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Final Design Report for the Bioburden Pre-cleaning Device and Dr. Mark Rasnake at the University of Tennessee Medical Center

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May 10, 2018
Dr. Mark Rasnake
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Dear Dr. Rasnake:

Thank you for attending our Senior Design Showcase presentation on April 25, 2019. We have appreciated your continued support and feedback throughout this year of our design and build process. We would like to ask if you could give us some feedback on our presentation, poster, and prototype for our benefit. This will allow us to improve our presentation skills and will give you the opportunity to give us any comments you may still have about our project. To reach this feedback form, please navigate to the address below.

http://rrg.utk.edu/resources/BME469/design_review.html

Attached to this letter is a summary of our work this semester and proposed future directions for this project. If you have any questions, comments, or concerns about anything stated in this report, please let us know by emailing Kate Stiles, Communications Director, or Megan Pitz, Team Leader.

Thank you for your time and consideration,

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1. EXECUTIVE SUMMARY

Orthopedic surgeries require the use of many specialized instruments and tools throughout hours-long procedures. Throughout the surgery, bioburden (blood, tissue, and bone) can dry on these instruments with little to no precleaning, making them extremely difficult to clean upon reaching the decontamination area. Microscopic and macroscopic levels of bioburden remaining on instruments after sterilization can lead to infection in later patients, which may result in failure of the surgery or implant or even death. A new method for precleaning orthopedic instruments is required in order to prevent infection and accidental unsterile use of instruments. Current precleaning methods are ineffective and time-consuming. Any new method should quickly and easily clean instruments of bioburden in the operating room (OR) during surgery.

Many different ideas were considered to solve this problem; however, an automated method seemed essential to minimize time required to preclean instruments. Several washing methods were considered such as a conveyor belt or targeted water jets. However, our final design needed to be small, work quickly, and minimize contact with the OR. Our final design features were inspired by a deep fryer design including a stainless steel basket in heated enzymatic fluid that is easy to remove and refill or replace with another round of instruments. This method allows a nonsterile nurse to minimize time away from a surgery by quickly removing and replacing baskets instead of a method that involves placing and cleaning instruments one at a time.

Our final design requires little manufacturing and is small and portable for use in the OR and easy transport throughout the hospital when necessary. It also easy to disassemble and clean, and is modular, allowing for easy replacement of any pieces should that become required or ideal. Finally, our design was tested and proven to efficiently preclean instruments in less than 20 minutes.

2. BACKGROUND

Bioburden can be blood, bone, or tissue fragments left on surgical tools after surgery. This bioburden can include microscopic or macroscopic debris. Biofilm formation (thin, slimy film of bacteria that is difficult to remove even with the most powerful antibiotics or sterilizing systems) occurs after the accumulation of bioburden on the instrument [1]. Therefore, it is necessary to effectively remove bioburden from surgical instruments to reduce the risk of infection. Moreover, it has also been noted that the presence of endotoxin on orthopedic surgical instruments may contribute in the loosening of the installed prosthesis [1]. National regulations, standards, and guidelines for surgical instrument cleaning are defined by the Association for Advancement of Medical Instrumentation (AAMI) [2]. The AAMI stresses the importance of timely cleaning of soiled medical instruments to avoid microbial contaminations from drying and prevent formation of biofilms. Prompt cleaning also reduces the time required for the overall cleaning process by minimizing the instrument's exposure to an environment that supports gross soil growth [3].

Currently, the bioburden pre-cleaning of orthopedic instruments is being done by hand because there is no device on the market that can be used in the operating room (OR). The current method usually entails spraying instruments with a water and enzymatic solution and wiping them down with gauze. With this method, instruments can only be cleaned toward the end of the surgery, meaning there has been ample time for bioburden to dry. The goal of our project is to accomplish more timely and efficient cleaning by creating a mechanical device that cleans bioburden before it dries. The device will be small and portable, making it suitable for use in the OR.

A study performed by The Center for Disease Control and Prevention found that automated methods of bioburden precleaning achieved a >99% reduction in soil parameters (i.e., protein, carbohydrate, hemoglobin) [4]. The study emphasized that ultrasonic technology alone does not denature proteins, but can enhance the properties of enzymatic cleaning solutions or other disinfectants. The addition of cavitation bubbles induced by high frequency waves producing high forces on bioburden contaminants adhering to the surgical instrument. This method is currently used in the decontamination area to clean surgical instruments. While it is an valid method, its effectiveness is severely diminished if the bioburden has time to dry on the surgical instruments.

