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Breathe Easy: A More Efficient Way to Avoid Tracheostomy Airway Blockages

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A More Efficient Way to Avoid Tracheostomy Airway Blockages

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ABSTRACT

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Over 100,000 people receive tracheostomies each year in the United States when mechanical ventilation is needed for longer than 48 hours, a patient has a chronically obstructed airway, or the patient is unable to protect their airway from aspiration. A tracheostomy is inserted into a patient's trachea in order to modify their airway through a tracheotomy procedure. A tracheostomy tube alters the natural lining of an airway which normally has a 5-50 μm thick layer of mucus. An airway with a tracheostomy tube produces more mucus than the average airway of a healthy person, and it also limits the patient's ability to swallow mucus causing mucus to build up on the walls of the tube.Mucus buildup is one of the major issues seen with tracheostomy tubes. Our device, Breathe Easy, aims to make cleaning a tracheostomy tube easier and faster. Breathe Easy limits the use of suctioning and is easy for not only caretakers to use but also the patient themselves. Breathe Easy is used by simply inserting the tube until the stopper prevents further descent, then the pump is squeezed to inflate the balloon located at the end of the tube. After inflation the outer ring on the balloon touches the sides of the tracheostomy tube. The user pulls the balloon out of the tracheostomy and the outer ring scrapes the inner wall of the tracheostomy. This scraping removes most of the mucus resulting in a clear airway so that the patient can breathe easy again.

Background

Tracheotomy Background:

A patient undergoes a tracheotomy procedure when mechanical ventilation is needed for longer than 48 hours, a patient has a chronically obstructed airway, or the patient is unable to protect their airway from aspiration [1]. A tracheotomy procedure is a modification of the patient's airway in which a tube, known as a tracheostomy tube, is inserted into the trachea of the patient [1]. Over 100,000 people receive tracheostomies each year in the United States [1]. A tracheostomy can be a short term solution that stays in the patient for a few days, or it can remain with the patient for the rest of their life. During the procedure, a surgical opening, called the stoma, is created in the neck by making an incision between the cricoid cartilage and sternal notch, exposing the trachea, and another incision is made in the second or third cartilage ring [2]. After these incisions are made, the tube is inserted and secured to the patient by sutures [2].

Tracheostomy Tube Description:

A tracheostomy tube consists of an outer cannula, an inner cannula, obturator, and a neck flange (Figure 1) [3]. A patent for the standard tube is given in Appendix 1. The outer cannula is the initial tube that is inserted into the trachea through the stoma in order to keep the airway open. The neck flange and outer cannula provide support in holding the tracheostomy in place [4]. In some cases, the outer cannula is cuffed with an inflatable balloon-like structure that is attached to the end of the

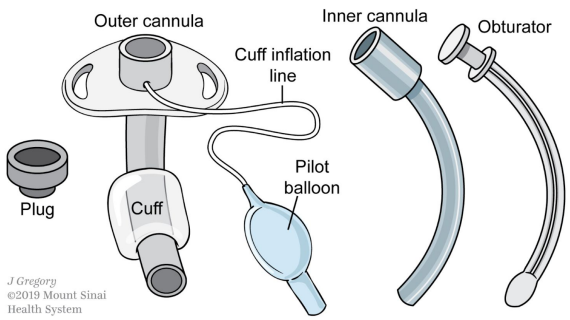

Figure 1. This is a labeled picture of a tracheostomy tube showing the inner and outer cannulas, the cuff, the obturator, and the pilot balloon that inflates the cuff.
Source: Adapted from [5]

tube that is inside the trachea. Once the outer cannula is inserted, the cuff is inflated until it comes in contact with the tracheal walls in order to prevent the outer cannula from becoming displaced during assisted breathing through ventilation and to decrease the chances of aspiration [4]. Commonly, a piece of gauze sits between the neck flanges of the outer cannula and the stoma. The gauze is used to absorb any saliva or mucus that is secreted out of the stoma. The inner cannula is a tube, thinner than the outer cannula, that is inserted into the outer cannula [3]. It is not necessary to have an inner cannula in all tracheostomy tubes. However, when increased mucus production is an issue, it is used to prevent obstructions without having to change the outer cannula, which can be a stressful process for patients [2]. The obturator is used to help guide the inner cannula into the outer cannula, but is immediately removed once the inner cannula is properly set in place [3].

