

This test method will encompass testing the ability of the sealant to withstand the appropriate tensile strength at the various connection points of the device.

Materials Table:

Material	Quantity	Description
Medical Sealant/ SuperGlue 	1	The medical sealant will be applied to seal the junction/connection points on the device.

Y-Connector 	1	The Y-connector that is found at the junction of the inflation line to the pressure gauge and the inflation pump.
Connective Tubing 	1	The tubing connecting the Y-connector and other components of the device.

Significance and Intended Use:

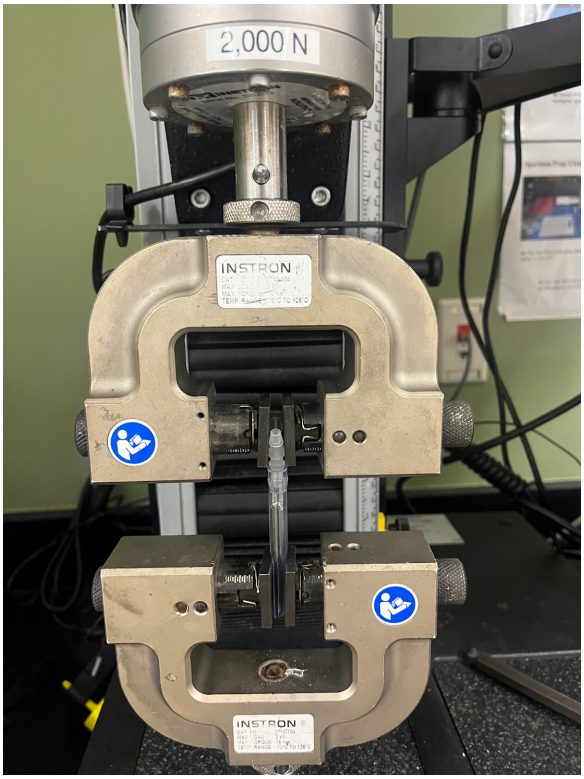
The significance of this test method is to ensure the sealant used on the device is able to withstand the physiological forces encountered by the device. Additionally, the force required to separate the tubing from the connection piece is greater than the force the device will routinely encounter. This method will address the required design specifications and will allow for analysis of the quantitative specifications for testing. This method is intended solely for proof of concept of the rescue prototype and does not represent the device's biocompatibility or proof of functionality for hemorrhage reduction.

Apparatus Chart

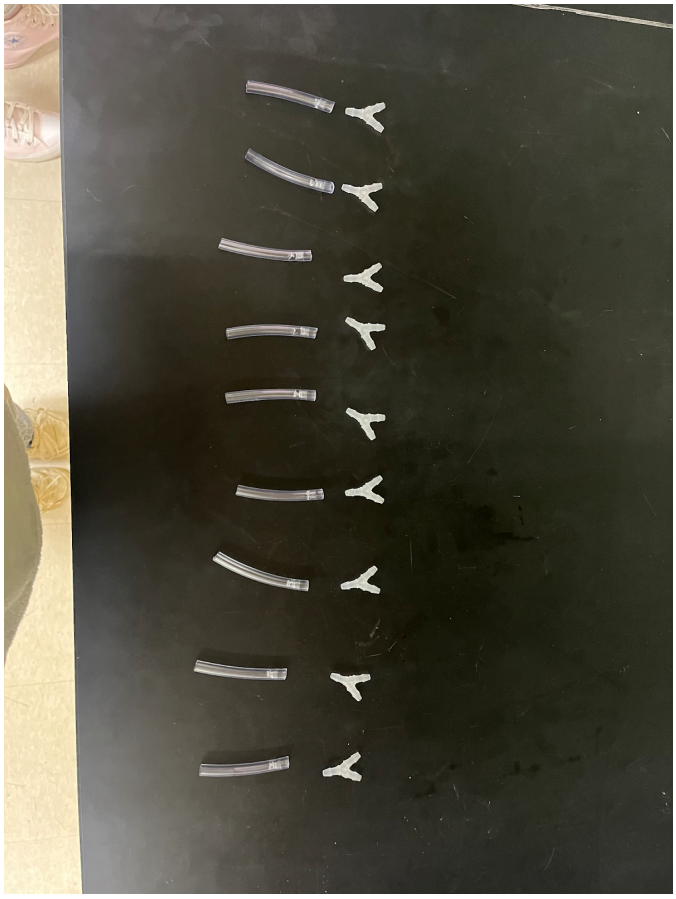
Apparatus	Measurement
Instron Machine and associated load cells.	Measurement of tensile strength, time and force.
Calibrated Ruler	Measurement of the length of tubing remaining external to the connection piece

