BME 301

Design of a Cuffed, Microcidal Surgical Drain Tube to Prevent Surgical-Site Infections

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Client: Dr. Samuel Poore, Department of Surgery, UW School of Medicine and Public Health
Advisor: Professor John Webster, Department of Biomedical Engineering
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Abstract: Dr. Samuel Poore, a surgeon at the UW hospital, performs many breast reconstruction operations. This operation typically results in an accumulation of fluid within the body cavity – surgical drain tubes are used to drain this fluid. Unfortunately the patients are then prone infection – infection rates are upwards of 20% with 5% requiring the tube to be taken out and replaced. Dr. Poore asked the design team to develop a drain tube which will be effective for up to two weeks, will not alter the current drain tube procedure, will not result in harmful interactions with the body, and will reduce the infection rate. The team has looked into three design form options; the tube design, cuff design, and suture tab design. The team has also looked into using either silicon or polyurethane foam for the design. Design matrices were constructed to weigh the costs and benefits of each design. The results of the design matrices led the team to decide upon a final design which incorporates aspects of both the cuff and the suture tab designs. The team still has considerable testing to complete in order to officially determine what material will be used in the design.

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Introduction

Surgical drain tubes are commonly used devices to decrease pressure buildup inside wounds after surgical procedures. Surgical drains are fluted silicone tubes that drain fluid from the wound into a bulb on the outside of the body. Although surgical drains are a very useful device, they commonly become infected because they leave a constant opening for bacteria to get into the tissue or blood streams surrounding the drain. Dr. Poore is a surgeon at the University of Wisconsin –Madison Hospital and focuses on mastectomies and breast reconstruction surgeries. Thus, Dr. Poore deals with a lot of infected surgical drain tubes and would like a new design to decrease the infection rate. He submitted a design proposal to the biomedical engineering design course and this BME 301 team chose to work on his project. Dr. Poore will be mentoring the team throughout the semester as well as funding the project. The goal of the research project is to design a surgical drain that has an antimicrobial agent to keep the skin around the drain tube clean and prevent bacteria from getting inside the body.

Background

Over 200,000 patients are diagnosed with breast cancer every year. Breast cancer is caused by an abnormal amount of cell growth in the breast tissue and/or the surrounding ducts. In order to control the spread of the breast cancer many patients undergo a mastectomy, or a surgery that removes either part, or all of the breast tissue. Mastectomies are a routine procedure but are very invasive and cause a lot of fluid drainage from the wound site [5].

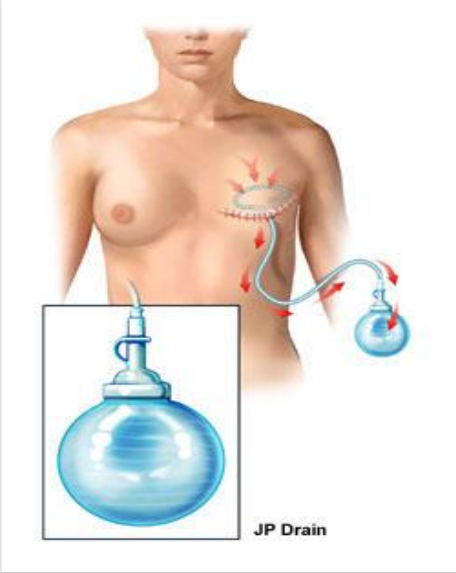


Figure 1: Diagram of a surgical drain tube. [3]

Figure 2: Close up view of a fluted drain tube. [4]

In order to prevent fluid buildup inside the wound doctors use a surgical drain tube. A drain tube, pictured in figure 1, is a small tube that allows excess blood and fluid to drain from the wound site into a bulb on the outside of the body. This decreases the pressure inside the wound and allows the body to heal faster. The most common type of drain tube is called a fluted drain tube, pictured in Figure 2. It contains slits all the way down the section of tubing that is inside the body. The fluid follows the slits until it reaches the skin, where the slits close and form normal cylindrical tubing. Drain tubes are usually worn for an average of 14 days and need to be cleaned regularly to keep the wound infection free.

In order to keep the inside of the drain tube clean, the patients are instructed how to clean and remove fluid from the bulb of the drain tube. The patients keep track of the amount of fluid that is drained each day so the doctors can tell if the wounds are healing properly. The doctors can predict leaks or hemorrhages if there is a large amount of fluid draining out of the wound [7]. Drain tubes are very useful for removing fluid from wound sites; however, they have a high rate of infection due to the open

wound site where the drain tube is inserted. This is why Dr. Poore would like a new design for a drain tube.