Build-up of Mucus:

A normal airway has a 5-50 μm thick layer of mucus that is constantly moved by the cilia up and out of the respiratory system via the gastrointestinal tract [6]. This movement results in an average of 30 mL of mucus being swallowed or coughed up every day in patients with a normally functioning airway [6]. A tracheotomy procedure alters the natural lining of the airway and can cause the body to produce more mucus than it normally does. The insertion of the tracheostomy tube limits, or in some cases eliminates, the ability of patients to swallow these secretions. They attempt to expel the mucus from the natural airway and from the tube by coughing, but, as they cough, the mucus begins to build up in the tube [6]. As this mucus builds up, it dries along the inner sides of the tube and forms crusts [7].

Secretions that build up in the tube can cause infection in either the lungs or at the stoma if left untreated. One of the main concerns is the leakage of mucus into the lungs because it can lead to pneumonia, an illness that not only leads to more time in the hospital, but also puts the patient's life at risk. Pneumonia develops in 34% of tracheostomy patients in the hospital, and leads to an additional nine to twelve days in the hospital [8]. This comorbidity can lead to an additional $40,000 to $80,000 in healthcare costs for the patient [8]. Secretions that dry in the tube can obstruct the patient's airway causing respiratory distress or even death [7]. This can cause a person who should live a relatively normal life with their new airway to die because of an improperly cleaned tube.

Tracheostomy Tube Cleaning:

In order to keep the patient healthy, routine cleanings of the tracheostomy tube and the stoma must be performed. On average, the inner cannula and gauze are changed twice a day to keep the airway sanitary [9,10]. The tracheostomy tube is cleaned whenever the patient begins having trouble breathing as a result of an inability to clear the tube of their own secretions [9,10]. This can happen multiple times a day depending on the health of the patient's airway. Suctioning is the current method used to prevent and clear obstructions from a tracheostomy tube. The process of cleaning and maintaining the tracheostomy can consume a large portion of both the patient's and caregiver's day.

Indications for suctioning include the patient's inability to clear secretions on their own, abnormal or anxious breathing, irregular respiratory patterns, or excessive coughing [9,10]. Current suction devices are designed to be used by clinicians in a sterile environment with a new, sterile suctioning catheter used for each cleaning [9,10]. During the suctioning, the clinician

opens the sterile catheter and maintains sterile technique. The catheter is then attached to a suctioning vacuum and inserted into the tracheostomy tube to the bottom [6]. Suctioning power is turned on, and a thumb-controlled valve allows suctioning to be applied to the tube in 10-second intervals [9, 10]. The patient cannot breathe during the intervals when the tube is suctioned, so ample time, about 3 minutes, must be given to the patient between suction passes and there should be no more than 3 passes per cleaning [9]. Suctioning can be very uncomfortable and even frightening for patients because they are unable to breathe during this process, and this can lead to the development of anxiety [11].

To prevent obstructions, the tube must be suctioned whenever necessary by a caregiver or clinician since the patient is unable to suction their own tube [10]. If the tracheostomy tube is suctioned too frequently the airway can dry out, causing the body to produce even more mucus, and making it more difficult for the patient to handle their secretions. There are also many complications to this procedure. One major complication for this procedure is if not done properly the catheter can go too far into the airway or at the wrong angle, leaving the trachea at risk for injury [9]. Additionally, if the catheter is not sterile, it can cause infection in the tracheostomy tube leading to further health issues for the patient [9].

Suctioning at home is possible, but it can be a difficult and an expensive process because the patient needs someone else to suction their tracheostomy, ideally a trained caregiver [9,10,11]. The procedure also requires an expensive suctioning source to connect the catheter to along with frequent purchasing of sterile catheters. Even if the patient is capable of suctioning their own tube it is very difficult for them to do so because they cannot see where they are

putting the suctioning catheter. In emergency situations this can make it very hard for patients to clear their airway [7].

Current solutions revolve around improving the suctioning procedure. Devices such as the Trach-Assist® have worked towards making the suctioning process better for patients [12]. This device provides a more effective way of storing secretions that are suctioned through the catheter (Appendix 2). However, it does not eliminate any of the risks or discomfort that are encountered when suctioning a tracheostomy. There are no current solutions on the market or in development for cleaning a tracheostomy tube without the use of suctioning.

