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REDESIGNING NASOGASTRIC FEEDING TUBES TO PREVENT DISLODGEMENT

by
Shelby Lynn Berry and Sydney Ruth Rester

A thesis submitted to the faculty of The University of Mississippi in partial fulfillment of the requirements of the Sally McDonnell Barksdale Honors College.

Oxford, MS
May 2023

Approved by:


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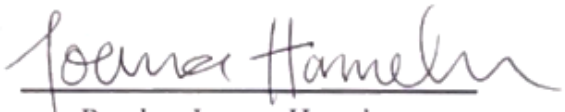
Reader: Joanna Harrelson

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DEDICATION

We would like to dedicate this thesis to our friends and family for their overwhelming love and support in all that we do:

Eddie Rester
Audra Rester
Ann Claire Rester
Molly Kate Rester
Ellen Williams

Jeff Berry
Missy Berry
Colten Berry
Pete & Evie Marie Berry
Arianna Swensen

And of course, Dr. Taylor Alison Swift, without whom, as we know *all too well*, we would not have been able to complete this thesis.

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Abstract

Seniors at the University of Mississippi studying biomedical engineering complete a senior project that seeks to solve a problem in healthcare. Our team, composed of Sydney Rester, Shelby Berry, Andrew Ulmer, and Alex Bromley, sought to improve care associated with nasogastric feeding tubes. We identified two major problems: clogging and tube dislodgement. To address the problem of dislodgement, the team crafted a new feeding tube design with a balloon attachment. The attachment prevents a patient from pulling the feeding tube out and keeps the tube from dislodging due to normal patient movement. We further determined that our tube should be made of silicone and printed a prototype with acceptable dimensions. Future works with this device will include producing a second prototype made of medical grade silicone, testing the prototype in animal subjects, patenting our device, and seeking FDA approval for our device so that it can be used in a clinical setting.

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Introduction

A nasogastric (NG) tube is a medical catheter that enters the body through the nostril and ends in the stomach. It is used to deliver a nutritious solution to patients who cannot otherwise nourish themselves. NG tubes may also be used to deliver necessary medications. The single-lumen NG tube can be placed in patients for several weeks and complications can include discomfort, clogging, and dislodgement ("Nasogastric Tube: What It Is"). In fact, unplanned dislodgement may occur in 25-50% of nasoenteric tubes, which deliver nutritious solutions to the intestines, and in an estimated 48.5% of NG tubes (Pancorbo-Hidalgo et al., Levy). Current solutions to this problem include the tape technique and the nasal bridle (Brugnolli et al.). However, the tape technique has side effects including skin irritation, and the nasal bridle has not been well received by patients due to its appearance, as well as only possessing limited data to support its routine clinical use (Brugnolli et al.).

Despite these preventative solutions already in practice, NG tubes may still become dislodged due to device failure or lack of widespread implementation. Tubes that become severely dislodged must often be replaced. Replacement feeding tubes may cost as much as $8,020 due to the necessary materials and labor required to insert a new feeding tube (Mayes et al.). Due to the limited solutions to this problem, there is a gap between patient and hospital needs and existing technology that prevents dislodgement. Our device will fill this gap; as a medical device, it will prevent tube dislodgement and ensure that patients are able to receive the nutrition they need with as few interruptions as possible. It will be an improvement on the current technologies because it will maximize patient comfort while keeping the overall dislodgement rate of the feeding tube low.

Literature Review

What Is a Nasogastric Feeding Tube?

Enteral feeding tube placement is routinely used to provide nutrients and medication to patients who cannot effectively nourish themselves. The American Society for Parenteral and Enteral Nutrition (ASPEN) asserts that 250,000 hospitalized patients per year require enteral nutrition support, often given using enteral access devices (EADs), at some point during their hospital stay (Boullata et al.). In addition, enteral nutrition support is also used outside of hospitalized settings, including at home and in rehabilitation facilities (Boullata et al.). Modern EADs, or "feeding tubes", are made from silicone or polymers; however, the earliest feeding tubes were long tubes made of silver with a funnel or syringe attached to the end (Cresci et al.). In the early 1600s, the silver tube was often used to feed tetanus patients (Cresci et al.). By 1649, leather tubes were used as they were more flexible (Cresci et al.). Present-day feeding tubes are much more advanced, but are still subject to a variety of potential complications.

The most common short-term feeding tube is the NG tube (Cresci et al.). NG tubes are inserted through the nares, or the "anterior opening of the nasal sinuses", and passed "through the posterior oropharynx, down the esophagus, and into the stomach" (Sigmon and An). The insertion technique of the small-bore, 8-12F NG tube involves "lubricating the tube, flexing the head, and having the patient ingest sips of water" (Delegge). A diagram displaying a simplified placement of an NG tube is shown in Figure 1.

Figure 1: NG Tube Placement (from "Nasogastric (NG) Tube")

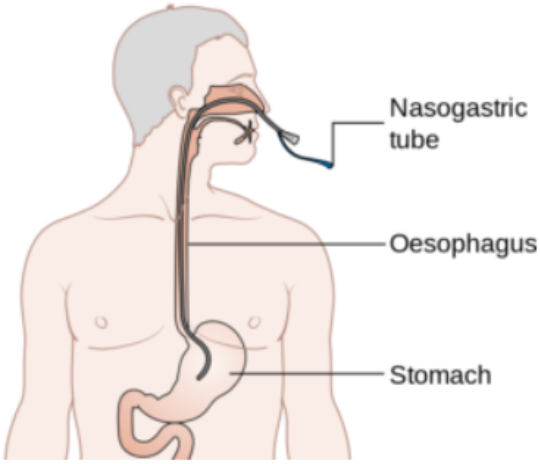

Figure 1 (from "Nasogastric (NG)"): A simplified diagram of how an NG tube is positioned in the body. The tube is inserted through the nose and moves through the esophagus to the stomach. Image courtesy of Oxford Medical Education.

There are several methods for determining the correct length of NG tube necessary for a patient. One particularly common method involves looping the tube over the patient's ear and positioning the tip of the tube at the "xiphoid process", or lower part of the sternum (Sigmon and An). Most patients will require an NG tube for less than a month (Pearce and Duncan).

What is Tube Dislodgement?

One limiting factor of NG tubes is dislodgement, which occurs when the feeding tube is moved out of its ideal placement (Levy). This limiting factor contributes to a low mean tube life of 10 days (Levy). In one observational study carried out in an intensive care unit (ICU), the tube dislodgement rate was 48.5% in a group of 64 patients fed by an NG tube (Pancorbo-Hidalgo et al.). Another study noted that NG tubes had a dislodgement rate of 28.9% (Mion et al.). These studies indicate that anywhere from approximately one-third to one-half of NG tubes will become dislodged.

In addition to being uncomfortable, tube dislodgement and displacement is problematic because it prevents a patient from receiving nutrition, water, and potentially medication when they are already vulnerable (Mayes et al.). Furthermore, nurses will likely have to attempt to reinsert the NG tube and reconfirm its placement in the patient. This may expose patients to unnecessary radiation as nurses perform additional x-rays to check tube placement (Mayes et al.). There is also a monetary cost associated with feeding tube dislodgement. This comes from the labor cost of nurses having to reinsert the feeding tube, and potentially monitor the patient more closely for future displacements, and the material cost of another NG tube and the resources necessary to insert another feeding tube (Mayes et al.). This cost is then put on patients in the form of an increased hospital bill. One study on tube dislodgement estimated that the cost of a single feeding tube dislodgement could result in a bill as high as $8,020, including the cost of the feeding tube, an x-ray to reconfirm tube placement, the cost to stay in a "nursing unit" for a day, and the approximate cost of an emergency room visit (Mayes et al.).

Current Solutions

Current solutions to the problem of dislodgement include the tape technique and the nasal bridle (Brugnolli et al.). The tape technique, in which NG tubes are taped to patients' skin using adhesive tape or another commercial fixation device, is the most common method to prevent dislodgement (Brugnolli et al.). The incidence of tube dislodgement with this method is around 40% (Brugnolli et al.). The tape technique is often affected by patient factors such as facial hair and oily skin, as they prevent effective

tape adhesion (Brugnolli et al.). Severe tube dislodgement can lead to tube replacement, which adds to hospital costs and patient distress.

Another solution to NG tube dislodgement is the "nasal bridle," which involves a device that enters the nostril, wraps around the nasal septum, and exits from the other nostril, at which point both ends are attached to the feeding tube (Brugnolli et al.). A diagram detailing how to insert an AMT Bridle Pro®, a type of nasal bridle currently on the market, is shown in Figure 2.

Figure 2: Nasal Bridle ("AMT")

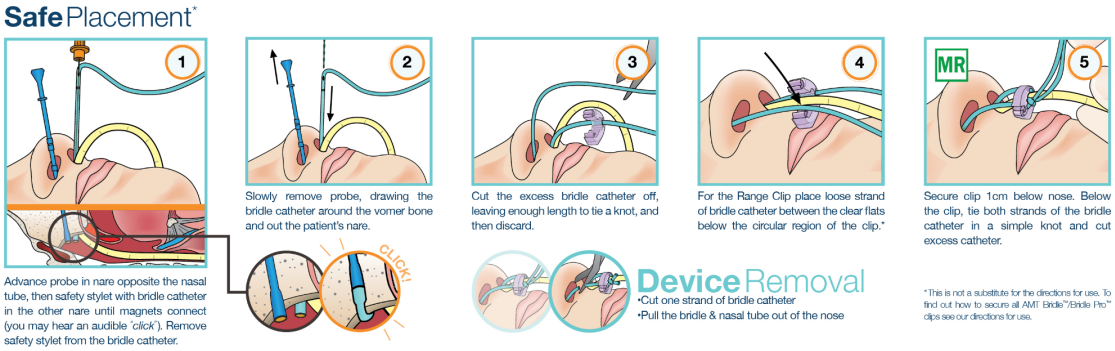

Figure 2 (from "AMT"): The AMT Bridle Pro® is inserted through one nostril, drawn around the vomer bone to hold it in place, then secured in place with a clip ("AMT").

Some studies indicate that bridling the feeding tube reduces the rate of unintentional dislodgement significantly and may decrease the likelihood of procedural complications (Brugnolli et al.). The nasal bridle has been shown to reduce the dislodgement rate of nasoenteric (NE) feeding tubes in ICU patients from 38% (without a bridle) to 4% (with the bridle) (Brandt and Mittendorf). The same study showed that the mean "time of tube use" increased from 16 days to 23 days with the use of the nasal bridle (Brandt and Mittendorf). Another study found that the nasal bridle reduced the displacement rate of the feeding tube from 62% (without a bridle) to 32% (with the

bridle), but caused 19.5% (7 out of 37) of patients to develop nasal ulcers after the fifth day of use (McGinnis). However, Dr. Anna Brugnolli and her colleagues concluded that despite studies where a large number of patients received the device, there is not sufficient evidence to truly suggest the nasal bridle over the tape technique (Brugnolli et al.).

Additionally, many patients and doctors perceive the bridle to be uncomfortable and become concerned that it may cause nasal trauma (Seder et al.). Despite the lack of evidence to concretely link the nasal bridle to an increase in patient discomfort, the perceived discomfort is enough to limit the nasal bridle's clinical use (Seder et al.). Therefore, a device that can prevent dislodgement without causing actual or perceived patient discomfort is paramount to improving patient care.

The team's revised *Literature Review* document on NG tube dislodgement is shown in Appendix 2.

Prior Art Search

A key part of product design is analyzing previous products and patents to ensure that your design is not similar to an already-existing or otherwise patented technology. As a team, we identified six examples of prior art related to the issue of NG tube dislodgement or to that of balloon anchors in tube devices.

Reference 1: ***Improved inflatable retention system for an enteral feeding device AU2015258210C1***

Reference 1 is a patent for an inflatable retention system for a percutaneous gastrostomy (PEG) catheter tube. The balloon is tapered and widens towards its distal end to increase its surface area and holding force. This technology has not been adapted for NG tubes. The authors also proposed a multi-channel system to allow for a more uniform inflation.

Reference 2: ***Enteral feeding catheter assembly incorporating an indicator US10085922B2***

Reference 2 is a patent based on a PEG tube that utilizes a balloon anchoring system; however, the authors of this patent proposed the addition of a pre-biased indicator that is in fluid communication with the balloon at the distal end. This provides a visual signal to the medical professional that shows whether or not the inflation medium

or pressure inside the balloon is different from the predetermined values, which helps prevent surgical complications and indicates balloon integrity over time.

Reference 3: ***A nasal bridle insertion device US20170105904A1***

Reference 3 is a patent that describes a device that inserts a nasal bridle with a configuration switching mechanism. The device's first configuration is straight, which helps with passing the bridle to the point of the septum. The guide wire is then bent to pass the bridle around the septum and out of the other nasal cavity. The two ends of the bridle are connected using bridle tape and then connected to an NG feeding tube. The nasal bridle is expected to be our greatest competition, as it has been shown to decrease the dislodgement rate of NG tubes.

Reference 4: ***Bridle Device, EP2882481B1***

Reference 4 describes a magnet retrieval system within the bridge of a nasal bridle, which allows for easier bridle securing. This patent claims that the device has the ability to secure connection using the magnets, even when initial magnet orientation allows only for repulsion, by allowing one magnet to freely rotate. The bridle line outside of the nostrils can also be attached to the feeding tube and anchoring point via clip, tape, or other retention means. This is an improvement on the original nasal bridle design to better account for patient comfort.

Reference 5: ***Bridle system for placing and securing a nasal tube in a patient WO2014066572A1***

Reference 5 describes a device that includes the typical nasal bridle securing system with two magnets that are run through opposite nares to attract a flexible member through the nasal septum. Then, an external receiver attachment secures the NG tube outside of the nasal cavities. This external attachment can support different types of NG tubes and claims to allow for greater comfort and more reliable anchoring.

Reference 6: ***Anchored Working Channel US20130116549A1***

Reference 6 describes a device that creates a "working channel" with a tube that has a hollow lumen that guides medical instruments such as catheters or endoscopes. It has multiple inflatable balloons with textured surfaces to improve grip along different points of the channel to prevent problems with migration and dislocation. The channel is small enough in diameter to allow it to enter into body cavities that could not previously be passed through without compromising the channel's structural integrity. This example showcases the wide variety of applications for balloons as anchoring devices.