Deployment of Device: Procedure

1. All participants should don appropriate personal protective equipment (PPE) before test commencement.
2. Ensure the setup of the instron with tensile test grips, appropriate load cell and Bluehill tensile strength run file.
3. Assemble the connection pieces to the tubing using the superglue and leave approximately 3 inches of tubing able to be installed in the lower grips of the Instron.
4. Repeat this step for all samples to be tested.
5. Insert the assembled connection piece and tubing into the grips.



6. Run the Instron test.
7. Be aware the tubing may snap as it disconnects.
8. Note if the disconnection occurred at the sealant location or within the tubing length.
9. Remove the disconnected pieces and put them to the side.



10. Repeat steps 4-5 for the remaining trials.
11. Document all findings for these trials.
12. Save the Instron output files.

Safety Considerations

Although all materials involved contain a low toxicity or damage risk to humans, ensure proper lab etiquette, PPE use and document any injury or damage to the device or the operator and report per the WPI Standard Operating Procedure.

Data Collection

The majority of data collected during this test method is quantitative data stored within the Instron graph and output file. The required design specifications and will be analyzed using statistical software for applicability.

The quantitative data measurements will be analyzed using GraphPad and a capability six-pack analysis to determine statistical significance to an average value.

APPENDIX G

Pressure Loss: Pressure Reading Methodology 1.0

Scope:

This test method will encompass how much pressure is lost within the tubing from the inflation pump to the Y-connector at which the inflation pump, pressure gauge, and inflation line are all connected.

Apparatus Table:

Apparatus	Quantity	Description
Pressure Gauge 	1	The device gauge with millimeters of Mercury (mmHg) pressure readout.
Pressure Inflation Pump 	1	The pump that will be used to inflate the device balloon.

External Apparatus Table:

Apparatus	Measurement
Pressure Sensor	Testing and calibration of pressure readings

Significance and Intended Use:

The significance of this test method is to ensure a significant amount of pressure is not lost within the tubing when the pressure inflation pump is used to inflate the device balloon. This method will address the required design specifications and will allow for analysis of the quantitative specifications for testing. This method is intended solely for proof of concept of the rescue prototype and does not represent the device's biocompatibility or proof of functionality for hemorrhage reduction.

Pressure Loss: Procedure

1. All participants should don appropriate personal protective equipment (PPE) before test commencement.
2. Disconnect the inflation line from the Y-connector.
    1. Ensure the tubing connected to the pressure gauge is sealed to the gauge. Ensure the tubing connected to the inflation bulb is sealed to the bulb.
    2. Ensure the tubing connected to the pressure gauge is sealed and connected to the Y-connector. Ensure the tubing connected to the inflation pump is sealed and connected to the Y-connector. Leave the bottom prong of the Y-connector open and unconnected to any component.
3. Ensure the units of measurement are set to inches of Mercury (inHg) on the pressure sensor.
    1. Follow the sensor's instruction manual.
4. Connect one of the lines of the pressure sensor to the open, bottom end of the Y-connector.
    1. Ensure any other lines of the pressure sensor (if any) are closed.