Problem Statement

Tracheotomy procedures are performed in over 100,000 patients in the United States per year in order to reopen chronically obstructed airways or to replace mechanical ventilation [1,2]. The tracheostomy can be a short-term or long-term solution for the patient depending on the severity of their condition [3]. This procedure greatly limits the patient's ability to swallow, so the 30mL of mucus and saliva that are normally eliminated from the airway by swallowing have to be dealt with in a different way [4,6]. The patient will cough up most of these secretions, which then become lodged in the tracheostomy tube, leak out of the stoma and settle on the skin, or settle deeper into the airway [4,9]. These possible outcomes resulting from mucus accumulation will cause infections, either of the respiratory tract or of the skin, if left untreated [9]. **It is necessary to mitigate mucus accumulation in long term tracheostomy patients in order to decrease the likelihood of airway blockage and address other substantial shortcomings of the current cleaning method.**

Design Objectives

Based on our continued research and conversations with medical professionals, we updated our design objectives and weightings from our original set last term (Appendix 2). The new weighted objective tree starts with safe, convenient, and marketable. We felt that since our device was meant to easily clean tracheostomy tubes, patient safety and convenience had to be equally weighted. Marketable was an important objective, but not as important as the other two, which is why it was given a lower weight . Following safe, the two second-level objectives our group determined were robust and reliable. Reliable was our top weighted objective after running the calculations, coming in at 0.28. It was incredibly important to us that our device works reliably for patients since their ability to breathe is dependent on it working correctly. The final weighting of robust came out to be 0.12 which falls in the middle of our final objective weightings. It was important to us that our device is strong, but it was not an absolutely essential objective. Under convenient, we placed quick and portable. Quick was our second most important objective with a final weighting of 0.24. Our device must be able to be used quickly to ensure patient comfort. Portable was given a weight of 0.16. Although not essential, we wanted our device to be easy for patients to bring anywhere so they can clean their tracheostomy tubes whenever they need to. Under the marketable category, we placed the objectives easy to use and cost effective. We weighted easy to use higher than cost effective with a final weighting of 0.12. The ease of use of this device was important when considering the construction of it. To be competitive to the relatively simple suctioning method patients and clinicians have to be able to easily figure out how to use the device. Our lowest weighted objective was cost effective. We wanted to make lives easier for patients, and design this device in a way so that patients would

be able to spend less money over time on cleaning their tracheostomy tube was still important to us.

Design Functions and Specifications

The overall goal for our device was to improve upon the current suctioning method for cleaning tracheostomy tubes. We chose three desired functions for our device while keeping in mind that our device needed to be not only effective, but also an improvement to the current suctioning techniques (Table 1).

Table 1. The functions and specifications for our device.

Function	Specification	Metric
Clean tube in 10s or less	Less than 10s [12]	Time to clean tube
Clear different viscosity obstructions with same effectiveness	P>0.05	Mass of obstruction removed
Clear tube more effectively than current suctioning	More than 50% cleared in one use	Mass of obstruction removed

The specification for the first function of our device was based off of a suctioning standard [13]. That standard states that suctioning cannot be done for more than 10 seconds at a time in order to prevent suffocation for the patient [13]. In addition, suctioning often has to be done two or three times before the tube is sufficiently clear, and after the third round of suctioning for 10 seconds, the patient needs additional oxygen which may not be available [13].

The second function of our device addressed the limitations of suctioning different consistencies of mucus. Current suctioning can clear the liquid and runny obstructions with ease, but the crusty obstructions cause issues and can block the suction catheter, rendering it ineffective [7]. As we learned both in our research and meeting with Dr. Leapman, obstruction

consistencies have wide ranges, from liquid saliva to runny mucus to rigid, crusty mucus [7]. The extreme cases would require different forces to remove than the intermediate cases. Dr. Leapman mentioned to us that, because suctioning cannot clear the crusts effectively, the caretaker may resort to pushing the crusts down into the lungs. We aimed for our device to be able to clear all consistencies of mucus with the same success rates. The specification for this was to have no significant differences in amount of mucus removed when comparing the different consistencies we tested.

The final function of our device aimed to improve efficiency of cleaning the tube compared to the suction catheters, which often need to be inserted into the tube two or three times before the airway is clear [13]. Our device should sufficiently clear the tube in one insertion in order to save time and save the patients from unnecessary discomfort and lack of air. With these functions and specifications in mind, we were able to begin the design process of our device to mitigate mucus accumulation and decrease the likelihood of airway blockage.