The team's revised *Prior Art Search* document on NG tube dislodgement is shown in Appendix 4.

Problem Statement

Our project aims to design and develop a way to decrease rates of dislodgement in teenage-adult nasogastric feeding tubes to prevent the need for tube replacement and provide a more “aesthetically-pleasing” and comfortable alternative to the nasal bridle.

Value Proposition

Our product aims to prevent the dislodgement of nasogastric feeding tubes in teenage-adult patients in order to increase patient comfort and decrease hospital costs associated with replacement due to dislodgement. Based on available data, we estimate that our device could save as much as $8,000 in materials and labor for hospitals per patient (Mayes et al.). These costs include a new NG tube, an x-ray to confirm tube placement, a day's stay in a "nursing unit", and an emergency room visit (Mayes et al.).

Brainstorming Process and Notes

Early Brainstorming

In the beginning of the design process, our group wanted to design a product that would reduce or eliminate clogs in NG feeding tubes. We found that the chance of a feeding tube becoming occluded over its lifetime was 12.5-45% (Fisher and Blalock). After researching the problem, we decided to design a valve and pump system that would negate the need for regular maintenance and prevent the buildup of proteins and other debris in the tube. The valve would be connected to a reservoir of enteral solution, a water pump, and the NG feeding tube in the patient. Inside the valve, a tube would rotate to connect the two inlets (the enteral solution and distilled water) to the outlet (the feeding tube) at regular intervals. This would automate the flushing process for nurses and prevent buildup in the tube that could result in a clog. A rough sketch of the design is shown in Figure 3.

Figure 3: Drawing of Valve

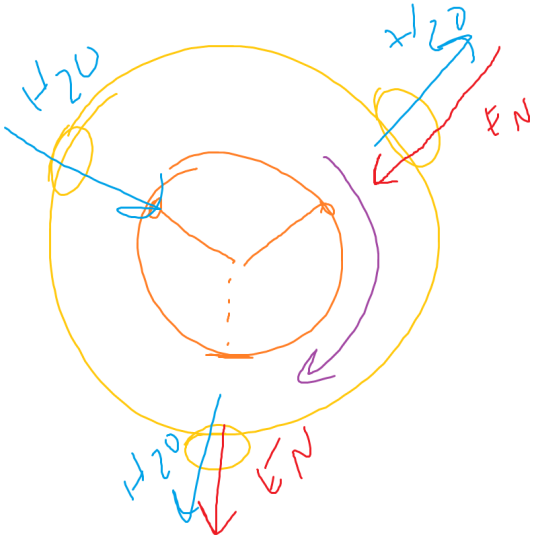

Figure 3: Rough sketch of the team's idea for providing regular tube maintenance to prevent clogs. Drawing done by Shelby Berry.

The team's *Literature Review* and *Prior Art Search* documents on NG tube clogs are shown in Appendices 1 and 3, respectively.

However, after an interview with Dr. Leigh Holley, a professor and administrator at the University of Mississippi School of Nursing, our group realized that, while clogging was a serious problem, it was not as prevalent as we had originally thought. Furthermore, there were already many solutions implemented by nurses to unclog feeding tubes, making our device expensive and redundant. With this in mind, we decided to switch the focus of our project to another problem.

Instead of clogging, we decided to focus on NG feeding tube dislodgement. To achieve this, we came up with several solutions.

Previous Designs

The first solution involved a mechanical component at the end of the NG tube which, in response to a signal, would "open" like an umbrella. This would make the tube too large to move back into the esophagus, preventing unintentional displacement of the tube. In response to another signal, the component would "close" so that the tube could be easily removed. However, we quickly abandoned this idea after realizing the number of moving parts that this solution would require; we were desirous of a simple solution that would be easy to implement and would not cause a significant process change for use and maintenance from the status quo.

A similar solution involved the use of a "puppet arm-like" component. Like the previous solution, we would design and attach a part at the end of the tube that would

make the tube too large to move into the esophagus. However, instead of an umbrella-like component, we would use two pieces that would "bend" outwards as they were pulled by a nurse. We would then employ a locking mechanism at the top of the tube to hold the pieces in place. When it was time to remove the tube, the nurse could simply unlock the pieces and move them back into their original configuration. A preliminary sketch of this device is shown in Figure 4. Similar to the previous design, though, we decided to not utilize this solution as we were concerned that the potential number of moving parts would provide too many opportunities for device failure and patient harm.

Figure 4: Ideas for Design

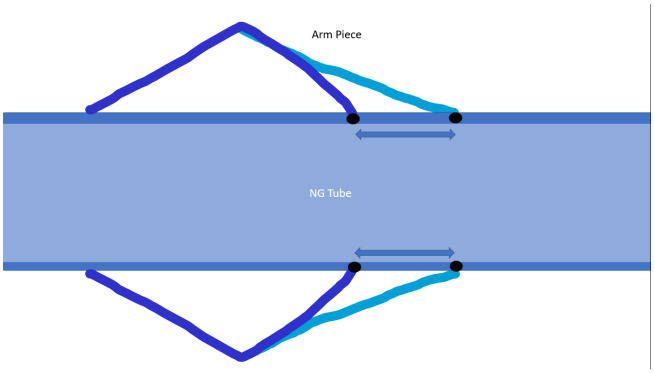

Figure 4: Ideas for design, originally drawn by Troy Drewry on a whiteboard and adapted by Sydney Rester.

Final Design

Our group ultimately settled on a design that utilized balloons to anchor the feeding tube in place. There will be one balloon on each side of the tube and, when they are expanded with saline solution, their size will prevent the NG tube from moving through the lower esophageal sphincter (LES). When nurses are ready to remove the tube, the balloons can be easily deflated. We liked this design because it had very few moving parts (soft silicone balloons instead of hard mechanical pieces) and because

balloons are a well-established device used for anchoring medical devices (Kim et al.). Figure 5 shows our SolidWorks drawing for this design.

Figure 5: SolidWorks Drawings

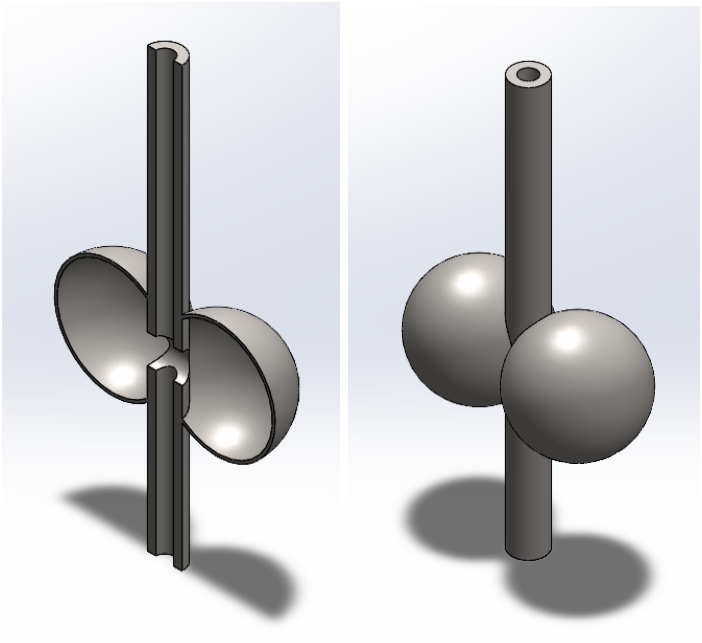

Figure 5: SolidWorks Drawings by Shelby Berry. Note: this is not the final design for our product and is merely a rough 3D printed prototype. Balloons will not be open to the feeding tube and nutrition solutions will not enter the balloons. Slight changes have been made to the design for the purposes of printing a prototype.The inflated diameter of the device at its widest point is 3.5 cm, which is greater than the LES at 3 cm. The external diameter of the tube is 6 mm and the internal diameter of the tube is 3 mm.

Our final design has several benefits:

1. **Dislodgement prevention.**
    a. *Balloon size.*

        When the balloons are inflated, they will be too large to pass through the LES. This will keep the tip of the tube in the stomach and will prevent the tube from being accidentally dislodged,

whether that is by unintentional migration of the tube or patients intentionally pulling the tube in an attempt to remove it.

b. *Balloon weight.*

Another feature of our design is the weight of the balloons themselves. When filled with saline, we estimate that they will weigh approximately 6.7 g. This will provide an additional safeguard against dislodgement, as it will require more force for our NG tube to move up the esophagus than an unweighted or weighted tube. In our examination of weighted tubes given to us by the University of Mississippi School of Nursing, we found that the weighted tip weighed about 3.5-4 g. Based on our understanding that the weighted end of the NG tubes does not cause significant issues in treatment, we believe that the weight of our balloons will also not cause significant issues in treatment.

2. Maintains space between tube tip and stomach wall.

a. *Balloons act as a buffer.*

Another complication with NG tubes occurs when the tip of the feeding tube where the enteral solution enters the stomach interacts with the stomach wall. This blocks the exit holes in the NG tube and prevents patients from receiving necessary nourishment and may cause other complications as well (Pillai). We theorize that our device will be able to decrease the chances of this happening,

as the balloons will provide a buffer between the end of the tube and the walls of the stomach to keep the tube in the center.

3. **Inhibits feeding tube knotting.**

    a. *Balloon size*

    The knotted feeding tube complication is a lesser known complication where the tube loops back on itself to create a knot or kink (Liu et al.). This prevents effective nutrition delivery and the safe removal of the tube. The balloons on our device are large enough that the tip could not easily or naturally twist back on itself to create this knot, thereby preventing this particular complication.

Materials

We decided to use FDA approved silicone as our material. This decision was initially influenced by the large number of FDA approved medical devices already in use that contain silicone, including, but not limited to, specialty contact lenses, urinary catheters, reconstructive gel fillers, and medical inserts (Zare et al.). Silicone possesses many desirable qualities for our product, such as “chemical inertness”, meaning it will not undergo a chemical reaction and change form in the body, and a high biocompatibility, meaning it is not toxic or harmful to the body (Rahimi and Mashak). One study found that silicone rubber has an average ultimate strength, defined as the maximum stress a material can bear before it ruptures or fails, of 6.54 MPa and an elastic modulus, or a material’s resistance to impermanent deformation, of 0.53 MPa over a temperature range of -20°C to 45°C (Muslov et al.). The low elastic modulus indicates that silicone is capable of returning to its original shape after being stretched or

compressed due to its softness and high flexibility. This is an important property for our device, as the silicone NG tube will need to be able to withstand the stress of being bent or curved as it moves through the nasal cavity and esophagus. Additionally, the silicone balloons will need to be able to stretch as they are inflated and then return to their original size (flush against the side of the tube) for safe removal.

Furthermore, being able to withstand a large amount of stress before fracturing ensures that our device will be resistant to damage from intentional and unintentional dislodgement. The maximum pull strength of an adult man is 400 N (Das and Wang). We estimated the surface area of the balloon attachment interface (described below) to be 0.00063 m^2, giving us a maximum pressure on the balloon from pull strength to be $6.35*10^5$ N/m^2, or 0.635 MPa, which is well below the ultimate tensile strength of silicone. This will prevent the tube or the balloon from rupturing should a patient or other entity attempt to pull the tube out by force. The ability to withstand a large amount of stress is also important for inflating the balloons. By choosing silicone as our material, we have ensured that there will be a large enough margin of error for balloon inflation. This means that, should too much saline be put into the balloons, the likelihood of the balloons popping or deforming is low.

Additionally, most silicones are “temperature and moisture resistant” and are generally unaffected or harmed by the sterilization process (McKeen). Medical devices made of silicone are commonly sterilized via “dry heat, steam autoclaving, EtO, gamma radiation, and electron beam (e-beam) radiation”, giving us several options for sterilization during production (McKeen). This offers our team several options to safely sterilize our device, as it will be composed mostly of silicone.

Design Overview

Our design features a silicone tube with an external diameter of 6 mm and an internal diameter of 3 mm. This internal diameter will provide the path for the actual enteral feedings that will be delivered with our device. We will produce a range of feeding tube lengths to match the current standard range of 90-160 cm (Ergopix). However, we will start with 1 m (100 cm) for our initial tube. Two additional tubes will be embedded in the wall of the NG tube directly across from each other. These tubes will be 1 mm in diameter and will feed directly into the silicone balloons.

The balloon attachment will lie flush against the outer wall of the NG tube when the tube is inserted. Once the tip of the NG tube is correctly placed, the user will fill the balloons with saline via the aforementioned side tubes. This will cause the balloons to expand. The outer radius of the fully expanded balloons will be 10 mm, and the inner radius of the fully expanded balloons will be 9.5 mm. We estimate that each balloon will require 3.35 mL of saline to completely expand it. Therefore, the total weight of the balloons will be approximately 6.7 g, based on the density of saline used in this application (“Fluid and Electrolyte”). The balloons will be inflated via a syringe inserted into a balloon port at the top of the feeding tube. This port will be similar to balloon ports already used in PEG tubes. The port contains a valve that is opened when the syringe is inserted into the port to inject or aspirate saline into or from the tubes (Fuchs). When sealed, the valve prevents the fluid from leaving the balloons while the device is in use.

The balloons will initially be placed at 10 cm from the end of the NG tube. This is to allow enough room for the enteral solution to escape the NG tube without interference

from the balloons. Additionally, this distance will ensure that the tip of the feeding tube remains close to, or exactly in, the initial, ideal position, which is about 10 cm below the gastro-oesophageal junction (Phillips et al.). However, additional literature indicates that the tube can be placed 3-10 cm below the LES, so we will later offer a variety of placements of the balloon including at 3, 5, 7, and 10 cm from the end of the tube to account for different stomach anatomies (Vadivelu et al.).

The printed prototype for our device is shown in Figure 6.

