

Surgical Tools for use in Challenging Conditions Proposal

Michigan State University

ECE 480 - Team 1

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Executive Summary

The goal of this project is to create a surgical tool which is capable of suffusing antimicrobials continuously throughout a surgery to help improve the sanitization of the tool and reduce surgical infections experienced by a patient. A pump powered by a battery will utilize micro-channels to deliver the desired fluid to the tool at a calculated flow rate. The tool will be capable of functioning for a minimum of six hours and will be able to run for the duration of the surgery, minimizing the growth of bacteria.

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Introduction

Surgical Site Infections (SSI) occur at the location where the surgery was performed and can be a result of unsanitary surgical settings and practices. These infections can lead to extended hospitalization, treatment, and even death. In a study conducted by the Center for Disease Control (CDC) in the United States from 2006-2008, there were over 16,000 surgical site infections which equated to an overall rate of 1.9% of all operative procedures [1]. However, the prevalence of these infections drastically increases when compared with underdeveloped countries. A similar study conducted in India in 2007 showed 21.6% of patients suffered from surgical site infections [2]. The infection control practices such as sterilization methods, operating room ventilation, and availability of antimicrobials in these countries are not comparable to that of the United States.

The goal of this project is to develop a surgical tool which would be capable of continuously suffusing antimicrobials increasing the cleanliness of the surface of the tool. This will be implemented using a pump connected to microchannels to transport the antimicrobial to the device. Once the device is designed, it can be created through the use of an advanced 3D printer. Algorithms will need to be calculated to determine the correct flow rate of the fluid from the pump to disinfect the entire surface of the tool. The completion of this improved surgical tool can help reduce the occurrence of surgical site infections within patients in unsanitary operating settings.

Background

The demand for self-cleaning surgical tools is very high in the modern age, especially in countries with developing economies. Surgical operations in these countries are often conducted

in unhygienic settings which are conducive to the growth of bacteria and disease. Without a sterile surgical environment, the patient is put at higher risk of infection which could lead to a significantly longer recovery time or death. To prevent this from happening, a new class of self-cleaning surgical tools must be developed to increase the safety for the patient. This project is focused on the development of one of those tools.

The tool is to be continuously suffused with an antimicrobial solution, which will be administered through a series of micro-channels by a micro-pump. The solution will diffuse throughout the tool effectively creating a coating across the surface. This will prevent the growth of bacteria on the tool itself, which comes in direct contact with the patient. This is critical to the safety of the patient and will greatly minimize the chances of infection to occur. The tool is to be suffused with the solution for the duration of the surgery. This means that even while the tool is not in use, the surface will still be disinfected despite any bacteria present in the surgical environment.

The tool developed will be of great assistance to surgeons performing in unsanitary environments. With the tool being constantly suffused with the anti-microbial solution, the surgeon can operate without worrying about the tool becoming unsterile. The surgeon can set the tool down on any counter or tray and later continue using it during the operation.

The average runtime of a surgical operation is 3-4 hours [3], so the battery life of the tool must minimally be able to run for that length of time. The surgeon must also be able to maneuver with the tool, eliminating any bulky attachments or cumbersome loads attached to the tool itself.

Prior to the development of this project, there have been very few attempts to create self-cleaning instruments. Most medical equipment manufacturers cater to developed economies due to higher profit margins. Such economies have very little need for self-cleaning tools because the

surgical environments in these countries are sterile and disinfected. Most projects focus on equipment to better clean surgical tools after the surgery. The most similar project that has been developed is a self-cleaning holster [4]. This holster is meant to clean electrosurgical tools while not in use by the surgeon. While effective at cleaning the tool when not in use, this holster does nothing to prevent the growth of bacteria while being used in surgery. Also it does not prevent the growth of bacteria if the surgeon forgets to insert the tool into the holster.

The goal of this project is to develop a new set of tools that will increase surgical safety for the patient and decrease the risk of infection. This will be achieved through the use of a micro pump, micro channels and antimicrobial solution. The result of such efforts will produce an increased level of sterilization and a new standard of surgical sanitation.