Problem Statement

Dr. Poore is a surgeon at the University of Wisconsin Madison and came up with the idea of creating a surgical drain tube with a section that has antimicrobial layer to stop bacteria from getting inside the body. According to Dr. Poore, upwards of 20% of his mastectomy patients develop an infection during the two weeks that they wear the drain tubes, and 5% have to get the drain tube removed because of the severity of the infection (personal communication, Feb 11th, 2011). The Mayo clinic conducted a study on infections after breast surgery during 2003-2006 and found that 26% of patients that underwent breast surgery developed a surgical site infection. Of those patients, 28% had to be readmitted to the hospital to receive antibiotics. Moreover, 10% of the patients with an infection had to undergo an operation to replace the infected drain tube [6]. Extra operations cause the patient to have a longer recovery time, more complications, and more medical bills. Dr. Poore has requested a cuffed surgical drain tube that will release a microcidal agent to fight and prevent infections in his breast reconstruction patients.

Client Specifications

The client requires first and foremost that the device decrease the rate of infection in his patients. In addition to this, a few other requirements were proposed. The drain tube's overall form must be small and flexible enough to fit through a 5 mm incision at the site of entry for the drain tube. The microcidal agent in the tube must be able to be effective in vivo for up to two weeks. The client would like the microcidal agent to be a part of the tube as much as possible. In hopes that the device is effective, the client wishes the device to be able to reduce the amount of dressing needed to cover the wound site, by this Dr. Poore means that the tube should be effectively secured on its own to avoid the necessity of additional bandages around the area. As with all drain tubes, the materials used in the design must be biocompatible. Also, the client would like this product to be economical enough so it may

be mass produced for use throughout many hospitals.

Competition

There are two major competitors for the proposed device currently out on the market. The first is known as the BIOPATCH®. The BIOPATCH® is the device currently in use by the client in union with the surgical drain tube. The BIOPATCH®es are discs that are polyurethane in nature with a microcidal agent known as chlorhexidine used to fight infection on the surface of the skin. There is a smaller hole concentric with the disc that allows room for a drain tube. There is a slit from the outer circle to the inner circle to allow the disc to slide around the drain tube. Figure 3 displays the BIOPATCH® as it is used. The arrows represent the release of chlorhexidine to the wound site. After the drain has been situated the client places the disc around the tube, sutures the disc to the drain tube, and places additional dressing around the BIOPATCH® to secure the path and tube to the skin. The main reason that the BIOPATCH® method does not work very well for the client is that it requires extra work to be done during the procedure. In order to prevent the tube from sliding in and out of the wound site, the BIOPATCH® must also be attached to the tube via suture in addition to being secured to the skin. The BIOPATCH® is also only effective for up to seven days – the client would like the device to remain in use for up to two weeks, thus the BIOPATCH® is insufficient for this application. Avoiding the necessity of replacing the device during the draining period would decrease risk of infection. The shortcomings of the BIOPATCH® are a few of the main reasons why the client requested a new device.

The second possible competitor to the proposed device is a microcidal catheter (figure 4). In this device the microcidal agent is built right into the tubing in the catheter.

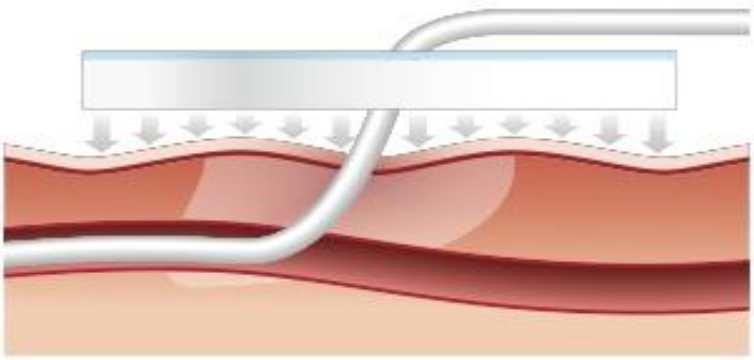


Figure 3 The Biopatch releasing chlorohexadine around a wound site with drain tube shown. [1]

The agent is released from all sections of the catheter via micropores [2]. One of the main issues with this device is that is not intended to be used as a surgical drain tube. The second issue is that the microcidal agent is released in all regions of the tube. This is not desired by the client as it may be harmful to the patient. An additional flaw to this design is that it leaves the potential for the tube to slide in and out of the incision site with ease, which again, is not ideal.