Figure 6: Printed Prototype

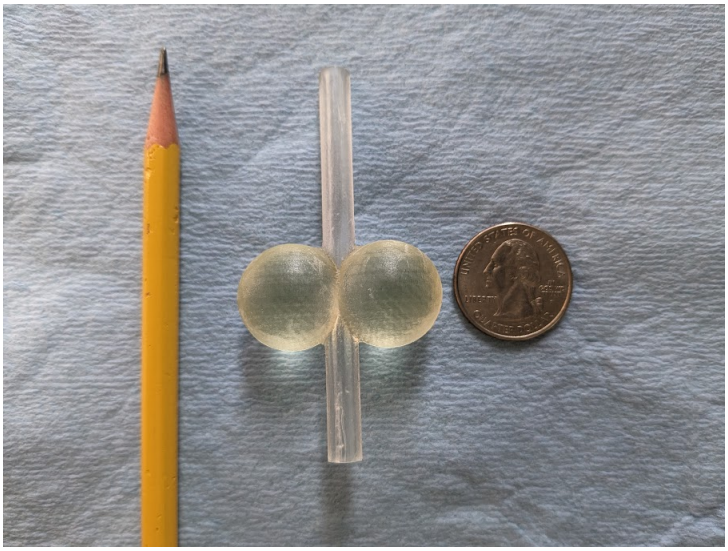

Figure 6: The middle figure is our printed part. It is shown to scale with a pencil (left) and a quarter (right). In this configuration, the balloons are expanded to show the final size of the device. Neither balloon is filled with saline, as this prototype is made of a hard material to show the approximate size of the device. The device will also have a standard balloon port, which will prevent saline from escaping due to pressure.

Design and Development Plan Summary

After a meeting with Dr. Holley on February 22, 2023, the team pivoted the design idea significantly. The design project was changed from an improvement based on clogging to an improvement based on dislodgement. Dr. Holley and the nursing school also provided supplies including an NG tube, various syringes, a PEG tube, and a guide wire to the team so that we could get a sense of the materials we were working with. As a group, we completed a new literature review and prior art as well as solidified our SolidWorks design over spring break from March 13, 2023 to March 19, 2022. We anticipate our device to be a class II medical device with our biggest competitor being the nasal bridle system. Our potential market mostly includes hospitals with our patient population being adult and teenage patients. We anticipate our device to be made from silicone with its intended use being the prevention of dislodgement in NG tubes. The components of our design will include silicone tubing, a feeding port, a silicone balloon attachment, and a separate port for saline injection to the balloon attachments.

We have determined eight user needs:

1. **Prevention of dislodgement.**
    a. This will prevent replacement due to this issue and resolve our problem statement.
2. **Design does not interfere with tube feeding.**
    a. Tube feeding is the necessary medical treatment and our device must not interfere with it.
3. **Tube insertion process is unchanged.**

   a. This will prevent extensive retraining for nurses, who insert the tubes.

4. **Compatible with existing technology (pumps, feeding ports, etc).**
   a. Connectors will match existing technology's dimensions to more seamlessly integrate our device in existing settings.
5. **Ease of use/access.**
   a. This will ensure proper use of our technology to prevent misuse of our product or discomfort while using our technology.
6. **Meets design specifications.**
   a. We will do quality checks to ensure that patients receive high-quality, working products that will not fail and cause unnecessary harm.
7. **Durability.**
   a. We will use materials able to withstand environmental strains, as part of our device will be placed in the stomach, which has extreme conditions.
8. **Biocompatibility.**
   a. We will use biocompatible materials (FDA-approved medical grade silicone) to prevent patient harm.

The team's revised *Design and Development Plan Summary* is shown in Appendix 5.

Design Summary Matrix Summary

We determined design inputs and outputs for each of our user needs as well as verification activities for each design output in the design summary matrix.

User need 1 will be addressed with a balloon attachment, which we have drawn in SolidWorks and have 3D printed. This is an essential requirement because without this element we will not have solved the dislodgement issue. We will verify this design solution by testing materials similar to existing medical grade balloons and drawing comparisons to current devices. A future validation activity could include clinical studies and visual inspections of the product.

User need 2 will be addressed with specialized tubing, which is also part of the SolidWorks drawing and has been 3D printed. If our design interferes with feeding, it may slow treatment of the patient. We will test this by inflating the balloon and visually inspecting whether feeding is still able to occur/nutritional solution can still travel through the tube. A future validation activity could include clinical studies and visual inspections of the product.

User need 3 will be addressed by using materials and attachments that are still thin enough to be inserted into the nostril. This will be tested visually and is a critical aspect of our design. Validation activities include cadaver studies, visual inspection, and clinical studies.

User need 4 will be addressed using our SolidWorks drawings, matching specifications with existing technology, and using 3D connectors. We will verify visually

that our design can be used with current pumps as well as other equipment. Validation activities will include visual inspections.

User need 5 will be addressed by making our components user-friendly and intuitive. We will verify this has been achieved by ensuring that those who are unfamiliar with the technology are still able to intuitively understand how it works by asking nurses to use it on a dummy. We will validate this by regularly testing our design for user-friendliness. Additionally, we will provide a user manual with clear instructions for use.

User need 6 will be addressed using quality checks and visually inspecting our 3D prints to ensure they match the designs. Validation will occur with visual inspections and performing quality checks on each batch of feeding tubes to ensure they meet our design standards and specifications. Quality checks will involve selecting one device from each batch and testing it for strength, durability, and function.

User need 7 will be addressed by using durable materials that are known not to break down in the stomach. We will also conduct durability testing by ensuring that the tube and balloon attachment can last for at least six weeks in the harsh conditions of the stomach to give nurses and patients a healthy error margin for use. Validation activities will include animal testing and later clinical studies.

User need 8 will be addressed by using materials known to be biocompatible and validated and verified using animal studies and later clinical studies to ensure biocompatibility.

The team's revised *Design Summary Matrix* is shown in Appendix 6.

Design Review Meeting I Summary

The team met with Troy Drewry to discuss the project moving forward at the end of February as we were making the difficult decision to switch to dislodgement. Mr. Drewry supported this decision and encouraged us to collect materials from Dr. Holley, who offered them, in order to complete testing. We then began discussing our ideas for future designs. We had a final design-based meeting in mid-March, where some of our further designs were created and drawn initially on a white board (please see the brainstorming and process section above for more information about those designs). Following this meeting, the team began revising all previous documents to reflect the new problem that we were solving. However, the original *Literature Review* and *Prior Art Search* are shown in Appendices 1 and 3. The revised documents include those in Appendices 2 and 4.

Risk Management Plan Summary

Risk management is an important aspect for any company and product, but it is especially important for medical device companies and products. This is due to the strict regulations put in place by the FDA and the ethics engineers and businesses are beholden to due to the nature of their products. For example, a malfunction in a medical device can cause unnecessary and undue trauma to a patient and may even exacerbate or worsen the problem or disease they were originally created to treat.

To mitigate the risks inherent to our product, we have developed several key steps and policies that will prevent failures in our product:

1. **Develop an instruction manual for our product.**

Our first control involves developing an instruction manual for our product. This manual would include a step-by-step walkthrough for how to insert the NG tube, ensure its correct placement, inflate the balloons, conduct enteral feedings, deflate the balloons, and remove the tube. By providing these instructions and educating users, we will be able to minimize as much user error as possible. Our instructions will include the exact volume of fluid necessary to inflate the balloons to prevent over- and underinflation, as well as ensure the balloons are completely deflated before the tube is removed. Additionally, our instructions will specify that only trained personnel, such as nurses and doctors, can use our product to prevent failures or risks born from improperly trained users.

This instruction manual will also detail the specifications for our product. This will include the recommended patient profile, such as the age and weight rating for our

product, as well as the max usage time. The recommended patient profile will prevent an improperly sized tube being used in a patient, and the max usage time will prevent material degradation while the tube is in use. We will also include a recommended maintenance schedule to prevent blockages and unnecessary protein buildup in the tube. This will help to keep our product working properly and minimize the risks intrinsic to NG feeding tubes. A physical copy of the instruction manual will be provided with each device and a digital copy of the manual will be available online.

2. **Sterilize our product.**

Additionally, our product will be sterilized prior to arriving at the hospital and will be rated for a single use. This will prevent cross-contamination of the products and minimizes the risk of disease transfer in a hospital setting. It also allows us to ensure that the proper sterilization procedures are being followed and that patients receive a product in good condition.

3. **Perform strict quality control checks.**

Finally, we will perform strict quality control to ensure that no products containing defects are sold. This is especially important due to our class II FDA classification. Without strict quality control, our product may malfunction in a way that neither we, nor the personnel using our products, can predict. Reducing this unpredictability will allow us to effectively manage the risks associated with our product.

The team's original *Risk Management Plan Form* is shown in Appendix 7.

Failure Modes and Effects Analysis (FMEA) Summary

To better understand the risks of our product and develop a risk management plan, we conducted a Failure Modes and Effects Analysis (FMEA) study and have identified several characteristics of our product that have the potential to cause harm:

1. **Material degradation.**
    a. Our material must be able to withstand the harsh, highly acidic environment of the stomach.
    b. Our device must not break down, degrade, or otherwise undergo any loss of functionality while in the body.
2. **Device failure.**
    a. The balloons will be subjected to anchor forces against the LES and thus must be able to withstand these forces without popping or becoming deformed.
    b. Other portions of the device will be exposed to minor forces as part of normal bodily functions, so the device will need to be tested to ensure it will not break when it is in various different configurations.
    c. We have identified several key failure points in our device which are further discussed below.
3. **User error.**
    a. Improper insertion, maintenance, and use of our product may cause a device failure or harm patients.

Table 1: Severity Rating Table (from Troy Drewry)

Severity (SEV)		
Ranking	Definition	Effect
5	Catastrophic	Device failure or defect may cause death or permanent injury with or without warning of failure
4	Severe	Device failure or defect will cause severe injury which would necessitate revision surgery
3	Moderate	Failure renders device useless or will result in a minor injury of a non-permanent nature
2	Minor	Failure will result in no loss of product performance but may create some annoyance to user
1	None	No effect

Table 1: This table shows the ratings for various severity levels of a device failure. A low rating would have no effect on product performance, whereas a high rating may severely harm a patient using the product. These numbers are used to calculate the Risk Index of a device failure (shown in Table 3). Table provided by Troy Drewry.

Table 2: Occurrence Rate Table (from Troy Drewry)

Occurrence (OCC)		
Ranking	Definition	Frequency
5	Extremely High	Failure almost inevitable
4	High	Repeated failure
3	Likely	Occasional failure
2	Rare	Failure unlikely
1	Remote	Remote chance of failure

Table 2: This table shows the occurrence rates and their definitions of device failures. A low occurrence rate indicates that there is a very small chance of device failure, whereas a high occurrence rate suggests that the device will certainly fail in that area. These numbers are used to calculate the Risk Index of a device failure (shown in Table 3). Table provided by Troy Drewry.

Table 3: Risk Index Table (from Troy Drewry)

Risk Index Table							
			Hazard Severity Level (S)				
			None	Minor	Moderate	Severe	Catastrophic
			1	2	3	4	5
Occurrence	Extremely High	5	5	10	15	20	25
	High	4	4	8	12	16	20
	Likely	3	3	6	9	12	15
	Rare	2	2	4	6	8	10
	Remote	1	1	2	3	4	5

Table 1: This table shows the Risk Indices of various device failures relative to their severity level and occurrence rate. This table was used to judge the overall risk of a device failure. Table provided by Troy Drewry.

Table 3 shows the risk indices of failures based on their occurrence rate and their severity level. The severity rate of a device failure, shown in Table 1, defines the overall severity or danger of a particular failure. The scale ranges from 1, which has “no effect”, to 5, which has an effect that “may cause death or permanent injury without warning of failure.” Similarly, the occurrence rate of a particular failure is outlined in Table 2. This scale also ranges from 1, indicating a “remote chance of failure”, to 5, suggesting that “failure [is] almost inevitable.” Together, these values define the risk index of a particular device failure. The risk index is found by multiplying the occurrence rate by the severity level. As shown in the table, risk indices that are less than 5 are not considered particularly dangerous, while risk indices greater than 10 are considered extremely dangerous and harmful. We have used Table 1 to rate the failure points of our product.

1. Balloon attachments.

a. *Failure to expand.*

Should the balloons fail to expand, our product will be rendered useless as there will be nothing to anchor the NG tube to the stomach and prevent dislodgement. Additionally, if the balloon is only able to partially inflate, it may become lodged in the LES and become difficult to remove or carry out enteral feedings. This failure could be caused by user error (not injecting enough saline to adequately fill the balloons or creating a good seal between the syringe and the injection point) or instrument failure (the balloon or its material is defective or the injection point seal is defective). We assigned a severity rating of 3 and an occurrence rate of 2, for a risk index of 6.

b. *Failure to deflate.*

The balloons failing to deflate is less likely to occur than the balloons failing to expand, however, the consequences of a failure to deflate are much greater than failing to expand. If the balloons cannot deflate, the nurse may be unable to remove the NG tube. This may necessitate a surgery or more invasive removal technique. The balloons failing to deflate would likely be caused by a failure in the seal where the syringe is not able to pull fluid from the balloons or user error (not pulling the entirety of the fluid from the balloons or not getting a good connection between the syringe and the seal). Therefore, this risk receives a severity

rating of 4 and an occurrence rate of 1, for a risk index of 4.

c. *Balloons popping.*

If the balloons pop, all of the saline in the balloons would be released into the stomach. This could have negative consequences for patients, as it may upset the nutrition balance of the patient's diet or overfill the stomach. Furthermore, pieces of the balloons could be released into the stomach. Should the balloons pop, the device will be rendered useless as there will be nothing to stop the tube from migrating into the esophagus. A balloon being popped could be caused by overinflating the balloon so that the material breaks down, the balloon being exposed to excessive pressure against the LES, or a defect in the product that was present when it was sold. We assigned this failure a severity rating of 3 and an occurrence rate of 2, for a risk index of 6.

d. *Irritation of the LES.*

The balloons could irritate the LES if they are constantly touching or rubbing against the tissues, especially if they are doing so with excessive force. This excessive force could be due to patients attempting to remove the NG tube or the balloon attachments coming into constant contact with the walls of the stomach or LES. This failure received a severity rating of 2 and an occurrence rate of 3, for a risk index of 6.

2. NG tube.

a. Poor tip placement.

Poor placement of the tube tip can be caused by a variety of factors, including user error. However, as previously mentioned, the tip of the NG tube can migrate to the stomach wall and block the flow of the enteral solution. This would cause an interruption of the patient's feeding schedule and may also result in backups and blockages in the tube. While our product design may mitigate this failure, it is still possible for it to occur depending on the stomach anatomy of the individual and the initial placement of the tube.Poor tube tip placement received a severity rating of 3 and an occurrence rate of 2, for a risk index of 6.