Design Specifications

There is a significant problem in developing nations that involve the conditions in which their medical teams operate. Sometimes, the so called clean surgery room is filled with particles in the air and bacteria on the surfaces where surgeons place their tools. This is a leading cause of patients developing deadly infections or significantly longer recovery time from the surgery. Over 2.7 billion people live in extreme poverty, and the market for surgical tools could be large if the tools are easy to use, cheaper, and safer than the alternatives.

The task of the group is to create a surgical tool connected to a system that pumps antimicrobial to the surface of the tool to clear possible deadly bacteria. The surgical tool can vary from forceps, to clamps, or a scalpel. To develop the tool, the group needs to learn CAD software to create the tool on the computer. After the tool is created, a high resolution 3D printer will be utilized to print out the created tool to the exact specifications designed on the computer. The material of the tool also needs to be able to be used in a surgery. Therefore, the tool will

most needed to be created out of stainless steel. However, the method of delivery to the surface of the tool that will be needed during the surgery needs to be from microchannels built inside the tool for the antimicrobial. The microchannels need to receive the antimicrobial from the back of the tool and have it pumped to the surface to release the liquid there.

Moving back from the surgical tool, a pumping system needs to be developed to transport the antimicrobial to the tool. It is vital that this operates at the correct flow rate. If the microchannels are oversaturated with antimicrobial, this can lead to an excess flow on the tip of the tool that is being cleaned. This would also be unnecessary as only a minor amount of fluid is required to clean the surface. One constraint is to regulate the pump so the antimicrobial is flowing on the microliter scale. This places a necessity to have a pump that operates within the desired range. The pump may need a power circuit which connects the battery to the pump or purchasing a pump that comes with a battery. The pump also needs to have the ability to be controlled through a microcontroller. This will insure the right amount of fluid is going to the surface of the tool while creating the ability to cycle through different flow rates.

The microcontroller is the next device which needs to be examined. This needs to be compatible with the pump and have a way to be controlled by software from a smartphone. The connection needs to be wireless so there are no wires interfering in the operating room that can create complications for surgeons. The developed software can be iOS or android and needs to have the ability to change the flow rate to several other possibilities in the event the tool needs more or less fluid supplied to the surface.

The time constraint for this project is a lot sooner than other design projects for ECE 480. Unlike the other designs, the sponsor would like to schedule a surgery for a test date of the final design. This will allow a true testing situation to study the performance of the device and

discover if there are any corrections that need to be made prior to the final product displayed on design day. The goal is to have a final prototype completed a month before design day so a surgery can be scheduled in the veterinary hospital at Michigan State University.

FAST Diagram

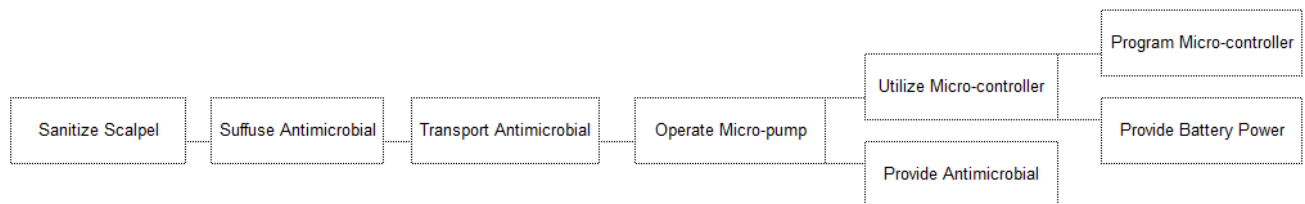


Figure 1: The FAST Diagram for proposed project solution.

Proposed Designs & Solution

The team made a decision based on three possible designs that depended on what tool would suffuse the antimicrobial:

1. A scalpel with a modified tip that would carry additional antimicrobial to additional sites where a main group of channels could not reach due to the blade surface area.
2. Mayo Needle Holders which would contain 2 different sets of microchannel networks.
3. Mayo Scissors which, similar to the needle holders, would have a similar distribution of the antimicrobial.