5. Zero the pressure sensor.
    1. Follow the sensor's instruction manual.
6. Close the inflation bulb by turning the knob all the way to the right.
7. Pump the inflation bulb until the pressure reading is 60 mmHg according to the pressure gauge.
    1. Ensure the pressure holds and that the needle stays stationary at 60 mmHg.
8. Record the pressure reading on the pressure sensor.
9. Release the pressure from the tubing by opening the inflation bulb (turning the knob all the way to the left).
    1. Disconnect the pressure sensor.
10. Repeat steps 4-9 for a total of 5 trials.
11. Document all findings of these trials.
    1. Compare pressure gauge readings to pressure sensor readings.
        i. Convert inHg to mmHg (or vice versa) as necessary.

Safety Considerations

Although all apparatus involved contain a low damage risk to humans, ensure proper lab etiquette, PPE use and document any injury or damage to the device or the operator and report per the WPI Standard Operating Procedure.

Data Collection

The majority of data collected during this test method is qualitative data, per the required design specifications and will be analyzed as a percentage of trials, with and without the desired outcome.

The quantitative data measurements will be analyzed using Minitab and a capability six-pack analysis to determine statistical significance to an average value. Data will be normalized prior to analysis using Python Programming, making use of the MinMaxScalar() function, if a bell curve is not achieved organically through testing.

APPENDIX H

Pressure Gauge Calibration: Pressure Reading Methodology 2.0

Scope:

This test method will calibrate the device pressure gauge indirectly by first assuming the device pressure gauge is pre-calibrated, then calibrating the pressure sensor used in Pressure Reading Methodology 1.0 to a range of pressures.

Apparatus Table:

Apparatus	Quantity	Description
Pressure Inflation Pump 	1	The pump that will be used to apply pressure to the pressure sensor.

External Apparatus Table:

Apparatus	Measurement
Pressure Sensor	Testing and calibration of pressure sensor readings

Significance and Intended Use:

The significance of this test method is to ensure the results obtained from Pressure Reading Methodology 1.0 are calibrated and valid. The team did not have sophisticated calibration devices or machinery in order to apply a calibrated amount of pressure to the device pressure gauge, so it was assumed pre-calibrated prior to use as it is not intended to be calibrated after every use. The team calibrated the pressure sensor to ensure it could be calibrated to a range of pressures. This ensured the results from Pressure Reading Methodology 1.0 were calibrated and valid and that pressure loss was indeed identified through the device lines.

Pressure Gauge Calibration: Procedure

1. All participants should don appropriate personal protective equipment (PPE) before test commencement.
2. Ensure the units of measurement are set to inches of Mercury (inHg) on the pressure sensor

a. Follow the sensor's instruction manual.

3. Zero the pressure sensor

a. Follow the sensor's instruction manual.

4. Obtain an inflation bulb and close the valve by turning the knob all the way to the right.
5. Connect the inflation bulb to one of the lines of the pressure sensor using a connector/connection piece.

a. Push the bulb, connection piece, and sensor line together to ensure a tight seal.

6. Zero the pressure sensor again.

a. Follow the sensor's instruction manual.

7. Gently pump the inflation bulb until a constant pressure is read.

a. Ensure the pressure holds and stays stationary at the obtained pressure.

8. Record the pressure reading on the pressure sensor.
9. Disconnect the pressure sensor.
10. Repeat steps 3-9 for a total of 10 trials, attempting to get pressures both above, below, and at the target pressure of 60 mmHg (approximately 2.36 inHg).
11. Document all findings of these trials.

a. Convert inHg to mmHg (or vice versa) as necessary.

Safety Considerations

Although all apparatus involved contain a low damage risk to humans, ensure proper lab etiquette, PPE use and document any injury or damage to the device or the operator and report per the WPI Standard Operating Procedure.

Data Collection

The majority of data collected during this test method is qualitative data, per the required design specifications and will be analyzed as a percentage of trials, with and without the desired outcome.

The quantitative data measurements will be analyzed using Minitab and a capability six-pack analysis to determine statistical significance to an average value. Data will be normalized prior to analysis using Python Programming, making use of the MinMaxScalar() function, if a bell curve is not achieved organically through testing.