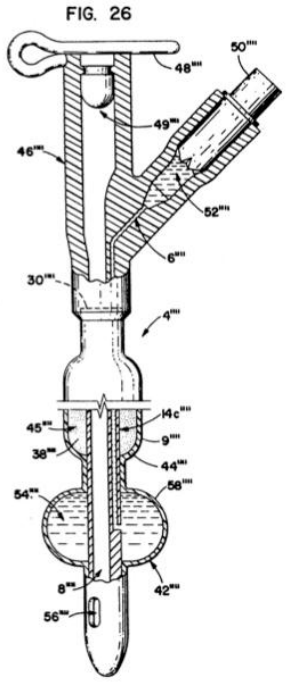


Figure 4: A diagram of the microcidal catheter. [2]

Design Options

The team has constructed three design options for the form of the design.

Tube Design

The tube design is modeled after the existing fluted drain tube as shown in Figure 5. During manufacturing, the silicone would be impregnated with the microcidal agent Chlorhexidine Gluconate. However, the Chlorhexidine Gluconate would only be impregnated in the silicone to a certain point in order to prevent interaction between the microcidal agent and mucous membranes. There is a possibility that this interaction could cause complications for the patient.

Because this design is modeled after the existing tube, it has a few advantages. Mass production of the tubes would be relatively easy as only one step in the process is changed. In addition, the surgeons would not have to alter the procedure. However, because the tube does not cover the wound site, infection could still be a common occurrence. Lastly, the tube does not provide a convenient method of securing to the skin to prevent movement of the tube.

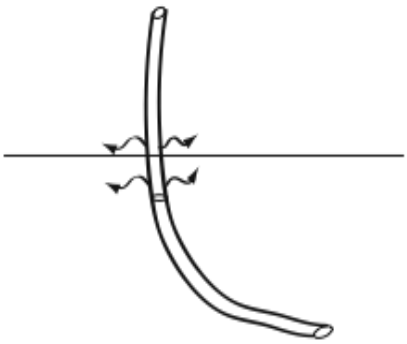
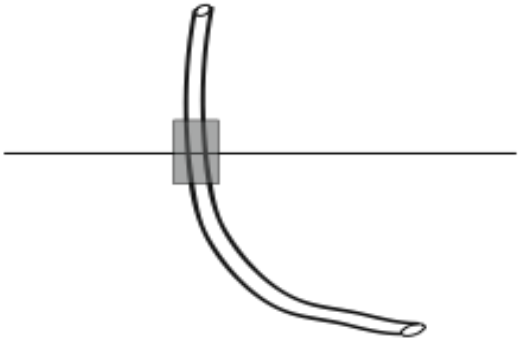


Figure 5: Tube Design

Cuff Design

The second design option is a cuff design. The cuff design would have polymer foam wrapped around the silicone fluted drain tube, as shown in Figure 6. The foam would be impregnated with Chlorhexidine Gluconate using a similar process used in the production of the BIOPATCH®. The foam would act as a barrier to seal around the wound site, thus preventing bacteria and other foreign bodies from entering through the incision. Because the microcidal agent is localized to the cuff, there should not be any interaction between the cuff and the mucous membrane.



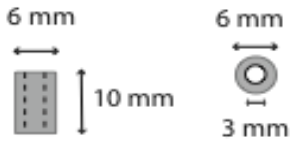


Figure 6: Cuff Design

Suture Tab Design

The final design form the team constructed was the suture tab design. This design would use a polymer foam disc impregnated with the Chlorhexidine Gluconate agent, similar to the concept of the BIOPATCH® (Figure 7). This design would differ from the BIOPATCH® in that the foam would be attached to the silicone tube using a silicone-bonding polymer. The disc would be small and flexible enough to fit through the 5mm incision.

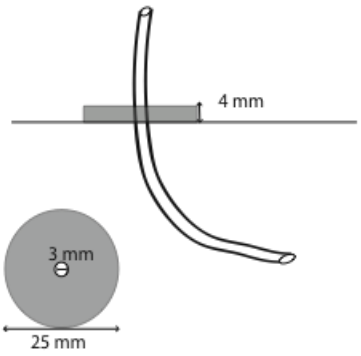


Figure 7: Suture Tab Design

This design has many advantages. Because of the additional surface area around the wound site, it not only provides protection from entering foreign bodies, but also acts as a place for surgeons to secure the tube to the skin of the patient. Additionally, the

Chlorhexidine Gluconate only acts on the surface, minimizing any interaction between the microcidal agent and the mucous membrane. However, mass production could be difficult or inefficient. In addition, the surgeon may have to alter the procedure to make sure the disc fits on top of the skin.