3. User error.

a. Improper tube insertion.

Improper tube insertion would be caused by user error and may be attributed to improper personnel training. Tube insertion failure received a severity rating of 3 and an occurrence rate of 2, for a risk index of 6.

b. Improperly sized device.

Independent of an actual device failure, a nurse or healthcare professional may use an improperly sized device on a patient. This could happen due to improper measurements of the patient being taken, an unexpected patient geometry, a manufacturing error that causes the device to not meet the

design specifications, or a packaging error where a tube is mislabelled. This failure received a severity rating of 3 and an occurrence rate of 1, for a risk index of 3.

4. Material degradation.

a. *Tube degradation.*

If the material that makes up the tube degrades, the enteral solution might not make it to the stomach and/or be deposited somewhere unfavorable or harmful to the patient. It may also make it difficult or impossible to inflate or deflate the balloons. In the tube, material degradation could be caused by the forces exerted on the tube, the orientation of the tube, the body's environment, or a defect present in the tube prior to insertion. Tube degradation received a severity rating of 3 and an occurrence rate of 1, for a risk factor of 3.

b. *Balloon degradation.*

If the material in the balloons breaks down, the balloons may experience a myriad of failures, including a failure to inflate or deflate, releasing saline into the stomach, popping, or becoming so deformed that they become lodged in the LES. Material degradation in the balloons could be caused by the forces exerted on the balloons, the harsh environment of the stomach, or a defect present in the balloons prior to use. Balloon

degradation received a severity rating of 3 and an occurrence rate of 1, for a risk factor of 3.

Our team has taken great care to mitigate these failures and provide failsafes and instructions to prevent these failures from occurring. With our risk management policies in place, and taking into account the inherent risk of harm from each of the failures, we have determined that the overall risk of harm from our product is low.

The team's original *FMEA Form* can be found in Appendix 8.

Verification and Validation Plan Summary

Our verification and validation activities are discussed in the Design Summary Matrix section. However, more specifically, our verification plans include:

1. **Mechanical testing.**
    a. To further develop our product and gather data showing that it can withstand the necessary forces to effectively prevent dislodgement, we need to conduct mechanical testing with materials similar to existing medical grade balloons.
    b. This will account for user need 1.
2. **Time-based testing.**
    a. Time-based testing is important to ensure that the inflated balloons do not interfere with the delivery of enteral solution through the tube. This will be done by implementing the device over a set period of time and comparing that amount of solution delivery to the amount of solution delivered without the balloon attachments.
    b. This will account for user need 2.
3. **Quality checks and measurement verification.**
    a. In order to ensure that we only distribute the highest quality products, we will perform strict quality checks to verify that our products were printed with the correct measurements and specifications and do not contain any defects.
    b. This will account for user need 3 and user need 6.
4. **Ease of use and integration checks.**

a. To ensure that our technology is user-friendly, we will check-in with nurses or student nurses at the University of Mississippi School of Nursing and ensure that it is intuitive for them to use.
b. Additionally, we will need to ensure that our product can be used with existing technology such as feeding tube pumps.
c. This will account for user need 4 and user need 5.

5. **Durability and biocompatibility checks.**
    a. To ensure that our product is durable enough to withstand the harsh environment of the stomach, we will need to undergo certain durability tests including testing involving pH.
    b. We will also ensure that our product is compatible with the human body so that it does not cause unnecessary harm to patients through biocompatibility testing such as irritation testing and sensitization testing.
    c. This will account for user need 7 and user need 8.

These verification plans will ensure that our technology is user-friendly and functional as well as safe and compatible with existing technology and the human body.

Our validation activities will include:

1. **Visual inspections/quality checks of the product.**
    a. Similar to the verification plans, performing regular visual inspections and quality checks will ensure that only functioning products with the correct specifications are sold to customers.

b. This will account for user need 3, user need 4, user need 5, and user need 6.

2. Animal testing.

a. Animal testing will validate certain elements of our design including biocompatibility, durability, and whether or not our design solves the dislodgement problem *in vivo*.

b. This will account for user need 1, user need 2, user need 7, and user need 8.

3. Clinical trials.

a. As an extension of animal testing, clinical trials will more accurately show how our device behaves in a patient. We will learn more information about the biocompatibility and durability of our device in the human body, as well as gather meaningful data about the dislodgement rate for our device *in vivo.*

b. This will account for user need 1, user need 2, user need 7, and user need 8.

Gillespie Business Plan Competition Summary

The team entered the business competition on March 29, 2023 under the team and company name “Food Tube Dudes” as part of the senior design project with the following logo:

Figure 7: Food Tube Dudes Logo

Figure 7: Food Tube Dudes Logo, designed by Sydney Rester.

Our idea was the NG tube with the balloon attachment to prevent dislodgement from patients. “The Company” has a goal of solving common feeding tube problems that have largely been ignored for decades. We do not currently have a patent as we are still finding proof of concept. We would plan to market the product through online vendors including medical device distributor websites as our primary customers are hospitals and healthcare professionals. To more effectively reach and train nurses and healthcare professionals to use our device, we would specifically target teaching hospitals as an initial consumer of our device. This way, nurses can train on our product and can see that it is easy to use and highly effective. Then, as they continue their professional careers,

they are more likely to recommend our device to other nurses and healthcare professionals. This will allow us to achieve our eventual goal of selling our product to hospitals. Additionally, the product, which would be priced at $75/unit would be priced competitively with the nasal bridle, which is our main competition and priced at $80/unit. The team competed on April 21, 2023.

Lean Business Model Canvas

Table 4: Lean Business Model Canvas

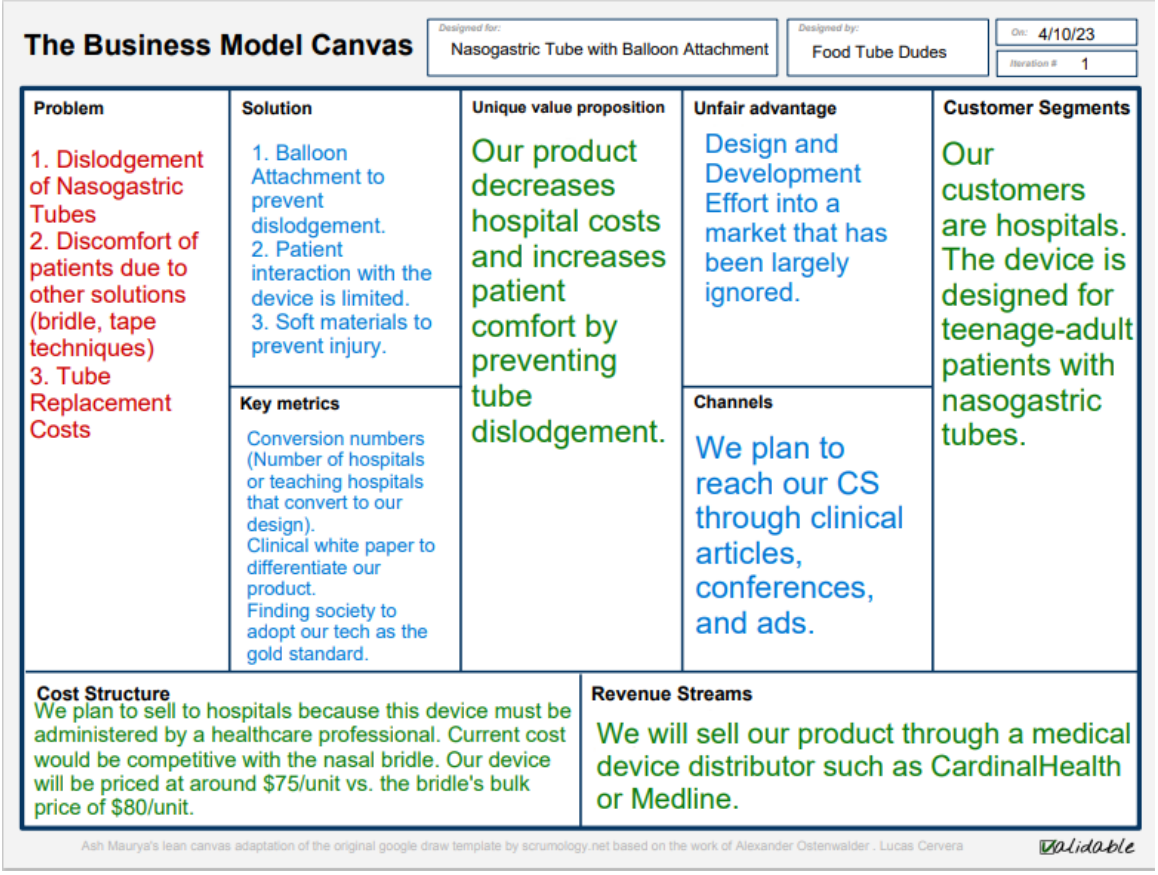

Table 4: Lean Business Model Canvas, written by Sydney Rester

Future Works

As part of the design process, our senior design project underwent significant changes throughout the academic year that the team worked on it. Before entering the market as a finalized product, our NG tube with a balloon attachment needs to undergo rigorous testing in areas such as biocompatibility, durability, and strength testing. This should be done with animal studies and later clinical studies. Alongside these trials, we also plan to make a comprehensive user manual that would detail how to use our product. This manual will be included with our product as a resource for nurses and other healthcare professionals.

After the market launch of our product, we would continue to develop our company. The next area of study for our product, and subsequent future products, is to design an NG tube with a balloon attachment for use in pediatric patients. Once this is accomplished, we would start designing new products for nasoenteric and nasojejunal tubes to expand our product line. Each of these products will require significant research, planning, and testing.

These new products will be accompanied by a dedication to continuous improvement of our current products. As we and other researchers and healthcare professionals learn more about anatomy and physiology, we plan to modify the design of our product to better serve patient needs. For example, we would like to design a way to implement differently sized balloons to account for differently sized stomachs and esophaguses. To account for these differing anatomies, we would place the balloons at different lengths from the end of the tube including at 3, 5, and 7 cm. We would also look

for improvements in biocompatibility, durability, and strength in our material, whether by modifying our material formulation or identifying/developing a new material entirely. Our commitment to improvement and development will keep us competitive in the market and ensure that we provide the highest quality of products possible to patients.

Appendix 1

BACKGROUND

♦ Summary:

Area of focus: Enteral feeding tube placement is a common medical technique used to provide nutrients and medicines to patients that have experienced loss of function or insufficient oral intake. Keeping these feeding tubes fully functional is vital as a deficiency or excess of calories, electrolytes, vitamins, and medication can cause major complications and significantly increase patient recovery time. The formation of an occlusion is one common issue that inhibits adequate nutrients or scheduled medication from being delivered. Blockage can occur due to crushed medication, inadequate flushing, and with precipitation of protein in the eternal nutrition solution. The chance of occlusion occurrence over the lifetime of a feeding tube is estimated to be between 12.5 – 45% with the cost of replacement reaching upwards of $1,000. We are seeking to develop a way to better prevent feeding tube occlusions and/or develop a more efficient way of unblocking a feeding tube; a way to ensure that a feeding tube is the correct length for a patient without causing additional patient trauma.

Historical/evolution of treatment: Gastric feedings have existed since the 16th century, with the most popular being a long tube with a funnel/syringe attached to the end. In 1617, the most popular gastring feeding method was a silver tube used to feed tetanus patients. Flexible leather tubes were used in 1649. In the 1800s, feeding tubes were often used to feed mentally ill patients. A rubber feeding tube was introduced in the back half of the 19th century that was used in children - this device could be given by a medical professional or by the child's parent, provided the parent was adequately taught. In 1921, the first Levin (single-lumen) feeding tube was designed. However, this tube was very stiff, which made it difficult to insert. During the 1960s, people started using feeding tubes made of silicon or polymers, which were not as stiff and easier to insert. As of 2006, the majority of feeding tubes are nasogastric tubes.

State of the art: The best method for preventing feeding tubes from becoming blocked is prevention. ASPEN recommends that, when administering food or medicine through a feeding tube, healthcare professionals are careful and mindful of how they are administering the fluids and what fluids they are mixing, as improperly combined fluids may result in occlusions. Furthermore, performing regular water flushes will help prevent buildup in the tube that may result in large occlusions later. If an occlusion does occur, they recommend gentle water flushes accompanied by a very gentle, mechanical "pumping" system to remove the blockage .

♦ Search Terms:

"eternal nutrition, feeding tube occlusion, blockage prevention, blockage treatment"

♦ References:

Fisher, Charles, and Bethany Blalock. "Clogged feeding tubes: a clinician's thorn." Pract Gastroenterol 38.3 (2014): 16-22.

Pearce, C B, and H D Duncan. "Enteral feeding. Nasogastric, nasojejunal, percutaneous endoscopic gastrostomy, or jejunostomy: its indications and limitations." Postgraduate medical journal vol. 78,918 (2002): 198-204. doi:10.1136/pmj.78.918.198

Silk, D.B.A., et al. "Clinical Evaluation of a Newly Designed Nasogastricenteral Feeding Tube." Clinical Nutrition, vol. 15, no. 6, 1996, pp. 285–290., https://doi.org/10.1016/s0261-5614(96)80001-x.

Cresci, Gail, and John Mellinger. "The History of Nonsurgical Enteral Tube Feeding Access." Nutrition in Clinical Practice, vol. 21, no. 5, 2006, pp. 522–528., https://doi.org/10.1177/0115426506021005522.

Bankhead, Robin, et al. "A.S.P.E.N. Enteral Nutrition Practice Recommendations." Journal of Parenteral and Enteral Nutrition, vol. 33, no. 2, 2009, pp. 122–167., https://doi.org/10.1177/0148607108330314.

CURRENT TREATMENT OPTIONS

♦ Summary:

Current treatment options for unclogging feeding tubes are typically to administer warm water as soon as the clog occurs as it is the easiest and most effective way to unclog the feeding tube. Another method for unclogging feeding tubes is to use a syringe and pump mechanism to slowly and carefully dislodge the clog. This method must be done very carefully, as excessive pressure can be detrimental to a patient. However, sometimes a specific substance is administered to a patient that will break up the clog - commonly used substances include Coca-Cola, cranberry juice, and pancreatic enzymes. These substances are acidic enough to break up the clog, but not so acidic that they are detrimental to the stomach/small intestine. Unfortunately, this treatment option is not always effective - these substances can worsen the clog by precipitating proteins out of the tube.