APPENDIX I

Hemorrhagic Occlusion: Test Methodology

Scope:

This test method will evaluate the device's ability to occlude esophageal variceal hemorrhage and reduce catastrophic hemorrhage.

Materials Table:

Apparatus	Quantity	Description
Rescue Prototype	1	The rescue prototype will be inserted into the intubation dummy for testing purposes. The Rescue prototype contains one (1) large leading tube section and an inflatable balloon.
Small tubing	1	Tubing will be connected via a hole in the PVC pipe to model a ruptured varix
PVC Pipe	1	The pump that will be used to inflate the device balloon.
60 mL Syringe	1	The syringe will be filled with water
Griffin Beaker	1	Used to catch the water discharged during the text

Significance & Intended Use:

The significance of this test is to determine if the device prototype will occlude esophageal variceal hemorrhage and to what degree it will reduce such hemorrhage. This method will address the required design specifications and will allow for analysis of the quantitative specifications for testing listed in the materials table. This method is intended solely for proof of concept of the rescue prototype and does not represent the device's biocompatibility or proof of functionality for hemorrhage reduction.

Procedure:

1. All participants should don appropriate personal protective equipment (PPE) before test commencement, including gloves.
2. Remove the rescue prototype from packaging and lay flat alongside the dummy patient.

a. Ensure the balloon is in the deflated position before insertion.

3. Stand the PVC pipe in a vertical position above the catch beaker.
4. Connect the source of water to the hole in the esophagus tube via the tubing attached to the syringe.

a. Measure 60 mL of water into the syringe

5. Insert the prototype device into the PVC tube.
6. Inflate the device to 60 mmHg according to the pressure gauge while inside the PVC tube.
7. Push the syringe plunger to mimic an esophageal variceal rupture.
8. Once finished, remove the water source, deflate the balloon, and remove the device from the dummy esophagus tube.
    1. Measure the amount of water left in the catch beaker beneath the tube.
9. Document all findings for this trial.
10. Repeat steps 1-10 for a total of 10 trials.
11. Repeat this procedure without the device in place in the PVC pipe as a control.

Safety Considerations

Although all minerals involved contain a low toxicity or damage risk to humans, ensure proper lab etiquette, PPE use and document any injury or damage to the device or the operator and report per the WPI Standard Operating Procedure.

Data Collection

The majority of data collected during this test method is quantitative data, per the required design specifications and will be analyzed as a percentage of trials, with and without the desired outcome.

The quantitative data measurements will be analyzed using GraphPad Prism and a Student's *T*-Test.

APPENDIX J

Inflation Bulb: Test Methodology

Scope:

This test method will evaluate the inflation bulb's ability to inflate the balloon to a desired pressure and hold pressure for an extended length of time.

Apparatus Table:

Material	Quantity	Purpose
Inflation Pump 	1	Inflate the balloon

Significance & Intended Use:

The purpose of this test is to determine whether the inflation bulb can inflate the balloon to the desired pressure for an extended length of time.

Procedure:

1. Connect the inflation bulb to the device.
2. Close the valve on the bulb and pump the inflation bulb to a pressure of 40 mmHg according to the pressure gauge.
3. Check the balloon inflates with each pump of the inflation bulb
    1. If air leakage is noticed via sound or balloon deflation, check for air leakage points around the balloon and seal as needed
4. Continue to pump the bulb until it reaches the desired pressure.
5. Close the inflation pump valve to keep the balloon inflated.
6. Wait for a minimum of 40 minutes, checking every once in a while to ensure the balloon is still inflated and checking the measurement on the pressure gauge
    1. A longer period of time may be waited if desired
7. When finished, open the valve on the inflation bulb to release the air from the balloon.
8. Check the balloon deflates quickly.
9. Record results.

Safety Considerations:

The inflation bulb poses a relatively low risk to humans. However, it is important to ensure proper lab etiquette, wear PPE, and document any damage or injury to the device or operator.