To come up with the final proposed design, a Design matrix, as shown in Figure 2 was created to compare which type of tool would be the most feasible to implement. One of the main points taken into consideration was the ability of the microchannels to re-suffuse or cover the entire surface of the surgical tool. Because of the scalpel's dynamic use in a surgical setting such

as the different orientations and a blade that is changed each time in surgery, it would be extremely difficult to fully coat the blade with antimicrobial without sacrificing functionality of the tool or over-usage of the antimicrobial. The Mayo scissors proved to be a good contender but as this project is being planned to be 3D printed, the cutting edges would be difficult to reach with microchannels. Ratings included a rating of a 1-9 system where 1 consisted of poor fulfillment of criteria while 3 was moderate and 9 was excellent.

Solution Design Matrix				
Engineering Criteria	Importance	Possible solutions		
Criteria Utilized to select solution	Rated from 1-5	Scalpel with fluid micropump	Needle Holders with fluid micropump	Mayo Scissors with fluid micropump
Bluetooth communication is User friendly.	4	3	3	3
Sufficient power to last a 6 hour surgery.	5	9	9	9
Entire surface of tool is suffused	5	3	9	9
Portability	4	3	3	3
Cost	5	3	1	1
Speed of re-suffusion time	5	1	9	3
Ease of reproduction in 3D printer	5	9	3	3
Total		149	179	159

Figure 2: Design Matrix weighing the feasibility of the three proposed designs.

To make a final decision, a second solution design matrix was constructed as a group to compare the top two designs to make sure the results made sense in terms of feasibility. New ratings were given to the criteria individually. They were then discussed as a team where a consensus was reached and once again the winning design was the Mayo Needle Holders. The same 1-9 rating system was utilized for this matrix as well.

Solution Design Matrix Second Round			
Engineering Criteria	Importance		
Criteria Utilized to select solution	Rated from 1-5	Needle Holders with fluid micropump	Mayo Scissors with fluid micropump
Bluetooth communication is User friendly.	4	9	9
Sufficient power to last a 6 hour surgery.	5	9	9
Entire surface of tool is suffused	5	9	3
Portability	4	9	9
Cost	5	3	3
Speed of re-suffusion time	5	9	3
Ease of reproduction in 3D printer	5	3	3
Total		237	183

Figure 3: Design Matrix weighing the feasibility of top two designs.

The final proposed design consists of a lithium ion battery or some variant of a cellular phone battery which will be integrated with a wall plug in charger provided by a supplier. The battery will have the task to output two different voltages; one for the Servoflo mp6 pump and one for the microcontroller. The microcontroller is planned to be programmed so it will be able to receive Bluetooth signals. The pump will control the flow of the antiseptic, which will be Chlorhexidine, on the order of microliters per second. Finally the previous systems mentioned will be tailored so the selected tool will constantly be suffused on the surface of the tool through a network of microchannels that will contain the approximate width of a human secretory sweat gland known as the eccrine gland. This width ranges anywhere from 500 μ to 700 μ meters.