It is easier to prevent a feeding tube from being clogged at all than it is to unclog the feeding tube itself, which is why nurses will perform routine tube flushes. Additionally, being mindful of what fluids/nutrients/drugs are being administered together can help prevent a clog from occurring. Furthermore, it is easier to unclog a feeding tube than replace it altogether. If a clog does occur, a gentle water flush with an even more gentle pumping mechanism is usually recommended to remove the clog.

♦ Search Terms:

"clog treatment, water flush, mechanical pump, clog prevention"

♦ References:

Fisher, Charles, and Bethany Blalock. "Clogged feeding tubes: a clinician's thorn." Pract Gastroenterol 38.3 (2014): 16-22.

Hayes, Kimberly Drummond, and Denise Drummond Hayes. "Best Practices for Unclogging Feeding Tubes in Adults." Nursing, vol. 48, no. 6, 2018, pp. 66–66., https://doi.org/10.1097/01.nurse.0000532744.80506.5e.

Bankhead, Robin, et al. "A.S.P.E.N. Enteral Nutrition Practice Recommendations." Journal of Parenteral and Enteral Nutrition, vol. 33, no. 2, 2009, pp. 122–167., https://doi.org/10.1177/0148607108330314.

IDENTIFY USER NEEDS

♦ Summary:

Feeding tube occlusions interrupt the scheduled administration of nutrients and medicines to patients. If not properly flushed, these occlusions can become severe and require tube replacement. The process of replacing a feeding tube can be costly and uncomfortable for the patient – especially for those utilizing feeding tubes at their homes. The most effective flushing processes require constant supervision of the patient to catch the occlusion extremely early in its formation. However, early detection does not often occur and even if it does, significant delays in nutrient administration can still occur.

Relying on an observer to identify and manage the early onset of an occlusion is inconsistent and inefficient. Users need a better device for monitoring the formation of occlusions and automatically flushing the system before significant blockage occurs. This device would allow for immediate treatment with limited delay to the scheduled administration of the eternal nutrition and medication. It would eliminate the reliance on a nurse or another observer's close supervision to identify occlusion formation. Lastly, it has the potential to save patients and hospitals time and money by significantly reducing the number of blocked tube replacements per year. The user and caregivers will be more confident in the prevention of occlusion formation and any excess discomfort will be limited.

♦ Search Terms:

"eternal nutrition, feeding tube occlusion, blockage prevention, blockage treatment"

♦ References:

Bankhead, Robin, et al. "A.S.P.E.N. Enteral Nutrition Practice Recommendations." Journal of Parenteral and Enteral Nutrition, vol. 33, no. 2, 2009, pp. 122–167., https://doi.org/10.1177/0148607108330314.

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MARKET RESEARCH

♦ Summary:

There is market potential for this technology because feeding tube clogs are a frequent occurrence for those with nasogastric feeding tubes. While many solutions to this problem do exist, many may cause unnecessary complications, like precipitating out proteins and making the clog worse. Even routine maintenance for preventing clogs can be a difficult and inconvenient thing to do - nurses reported that they had to flush feeding tubes every 4 hours both as a preventative measure to prevent clogging and to break up clogs. While no recent estimates on clogging rates have been reported in academic studies, older data reports a rate of 9% in 1993, and at least 245,000 hospitalizations require the usage of a feeding tube, not accounting for instances outside of the United States nor for the number of tubes required in a single hospitalization. With all of these factors considered, having a technology that lowers the chance for feeding tubes to clog or eliminates the clogs once they occur would save hospitals time, money, and resources spent on nurses fixing said clogs and possible patient complications.

♦ Search Terms:

"feeding tube clogging rates, total feeding tube clogs, total feeding tube usage"

♦ References:

Bankhead, Robin, et al. "A.S.P.E.N. Enteral Nutrition Practice Recommendations." Journal of Parenteral and Enteral Nutrition, vol. 33, no. 2, 2009, pp. 122–167., https://doi.org/10.1177/0148607108330314.

"Enteral Nutrition-An Overview." Fact Sheet. *American Society for Parenteral and Enteral Nutrition.* April 2012.
https://www.nutritioncare.org/About_Clinical_Nutrition/EN_Fact_Sheet_April_2012/.

Silk, D.B.A., et al. "Clinical Evaluation of a Newly Designed Nasogastricenteral Feeding Tube." Clinical Nutrition, vol. 15, no. 6, 1996, pp. 285–290., https://doi.org/10.1016/s0261-5614(96)80001-x.

COMPETITIVE LANDSCAPE

♦ Summary:

An occlusion prevention device or solution would be utilized in feeding tubes that are administered in both the hospital and at the patient's residence. There are currently some enzyme treatment options

available like Viokace and ClogZapper™ that rapidly dissolve an occlusion by altering the pH of the solution. However, this change in pH often leads to protein precipitation which can worsen the blockage or cause additional blockages elsewhere in the tube. Viokace is also limited to a clinical setting because the patient must have a prior prescription for it to be used. ClogZapper™ can be recommended for home use, but only after proper medical training. There are some mechanicals that can be used for clearing feeding tubes as well. Some of these included The Bard brush and the Bionix Feeding Tube Declogger, but these can only fit certain sized tubes and cannot be used in nasoenteric tubes. Recently, the FDA cleared the TubeClear® system which creates a jackhammer-like motion inside the tube to clear blockages in nasoenteric, gastrostomy, and jejunostomy tubes sizes 10-18. The Bard brush, Bionix Feeding Tube Declogger, and TubeClear® system all have specific situations in which they can be used and none of them can be used outside of the hospital setting and without proper training. Ultimately, there are some occlusion treatment options but they all still require early detection and implementation from a healthcare provider and most cannot be used in the patient's home.

♦ Search Terms:

"enzyme treatment, mechanical declogger, feeding tubes, ClogZapper™ , The Bard brush, Bionix Feeding Tube Declogger, TubeClear®"

♦ References:

Pearce, C B, and H D Duncan. "Enteral feeding. Nasogastric, nasojejunal, percutaneous endoscopic gastrostomy, or jejunostomy: its indications and limitations." Postgraduate medical journal vol. 78,918 (2002): 198-204. doi:10.1136/pmj.78.918.198

Fisher, Charles, and Bethany Blalock. "Clogged feeding tubes: a clinician's thorn." Pract Gastroenterol 38.3 (2014): 16-22.

"Actuated Medical's TubeClear System Gets Additional FDA Clearance, can Now be used for NE, NG, G and J Feeding Tubes." Health & Beauty Close - Up, Sep 30, 2013. ProQuest, http://umiss.idm.oclc.org/login?url=https://www.proquest.com/wire-feeds/actuated-medicals-tubeclear-system-gets/docview/1437511187/se-2.

Appendix 2

BACKGROUND

♦ Summary:

Area of focus: Enteral feeding tube placement is a common medical technique used to provide nutrients and medicines to patients that have experienced loss of function or insufficient oral intake. Keeping these feeding tubes fully functional is vital as a deficiency or excess of calories, electrolytes, vitamins, and medication can cause major complications and significantly increase patient recovery time. One complication that hinders feeding tube function is dislodgement, with nasogastric tubes having a dislodgement rate of around 28.9%. Currently,the cost of replacement reaches upwards of $1,000 and involves a considerable amount of hospital time, effort, and funds. One current solution is a "nasal bridle," which has a poor patient perception. Many believe (although evidence does not indicate this) that the device is uncomfortable and causes nasal septal trauma. We are seeking to develop a way to better prevent feeding tube dislodgement that is both effective and is less invasive/has a better patient perception than the current nasal bridle.

Historical/evolution of treatment: Gastric feedings have existed since the 16th century, with the most popular being a long tube with a funnel/syringe attached to the end. In 1617, the most popular gastring feeding method was a silver tube used to feed tetanus patients. Flexible leather tubes were used in 1649. In the 1800s, feeding tubes were often used to feed mentally ill patients. A rubber feeding tube was introduced in the back half of the 19th century that was used in children - this device could be given by a medical professional or by the child's parent, provided the parent was adequately taught. In 1921, the first Levin (single-lumen) feeding tube was designed. However, this tube was very stiff, which made it difficult to insert. During the 1960s, people started using feeding tubes made of silicon or polymers, which were not as stiff and easier to insert. As of 2006, the majority of feeding tubes are nasogastric tubes.

State of the art: Current State of the Art treatment is the nasal bridle, which is considered highly cost-effective, but is not routine in clinical practice. Currently, the tape technique is the most commonly used technique to keep tubes from becoming dislodged. The tape technique involves taping the tube to patients skin using an adhesive tape or another commercial fixation device. The dislodgement rate with this technique is around 40%. The nasal bridle is a device that enters one nostril, wraps around the nasal septum and exists from the other nostril. Both ends are attached to the feeding tube, forming the bridle. Some studies do indicate that bridling the feeding tube reduces the rate of unintentional dislodgement significantly; however, currently, there is not enough evidence to truly suggest the bridle technique over the tape technique.

♦ Search Terms:

"eternal nutrition, feeding tube dislodgement, nasal bridle"

♦ References:

Brugnolli, A., et al. "Securing of Naso-Gastric Tubes in Adult Patients: A Review." International Journal of Nursing Studies, vol. 51, no. 6, 2014, pp. 943–950., https://doi.org/10.1016/j.ijnurstu.2013.12.002.

Seder, Christopher W., and Randy Janczyk. "The Routine Bridling of Nasojejunal Tubes Is a Safe and Effective Method of Reducing Dislodgement in the Intensive Care Unit." Nutrition in Clinical Practice, vol. 23, no. 6, 2008, pp. 651–654., https://doi.org/10.1177/0884533608326139.

Pearce, C B, and H D Duncan. "Enteral feeding. Nasogastric, nasojejunal, percutaneous endoscopic gastrostomy, or jejunostomy: its indications and limitations." Postgraduate medical journal vol. 78,918 (2002): 198-204. doi:10.1136/pmj.78.918.198

Silk, D.B.A., et al. "Clinical Evaluation of a Newly Designed Nasogastricenteral Feeding Tube." Clinical Nutrition, vol. 15, no. 6, 1996, pp. 285–290., https://doi.org/10.1016/s0261-5614(96)80001-x.

Cresci, Gail, and John Mellinger. "The History of Nonsurgical Enteral Tube Feeding Access." Nutrition in Clinical Practice, vol. 21, no. 5, 2006, pp. 522–528., https://doi.org/10.1177/0115426506021005522.

Bankhead, Robin, et al. "A.S.P.E.N. Enteral Nutrition Practice Recommendations." Journal of Parenteral and Enteral Nutrition, vol. 33, no. 2, 2009, pp. 122–167., https://doi.org/10.1177/0148607108330314.

Bechtold, Matthew L et al. "Nasal bridles for securing nasoenteric tubes: a meta-analysis." Nutrition in clinical practice : official publication of the American Society for Parenteral and Enteral Nutrition vol. 29,5 (2014): 667-71. doi:10.1177/0884533614536737

CURRENT TREATMENT OPTIONS

♦ Summary:

The most commonly used short-term feeding tube is the nasogastric tube, which is inserted by a nurse and is made of stiff polyvinyl material often. The insertion process involves "lubricating the tube, flexing the head, and having the patient ingest sips of water," which is a deeply uncomfortable process that patients generally do not wish to repeat. The majority of patients requiring a nasogastric tube will need it for less than one month; however, its limiting factors of clogging and dislodgement contribute to the tube's low mean life of 10 days. In fact, in one observational study, the dislodgement rate was 48.5% for this kind of tube. Routine clinical practice is to tape the tube or adhere the tube to the patient's skin, which is not aesthetically pleasing and contributes to some skin irritation. This method also faces challenges that vary from patient to patient including factors such as oily skin and facial hair. The tape method also involves marking where the tube is relative to the patient's nose and noticing when it has moved to try and prevent complete dislodgement. Severe tube dislodgement can lead to tube replacement, which adds to hospital costs and patient discomfort.

The nasal bridle technique, which involves a device that wraps around the nasal septum and forms a "bridle" with the feeding tube, is considered to be highly cost effective with limited patient discomfort. However, despite a number of studies indicating its efficacy, there is not enough evidence to truly recommend it over the tape technique. Also, many patients and doctors perceive the bridle to be uncomfortable and that they cause nasal septal trauma. Additionally, associations of bridles with horses makes the marketing for this

device difficult. Our solution will be more aesthetically pleasing and less likely to be perceived as uncomfortable.

♦ **Search Terms:**

"feeding tube dislodgement solutions"

♦ **References:**

Bankhead, Robin, et al. "A.S.P.E.N. Enteral Nutrition Practice Recommendations." Journal of Parenteral and Enteral Nutrition, vol. 33, no. 2, 2009, pp. 122–167., https://doi.org/10.1177/0148607108330314.

Pearce, C B, and H D Duncan. "Enteral feeding. Nasogastric, nasojejunal, percutaneous endoscopic gastrostomy, or jejunostomy: its indications and limitations." Postgraduate medical journal vol. 78,918 (2002): 198-204. doi:10.1136/pmj.78.918.198

Cresci, Gail, and John Mellinger. "The History of Nonsurgical Enteral Tube Feeding Access." Nutrition in Clinical Practice, vol. 21, no. 5, 2006, pp. 522–528., https://doi.org/10.1177/0115426506021005522.

DeLegge, Mark H. "Enteral Access—the Foundation of Feeding: Endoscopic Nasoenteric Tube Placement." Techniques in Gastrointestinal Endoscopy, vol. 3, no. 1, 2001, pp. 22–29., https://doi.org/10.1053/tgie.2001.19909.

Brugnolli, A., et al. "Securing of Naso-Gastric Tubes in Adult Patients: A Review." International Journal of Nursing Studies, vol. 51, no. 6, 2014, pp. 943–950., https://doi.org/10.1016/j.ijnurstu.2013.12.002.