The current optimal situation for bioburden removal in the operating room requires a nurse to remove gross soil with gauze and water as soon as possible after use. Additionally, transportation to the decontamination hub should occur as quickly as possible. These optimal scenarios are very improbable and highly unrealistic especially in surgeries where unforeseen complications can arise. In these instances, Dr. Rasnake informed us that nurses are often tempted to soak the used surgical instruments in saline solution, as it is readily available in the operating room. This method is ineffective as the salt within the solution can cause microscopic scratches on the instruments and lead to eventual corrosion. In devising an effective pre-cleaning solution, we hope to prolong the lifetime of these expensive surgical instruments.

We were informed by nurses in the decontamination area that surgical instruments used to be thrown in a bucket of enzymatic solution for pre-cleaning purposes. While it prevented biofilm formation and quickly denatured harmful proteins, this solution resulted in sticky surgical instruments. Additionally, the open containers of enzymatic solution were a hazard, especially during transportation of the instruments to the decontamination area.

In an attempt to solve this problem, our team has designed the Bioburden Precleaning Device which can be placed and used in the operating room. The working prototype is a combination of induction heater with ultrasonic probe enclosed in an outer stainless steel case. The ultrasonic probe is suspended from the top lid to enter the stainless steel tray holding the water and enzymatic solution. A fry basket is also incorporated into the design for easy insertion and removal of surgical instruments. Additionally, the top lid is attached to the box using a hinge and handles are

incorporated on the sides of the box as well as on the lid. Through our testing with bioburden simulated with dog bones, positive results have been seen. The optimal temperature for bioburden cleaning has been determined to be 140 Fahrenheits. This temperature along with 10-20 minutes run cycle allows for proper loosening and removal of bioburden. This design is efficient, small, and portable, performs the required function, and fulfils all the requirements given by our stakeholder.

3. PROBLEM DEFINITION

As stated above, the current problems with surgical instrument precleaning are the inefficiency of hand cleaning and the time elapsed between instrument use and instrument cleaning. To create the most effective product to solve these problems and meet our stakeholders' expectations, there are several needs which must be met:

1. bioburden must be removed from surgical instruments, including orthopedic tools with small crevices
2. the device must work quickly and be easy to use
3. the device must pose no risk or distraction to nurses or others in the OR
4. the device must be portable and easy to transport
5. the device must be easy to clean and sterilize.

Our goal as a design team is to meet or exceed these needs with a novel product; our progress on this goal will be measured by periodic deliverables and the feedback of our stakeholders and consultants. Efficacy and success of our product will later be determined using prototype testing and market appeal.

To ensure our product meets the needs listed above, several basic design aspects such as size, material composition, and complexity were considered. After considerable brainstorming, we converted the needs listed by our stakeholders into specific, measurable requirements for our device:

1. macroscopic and microscopic bioburden should be completely removed from surgical tools
2. the device must have a simple wash cycle of no more than 15 minutes
3. the device must be quiet and safe to touch or handle in any way
4. the device will be small enough to fit on a cart or be carried if necessary
5. the device will be disassemblable for easy cleaning and sterilization.

As this device will be used in the OR with stainless steel instruments, there are certain expectations that our design must satisfy. Saline solution must not be used in our device, as saline can cause corrosion and pitting in stainless steel over time. Our device must also not produce any aerosols, as an operating room is expected to remain sterile and any particles released into the air could compromise the sterile environment. An important aspect to note is that our device *will not* sterilize surgical tools. Sterilization will continue to occur in the decontamination area of the hospital using the hospital's current methods and equipment.

4. CONCEPT DEVELOPMENT

When initially given this problem, we considered multiple approaches. One idea consisted of using water jets and automated scrubbers to clean devices as they rotated through a conveyor belt. Depending on which surgical tools were being cleaned, various cleaning solutions would have been used in addition to DI water. These solutions would have been used to clean small crevices using a water pick. Small robotic scrubbing devices would then clean large flat areas of the instruments. Both of these processes would be applied to both sides of each instrument as it progresses through the conveyor belt.

Another idea was to improve on a sonic cleaning device design. The air bubbles created by the Ultrasonic Waves create a force when they come in contact with objects. This process would allow bioburden to be dislodged from medical instruments while avoiding damage. To improve the device, we thought of using a cleaning solution besides water with a sonic cleansing device. With the addition of a conveyor belt, we believed that there would have been an increase in the amount of surface area that was accessible to be cleaned.