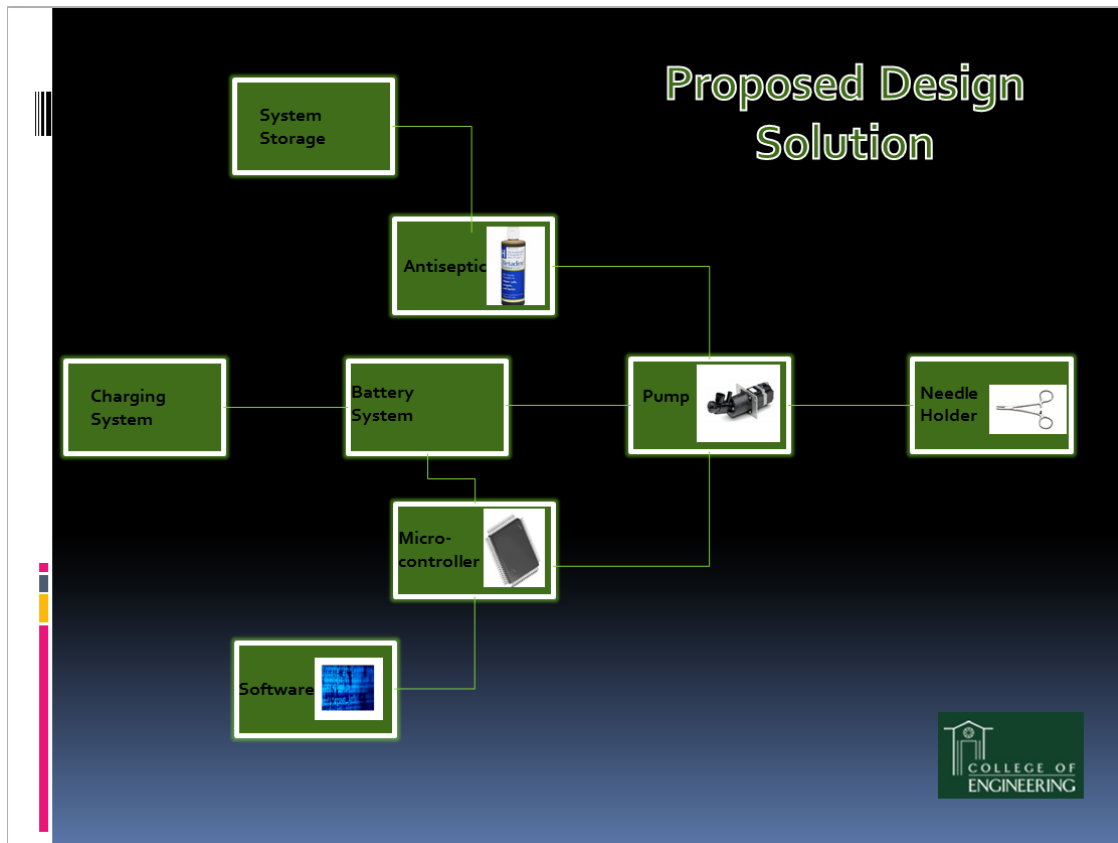


Figure 4: Proposed design solution diagram.

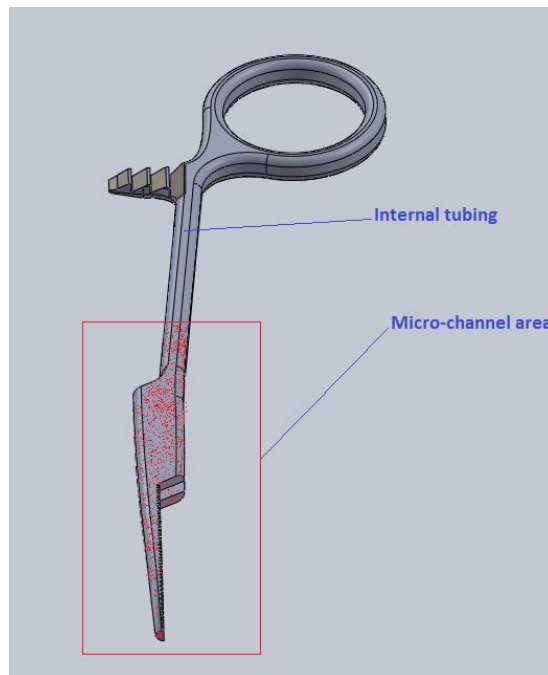


Figure 5: Proposed design solution. (Note: Only half of the tool is depicted)

Test Plan and Evaluation

The initial tests will be to handle similar materials comparable to surgical surfaces to observe how long it takes for the tool to suffuse again with Chlorhexidine. Chlorhexidine is already a colored liquid so no additional colorant is needed in order for the solution to be observed. An absorbent tissue or piece of paper could measure if the entire tool is suffused and is a method of inspecting the tool. The time it takes to re-suffuse is critical and calibrations of the tool's software and pumping will be conducted until there is an equal balance between timely suffusion and a lack of leakage or spillage of the antiseptic. The device will also be tested under "worst case" which will be a continuous operation for a length of approximately 6 hours. In addition, a test to measure if the tool reduces infections will include a normal set of needle holders and will be in contact with a culture of bacteria. The amount of bacteria will be measured and compared to the amount of bacteria formed on the designed surgical tool.