Levy, Howard. "Nasogastric and Nasoenteric Feeding Tubes." Gastrointestinal Endoscopy Clinics of North America, vol. 8, no. 3, 1998, pp. 529–549., https://doi.org/10.1016/s1052-5157(18)30247-2.

IDENTIFY USER NEEDS

♦ **Summary:**

Feeding tube dislodgement interrupts the scheduled administration of nutrients and medicines to patients. If not properly identified these dislodgements can become severe and require tube replacement. The process of replacing a feeding tube can be costly and uncomfortable for the patient – especially for those utilizing feeding tubes at their homes. The most effective processes to prevent dislodgement require constant supervision of the patient to catch the dislodgement extremely early before it worsens. However, early detection does not often occur until the tube displacement is severe.

Relying on an observer to identify and manage the early onset of a dislodgement is inconsistent and inefficient. Users need a method or device that has a better public perception than the bridle and is more effective than just the tape method. Lastly, our device has the potential to save patients and hospitals time

and money by significantly reducing the number of tube replacements per year. The user and caregivers will be more confident in the use of nasogastric tubes and any excess discomfort will be limited.

♦ **Search Terms:**

"eternal nutrition, feeding tube dislodgement"

♦ **References:**

Bankhead, Robin, et al. "A.S.P.E.N. Enteral Nutrition Practice Recommendations." Journal of Parenteral and Enteral Nutrition, vol. 33, no. 2, 2009, pp. 122–167., https://doi.org/10.1177/0148607108330314.

Brugnolli, A., et al. "Securing of Naso-Gastric Tubes in Adult Patients: A Review." International Journal of Nursing Studies, vol. 51, no. 6, 2014, pp. 943–950., https://doi.org/10.1016/j.ijnurstu.2013.12.002.

Pearce, C B, and H D Duncan. "Enteral feeding. Nasogastric, nasojejunal, percutaneous endoscopic gastrostomy, or jejunostomy: its indications and limitations." Postgraduate medical journal vol. 78,918 (2002): 198-204. doi:10.1136/pmj.78.918.198

MARKET RESEARCH

♦ **Summary:**

There is market potential for this technology because feeding tube dislodgement is a frequent occurrence for those with nasogastric feeding tubes. While some solutions to this problem do exist, some have poor public perception and others lead to skin irritation and are not very effective. Some studies have noted dislodgement rates of up to 48.5%. Even routine maintenance for preventing dislodgement can be a difficult and inconvenient thing to do - nurses must mark and notice when the tube has moved significantly. The current bridle and tape techniques were all that our team could find in terms of current solutions to fix the dislodgement problem. Both techniques either involve significant efficacy issues or significant patient perception issues. With all of these factors considered, having a technology that lowers the chance for feeding tubes to dislodge would save hospitals time, money, and resources spent on nurses fixing said dislodgements and possible patient complications.

♦ **Search Terms:**

"feeding tube dislodgement, nasal bridle"

♦ **References:**

Bankhead, Robin, et al. "A.S.P.E.N. Enteral Nutrition Practice Recommendations." Journal of Parenteral and Enteral Nutrition, vol. 33, no. 2, 2009, pp. 122–167., https://doi.org/10.1177/0148607108330314.

"Enteral Nutrition-An Overview." Fact Sheet. *American Society for Parenteral and Enteral Nutrition.* April 2012.
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Silk, D.B.A., et al. "Clinical Evaluation of a Newly Designed Nasogastricenteral Feeding Tube." Clinical Nutrition, vol. 15, no. 6, 1996, pp. 285–290., https://doi.org/10.1016/s0261-5614(96)80001-x.

Brugnolli, A., et al. "Securing of Naso-Gastric Tubes in Adult Patients: A Review." International Journal of Nursing Studies, vol. 51, no. 6, 2014, pp. 943–950., https://doi.org/10.1016/j.ijnurstu.2013.12.002.

Seder, Christopher W., and Randy Janczyk. "The Routine Bridling of Nasojejunal Tubes Is a Safe and Effective Method of Reducing Dislodgement in the Intensive Care Unit." Nutrition in Clinical Practice, vol. 23, no. 6, 2008, pp. 651–654., https://doi.org/10.1177/0884533608326139.

COMPETITIVE LANDSCAPE

♦ Summary:

The greatest competition to this project will likely be the nasal bridle. Currently, Applied Medical Technology, Inc (AMT) produces and sells the nasal bridle. AMT claims the nasal bridle is comfortable and is "Used to discourage patients, young or old, from pulling on their nasoenteric feeding tube." They currently sell a nasal bridle system that includes a blue retrieval probe, a catheter, blue bridle tubing, a clip, and a lubricant packet. They further write, "The catheter and retrieval probe have strong rare earth magnets at their tips." This allows the pieces of the bridle to attach to form the bridle loop. The vomer bone (part of the structure of the nasal cavity) holds the feeding tube in place, and when patients pull on the tube, this causes them to feel "a little" pressure, which discourages them from pulling on the tube. It does only take a minute or two to place and has limited visibility. It also allows movement of the patient. Additionally, the device components are designed to break before the amount of force needed to cause injury. The cost of this device seems to range from $700-2,000. However, another source noted that this ends up costing around 76 british pounds per patient. Yet, this source also discussed a study that found that the mean cost per patiet was higher in the bridle group (426 vs 338 British pounds).

♦ Search Terms:

"AMT Nasal Bridle, AMT Nasal Bridle Cost"

♦ References:

Pearce, C B, and H D Duncan. "Enteral feeding. Nasogastric, nasojejunal, percutaneous endoscopic gastrostomy, or jejunostomy: its indications and limitations." Postgraduate medical journal vol. 78,918 (2002): 198-204. doi:10.1136/pmj.78.918.198

Bechtold, Matthew L et al. "Nasal bridles for securing nasoenteric tubes: a meta-analysis." Nutrition in clinical practice : official publication of the American Society for Parenteral and Enteral Nutrition vol. 29,5 (2014): 667-71. doi:10.1177/0884533614536737

Seder, Christopher W., and Randy Janczyk. "The Routine Bridling of Nasojejunal Tubes Is a Safe and Effective Method of Reducing Dislodgement in the Intensive Care Unit." Nutrition in Clinical Practice, vol. 23, no. 6, 2008, pp. 651–654., https://doi.org/10.1177/0884533608326139.

https://www.appliedmedical.net/enteral/bridle/

https://www.ciamedical.com/amt-bridle-pro-p-921048

https://www.theajo.com/article/view/4000/4708#:~:text=They%20fashioned%20nasal%20bridles%20themselves,cost%20only%20%246%20per%20patient.

Appendix 3

I would like a minimum of two (2) prior art references to be from international sources – i.e., outside the US Patent Office and from international journals or sources.

Prior Art Reference #1 (*Apparatus and Method to Maintain Flow Through and Prevent Clogging of a Feeding Tube and Application number US 2017/0340409 A1*)

♦ **Search Terms:**

"Feeding Tubes clogging"

♦ **Summary:**

The invention from Lustberg provides a squeegee-like cleaning to the inside of a clogged feeding tube. It is inserted into the feeding tube and has a length so that when inserted, its cap aligns with the proximal end and the blunt tip extends partway out of the distal end. It has 4 discs along its length that have a diameter equal to or greater than the first diameter of the internal bore so that tip proportions of the disk "deflect and travel along the internal bore" to provide the clearing effect. This patent is abandoned, but further claims that the patent is for the combination of a feeding tube and a cleaning apparatus. The feeding tube has a first length and an internal bore that extends through the feeding tube for the entire first length while the internal bore has a first diameter. The cleaning apparatus has a shaft with a distal end and an opposing proximal end. The distal end terminates at a blunt tip and the proximal end terminates at a cap and has a second length so that when inserted into the feeding tube, the cap aligns with the proximal end of the tube and the blunt tip extends partway out of the distal end of the feeding tube. The cleaning apparatus further has at least one disc mounted on the shaft with each disc having diameter that is smaller than the internal bore diameter of the tube. This apparatus allows for a cleaning motion within the tube to disrupt clogs.

♦ **Source:**

Google Patents (https://patents.google.com), US based

https://patents.google.com/patent/US20170340409A1/en?assignee=Lustberg&oq=Lustberg

Prior Art Reference #2 (*Improved feeding tube, EP1721562 B1*)

♦ **Search Terms:**

"Improved Feeding Tube"

♦ **Summary:**

The invention combines a variety of devices useful with endoscopes to improve the placement of feeding tubes to be less invasive. It is a medical apparatus that can use endoscopes in a way that allows placement to happen in a less invasive way for the patient and allows greater accuracy in terms of placement. The actual claims of the patent include a medical device that comprises a feeding tube with a proximal and distal end. A proximal end has an opening and there is a second distal

opening with an internal passageway that extends from the first opening to the second opening. The medical device further has a feature that is positioned along a portion of the length of the tube and is shaped to provide releasable engagement of the feeding tube with a separate member. The patent further claims that this feature is characterized so that the feeding tube "has a portion extending distally of the second distal opening, the distal end of the feeding tube is formed to be inclined with respect ot the longitudinal axis of the internal passageway and the second distal opening is aligned with the longitudinal axis of the passageway." Overall, the device involves an endoscopic sheath and track, a feeding tube carrier, and a variety of other devices to improve the feeding tube device as a whole.

♦ **Source:**

Google Patents (https://patents.google.com), European/International
https://patents.google.com/patent/EP1721562B1/en?oq=EP1721562+B1

Prior Art Reference #3 (*Detecting obstructions in enteral/parenteral feeding tubes and automatic removal of clogs therefrom EP 1129288B1*)

♦ **Search Terms:**

"Feeding tube clog"

♦ **Summary:**

The inventors are taking advantage of Poiseuille's Law and the fact that pressure in the feeding tube decreases as fluid flows out of the tube if the tube is not clogged. If an increase in pressure is detected, the normal pumping cycle is changed to expel the clog from the tube. It does not require assistance from a nurse or operator, which decreases the time and labor spent on these kinds of medical situations. The patent claims include a method of automatically clearing a tube in a pumped fluid system in response to an obstruction. It involves steps such as pumping a fluid through the tube under positive pressure control; providing an obstruction signal and applying a modified pressure control to the fluid to urge a clog to move, expelling the clog and preventing or fixing the obstruction. Normally, if there is a device involved in detecting clogs, nurses and other medical staff are alerted to it and must manually dislodge the clog. However, with this device, the patent claims it can attempt to dislodge the clog itself, limiting the amount of labor and time spent dislodging feeding tube clogs in the clinic.

♦ **Source:**

Lens.org (https://www.lens.org), European/International/US-based inventor
https://www.lens.org/lens/patent/055-129-472-381-802/frontpage?l=en

Prior Art Reference #4 (*Free Flow Detector For an enteral Feeding Pump, US Pat. No. 5562615*)

♦ **Search Terms:**

"feeding tube clog detection"

♦ **Summary:**

The detector includes a sensor for the peristaltic pump that measures the flow of the fluid and compares the operation of the pump with predetermined criteria–if flow is sensted when the pump is not operating it will initiate an alarm. The patent claims that the device is a fluid administration system that is enteral and comprises a tube connected to a supply of predetermined fluid to be administered, a peristaltic pump with a rotor means engaging the tube with a motor so that the rotor rotates intermittently in duty cycles. There is also a rotation sensing device that determines if the rotor means are rotating along with a free flow sensor and alarm connected with the rotation sensing means so that an alarm can be triggered when the device is improperly pumping the fluid or there is a clog.

♦ **Source:**

Google Patents (https://patents.google.com), US based
https://patents.google.com/patent/US5562615A/en?oq=US+Pat.+No.+5562615

Prior Art Reference #5 (*Cleaning Brush for Medical Devices US No. 6725492*)

♦ **Search Terms:**

This was referenced in the herb patent so I found it by searching the number.

♦ **Summary:**

This is for cleaning the tubes when they are in the body–the brush is attached to a coil that is inserted into the tube to clean it and the tip includes a NiTiNOL core wire with a gold-plated tungsten coil readily visible under a fluoroscope. The benefit of this technology is that it is designed to clean passages in medical devices without removing the device/passageway from the body. This involves physically inserting the brush into the passageway, so it may be difficult to effectively clean and remove debris in tubes that are long, deep inside the body, or in a sensitive area where jostling the tube may cause trauma and discomfort to the surrounding tissues and/or the patient. However, the shaft and bristle area of the brush are highly flexible, as illustrated by the reference drawings, and will be able to easily navigate the passageways of many types of medical devices.

♦ **Source:**

Google Patents (https://patents.google.com), US-based
https://patents.google.com/patent/US6725492B2/en?oq=US+No.+6725492

Prior Art Reference #6 (*Feeding Tube cleaning Devices and Methods No. 61/488,281 or WO 2012/162230 A1*)

♦ **Search Terms:**

"feeding tube clog"

♦ **Summary:**

The device involves a pressure sensor that monitors static pressure in the tubing set and causes fluid to go into the tubing set until there is a target static pressure reached. The device will inject

additional fluid into the system, adjust the amplitude of the linear motor, and retune the operating frequency of the linear motor if a drop in pressure is detected. This can go on an automated control loop or rely on a human operator to manually change the static pressure and dynamic pressure frequency. This technology forms a feedback loop - a pressure wave is created in the tube and the system monitors the amplitude of the pressure wave and uses this information to determine the most efficient and effective motor position and pressure wave amplitude to clear the blockage. The feedback loop is important because it will allow the system to quickly respond to any changes in pressure, enabling it to avoid pumping the tube too forcefully and harming the patient or the device itself. Additionally, this system will also be able to constantly monitor the pressure inside the feeding tube, allowing nurses and medical professionals to become aware of any issues or blockages in the tube much faster than if they were simply monitoring them at regular time intervals and relying on their own observational skills to alert them of any problems.

