

Removal of contraceptive arm implants for low and middle income countries

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EXECUTIVE SUMMARY

Contraceptive arm implants are the most effective reversible contraceptive and a low-maintenance, long-lasting method appealing to many people. However, the current removal procedure is difficult to perform as providers must find and maneuver the implant through a tiny incision, discouraging them from offering this type of contraceptive to patients and limiting access to a contraceptive that can meet patients' needs and desires. Since limited removal methods currently exist, there is a need for a solution to assist providers with removal to increase provider acceptance and accessibility of contraceptive arm implants.

When approaching our requirements and specifications we wanted to ensure that we were prioritizing the input of our primary stakeholders in their development. Our high priority requirements are: does not cause skin irritation, cytotoxicity, or sensitization, does not add additional complications, simplifies removal process, minimizes active removal procedure time, is durable, does not increase incision size, allows easy access to implant during the procedure, easy to clean, and minimizes movement of the implant during the procedure. Our medium priority requirements are: minimize set up time, easily hand held, low cost, and does not increase the risk of breaking the implant. Our low priority requirements are: made from locally available materials and aesthetically pleasing to the patient.

We then saturated the solution space with 26 different categories from which we chose the most effective design functions based on our high priority requirements and specifications; these include solely stabilization, stabilization and extraction, stabilization and incision, and an all-in-one device. Based on a Pugh chart and feedback from our sponsor, we found that we wanted a design that does not replace the practitioner but solely aids in the most difficult area of extraction, which is stabilization. From here, we developed concepts which included an internal stabilization device (through the incision to prevent lateral motion) and an external stabilization device (meant to tent the implant from the outside of the skin). After going through multiple iterations of these two designs, we finalized on the designs shown in the Build Design and Final Design section. Our internal design is made out of 316 stainless steel and can be manufactured on the manual or CNC mill and lathe. Our external device is made of biocompatible photopolymer resin and is 3D printed. The external device also includes other parts (spring and hand screw) which are included in the cost. The total price of the device, including materials and manufacturing, is about \$19.39.

While some requirements were met by design choice, the remaining requirements were verified and validated through a series of empirical testing and engineering analysis. Durability of the devices was verified using cyclic use testing on main failure points of the devices, objective use requirements, such as ease of use and aesthetics, were verified using Likert Scales, and the remaining physical use requirements, such as the simplification of the removal process and time constraints, were verified through user testing with our sponsor.

While our devices met all of the functional requirements, there are improvements in the design and testing process we recommend for usability and accuracy. With our new final design, it is recommended to reconduct the verification tests for Does Not Increase Incision Size and Easy Access to the Implant. We also recommend conducting the user tests with multiple providers of varying skill sets and with an improved arm model that includes a simulation of the capsule. With these tests, we would hope our design can be fully improved and verified for use in clinical settings to aid in the removal process and the accessibility to contraceptive arm implants.

ABSTRACT

Although family planning is considered a human right, not all people have access to contraceptive methods aligned with their needs and desires. Contraceptive arm implants are the most effective reversible contraceptive and a low-maintenance, long-lasting method appealing to many people. However, the current removal procedure is difficult to perform as providers must find and maneuver the implant through a tiny incision, discouraging them from offering this type of contraceptive to patients. Since limited removal methods currently exist, there is a need for a solution to assist providers with removal, which will increase provider acceptance and accessibility of contraceptive arm implants.

PROBLEM INTRODUCTION

To effectively create a solution to a problem, it is important to understand the origins of the problem, the motivation behind it, and the main objectives. We conducted research and stakeholder interviews to understand the way in which to frame and scope the problem, which will impact the design approach we use and what solution space we will explore in the future [1].

Problem Background

Family planning is considered human right by the United Nations, as outlined in The Programme of Action of the International Conference on Population and Development (ICPD) and reaffirmed in the 2030 Agenda for Sustainable Development [2], [3]. A large aspect of family planning is the use of contraceptives with the most appropriate method of contraception for an individual widely varies from individual to individual and depends on a number of factors including medical history and personal preference [4]. To best meet these different needs, having many different types of contraceptive methods available is important. However, in 2022, only 77.5% of women globally of reproductive age had their need for family planning satisfied by modern methods, signifying that there is a large population of women who do not have adequate access to their preferred methods of contraception [5]. This problem is especially pronounced in Sub-Saharan Africa, where the proportion of women who have their family planning needs met by modern methods is only 56%, and among the lowest in the world [6]. This project specifically addresses the accessibility of the contraceptive arm implant, shown in Figure 1, which offers a promising avenue for addressing the unmet need for modern contraceptives in Sub-Saharan Africa [7].