Risk Analysis

A possible risk of the proposed design would be if the fluid was not being pumped at the desired flow rate. If there is too little of the fluid being pumped to the tool, the surface of the tool would not be completely immersed with the antimicrobial. This would allow the growth of bacteria on the surface of the tool. If too much fluid was pumped to the tool, there would be an overdose of the antiseptic which could be deadly to the patient depending on the concentration and type of antiseptic used. Therefore the pump must be accurate and precise when calculating the flow rate. This is a low level risk because through extensive research and thorough calculations the team can choose a pump with the accuracy needed to complete the task.

Another risk that needs to be considered is the type of antiseptic used to disinfect the tool. As stated before, some antiseptics can be toxic to a patient if the concentration is too high or there is too much applied. Also some antiseptics react when in contact with metal, causing the metal to rust and become brittle. This could lead to pieces of the tool breaking off or wearing away which would be detrimental to the functional ability of the instrument. This is a high level risk because this could potentially have fatal repercussions. To minimize this risk, in-depth research will be conducted on the types of antiseptic that will disinfect the tool and will be non-toxic to the patient. A medical technician will also be consulted to guide and direct the team in the correct antiseptic.

Project Management

Personal and Tasks

The team decided that the best way to get aspects of the project done is to handle them as a unit. Throughout the weeks so far, the team has handled every event together. This includes meeting with the sponsor and facilitator, the created design path, the homework and papers, and the parts needed to complete this solution. The team will also come together to put the final working prototype together as this is the most important part of the project.

However, there are some jobs that do not involve the entire group. Since Parker is the lab coordinator, he was in charge of obtaining the parts. Stephanie is the webmaster and she is in charge of the website and the simple coding to the microcontroller. Kasey is the document prep coordinator and is in charge of making sure the papers and homework come together and look professional. Jose is the presentation prep coordinator and is in charge of making sure the presentations to everyone are professional and without flaw. He also took on the task to create the 3D modeling of the tool and will be working with help from available teammates. Adam is

the project manager and is in charge of communication between the sponsor, facilitator, other help, teammates, and the scheduling.

Resources

Design Team One will utilize many different resources provided by the Electrical and Computer Engineering (ECE) department. Through the ECE department the team will be able to order parts such as the pump, micro-controller and battery from different sources such as Texas-Instruments and Digikey. The ECE department also provides access to different programming languages, as well as the integrated developing environments (IDE's) to build the necessary software. The team will use Java to develop and code the phone application's user interface.

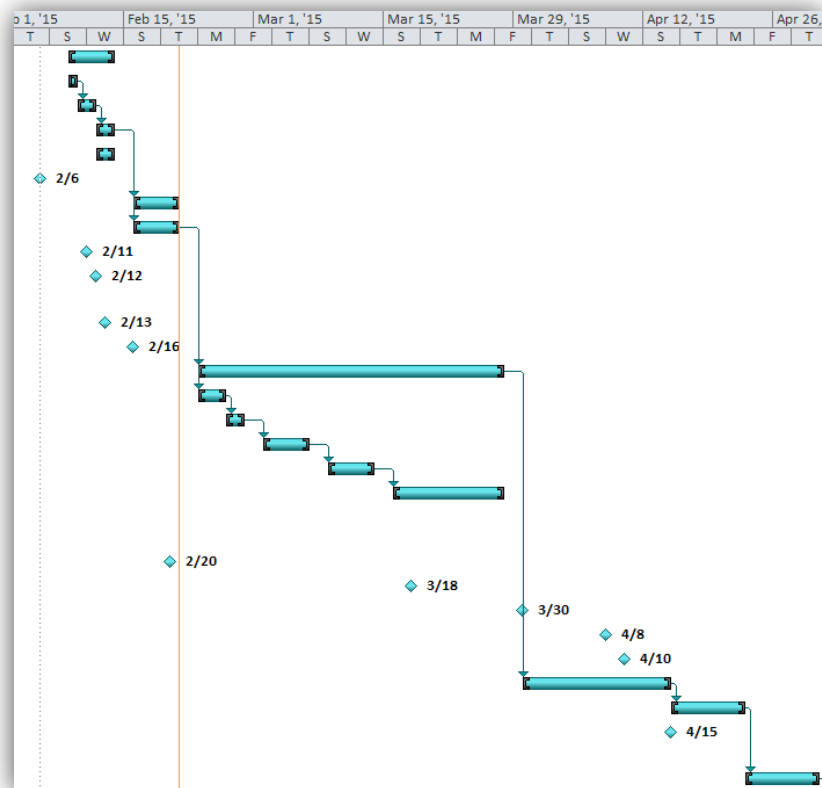
As well as the resources provided by the ECE department, the team will use 3D printing capabilities provided by the Chemistry department. The printer will be used to construct the tool in a ceramic material. Furthermore, the tool will be coated with a porous metal with a semi-permeable membrane also to be supplied by the Chemistry department or the Chemical Engineering department.