Design Requirements

There were requirements that our device had to meet so that it performed at the level that our team desired. These requirements pertain to the ability of Breathe Easy to successfully remove mucus obstructions in the tube. Our device had to be a quicker and more efficient method to clear all types of mucus obstructions than the current suctioning method. It also had to eliminate some of the risks that occur with suctioning due to the method itself or due to user error.

Our first requirement was that our device had to remove mucus successfully from the tracheostomy tube in 100% of its trials. We determined that as long some mucus is being removed then the obstruction has become smaller and the patient should be able to breathe easier. However, given that we are aiming to replace suctioning we decided our device had to remove at least 50% of the mucus that was in the tube. An obstructed airway is an airway that is greater than 50% occluded by an object or material [14]. When a patient has an occluded airway they have significant trouble breathing which can lead to anxiety and suffocation if not taken care of in a timely manner [14]. Therefore, our group determined that if we could remove at least half of the mucus in the tube then airway occlusions should not exceed 50%. This requirement would eliminate the respiratory distress the patient experiences when their airway is blocked quicker and more efficiently as it would take one swipe of the Breathe Easy and the obstruction would be cleared.

An underlying issue with suctioning is it causes anxiety for the patients due to the inability to breathe during the suctioning procedure [15]. After a few procedures, the noise of the machine alone can cause anxiety for the patient as well even before they are unable to breathe [15]. We determined it would be nearly impossible to clear an already obstructed airway without blocking airflow for a few seconds. We decided our device had to block the patient's airflow for as little time as possible, and at the very least less than 10 seconds, the amount of time suctioning blocks it. We also decided our device had to be silent so no noise induced anxiety would be added to the cleaning procedure.

Another risk that our device aimed to eliminate was damaging the trachea by inserting the device too far. If the suctioning catheter is inserted too far into the tracheostomy tube it can hit

the tracheal wall. This is uncomfortable for the patient, and will also cause scar tissue to form and cilia to be further damaged [16]. It can also dry the trachea outside the tracheostomy tube causing increased production of mucus which could lead to more occlusions. We determined that given the varying sizes of tracheostomy tubes it would be very difficult to make a device that the user never inserted too far. Instead, we decided to design our device so that if and when the device was inserted past the bottom of the tracheostomy tube it could not cause any damage.

This device could not cause any displacement of the tube as well. Movement of the tracheostomy tube would cause increased discomfort and would most likely lead to excessive coughing for the patient. Excessive coughing could lead to extreme exhaustion for the patient, and potentially cause a rib fracture if coughing persists for a long period of time with a great enough force [15]. We decided this was a risk our device had to eliminate as it causes further health issues beyond the tracheostomy tube for the patient.

Finally, we wanted our device to be able to remove more mucus from the tube in one swipe then suctioning could remove in an entire session. Currently, suctioning has to be applied to the tracheostomy tube multiple times during one suctioning procedure [15]. If our device could clear the obstructed airway quicker then one ten-second suction, the amount of time the patient needs to spend cleaning their tube is significantly decreased. With decreased cleanings, there would be less risk to the patient's well-being from potential dangers that come with cleaning.

Documentation of Proposed Design

Our device, Breathe Easy, is designed to be used by any tracheostomy patient who is in good enough health to clean their own tracheostomy, and by the caregivers of those who are not. It is a simple device that makes the cleaning of tracheostomy tubes easier and more efficient. If the patient is in good enough health, the design is simple enough to be used by the patient in their own home. This makes the cleaning of a tracheostomy tube quicker and more convenient for patients. The main task of the Breathe Easy is to remove mucus buildup from a tracheostomy tube in order to eliminate the obstruction to the airway and allow the patient to, as the name implies, breathe easy. The outer diameter of the device that would be inserted into the tube is about 3mm which is under half of the inner diameter of the tracheostomy tube (8mm). This allows the device to be inserted into the tube with ease and limits the amount of mucus that it comes in contact with while going down the tube. The scooping mechanism (balloon) is deflated as it is inserted to ensure that no mucus gets pushed down into the lungs during insertion.

When the tracheostomy tube is in need of cleaning, Breathe Easy is taken out of its package. When the device is taken out of its package the balloon (Figure 2a) is deflated and attached to the center rod that connects the balloon to the pump (Figure 2b). To begin cleaning the Breathe Easy is inserted into the inner cannula. The device is inserted until the bars on the top of the center rod (Figure 2c) reach the opening of the inner cannula to prohibit any part of the pump from entering the airway.