Both of these proposed methods would have included settings for different medical devices. The last step for both of these proposed designs was a drying setting using pressurized air in order to prep instruments for the autoclave.

After conducting more research, we contemplated using a deep fryer design. The handles on the fryer baskets would be used to easily move the instruments to different solutions. Adding pegs to the ‘fryer’ baskets would allow the instruments to be cleaned while in tension, therefore exposing small areas that are susceptible to harboring bone and tissue. One of the compartments of this design was intended to focus on chemical breakdown of the tissue and bone. The second compartment would have been used for the physical agitation of the remaining bioburden (i.e. ultrasonic motion or pressurized jets). Figure 1 below was our initial design that consisted of two separate compartments.

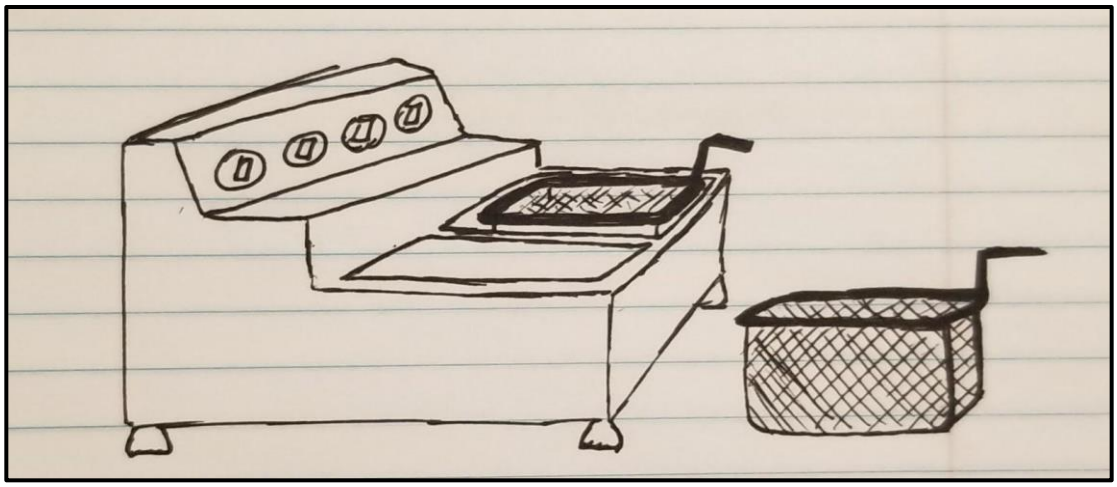


Figure 1: Our initial sketch

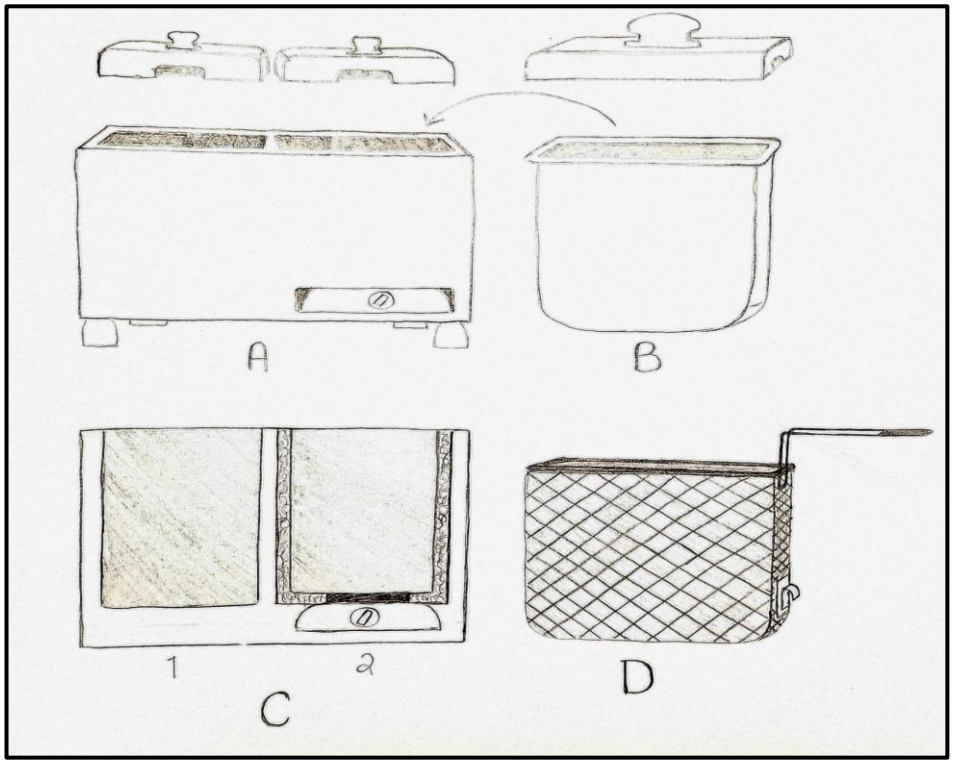


Figure 2: More defined sketch of our initial design

In Figure 2, we decided that both compartments should consist of removable trays. This way, the unsterile nurses or anyone else coming into contact with the device could easily clean and change the enzymatic and water solution.

As we progressed through the semester, we realized that our initial proposed solution would be harder to assemble and might not prove to be a feasible and optimal design. For the sake of organization and specialization, we had planned to separate the chemical and physical breakdown processes. After explaining the project design to Dr. Chris Wetteland from the Material Science

department at UTK, he thought that the most significant aspect of the pre-cleaning process that we could improve was reduction of time through process simplification. We had gotten caught up in the complex dual-compartment system, as it was the first idea that came to us, however, after hearing Dr. Wetteland's perspective, it made us reevaluate our design. Hence, after considerations were taken into account, we modified our two-compartment initial deep fryer design to a single compartment which combined both of the technologies. We settled on using the ultrasonic technology in a probe design structure with an electromagnetic induction heating to assist and improve the cleaning process.