Materials

After the form of the design is decided upon, the team will still have to determine what type of material to use for the design. There are two primary options at this point of time: Silicon or Polyurethane foam.

Silicone is a polymer containing silicone, carbon, hydrogen, and oxygen (Greenwood & Earnshaw, 1997). Because this compound is highly inert, medical devices and implants commonly use silicone (Shin-Etsu Silicone, 2005). Silicone also shows flex fatigue resistance (Shin-Etsu Silicone, 2005). The ease of fabrication is another benefit to this material, as silicone can be formed into virtually any shape. In addition, silicone bonds very well to other silicones, creating a very durable product.

Polyurethane is another type of polymer that is commonly used in medical equipment, including the BIOPATCH®. Because polyurethane remains durable and relatively inexpensive, it is commonly found in polymer foams that release drugs in a biological environment. Polyurethane also comes in various textures, all exhibiting different properties (McMaster-Carr, 2010). However, reticulated polyurethane foam would work the best for the drug delivery system. One concern is the bonding strength of silicone and polyurethane foam.

Design Matrix

A design matrix was used to determine both the shape of the final design and the type of material to be used (Tables 1 and 2). The categories that were used were determined from the client's specifications (see appendix). The categories that were chosen for the final design are as follows:

feasibility, cost, durability, safety, ergonomics, surface area, and flexibility. Each category was weighted (0-1) and multiplied by its score out of 4.

Safety was weighted the highest; the design's impact on the patients' health is of the utmost importance. Care must be taken to be sure that nothing, especially the antimicrobial agent, will inflict any harm upon the patient for its duration in use. The second highest weight was the design's flexibility. This is because it is vital that the design is able to fit through the 5 mm incision. Without being capable of fitting through the incision, the design is essentially obsolete. The third highest weighted category was ergonomics, followed closely by durability. Ergonomics is extremely important in that it must not significantly detract from the surgeon's normal procedure, surgeons are often wary of deviating from a specific procedure. It should also conform to a certain degree to the incision, thereby further preventing the entry of bacteria. Durability goes hand in hand with these, it should be able to stay functional for up to 2 weeks, as well as withstand the insertion procedure of the drain tube. Surface area played a small role in the decision matrix, it is important for the release of the microcidal agent; however, much of this mechanism rests in the overall design. Finally, cost was weighted the lowest; this is because the materials for production are relatively cheap. They would not cost significantly more than what is used now (drain tube + BIOPATCH®).

Of the three designs: tube, cuff, and disk, the disk scored the highest, followed closely by the cuff design, and then the tube in last. The disk scored the highest because of its large umbrella-like covering of the incision site. This design is extremely similar to the shape of the BIOPATCH®, except that instead of being its own separate piece, it's attached to the tube directly. The cuff design came in a very close second; this is mostly due to its possibility of slipping down into the wound site. Unlike the disk, it is simply a larger diameter version of the old tube, and will likely need to be secured the same way as the tubes are now, with a safety pin placed horizontally through the tube. The impregnated tube design

scored the lowest due to the feasibility of the design and its lack of safety. With this design, it would be difficult to impregnate the specific portion of the tube with the microcidal agent. If this was accomplished, the next task would be to make sure too much microcidal agent wasn't released too deeply into the wound site; this could cause further complications and is generally avoided if possible.

Table 1: Design Matrix for Design Shape/Form

	Weight	Tube	Cuff	Disc
Feasibility	0.50	1	3	4
Cost	0.10	2	2	2
Durability	0.70	4	3	2
Safety	1.00	1	3	4
Ergonomics	0.85	1	2	4
Surface Area	0.40	1	2	4
Flexibility	0.90	4	3	2
Total		**9.35**	**12**	**14.4**

The second criterion that was discussed is the material that the final design will be composed of. After extensive research, two recurring types of foam were repeatedly used in a clinical setting. The first type, and more widely used, is reticulated polyurethane foam. The other type is silicone based foam. The categories to score these were the same used for the form of the design, with the added categories of absorbency, manufacturability, and bonding. Absorbency and bonding were both weighted quite heavily. The ability to absorb the microcidal agent is quintessential to the design, as well as the ability of the foam to adhere to the surface of the tubing. Research and past experience proved that materials

bond better when they are of similar structure. Therefore, the silicone foam scored high in its ability to bond to the silicone rubber tubing. However, what also is a large governing factor is the ability for the foam to absorb and release the antibacterial agent. In this category the reticulated polyurethane foam was best. The polyurethane is more porous and is used more widely in the application of microcidal agent, and will be the material of choice for the final design.