APPENDIX K

Inflation Line Test Method: Air Leakage

Scope:

This test method will encompass the inflation line's ability to carry the air from the Y connector to the balloon without any leaks.

Materials Table

Material	Quantity	Description
Dish Soap	1 tsp	To mix with the water in order to create a spraying solution.
Water	1 bottle	To mix with the dish soap to create a spraying solution.
Spray Bottle	1	Used to spray soapy water on to the device.

Inflation line with balloon	1	The tubing that runs from the inflation pump and into the balloon.
Pressure inflation pump	1	The pump that will be used to inflate the device balloon.

Significance and Intended Use:

The purpose of this test is to determine if air can escape from any point in between the inflation pump and the balloon. This method will address the required design specifications and will allow for analysis of the qualitative specifications for testing. This method is intended solely for proof of concept of the rescue prototype and does not represent the device's biocompatibility or proof of functionality for hemorrhage reduction.

Air Leakage: Procedure

1. All participants should wear appropriate personal protective equipment (PPE) before test commencement.
2. Take the fully assembled device and place it on a table or in a sink.
3. Add 1 tsp of dish soap into the spray bottle, fill the rest of the bottle with water, ensuring that the two liquids combine.
4. Spray the device from the Y connector to the end of the balloon with soapy water.
5. Using the inflation pump, close the valve and begin to pump air into the balloon.
6. Watch closely to see if any soap bubbles begin to form, if they do there is a leakage of air at that location. If none form, there are no leaks.

Safety Considerations

Although all apparatus involved contain a low damage risk to humans, ensure proper lab etiquette, PPE use and document any injury or damage to the device or the operator and report per the WPI Standard Operating Procedure.

APPENDIX L

Balloon Strength: Test Methodology

Scope:

This test method will encompass testing the ability of the pressure balloon to withstand the appropriate tensile strength at the various connection points of the device.

Materials Table:

Material	Quantity	Description
Long Balloon	3	The balloon material will

		be cut into 2-inch strips from 3 larger balloons in order to fit in the instron grips.

Significance and Intended Use:

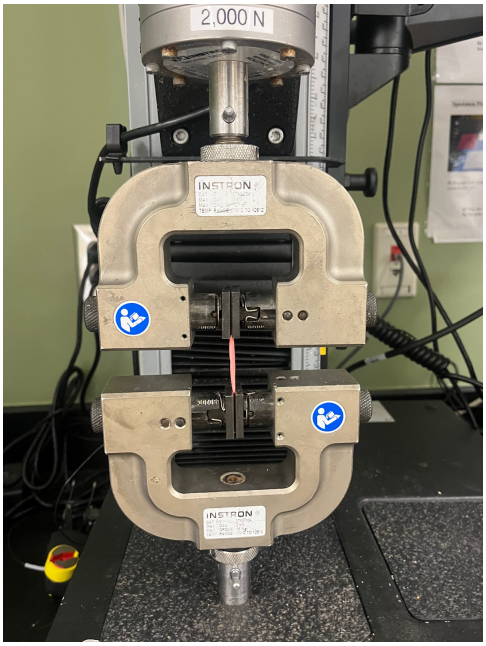
The significance of this test method is to ensure the balloons used on the device are able to withstand the physiological forces encountered by the device. Additionally, the force required to break the balloons must be greater than the force the device will routinely encounter. This method will address the required design specifications and will allow for analysis of the quantitative specifications for testing. This method is intended solely for proof of concept of the rescue prototype and does not represent the device's biocompatibility or proof of functionality for hemorrhage reduction.

Apparatus Chart

Apparatus	Measurement
Instron Machine and associated load cells.	Measurement of tensile strength, time and force.
Calibrated Ruler	Measurement of the length of the balloon.

Deployment of Device: Procedure

1. All participants should don appropriate personal protective equipment (PPE) before test commencement.
2. Ensure the setup of the instron with tensile test grips, appropriate load cell and Bluehill tensile strength run file.
3. Cut the balloons into 2-inch strips to be installed in the lower grips of the Instron.
    a. Repeat this step for all samples to be tested.
4. Insert the balloon into the grips.