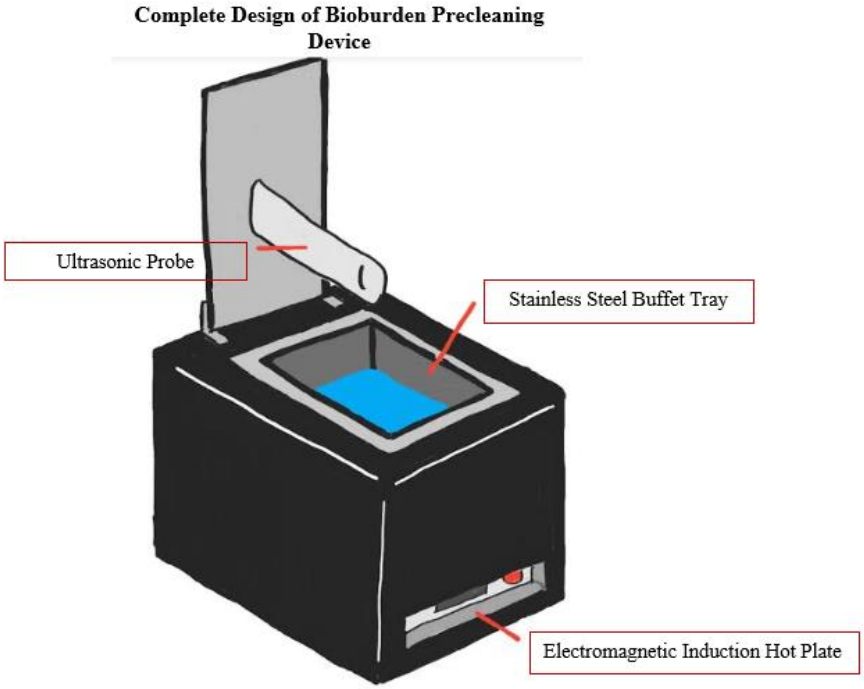


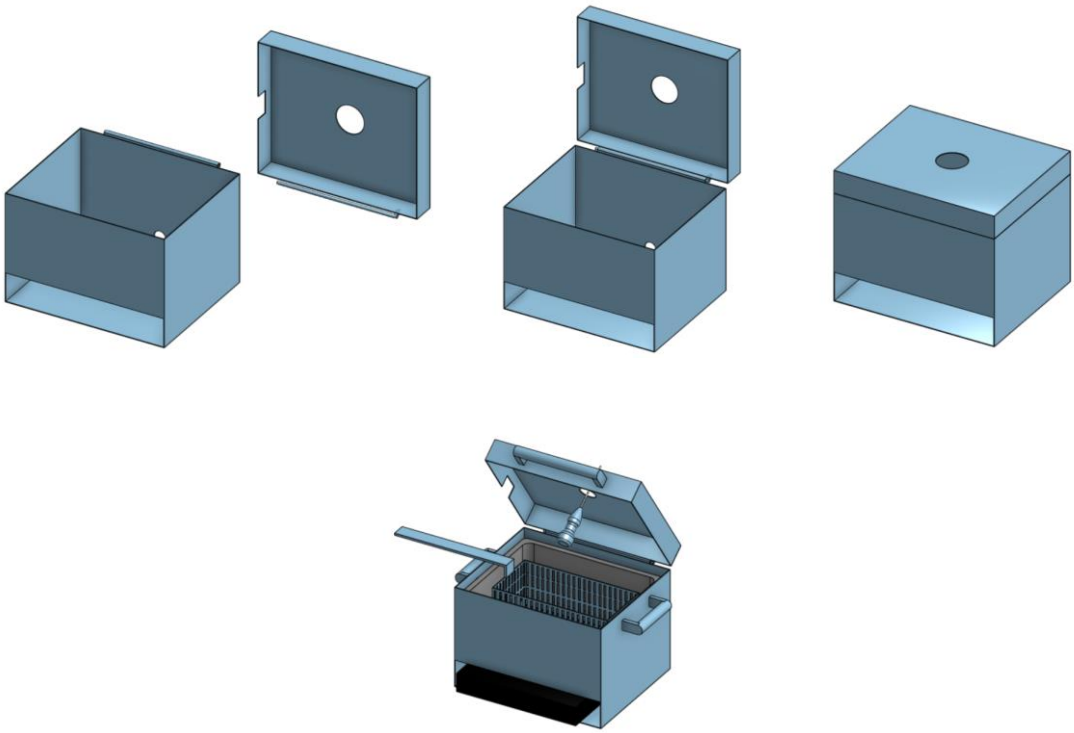
Figure 3: Our final design concept

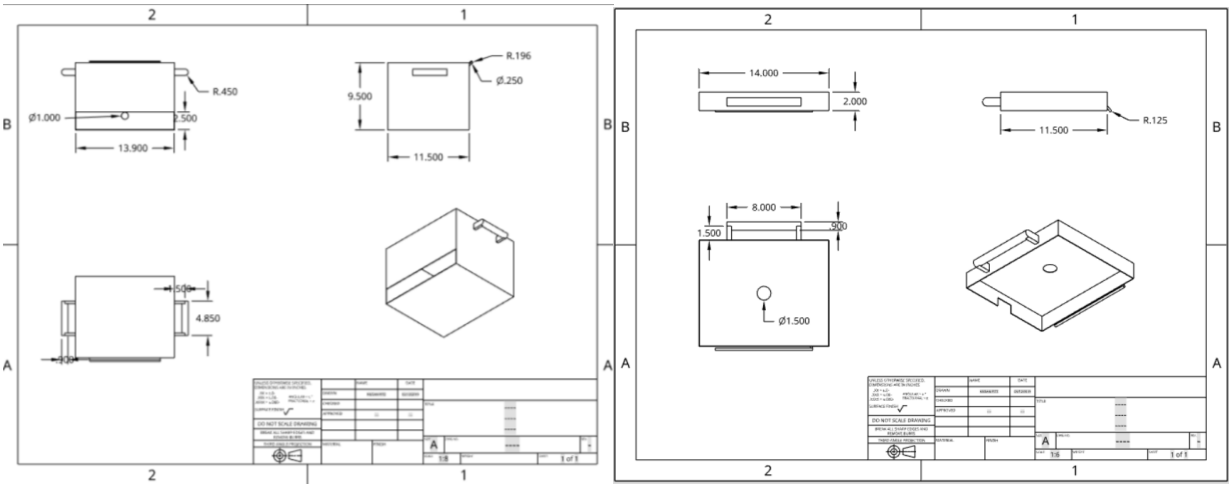
For this final design we used ultrasonic technology along with an electromagnetic induction heating system. The ultrasonic technology was incorporated into the device by using an ultrasonic cleaning probe connected to the lid of the device as seen in as Figure 3 above. When the lid is closed, the probe is lowered into the container where the instruments are being held. The lid also acts as a barrier to prevent any airborne pathogens from infecting the staff and/or patient, while also limiting the risk of contamination. The induction heating system is used at the bottom of the device. This hot plate is used to produce enough heat to further breakdown the bioburden on the instruments. The heating plate does not come into direct contact with the instruments. The instruments will be separated from the heating plate by a stainless-steel container. This container is filled with an enzymatic cleaning solution commonly used in the hospital. The separation of the instruments from the heating plate is to ensure that there is no damage to the instruments being cleaned.