Table 2: Design Matrix for Design Material

	Weight	Silicone	Polyurethane
Feasibility	0.50	2	2
Cost	0.10	2	3
Durability	0.70	4	3
Safety	1.00	4	4
Absorbency	0.85	2	4
Flexibility	0.70	2	3
Manufacturability	0.50	3	3
Bonding	0.90	4	3
Total		**15.7**	**17.1**

Final Design

Due to the high scoring aspects of the “cuff” design, the final design will incorporate aspects of both the “disk” design and the “cuff.” This final design will resemble a mushroom or umbrella-type shape. A preliminary graphic of the design is shown below in figure 8.

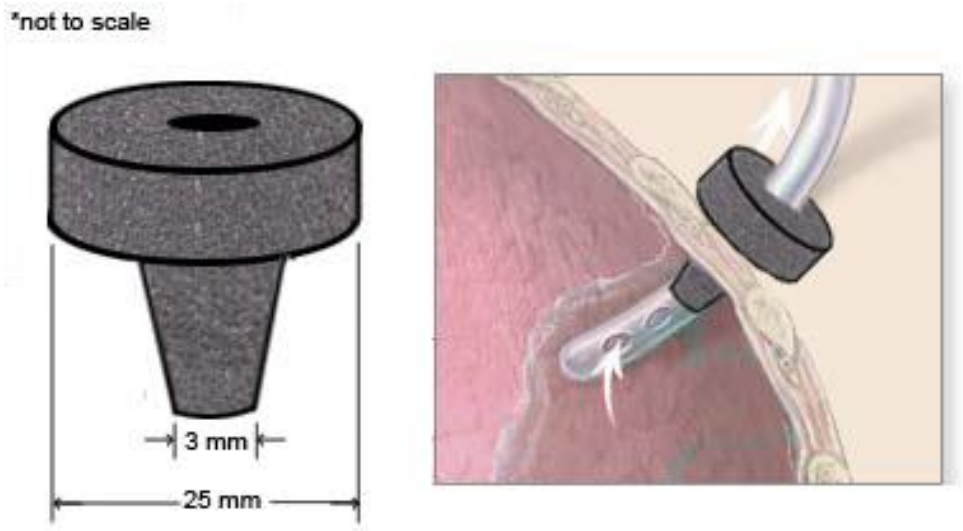


Figure 8: The final design concept that will be implemented. The design will fit over and be attached to the drain tube, as shown above. However, the dimensions are not to scale.

The circular disk that composes the top portion will serve as the main releasing site for the microcidal agent. The large surface area covers the incision site completely, which will help prevent bacteria from entering the wound. The foam piece will be bonded to the tube by a silicone-bonding agent. This is inert and will not have adverse effects if exposed to the body. The piece itself will be composed of reticulated polyurethane foam, a popular choice in the application of antibacterial agent (BIOPATCH® is also composed of polyurethane). The releasing mechanism will follow one of two paths (Figure 9). The first is a reservoir design; this is the most likely path to be taken. The reservoir design leads to the most linear release of microcidal agent, and will be the most likely to remain constant over two weeks. The second design is the matrix. This design releases much of its contents early on and tapers off as time elapses. However, testing must be done with both to ensure one over the other.

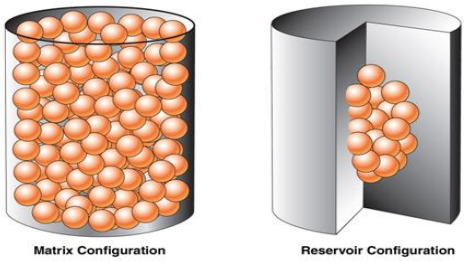


Figure 9: The matrix configuration is shown on the left, and the reservoir is depicted on the right. The reservoir allows a more constant release of contents