- **Source:**

  Lens.org (https://www.lens.org), International-Based
  https://www.lens.org/lens/patent/077-396-251-018-73X/frontpage?l=en

Appendix 4

Prior Art Reference #1 (*Improved inflatable retention system for an enteral feeding device AU2015258210C1*)

♦ **Search Terms:**

"PEF tubes, balloon anchor"

♦ **Summary:**

Patients experiencing long-term inability to take nutrients by mouth often require the surgical placement of a feeding tube directly into the patient's stomach. These tubes are referred to as percutaneous gastrostomy catheters (PEG tubes). In order to maintain proper feeding functionality, these tubes must be securely held in place in the patient's stomach. This patent proposes an improved inflatable retention system where a balloon is attached to a catheter and passed through the feeding device and into the stomach. The balloon is tapered, so it widens towards the distal end, increasing its surface area and holding force. There has been much recent success with utilizing balloons to prevent dislodgement in PEG tubes; however, this technique has yet to be translated to other feeding tubes like nasogastric (NG) tubes. Furthermore, they propose using a multi-channel system for balloon expansion to allow for more uniform distribution of the inflation medium. This channel system allows for a more controlled system and minimizes the risk of leakage and displacement, which would cause the patient discomfort.

♦ **Source:**

Google Patents (https://patents.google.com), US based
https://patents.google.com/patent/AU2015258210C1/en?q=(PEG+feeding+tube)&oq=PEG+feeding+tube

Prior Art Reference #2 (*Enteral feeding catheter assembly incorporating an indicator US10085922B2*)

♦ **Search Terms:**

"Improved PEG tube, balloon anchor, pre-biased indicator"

♦ **Summary:**

This patent is based on an improvement on percutaneous gastrostomy catheters (PEG tubes) utilizing balloon anchoring systems. Similar to previous devices, this system uses an inflatable balloon attached to the distal end of a catheter. The distal end is inserted through the stomach wall with the balloon deflated. A fluid inflation medium is then manually inserted into two channels that run along the sides of the device to inflate the balloon. The main improvement this device proposes is the addition of a pre-biased indicator located on the base in fluid communication with the balloon. This indicator provides a discrete visual signal to the medical professional(s) throughout implantation and inflation of the device that shows whether the volume of inflation medium or

pressure inside the balloon is different from the predetermined values. This indicator helps to limit surgical complications and patient discomfort due to feeding tube displacement because of damage because the balloon was not appropriately filled during implantation. It also helps determine balloon integrity over time and can signify inflation medium leakage.

♦ **Source:**

Google Patents (https://patents.google.com), European/International https://patents.google.com/patent/US10085922B2/en?q=(Low+Profile+PEG+tubes)&oq=Low+Profile+PEG+tubes

Prior Art Reference #3 (*A nasal bridle insertion device US20170105904A1*)

♦ **Search Terms:**

"nasogastric feeding tube bridle"

♦ **Summary:**

A device that inserts a nasal bridle utilizing a configuration switching mechanism. The first configuration is straight to assist in passing the bridle to the point of the septum easily. Afterwards, a bend is caused in the guide to pass it around the septum and back out the opposite nasal cavity. The two ends are then connected via bridal tape just outside of the nares. A nasogastric feeding tube is then connected to the same bridle tape to ensure placement remains steady. The device is intended to reduce the discomfort and increase the efficiency of bridal displacement.

♦ **Source:**

Google Patents - US Patent
https://patents.google.com/patent/US20170105904A1/en?q=(nasogastric+feeding+tube+bridle)&oq=nasogastric+feeding+tube+bridle

Prior Art Reference #4 (*Bridle device EP2882481B1*)

♦ **Search Terms:**

"nasal bridle"

♦ **Summary:**

This patent describes a magnet retrieval system within the bridle bridge, allowing for easier bridle securing. Another claim of this patent is the ability to secure the connection even when initial magnet orientation allows only for repulsion by having one magnet free to make corrective rotations. This bridle line may also be attached to the tube and anchoring point via multiple methods such as clip, tape, or other retention means. All of these developments should overcome the major problems with proper and easy bridge connection and bridle securement that caregivers face.

♦ **Source:**
Google Patents - EU Patent
https://patents.google.com/patent/EP2882481B1/en?q=(nasal+bridle)&oq=nasal+bridle

Prior Art Reference #5 (*Bridle system for placing and securing a nasal tube in a patient WO2014066572A1*)

♦ **Search Terms:**
"nasal bridle"

♦ **Summary:**
A device consisting of a typical nasal bridle securing system with two magnets which are run through opposite nares to attract a flexible member through the nasal septum. An external receiver attachment secures the physical nasogastric tube external to the body and gives the securing member an additional securing point other than the body of the patient. The external attachment claims to provide greater comfort and more reliable anchoring. This external receiver is also able to support many different types of nasogastric tubes including more specialized ones such as pediatric or infant patients.

♦ **Source:**
Google Patents - International Patent
https://patents.google.com/patent/WO2014066572A1/en?q=(nasal+bridle)&oq=nasal+bridle

Prior Art Reference #6 (*Anchored Working Channel US20130116549A1*)

♦ **Search Terms:**
"anchoring balloon system"

♦ **Summary:**
This patent describes a device that provides a "working channel" using a tube with a hollow lumen that guides other medical instruments such as catheters or endoscopes. This device overcomes previous problems of migration and dislocation by installing multiple inflatable balloons that use a textured surface to improve grip along different points of the channel. The channel also consists of a small enough diameter to allow passage through previous body cavities that were too small to pass through without compromising the channel's structural integrity.

♦ **Source:**

Google Patents - US Patent

https://patents.google.com/patent/US20130116549A1/en?q=(anchoring+balloon+system)&oq=anchoring+balloon+system

Appendix 5

Description of the Product

Executive Summary	Current feeding tubes are effective at nourishing patients who cannot nourish themselves. However, some feeding tubes can become dislodged, which may lead to feeding tubes being replaced, which can cause increased hospital costs and can be labor intensive. Currently nasogastric feeding tubes, which we are focusing on, become dislodged at about a rate of 28.9%. We plan to address this problem using a balloon attachment, which can be inflated with saline after insertion to prevent dislodgement and then deflated to allow removal. We also plan to decrease the amount of labor needed for these patients by producing a product that decreases the need for removal and reinsertion. Our product will be easy to use and prevent purposeful or accidental dislodgement.
Description of the Problem to be Solved	The chance of dislodgement for a nasogastric tube is 29.8% but could be as high as 48.5%. This can lead to replacement, which can cost up to 1,000 dollars and involves increased labor by healthcare professionals. We plan to prevent this.
Needs Statement	Our project aims to design and develop a way to decrease rates of dislodgement in teenage-adult nasogastric feeding tubes to decrease rates of tube replacement and provide a more "aesthetically-pleasing" and comfortable alternative to the bridle.
Literature Review	"Enteral feeding tube placement is a common medical technique used to provide nutrients and medicines to patients that have experienced loss of function or insufficient oral intake. Keeping these feeding tubes fully functional is vital as a deficiency or excess of calories, electrolytes, vitamins, and medication can cause major complications and significantly increase patient recovery time. One complication that hinders feeding tube function is dislodgement, with nasogastric tubes having a dislodgement rate of around 28.9%. Currently,the cost of replacement reaches upwards of $1,000 and involves a considerable amount of hospital time, effort, and funds. One current solution is a "nasal bridle," which has a poor patient perception. Many believe (although evidence does not indicate this) that the device is uncomfortable and causes nasal septal trauma. We are seeking to develop a way to better prevent feeding tube

	dislodgement that is both effective and is less invasive/has a better patient perception than the current nasal bridle. Current State of the Art treatment is the nasal bridle, which is considered highly cost-effective, but is not routine in clinical practice. Currently, the tape technique is the most commonly used technique to keep tubes from becoming dislodged. The tape technique involves taping the tube to patients skin using an adhesive tape or another commercial fixation device. The dislodgement rate with this technique is around 40%. The nasal bridle is a device that enters one nostril, wraps around the nasal septum and exists from the other nostril. Both ends are attached to the feeding tube, forming the bridle. Some studies do indicate that bridling the feeding tube reduces the rate of unintentional dislodgement significantly; however, currently, there is not enough evidence to truly suggest the bridle technique over the tape technique. “
Prior Art Search, Assessment, & Patentability	<u>Description of patents found:</u> ● Improved inflatable retention system for an enteral feeding device ○ This is a technique and system for a PEG tube with a balloon attachment. ● Enteral feeding catheter assembly incorporating an indicator ○ This uses an inflatable balloon attached to the distal end of a catheter, but there is an addition of a pre-biased indicator located on the base in fluid communication with the balloon. It provides a discrete visual signal to the medical professionals throughout implantation to limit surgical complications due to inappropriate filling during implantation. ● Nasal Bridle Insertion Device ○ This inserts a nasal bridle using a configuration switching mechanism, two ends are connected via bridal tape just outside of the nares. ● Bridle Device ○ This uses a magnet retrieval system within the bridle bridge allowing for easy bridge connection and bridle securement. ● Bridle System for placing and securing a nasal tube in a patient ○ A Secure system with two magnets that are run through opposite nares to attract a flexible

	member through the nasal septum, provides greater comfort and reliable anchoring. ● Anchored Working Channel ○ Device that provides a "working channel" using a tube with a hollow lumen that guides other medical instruments such as catheters or endoscopes, it solves dislocation by installing multiple inflatable balloons to be used along the channel.
Competition & Differentiation	The main competition for our solution would be the nasal bridle. However, because our product is so vastly different from the bridle, there is no need to worry about patent infringement.
Value Proposition & Differentiation	Our biggest composition, the nasal bridle system, currently sells between 700-2000 dollars. Our device would be more competitively priced.
Anticipated Regulatory Pathway	Class II device
Reimbursement Strategy	We plan to use cost-based reimbursement (Insurance companies including private will help with this.) Ultimately, we plan to sell this to hospitals to use.
Estimated Manufacturing Cost	$50 for 10 of the size we need for the balloons, tubes are sold for a range from $20-40 https://chamfr.com/product-category/balloons/silicone-balloons/ This means our cost of production is likely lower than 70-100, we will look into websites like the following: raumedic.com/competences/manufacturing/extrusion/thin-walled-tubing
Potential Market & Global Impact	Hospitals (ER, NICU, etc.) Global - this would be used wherever feeding tubes are needed and dislodge regularly.
Intended Use / Indications for Use	Prevent dislodgements from occurring in feeding tubes.
Patient Population	Adult/Teenage
Materials	Silicon – for the feeding tube and balloon
Features	Our features will include the balloon for dislodgement prevention and a functional tubing system for feeding. The balloon will have a separate port for saline injection

Food Tube Dudes	DHF #1	D&D Plan Revision: B

Components	1. Silicon Tubing + feeding port 2. Balloon Attachment 3. Separate port for saline injection

Add Rows as needed

User Needs

Transfer User Need # and Design Input to QD0006F02, Design Summary Matrix.

If a user need will not be fulfilled provide a rationale for not fulfilling need.

User Needs #	Description (User request)	Design Input or Rationale for Not Fulfilling Need
U1	Prevention of Dislodgement by patients	Prevents replacement due to dislodgement, solves need statement
U2	Balloon does not cut off feeding	Feeding is a necessary treatment
U3	Can still be inserted as per usual	Prevents extensive retraining for nurses.
U4	Compatible with existing technology so that hospitals do not have to adopt new systems and replace all of their existing tools.	Ensure connectors match dimensions of existing ones.
U5	Ease of use/access	Have Patients Check, make sure parts are easy to replace
U6	Meets Specifications	Quality Checks Presentation
U7	Durability	Use materials that are durable (especially for stomach materials)
U8	Biocompatibility	Use materials that are biocompatible

Add Rows as needed

Part Number

Part Number	Description	UDI[1]
1	Silicon Tubing for feeding	

2	Port for Feeding	
3	Balloon Attachment	
4	Port for Saline for Balloon	

[1] Document UDI if UDI needs to be included on the CAD and/or etched on the physical part.

Add Rows as needed or attach excel list.

Timeline

Attach a project timeline that defines at a minimum the project tasks, the name of the responsible team member, milestones, and the start date, and the due dates. The project timeline should be updated throughout the project and a copy of the current timeline should be reviewed during design review meetings. It is acceptable to use Excel, Project, or other project management tools.

Date	Event
02/22/23	Meeting with Dr. Holley leads to pivot away from clogging to dislodgement
2/27/23	Collected Supplies from Dr. Holley
3/3/23	Decision to pivot to dislodgment solidified as group and initial research done
3/14/23	New Literature Review Done
3/17/23	Initial Solidworks design finished
3/18/23	Business Plan Written
3/23/23	Business Video Recorded
3/24/23	New prior art done
3/28/23	Gillespie Business Plan Submitted
3/30/23	Design and Development Plan Updated/Revised to reflect pivot
3/30/23	Design Summary Matrix Updated/Revised to reflect pivot
3/30/23	Risk Management Report initially done
3/30/23	Decision to test using McKey Tube and either silicon or a pig stomach + esophagus made

Future goals:

3/31/23 - Write up what can be written in the senior design written portion

4/5/23 - Print solidworks design

4/12/23 - Anchor Force Testing Done

4/19/23 - Finish Testing, printing, prepare presentation and complete written portion

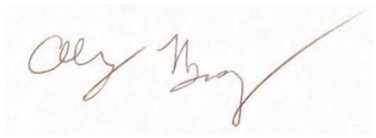
4/30/23 - Have presented thesis/Senior design project

Project Team

Function Required	**Name**
Product Development	Shelby Berry
Quality Assurance	Andrew Ulmer
Regulatory Affairs	Alex Bromley
Independent Reviewer	Troy Drewry
Additional Functions As Needed	
Manufacturing	Sydney Rester
Sterilization	Alex Bromley
Packaging	Sydney Rester

Approvals			
Title	Name	Signature	Date
Product Development	Shelby Berry		4/1/2023
Product Development	Sydney Rester		4/1/2023
Quality Assurance	Andrew Ulmer		4/1/2023

Food Tube Dudes	DHF #1	D&D Plan Revision: B

Regulatory Affairs	Alex Bromley		4/1/2023
Independent Reviewer	Troy Drewry	*Troy Drewry*	4/1/23

Description of Design and Development Plan revisions.