5. PRODUCT DESCRIPTION

Our stakeholder provided certain guidelines and requirements that needed to be fulfilled with our design. The working prototype is a combination of induction heater with ultrasonic probe enclosed in an outer stainless steel case. The Electromagnetic Induction Heater (with 13 x 11.5 x 2.5" dimensions) gently heats the Enzymatic Cleaning Solution contained in the Stainless Steel Buffet Tray (12.8"L x 6.93"W x 6"H), therefore softening the Bioburden remaining on the surgical instruments. A stainless steel fry basket (11" x 5-⅜" x 4-⅛") with a heat resistant handle (10" Handle) is incorporated into the design for easy insertion and removal of surgical instruments. The ultrasonic probe is suspended from the top lid where it enters the stainless steel tray holding the enzymatic solution and fry basket containing the surgical instruments. Cavitation, or rapid formation and collapse of bubbles in the liquid, results in energy release that leads to the physical removal of bioburden from the crevices of the surgical instruments. Additional baskets could be used in the Operating Room so the Nurses would not have to touch the instruments themselves, but simply replace the device's basket after a cleaning cycle. The top lid of the stainless steel case is attached to the base of our design using a piano hinge and bolts. For ease for use and portability, handles are incorporated on the sides of the box as well as on the lid.

The most involved process was the construction of the stainless steel case (base and lid) that contains the device's functional components. A steel sheet was cut, folded, and welded to achieve the





The CAD drawings depicted above accurately illustrate the assembly of our final prototype.

The working prototype meets the stakeholder needs, providing a compact and automatic solution to Bioburden Precleaning in the Operating Room. The custom stainless steel box houses the functional components of our prototype (the electromagnetic induction heater and ultrasonic probe) and allows the device to be easily transported throughout the hospital. When the working prototype was presented to Dr. Rasnake, he commented on the device's ability to be disassembled. This allows for easy-cleaning and allows the components of the design to be adjusted and upgraded individually.

6. DESIGN EVALUATION

Experimental testing was conducted using dog bones to simulate human bioburden and were placed within the grooves of the orthopedic instruments. The simulated bioburden was allowed to dry to the surface of the instruments for approximately 10 minutes before each trial, and then 2 instruments were placed in the prototype for the allotted cleaning cycle time. 4 cleaning cycle times were tested (5, 10, 20, and 30 minutes) and 2 cleaning temperatures were tested (140 and 250 F). 3 trials were conducted with each set of variables, as shown below. Each trial had a before and after picture of the instruments illustrating the efficacy of each set of variables. Experimental testing was conducted in a 3 day period. Overall, the most effective bioburden removal occurred after exposure to a 10-20 minute cleaning cycle at 140 F.

Each test was completed using the "clothes" setting on the ultrasonic cleaner. During testing conducted at the lab, the verification method of cleanliness was observational analysis after each cleaning cycle. Results were rated on the following 1-3 scale:

1. Little/no difference in bioburden on instrument after cleaning
2. Some difference but visible bioburden remaining on instrument
3. No visible bioburden remaining on instrument

Location	Time after exposure (min)	Temp (F)	Trial	Completion Status	Cleanliness
Lab	5	140	1	Yes	1
			2	Yes	2
			3	Yes	2
		250	1	Yes	2
			2	Yes	2
			3	Yes	2
	10	140	1	Yes	2
			2	Yes	3
			3	Yes	2
		250	1	Yes	2
			2	Yes	1
			3	Yes	2
	20	140	1	Yes	2
			2	Yes	3
			3	Yes	2
		250	1	Yes	2
			2	Yes	2
			3	Yes	1
	30	140	1	Yes	2
			2	Yes	2
			3	Yes	3
		250	1	Yes	2
			2	Yes	2