5. Run the Instron test.
    a. Be aware the balloon may snap as it disconnects.
    b. Note if the disconnection occurred at the grips or within the balloon length.
6. Remove the disconnected pieces and put them to the side.
7. Repeat steps 4-5 for the remaining trials.
8. Document all findings for these trials.
9. Save the Instron output files.

Safety Considerations

Although all materials involved contain a low toxicity or damage risk to humans, ensure proper lab etiquette, PPE use and document any injury or damage to the device or the operator and report per the WPI Standard Operating Procedure.

Data Collection

The majority of data collected during this test method is quantitative data stored within the Instron graph and output file. The required design specifications and will be analyzed using statistical software for applicability.

The quantitative data measurements will be analyzed using GraphPad and a capability six-pack analysis to determine statistical significance to an average value.

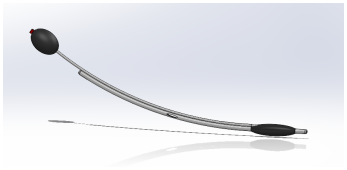
APPENDIX M

Deployment and Insertion of Device: Test Methodology 1.0

Scope:

This test method will encompass efficacy, safety and ability of the device to deploy for the primary prototype in an intubation dummy.

Materials Table:

Material	Quantity	Description
Rescue Prototype 	1	The rescue prototype will be inserted into the intubation dummy for testing purposes. The Rescue prototype contains one (1) large leading tube section, an inflatable balloon section and a port piece containing three (3) entrances for wire insertion through the device.
Intubation Dummy 	1	The intubation dummy will act as a representative human model for testing purposes.
Laryngoscope 	1	The Laryngoscope will be used to guide insertion of the drive into the dummy esophageal tube, mimicking a provider's method of insertion.
Surgical Lubricant 	1x 1 tube	Surgical Lubricant will be used to mimic the low friction factor that blood, mucus and emesis present in the body.

Significance and Intended Use:

The significance of this test method is to ensure the device is able to be properly inserted and deployed in a human esophagus, as well as removed without damage. This method will address the required design specifications and will allow for analysis of the quantitative specifications for testing listed in *Table 1.* This method is intended solely for proof of concept of the rescue prototype and does not represent the device's biocompatibility or proof of functionality for hemorrhage reduction.

Apparatus Chart

Apparatus	Measurement
Calibrated Stopwatch	Measurement of time of deployment and removal of the rescue device.

Deployment of Device: Procedure

1. All participants should don appropriate personal protective equipment (PPE) before test commencement, including gloves.
2. Intubate the dummy patient with an endotracheal tube prior to device insertion
3. Remove the rescue prototype from packaging and lay flat alongside the dummy patient.

a. The rescue prototype should be lightly coated in surgical lubricant for ease of insertion and condition simulation.

b. Ensure the balloon is in the deflated position before insertion.

4. Ensure the stopwatch is started from zero.
5. With the dummy in a supine position, open the mouth with the laryngoscope to visualize the esophagus tube.
6. Taking the distal end of the rescue device, insert into the esophagus model.

a. Inflate the balloon using the attached cuff inflation to 40mmHg, equal to approximately 30 mm balloon width.

7. Lap the timer and make note of the complete insertion time.
8. Visualize the airway, ensuring occlusion by the device is not present. Note any associated findings.
9. Deflate the balloon using the attached cuff deflation piece.
10. Slowly remove the device from the dummy patient.

a. Upon complete removal, make note of the time for complete removal on the stopwatch.

11. Visualize gloves for any tears or rips and document associated findings.
12. Document all findings for this trial.
13. Repeat steps 3-12 for subsequent trials.

Safety Considerations

Although all minerals involved contain a low toxicity or damage risk to humans, ensure proper lab etiquette, PPE use and document any injury or damage to the device or the operator and report per the WPI Standard Operating Procedure.