Lastly the team will combine forces with the College of Veterinary Medicine to evaluate and test the tool. If inspection is passed, the College will possibly be able to use the tool to perform surgery on an animal patient.

Schedule

The GANTT chart for the proposed project solution can be found on the following page.

	i	Task Mode	Task Name	Duration	Start	Finish	Predecessors
1			Research	5 days	Mon 2/9/15	Fri 2/13/15	
2			Meeting with Professor Jaberri	1 day	Mon 2/9/15	Mon 2/9/15	
3			Meeting with Professor Li	2 days	Tue 2/10/15	Wed 2/11/15	2
4			Buying Parts	2 days	Thu 2/12/15	Fri 2/13/15	3
5			Prepartation for oral presentation	2 days	Thu 2/12/15	Fri 2/13/15	
6			Turn in Pre proposal	0 days	Fri 2/6/15	Fri 2/6/15	
7			Receiving parts	5 days	Mon 2/16/15	Fri 2/20/15	4
8			Finalize prototype design on paper	5 days	Mon 2/16/15	Fri 2/20/15	4
9			Voice of customer assignment due	0 days	Wed 2/11/15	Wed 2/11/15	
10			Meeting with head of the Veterinary Department	0 days	Thu 2/12/15	Thu 2/12/15	
11			Meeting with Facilitator	0 days	Fri 2/13/15	Fri 2/13/15	
12			Oral Presentation	0 days	Mon 2/16/15	Mon 2/16/15	
13			Construction of prototype	25 days	Mon 2/23/15	Fri 3/27/15	8
14			Learn CAD	3 days	Mon 2/23/15	Wed 2/25/15	8
15			Develop tool on CAD	2 days	Thu 2/26/15	Fri 2/27/15	14
16			3D print designed tool	5 days	Mon 3/2/15	Fri 3/6/15	15
17			Develop power systems	5 days	Mon 3/9/15	Fri 3/13/15	16
18			Program microcontroller and develop software to control from phone	10 days	Mon 3/16/15	Fri 3/27/15	17
19			Final Proposal	0 days	Fri 2/20/15	Fri 2/20/15	
20			Progress report due to facilitator	0 days	Wed 3/18/15	Wed 3/18/15	
21			Technical Lecture	0 days	Mon 3/30/15	Mon 3/30/15	
22			Progress report number 2 due	0 days	Wed 4/8/15	Wed 4/8/15	
23			Design Issues Paper due	0 days	Fri 4/10/15	Fri 4/10/15	
24			Testing and Revision	12 days	Mon 3/30/15	Tue 4/14/15	13
25			Work on Final Report	6 days	Wed 4/15/15	Wed 4/22/15	24
26			Demonstration of Working prototype	0 days	Wed 4/15/15	Wed 4/15/15	
27			Work on Oral Presentation	6 days	Thu 4/23/15	Thu 4/30/15	25



Cost Summary

With the given budget of \$500 dollars several parts must be purchased for the surgical tool. **Table 1** below summarizes the items required and provides a justification for their need. The parts may change as the prototype is modified and improved. Also, several item quantities are listed as unknown until the design process is further developed. An estimate for the cost is included for the unknown quantity items based on average cost of the part/material.