			3	Yes	2

Figure #: Prototype testing results

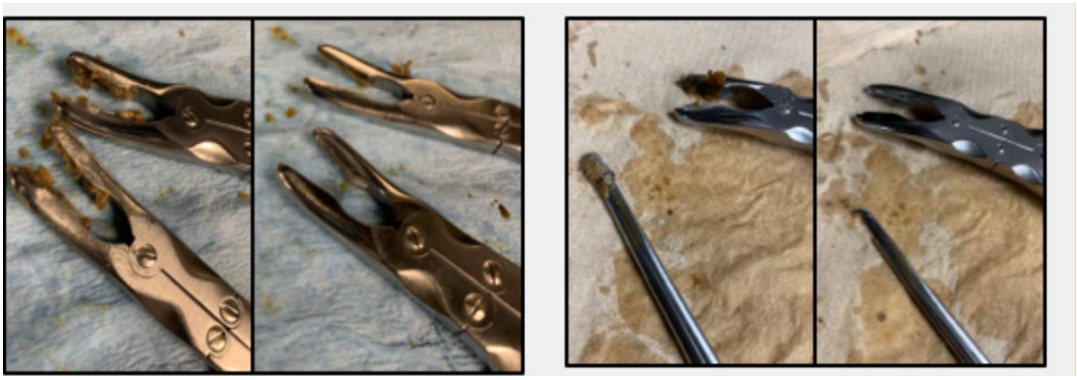


Figure #: Before and after pictures of instruments used for prototype testing

The final estimated costs for our prototype to be replicated is shown below. Throughout the semester, some adjustments have been made to our budget as our prototype has evolved throughout the design process, but most of the materials and supplies have remained the same. Overall, the total cost for the final design is actually slightly cheaper than our original design.

Materials/Supplies:	Estimated Costs:
Induction Heater	$50
Fry Basket	$40
Ultrasonic Cleaner Probe	$103
Stainless Steel Buffet Tray	$15
Outer Layer & Lid	$100
Debakey (Forceps)	$0
Rongeur	$0
Kerrison Rongeur	$0
Enzymatic Cleaner	$71/gal
Piano Hinge	$4
Outer Layer Handles	$24
Dog Bones for Testing	$25
Machining Costs	free
Documentation Costs	free
Testing Costs	free
Total Costs:	$432

Figure #: Prototype budget

7. RECOMMENDATIONS & FUTURE WORK

The most important features of the designed product are the Ultrasonic Probe and Electromagnetic Induction Heater. The combination of these technologies directly contributed to the function of our device and differentiated our design from other Bioburden precleaning solutions. The electromagnetic induction plate gently heats the Enzymatic Cleaning Liquid and helps soften the Bioburden remaining on the surgical instruments.The Ultrasonic Technology is then used to remove the bioburden through physical agitation. Ultrasonic technology has 3 main components to it. Electrical energy→ Transducer→ Ultrasonic energy. Transducer, which is a key component of ultrasonic cleaners, helps in the conversion of one energy type into the other. When the probe is plugged in, electrical energy from the wall outlet hits the transducer and is converted into ultrasonic energy, or high energy sound waves. This results in the rapid formation of bubbles in the liquid that release energy upon their collapse, removing remaining Bioburden.

In addition to our prototypes functionality, the materials contributing to our design are financially practical. In total, our prototype only used half of the allotted Senior Design budget (approximately $500). Due to the combination of novel technologies (Ultrasonic and Electromagnetic Induction Heating), energy efficiency, and low cost, we predict that our product would fair well on the 'Medical Market'. A bioburden precleaning device does not currently exist, therefore direct competitors would not be an initial concern. However, the unique aspects of our device--in additional to the functionality and feasibility--would be attractive to both the Surgical Department and Hospital management.

Continued development of our device could introduce testing with human bioburden in the UT Medical Simulation Lab, per Dr. Rasnake's recommendation. Our team would also recommend testing with different Ultrasonic Probes of varying Frequencies and Power Capabilities. While it was assumed that a higher frequency (20-60 kHz) would be more efficient in targeting the tiny features and crevices on the surgical instruments, higher frequencies could be more effective at bioburden removal due to the more powerful implosions they create. Lastly, the size of the device could be scaled up to enable simultaneous cleaning of multiple instruments, a more practical design for the Operating Room. The continued effort would require additional time (approximately 6-12 months) and costs ($500-700), but could lead to the production a valuable Medical Device. While a bioburden precleaning device does currently exist, the issues in properly removing bioburden from surgical instruments are faced by Decontamination areas in hospitals worldwide.

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