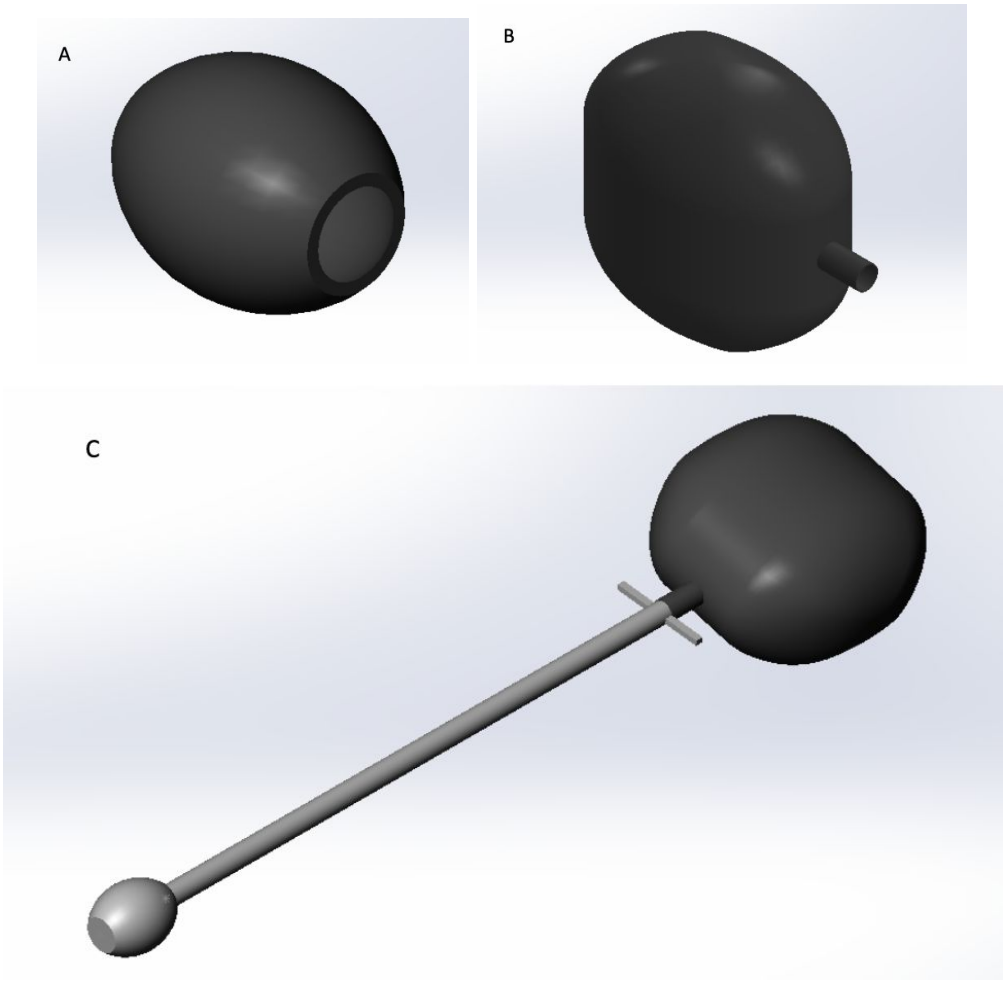

Figure 2. The inflated balloon (a) that goes into the tracheostomy tube and removes mucus. The pump (b) that inflates the balloon when squeezed. The entire device including the center rod and the handles at the top to stop insertion and allow for easier removal.

Once the device was fully inserted, the user would squeeze the pump once to inflate the balloon. The balloon inflates to the inner diameter of the inner cannula to ensure solid contact with the entire tube. The balloon does not deflate on its own so it will stay inflated to this diameter until the cleaning procedure is completed. The balloon has a ring attached to it (Figure 3) that scrapes the walls of the tube and allows for the removal of mucus that has become crusted to the wall. The ring is designed in a peak and valley formation to allow for the balloon to

collapse and stretch as the balloon goes from being deflated to inflated. The ring is made out of thermoplastic polyurethane (TPU) which is flexible enough to stretch during inflation, but is also rigid so as to be able to scrape the mucus without deforming and going around the mucus.