Data Collection

The majority of data collected during this test method is qualitative data, per the required design specifications and will be analyzed as a percentage of trials, with and without the desired outcome.

The quantitative data measurements will be analyzed using Minitab and a capability six-pack analysis to determine statistical significance to an average value. Data will be normalized prior to analysis using Python Programming, making use of the MinMaxScalar() function, if a bell curve is not achieved organically through testing.

APPENDIX N

Main Body Tube: Suction Test Methodology 1.0

Scope:

This test method will encompass the flow of air through the main body tube for the purpose of paramedic suctioning during an emergency variceal hemorrhage.

Apparatus Table:

Apparatus	Quantity	Description
Main Body Tube	1	The main body tube of the device.

External Apparatus Table:

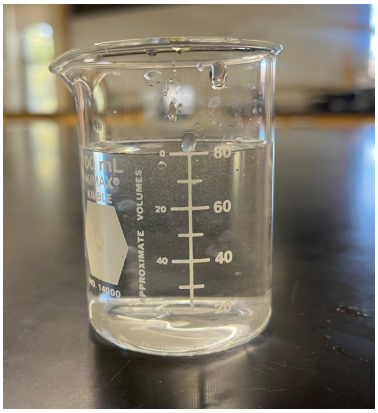
Apparatus	Measurement
60 mL syringe	Source of suction with appropriate suction catheter(s) for the effective suctioning of the main body tube

Significance and Intended Use:

The significance of this test method is to ensure the main body tube is able to maintain adequate air flow in order to facilitate efficient emergency medical suctioning of solid and fluid debris. This method will address the required design specifications and will allow for analysis of the quantitative specifications for testing. This method is intended solely for proof of concept of the rescue prototype and does not represent the device's biocompatibility or proof of functionality for hemorrhage reduction.

Fluid Suction Procedure: Control

1. All participants should use appropriate personal protective equipment (PPE) before test commencement.
2. Fill a small beaker with 80 mL of water.

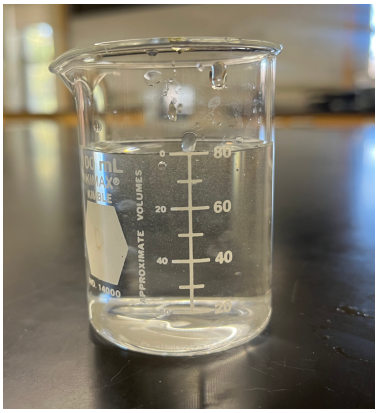


3. Assemble a tube fitting on the syringe to act as the suction line.

4. Suction the water using the 60 mL syringe tubing and note the water intake in the syringe. Do not insert the suction line into the main body tubing of the device for the control trials.
    1. (NOTE: this will be less than 60 mL due to air in the suctioning line)
5. Repeat steps 2-4 for all 10 trials.

Fluid Suction Procedure: Device Use

1. All participants should use appropriate personal protective equipment (PPE) before test commencement.
2. Fill a small beaker with 80 mL of water.



3. Assemble a tube fitting on the syringe to act as the suction line.

4. Insert the suction tubing into the main body tubing of the device.
5. Suction the water with the 60 mL syringe and note the water intake in the syringe. The suction line should run into the main body tubing of the device to determine if the main body tubing inhibits suctioning of the water.
    1. NOTE: this will be less than 60 mL due to air in the suctioning line
    2. NOTE: If the syringe is unable to suction the water make a note of this during the trial.
6. Repeat steps 7-10 for all 10 trials.

Safety Considerations

Although all apparatus involved contain a low damage risk to humans, ensure proper lab etiquette, PPE use and document any injury or damage to the device or the operator and report per the WPI Standard Operating Procedure.

Data Collection

The majority of data collected during this test method is qualitative data, per the required design specifications and will be analyzed as a percentage of trials, with and without the desired outcome. The

quantitative data measurements will be analyzed using Minitab and a capability six-pack analysis to determine statistical significance to an average value.

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