Table 1 - Parts Summary

Part Description	Estimated Cost	Quantity	Justification
Micropump (mp6)	~\$30	1	Provides a means to transport the antimicrobial to the surgical tool. The pump must be able to provide accurate flow rates at an acceptable amount which is typically a small number.
Tubing	\$0.50/ft	20ft	The will be used to connect the micropump to the tool and must be able to withstand corrosion from the antimicrobial liquid.
Bluetooth Capable Microcontroller	\$5	1	Since the amount of antimicrobial needed to keep the tool clean is a variable quantity, a method to adjust the flow rate is needed. The bluetooth radio will allow information from a cell phone app to adjust the flowrate of the pump.
Tank for Antimicrobial (if needed)	\$20	1	If the container containing the antimicrobial is not acceptable to use directly, an alternate storage tank must be purchased.
Battery	\$40	1	A battery is necessary to provide power to the microcontroller which will then power the micropump with the amount needed to run at a specific flow rate.
3D Printer Materials	\$10	unknown	The surgical tool will have to be produced with all of our design requirements and currently a 3D printer is the best option for this and will ultimately need a safe and reliable material to

			print with.
Antimicrobial	\$15	1 Gallon	Chlorhexidine will be the antimicrobial used to sanitize the tool. This estimate is based on a 32oz bottle size.
Battery Charger	\$40	1	The battery will require a charging method. This will most likely be an AC to DC power pack but until the design is further along the exact specifications are unknown.

- Total Estimated Costs: \$170

The total cost is within the budget however the actual costs of the parts may be higher or lower depending on the exact specifications needed. The costs displayed in the table were rounded up to allow flexibility but with the micropump being a vital component in the project, it will be important to ensure it can provide the accuracy and flow rate needed for the tool. In addition to this, the pump must be able to pump the antimicrobial without any issues.

The Micropump that will be utilized is the Servoflo mp6. This pump satisfies all of the flow rate requirements while providing the benefit of being compact in size. The pump can deliver a max flow rate of 7 ml/min and a max pressure of 600 mbar while consuming under 200 mW of power. The pump uses a piezoelectric diaphragm to operate. The microcontroller will be a prototyping MCU while the project is being designed and tested. This will take up additional space but when the design is finalized and produced there is the option of incorporating just the MCU and eliminating the prototyping portion which will reduce the design size.

The material used for the prototype will be a proof of concept material and will not reflect the material used in the final design. Surgical stainless steel is the material used for surgical tools and will be utilized in the final design. This will also have to be made by a third party with the tools and resources that are able to create many of the tools used in the medical

setting. When the prototype is made, the material will be tested to ensure that it shares many of the same characteristics as surgical stainless steel and will be an accurate representation of what the final design will be.

Initially a coating was going to be used to coat the tool and prevent any foreign material from getting into the microchannels. This was removed from the design in order to comply with the sanitizing procedures used in medical settings. The College of Veterinary Medicine at Michigan State provided insight to the methods of sanitizing commonly used. Frequently, this involves very high or very low temperatures and any porous membrane used as a coating would not be able to handle the extreme temperatures and therefore was removed from the design.

Chlorhexidine will be the antimicrobial used for our design. It will be purchased in a 2% solution and will have to be diluted to 0.5% prior to use. This was recommended by the College of Veterinary Medicine at Michigan State and is used in the medical field as a disinfectant. The diluted 0.5% solution it will be safe to use near surgical sites and pose no toxic threat while retaining its ability as a potent antimicrobial. This will not require any licenses to purchase and is relatively cheap at only \$15 per gallon for a 2% solution.

References

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- [4] J. M. Urueta and W. R. Ureta, “Self-Cleaning Holster for Electrocautery Tip”. United States Patent US 6367110 B1, 9 April 2002.