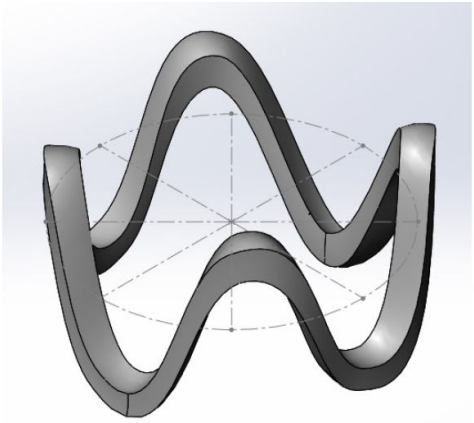

Figure 3. The ring that attaches to the balloon. Made out of TPU to allow for stretching when the balloon inflates. Scrapes the tracheostomy walls in order to remove mucus.

With the balloon inflated and the ring and balloon in contact with the tracheostomy walls, the user can begin to extract the device. The bars on the center rod can be used to establish a better grip on the device during removal. As the device is pulled out of the tracheostomy tube the balloon and ring begin to scrape the mucus off the walls and the mucus sits on the top of the balloon. The mucus is unable to go past the balloon because there is no space between the balloon and its ring and the tracheostomy wall. Therefore, the mucus follows the device out of the tracheostomy tube for removal. Once the device has removed the mucus and cleared the obstructed airway, the Breathe Easy can be thrown in the garbage as it is a one time use device.

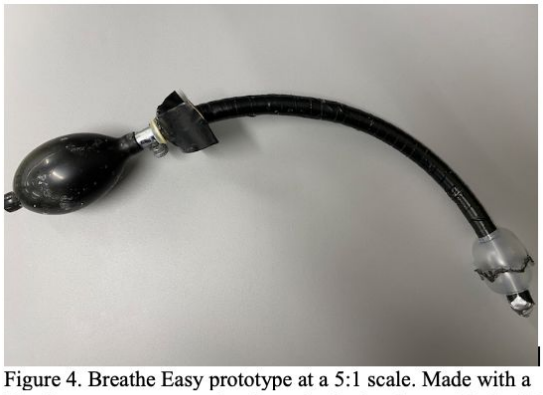

Figure 4. Breathe Easy prototype at a 5:1 scale. Made with a blood pressure pump and endotracheal tube along with the 3D printed ring for the balloon.

We developed a prototype (Figure 4) that was at 5:1 scale of our ideal device. This prototype would allow for us to create our device and test it at a more convenient scale. The prototype includes a pump from a blood pressure cuff and a balloon from an endotracheal tube. The blood pressure pump has an umbrella valve that allows for one

way flow of air. This allows the balloon at the end of the tube to remain inflated during the duration of cleaning. The endotracheal tube includes a balloon attached to the tube and, given the time and resources our group had, this is what we aimed to create so it made sense to use as a prototype. In order for the air from the pump to get into the balloon there is a whole in the endotracheal tube where the balloon is attached.

In the future, to make Breathe Easy an even more effective device we hope to include a few iterations. We would like to include a storage piece that collects the mucus as it is picked up by the balloon. This would avoid the potential of mucus spilling out of the tracheostomy during cleaning with the Breathe Easy. We also would like to manufacture this into a completely straight device as seen previously in Figure 2. This would allow for easier packaging and to potentially include more devices in a package then would fit with a curved device. Overall, this prototype of the Breathe Easy accurately simulates the device we hope to create.

Validation of Design

To validate our device, we designed testing parameters to measure whether the Breathe Easy fulfilled the functions and specifications that we aimed for it to achieve. We used three separate tests to measure the efficacy, one test for each main function of our device. The first test for our device measured the time to use our device. As a mock tracheostomy tube, we used a 1.5” diameter PVC pipe, the same material as the most common tracheostomy tubes. We cut the pipe to 8” long and secured it to the table with a clamp. This testing setup was used for all three tests. Again, for the first test, we were looking to find the average time it takes to use our device. We timed the same person using our device for 10 trials and averaged those times together

(Appendix 3). We found that the average time it takes to use Breathe Easy is5.8 seconds. This time is more than 40% faster than the time allowed for suctioning by St. Jude's [13].