Future Work

The team still has considerable work to do in order to complete the design process. Firstly the team would like to ensure the decision to use polyurethane foam rather than silicone foam will be best for the design. The two foams will each be adhered to the silicon drain tube to ensure the bond will be strong and stable if used in the final design. Silicon is not generally difficult to bond to silicone, so the biggest question is whether the polyurethane will allow for a similar stable bond. Another important aspect that the material has is high flexibility in order to fit through the incision site. Thus far the silicone foam does not appear to be flexible enough to fulfill this requirement, whereas the polyurethane foam seems like a much more flexible option, but the team would still like to look further into this issue. One way which has been suggested to test for this property is to try to bring the material through a slit in paper of equivalent size to that of the tissue – if the foam can be successfully pushed through the paper slit without tearing the paper, which should be easier to tear than tissue, then the material should be flexible enough to be acceptable for use in the final design. Lastly, the chosen material must absorb the microcidal agent well and release it at a rate slow enough to allow the device to be used for up to two weeks at a time. The team has recently received and order of Chlorhexidine Gluconate (the same microcidal agent used in the BioPatch) and is planning on beginning testing using this agent very soon.

There is also considerable testing that must be done for this project. The team would like to construct multiple simple prototypes. First the team would like to test these prototypes in a simulated environment to determine their ability to protect again bacterial growth. The best prototypes from these experiments would ideally then be tested on animals. One of the most important factors to learn about from these tests will be the effective duration of use of the design.

Finally, the team will need to construct a final design prototype. That design would likely be required to undergo more testing procedures to determine safe use for humans. If all these steps were

taken the design could be marketed to hospitals as a product to incorporate into their surgical operations.

Appendix

Surgical Drain Tube (PDS)

3/7/11

Laura Platner, Taylor Powers, Danny Tighe, Kelsey Hoegh, Tanner Marshall

Function: Dr. Samuel Poore would like a surgical drain tube that consists of a standard round, fluted tube to prevent surgical site infections. He would like the tube to have a microcidal chemical, such as Chlorhexidine Gluconate agent, incorporated into the design.

Client requirements:

- Must be flexible enough to fit through 5mm incision
- Must be able to be left in the body and fight infection for 2 weeks
- Microcidal agent should be part of tube
- Reduce amount of dressing on wound
- Material must be biocompatible
- Have ability to be mass produced

Design requirements:

1. **Physical and Operational Characteristics**
    a. *Performance requirements:*
        i. Must be flexible enough to fit through 5 mm incision
        ii. Must fight infection
        iii. Microcidal agent must be part of tube
        iv. Must fit tightly around the wound
        v. Must be disposable
    b. *Safety:*
        i. Materials cannot harm patient
        ii. Microcidal agent must not enter deeper anatomy
        iii. Must be sterile
    c. *Accuracy and Reliability*
        i. Deliver microcidal agent to only the skin
        ii. Microcidal agent should fight infection
    d. *Life in Service:*
        i. Microcidal agent should fight infection for 2 weeks
    e. *Shelf Life:*
        i. 2 years
        ii. Easily storable
    f. *Operating Environment:*

i. Inside the body, between the skin and pectoralis major
ii. Room Temperature and Body Temperature- 15-40 degrees Celsius

g. *Ergonomics:*
    i. Comfortable for the patient to wear for 2 weeks
    ii. Easy to use for surgeons
    iii. Decrease infection rates
h. *Size*
    i. Tubing
        1. 3 mm diameter
        2. 1 m total length
        3. 0.3 m of fluted tube
    ii. Disc
        1. 2.5 cm diameter
i. *Materials:*
    i. Silicone
        1. Foam, tubing
    ii. Polyurethane
    iii. Polyethylene
    iv. Chlorhexidine Gluconate
j. *Aesthetics, appearance, and finish:*
    i. Function over aesthetics

2. **Production Characteristics**
    a. *Quantity:*
        i. One prototype
        ii. Possibly mass produce
    b. *Target Product Cost:*
        i. $20 each
3. **Miscellaneous**
    a. *Standards and Specifications:*
        i. Follow hospital regulations, FDA regulations
        ii. Must be safe and comfortable for patients
        iii. Must decrease infection rates
    b. *Customer:*
        i. Easy to use for surgeons
    c. Patient-related concerns:
        i. Cannot get microcidal agent too deep into tissue
        ii. Must be comfortable for long-term use
        iii. Whole tube must be sterile
    d. *Competition:*
        i. Existing drain tube with BioPatch
        ii. Catheters with microcidal agents

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