Revision	Effective Date	Author	Description of Change
B	4/1/23	Shelby, Sydney, Andrew, Alex	Revised Development Plan

Revision History (Form)

Version	**CR number**	**Approval Date**
A		12/02/2022
B		4/1/2023

Project Name - Feeding Tube Improvements	DHF # 1	Matrix Revision: B

Appendix 6

User Need #[1]	Design Input[2]	Design Output[3]	Essential Req[4] (Yes/No)	Verification Activity[5]	Validation Activity[5]
U1	Balloon Attachment	CAD drawing, 3D printed part	Yes	Testing with materials similar to existing medical grade balloon, current device	Animal Testing, Clinical Studies
U2	Balloon Attachment + Specialized Tubing	CAD drawing, ensuring that design/blueprints do not cut off feeding	Yes	Time-based testing with inflated balloons and nutritional solutions.	Animal Testing, Clinical Studies
U3	Balloon Attachment is flat enough to still be inserted through the nostril.	CAD drawing, 3D printed part	Yes	Design must be less than a certain diameter when not inflated, we will measure the final product.	Visual Inspections/Quality Control
U4	Connectivity between devices (our device & tube)	CAD drawing, matching specs with existing technology, 3D printed connectors	Yes	Verify that our design can still be used with current pumps, other equipment	Visual Inspections/Quality Control
U5	Ease of Use/Access	Detachable components, user-friendly/intuitive interface, simple	Yes	Check that it is easy to use and also have nurses check.	Visual Inspections/Quality Control
U6	Meets Specifications	Ensure 3D prints match CAD drawings and that parts match designs	Yes	Check that it matches designs	Visual Inspections/Quality Control
U7	Durability	Durable materials that will not break down, non-degradable materials	Yes	Check durability through testing over time.	Animal Testing, Clinical Studies
U8	Biocompatibility	Use biocompatible materials	Yes	Use materials that are known to be biocompatible and check biocompatibility.	Animal Testing, Clinical Studies

Add rows as needed.

[1]Need # from QD006F01, Design and Development Plan

[2]Design Inputs are to be reviewed by team to ensure they are complete, not ambiguous, and do not conflict.

[3]Design outputs should include catalog numbers, drawings/specifications, material specifications, sterilization, packaging, labeling, features/components of the device, etc.

[4]Essential design requirements include those that if they are not met the product could cause harm to a patient or the device could malfunction. The essential design requirements are the features of the design that are deemed critical for function of the component. For these features, validation of the final parts should be performed or alternatively, 100% inspection of the essential design output requirement features may be performed.

Project Name - Feeding Tube Improvements	DHF # 1	Matrix Revision: B

[5] Verification activities could include mechanical testing, animal testing, review of drawings/specifications, tolerance stack-ups, labeling reviews, packaging, etc. List applicable document numbers and document names.

[6] Validation activities could include animal testing, clinical studies, saw bone labs, cadaver studies, visual inspection of product, etc. List applicable document numbers and document names.

Add Rows as needed

Approvals			
Title	Name	Signature	Date
Product Development	Shelby Berry		3/30/23
Product Development	Sydney Rester		3/30/23
Quality Assurance	Andrew Ulmer		3/30/23
Regulatory Affairs	Alex Bromley		3/30/23
Independent Reviewer	Troy Drewry	*Troy Drewry*	3/30/23

Add Rows as needed

Description of matrix revisions.

Revision	Effective Date	Author	Description of Change
A	11/29/2022	Shelby Berry, Alex Bromley, Andrew Ulmer,	Initial Design Summary Matrix

		Sydney Rester	
B	3/30/23	Shelby Berry, Alex Bromley, Andrew Ulmer, Sydney Rester	Pivot to dislodgement

Project Name - Feeding Tube Improvements	DHF # 1	Matrix Revision: B

Revision History (Form)

Version	CR number	Approval Date
A		12/02/2022
B		3/30/2023

Appendix 7

Project Name: Nasogastric Tube with Balloon attachment

1. Purpose of Revision

■ Risk Management Plan (initial) ☐ Risk Management Report

☐ Modification to Risk Management Plan ☐ Modification to Risk Management Report

2. Plan and Report Approvals

Revision	Team Member Function	Team Member Name (printed)	Team Member Approval Signature	Date
A	Product Development	Shelby Berry		3/30/31
	Quality Assurance	Andrew Ulmer		3/30/31
	Regulatory Affairs	Alex Bromley		3/30/31
	Executive Management	Sydney Rester		3/30/31
	Other	Troy Drewry	*Troy Drewry*	3/30/31

3. Risk Management Details

Risk Management Plan: This Risk Management Plan outlines Risk Management activities for the lifecycle of the products listed in Table 1-3 from the initial product development through post market surveillance. Post market surveillance will be performed as needed, but at a minimum an annual review is required for each product, as outlined in QD006, Design and Development.

Table 1: Part Number

Part Number	**Description**
	Balloon for dislodgement prevention

Add rows as needed or attach list.

Table 2: Indications for Use

Indications for Use	Fill with no more than 3.35 mL of Saline per balloon
Foreseeable Misuse (In what way(s) might the medical device be deliberately misused?)	More Saline than 3.35 mL Is not inflated Is partially inflated

Table 3: Description of the Product

Risk Item	Description
Materials and / components	Silicone
Energy delivered to and/or extracted	N/A
Substances delivered to and / or extracted from the patient	Enteral solution (main tube); saline (side tubes to balloon)
Duration of Use	2 weeks to 2 months
What is the lifetime of the device?	2 weeks to 2 months
Biological materials processed by the device for subsequent re-use	N/A
Supplied sterile or intended to be sterilized by users	Supplied sterile
Intended to be routinely cleaned and disinfected by the user	Yes, as all NG tubes, will require regular water flushes while in patient
Intended to modify the patient environment?	No

Risk Item	Description
Measurements?	Each balloon has a diameter of around 2.5 cm. It is spherical.
Is the device interpretative?	N/A
Intended for use in conjunction with medicines or other medical technologies?	Yes - intended for use with enteral nutrition solutions.
Unwanted outputs of energy or substances?	N/A
Is the device susceptible to environmental factors?	Must be able to withstand the stomach environment; low pH and acidic
Essential consumables or accessories associated with the device?	Saline solution
Routine maintenance and/or calibration?	NG tube must be water flushed as part of regular maintenance
Software?	N/A
Restricted “shelf life”?	N/A
Is the device subject to mechanical forces?	Yes - anchor force on balloon, stretching/stress on the balloon
Is the device intended for single use?	Yes
Is safe disposal of the medical device necessary?	Yes
Is installation or special training required?	No
How will information for safe use be provided?	We will provide a paper manual with each tube that gives instructions for how to fill the balloons and how to safely remove the tube from the patient.

Risk Item	Description
Can the user interface design features contribute to user error?	Yes, the user could over- or under-fill the balloons. Additionally, the user could insert the tube incorrectly.
Is the medical device used in an environment where distractions can cause use error?	Yes–the patient or other healthcare professionals could serve as a distraction leading to misuse or user error.
Will new manufacturing processes be established or introduced?	No-we plan to use existing manufacturing processes.
Is device critically dependent on human factors such as user interface?	Yes–it is in contact with the stomach which may cause issues. Additionally, the product is dependent on a user to insert and operate it correctly.
Does device have connecting parts or accessories?	Yes–the balloon is connected to the NG tube and must be filled with a syringe.
Does device have control interface?	No
Does device display information?	No
Is device controlled by menu?	No
Will the medical device be used by persons with special needs?	No
Can the user interface be used to initiate user actions?	N/A
Does the medical device use an alarm system?	No.
Does the medical device hold data	No.

Risk Item	Description
critical to patient care?	
Is device intended to be mobile or portable?	No
Does the user of the medical device depend on essential performance?	No.

3.1. For each risk area, mitigation activities actions are defined that are typically examined as part of risk management. For each action, the appropriate evidence consists of several different items. The evidence documents (physical copies or references) are placed in the Design History File and/or Risk Management File.

3.2. The following documents, at a minimum, should be included in the Risk Management File for each product:

3.2.1. Complaint Review

3.2.2. Clinical / Literature Review

3.2.3. Risk Analysis

3.2.4. Trending related to product complaints, CAPAs, Non-Conforming Reports (NCR)

4. Risk Management Report

4.1. At the completion of the project, this document becomes the cover sheet for the Risk Management Report. Documents are compiled and approved to verify that risk mitigation evidence is complete or a rationale has been written to justify why the activity was not necessary. Any key assumptions should be included in the objective evidence or rationale. Mark the items included in the report. For items not included a rationale to justify why the activity is not necessary must be attached.

☐ Complaint Review

■ Clinical / Literature Review

■ Risk Analysis

☐ Trending related to product specific complaints, CAPAs and/or NCRs

For items not included provide a rationale to justify why activity was not necessary:

Comments: ☐ n/a

5. Risk Acceptance Criteria

5.1. Risk acceptance is defined in QD006, Design and Development and QD009F01, FMEA and document in the risk analysis.

6. Risk / Benefit Summary

6.1. Document an assessment of overall residual risk, if applicable.

6.2. Address the following questions:

6.2.1. Is the risk level acceptable? ■ Yes ☐ No

6.2.2. Do the benefits outweigh the potential risk? ■ Yes ☐ No

If risk level is not acceptable, document how the benefits outweigh the potential risk.

Comments: ☐n/a

7. Post Market Surveillance

7.1. Post market surveillance will consist of periodic review and update, as needed, of applicable risk management documents, but at a minimum an annual review is required for each product, as outlined in QD006, Design and Development.

7.2. Specific post market surveillance activities will typically include complaint and adverse event analyses and review/update of appropriate risk analysis documents (i.e., FMEA).

8. Dates

8.1. Anticipated Launch Date: _5/1/2023_____

8.2. Next Risk Management Review (Month/Year): _TBD_____

Revision History (Form)

Version	CR number	Approval Date
A		3/30/2023

Appendix 8

Failure Modes and Effects Analysis (FMEA)

Process or Product Name:	Nasogastric Feeding Tube with Balloon Attachment
Responsible:	Shelby Berry, Sydney Rester, Andrew Ulmer, Alex

Prepared by: Shelby Berry, Sydney Rester, Andrew Ulmer, Alex Bromley

FMEA Date (Orig): 04/03/2023 (Rev:) 0 CR

Risk #	Feature / Function	Potential Failure Mode	Effects of Failure	SEV	Potential Causes	OCC	Current Controls	Risk Index	Recommended Actions (if needed)	Responsible Person(s)	Actions Taken	SEV	OCC	Risk Index
#	What is the feature/function under investigation?	In what ways does the key input go wrong?	What is the impact on the key output variables (customer requirements) or internal requirements?	How severe is the effect to the customer?	What causes the key feature/function to go wrong?	How often does cause or failure mode occur?	What are the existing controls that prevent either the cause or the failure mode?	Severity x Occurrence	What are the actions for reducing the RPN. Should be actions only on high RPNs or key fails.	Who is responsible for the recommended action?	What actions have been taken and date completed?			
1	Balloon expansion	Balloon does not expand or only partially expands	Balloon may not be able to effectively anchor to the LES, causing the tube to travel up the esophagus or become lodged in the LES	3	Not enough fluid injected into balloons, balloon is popped/defective, the syringe is not able to make contact with/break the seal to inject the saline	2	Instructions that detail how much fluid to use, strict quality control to ensure no defects in the tube/balloons/seal	6						
2	Balloon deflation	Balloon does not deflate or only partially deflate	The tube would not be able to be removed from the patient or would be removed with great difficulty	4	Not all of the saline is removed from the balloon, the syringe is not able to make contact with/break the seal to inject the saline	1	Strict quality control to ensure no defects in the tube/balloons/seal, instructions that detail how much fluid to use to inflate the tube so nurses know how much fluid to remove	4						
3	Balloon popping	The material making up the balloon has a weak spot or hole in it that leads to fluid leaking out of the balloon	The balloon would deflate or partially deflate (see Risk #1), the saline solution would be released into the stomach	3	The material making up the balloon is defective/has a weak spot, the balloon is punctured/a hole is made in the balloon, too much pressure and pops	2	Instructions that detail how much fluid to put into the tube so that it is not overinflated, strict quality control to ensure that no defective products are sold	6						
4	Balloon-LES interface	The balloon could make contact with the LES in a way that is irritating or damaging to those tissues	This may cause patient discomfort and additional trauma	2	Tube dislodgement, external force on the tube that holds the balloon against the LES	3	Carefully monitoring the tube position externally to ensure that the balloon does not rub uncomfortably against the LES and that there is no strong, external force pulling the balloon against the LES (such as a confused patient trying to remove the tube)	6						
5	Tube tip placement	The tube tip could be improperly placed so that it hits the stomach wall	Blockage of enteral solution, poor enteral solution delivery, patient discomfort	3	The tip of the NG tube migrates to the walls of the stomach and blocks the exit holes for the enteral solution, improper placement of the NG tube	2	Detailed instructions that outline how to properly place the feeding tube and how to check for proper placement, nurses monitoring the tube externally to ensure that it has not migrated in the body	6						
6	Tube insertion	The NG tube could not be inserted/placed correctly by nurses	Patient discomfort/trauma/injury, complete loss of function for the tube, the tube would have to be removed and re-inserted	3	Improper tube insertion technique	2	Instructions that detail how to insert the NG tube, only allowing qualified and trained personnel (nurses) to insert/remove NG tubes	6						
7	Tube/balloon size	An improperly sized NG tube or balloon for a patient	Patient discomfort/trauma/injury, complete loss of function for the tube, tube removal	3	Not verifying that the patient's anatomy is compatible with the tube/balloon size, using the incorrect size of tube/balloon	1	Instructions and information provided with the tube that give the patient requirements (such as age and health status) for usage of this product. Adhering to these guidelines would negate improperly sized tubes/balloons from being inserted in patients	3						
8	Material breakdown (tube)	The material in the tube is not able to withstand the body's environment and breaks down	Patient discomfort/trauma/injury, complete loss of function for the tube, tube removal, enteral solution delivered to the wrong location	3	Defects in the tube, improper usage (re-using old tubes, leaving the tube in place for too long)	1	Detailed instructions that outline how to properly use the NG tube, including how long the tube can remain inserted, strict quality control to ensure that no defective products are sold	3						
9	Material breakdown (balloon)	The material in the balloon is not able to withstand the body's environment and breaks down	Balloon popping (see Risk #3), balloon deflating (see Risk #2)	3	Defects in the balloon, overinflating the balloon, leaving the balloon/tube in place for too long	1	Detailed instructions that outline how to properly use the NG tube, including how long the tube can remain inserted and how they are not overinflating and how long the tube/balloons can remain in the body, strict quality control so no defective products are sold	3						

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