For the second test, we looked to prove that our device cleared different viscosity obstructions with the same effectiveness. Since it was not possible to use real mucus for our testing for various reasons, we used slime made out of liquid glue, water, and Borax detergent. By adding different amounts of Borax to an equal-part water and glue solution, we were able to control the viscosity of the test mucus. There were three different testing groups for this test. One group was very runny, another group was very viscous, almost solid like the crusts that can obstruct the tube, and the last group had a viscosity in the middle of the other two. The mucus was loaded into the tube (Figure 5), and then we took the mass of the tube with the mucus in it and recorded that mass. The device was then used to clear the mucus from the tube. After the mucus had been cleared, the new mass of the tube was recorded (Appendix 4). This procedure was repeated five times for each viscosity of mucus. Once we had the 15 values, we calculated t-tests between the data for all three groups (low-medium, low-high, and high-medium). All t-tests returned values of $P>0.05$, indicating that there were no significant differences in the ability for our device to clear mucus of different viscosities, a definitive improvement over the suction catheter (Appendix 5).

Figure 5. The mucus loaded into the tube for testing.

The third test again used the same setup. We looked to see if our device could clear mucus more effectively than the current suction catheter. We calculated the percent of mucus removed per use of our device by weighing the tube before and after clearance with our device. The mass of the tube was subtracted from both of these values before calculating the percentage. We found that our device clears at least 50% of the mucus in the tube per use (Appendix 6). This value is significant because a patient begins to feel respiratory distress when their airway is 50% occluded. Therefore, they will be able to clear their tube to at least 25% occlusion in those extreme cases when they begin feeling distress.

After completing these tests, we feel confident saying that our device is an improvement to the current suction catheter in all three desired functions. Our results show that our device can be used faster than suctioning and that it works to effectively clear the tube from all consistencies of mucus.

Anticipated Regulatory Pathway

We anticipate that our device would fall into the Class 1 device category. Current suctioning catheter devices have been given Class 1 status [17]. This classification means that our regulatory pathway is significantly less regulated than other devices. It also means that our device falls into the same category as 55% or so of all medical devices and poses little risk to the user. This being said, we would have to abide by general controls in order to get and keep our device on the market. This device would be considered a “Medical Device Accessory,” as it works in conjunction with a tracheostomy tube and does not work without one.

Suction catheters fall under the regulation number 868.6810. Devices under this number are exempt from premarket notifications and the 510(k) pathway. During production, however, our device must still be manufactured following Good Manufacturing Practices (GMP) and are subject to Quality System Regulation (QSR) [17].

To continue with getting our device to market, we must abide by the general controls. These controls state that we have to register the establishment and its connections with the FDA. This means providing the FDA with the location of the production facility and a list of all medical devices manufactured in that facility. General controls also require following GMP for production of the device. Third, we must follow all labelling guidelines, that includes posters, brochures, and pamphlets in addition to the labelling on the device and packaging. These requirements mandate not only the integrity of the label and its information but also where in the facility the labelling takes place in relation to the manufacturing and packaging. Lastly, general controls require that our device cannot be 'adulterated or misbranded' [17].

Since our device would be given Class 1 denomination, no predicate devices are needed to claim substantial equivalence. Again, our device is 510(k) exempt. That said, similar devices would be suction catheters. The tracheostomy tube, however, must obtain 510(k) clearance before going to market. One specific example is the Covidien LLC Shiley Pediatric Tracheostomy Tube Cuffless [18]. This device has a 510(k) number of K945513 [18]. It was deemed substantially equivalent to a predicate cuffless tracheostomy tube with 510(k) number K083641 [18]. This Class II device meets multiple ISO standards including ISO 10993-1 for biocompatibility, ISO 5366-1, ISO 5366-3, and ISO 5356-1 for anesthetic and respiratory

equipment [18]. To prove that the Shiley Pediatric Tracheostomy Tube Cuffless meets these ISO standards, Covidien, LLC performed benchtop testing and biocompatibility testing [18].

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Appendices

Appendix 1

Figure 1. (Top) The Trach-Assist is connected to the tracheal tube and a suction device. (Bottom) The Trach-Assist is used to connect the tracheal tube to a suction device, and it can store the secretions that are suctioned out. This device has to be used by a clinician.

Appendix 2

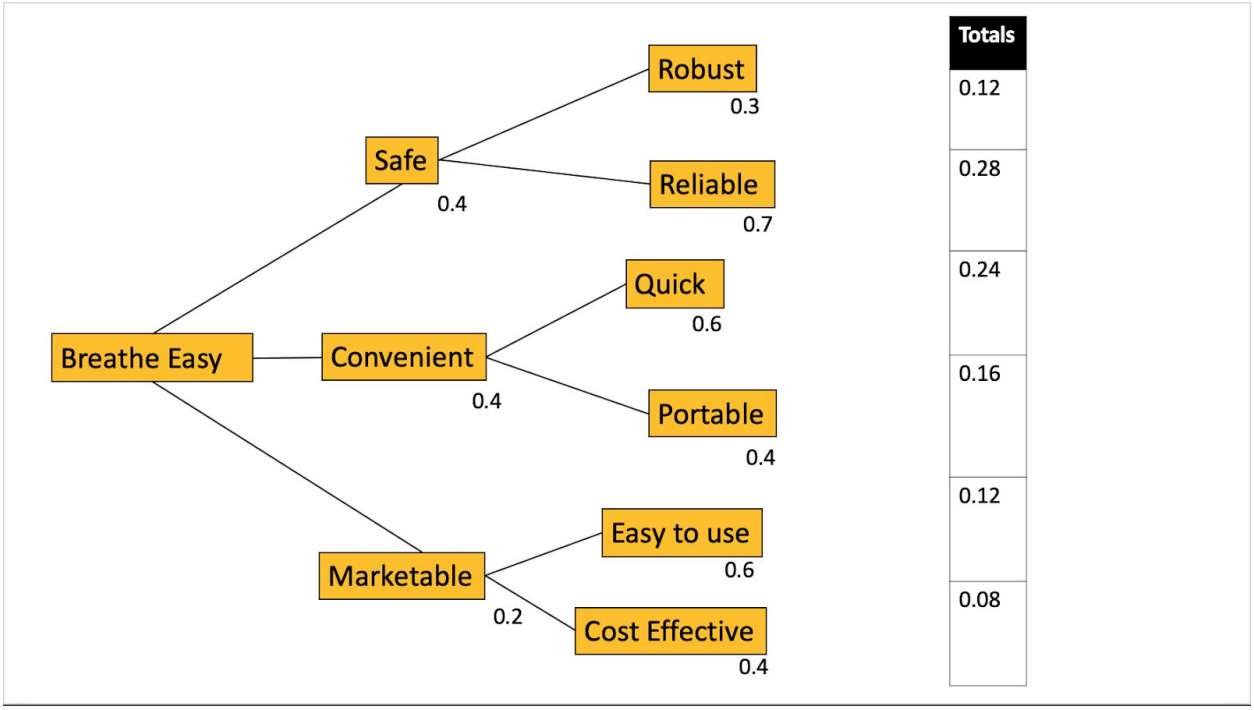

Figure 1. This is the objective tree showing the objectives and weightings that our team determined for our device.

Appendix 3

Table 2. The data for our time testing of the device.

Time to use device (1.5" tube)	
Trial #	Time (s)
1	5.37
2	5.19
3	6.39
4	6.56
5	6.28
6	5.69
7	6.54
8	5.08
9	5.72
10	5.14
Avg	5.796

Appendix 4

Table 3. The data for our third test measuring ability of the Breathe Easy to clear different consistencies of mucus

Viscosity	wt in g											
	Low				Medium				High			
Trial #	Before	mucus in tube	After	Diff	Before	mucus in tube	After	Diff	Before	mucus in tube	After	Diff
1	129	32	118	11	132	35	119	13	110	13	101	9
2	126	29	119	7	131	34	123	8	122	25	99	23
3	123	26	116	7	131	34	118	13	109	12	100	9
4	128	31	115	13	130	33	112	18	117	20	101	16
5	127	30	113	14	130	33	106	24	120	23	110	10
			AVERAGE	10.4			AVERAGE	15.2			AVERAGE	13.4
			STD DEV	3.286335			STD DEV	6.058052			STD DEV	6.107372

Appendix 5

Table 4. The t-tests measuring significance between clearance of different consistency mucus.

L-M	M-H	L-H
0.15800	0.65234	0.36175

Appendix 6

Table 5. The percentage of mucus removed using the Breathe Easy.

weight of tube			
97g	Low	medium	high
	0.34375	0.3714285714	0.6923076923
	0.2413793103	0.2352941176	0.92
	0.2692307692	0.3823529412	0.75
	0.4193548387	0.5454545455	0.8
	0.4666666667	0.7272727273	0.4347826087
average %	0.348076317	0.4523605806	0.7194180602

average % of mucus for all viscocities
0.5066183193