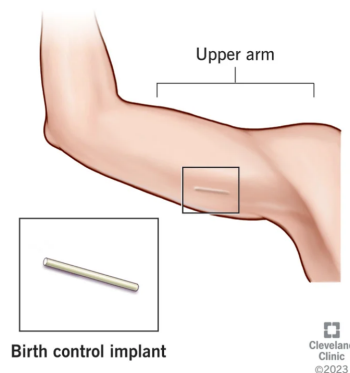


Figure 1. General placement location and form factor of the contraceptive implant. The implant is placed subdermally, just under the surface of the skin, in the upper arm [8].

Currently, contraceptive implants are becoming an increasingly popular method of contraception in Ghana, now being the second most common form of birth control following injectables, and from 2013 to

2017, the percentage of users increased 52% [9], [10]. From a survey conducted in 2022, 28.5% of married women and 22.5% of unmarried women who use contraception use the implant [11]. Some of the benefits of this contraceptive method are that the implantable arm contraception is the most effective, reversible contraceptive method and that there are very few contraindications, so a majority of patients are eligible for this method [12]. Additionally, they prevent pregnancy for up to 3-5 years after administration, with no need for routine clinical follow-ups or maintenance, making this contraceptive method convenient and appealing to patients [13], [14].

Although the placement of the implant is a very quick, relatively simple process, the removal process is difficult for both providers experienced and inexperienced in removal. The main steps of the removal process are shown in Figure 2 below.

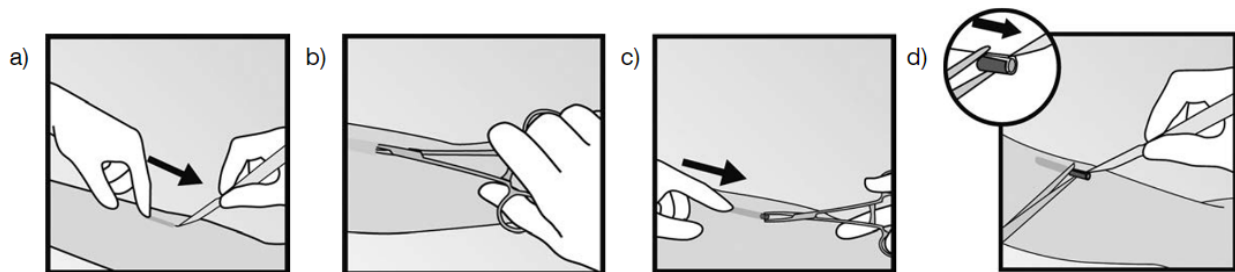


Figure 2. The main steps of the implant removal procedure, a) making the incision at the end of the implant, b) inserting forceps to try to grasp the hidden implant, c) grasping the implant while pushing the other end, d) cutting away the tissue capsule formed around the implant. [15].

In cases shown in Figure 2b and 2d, where the implant is not visible or is encased with fibrous scar tissue, which can also be called the capsule, the provider must attempt to grasp the rod with one hand through the small 2-3 mm incision. They must do this while maintaining steady pressure on the skin with the other hand to stabilize the implant, which can be frustrating, difficult, and time-consuming. Even in cases where there is no significant tissue capsule around the implant, it can be difficult to locate the tip of the implant, as it can shift between the provider making the incision and attempting to grasp it [16], [17].

The cumbersome removal procedure can create a barrier for widespread availability of this method of contraception, especially in locations such as Ghana [16]. In hospitals in more high-income countries such as the United States, multiple providers who feel comfortable with the removal procedure are commonly available and therefore removal is easily accessible, as patients are able to seek care from different providers. Conversely, in rural areas of Ghana, there may only be one midwife that can perform the removal in an area, and if they do not feel comfortable with the procedure, the midwife would be unlikely to administer an implant they cannot remove [16]. Although there are other contraceptive methods available, the importance of having different methods of contraception is that each method has benefits and drawbacks, so the more options that are available, the more likely the patient will find a contraceptive method that fits their needs. For that reason, it is important to address the difficulty of this procedure and create a solution that can make the process easier and quicker for providers to perform.

This project was identified in collaboration with clinicians in Ghana and Ethiopia from a needs assessment conducted through the Global Health Design Initiative, and is sponsored by Dr. Dhanu Thiyag, an OB-GYN at Michigan Medicine.

Problem Scope

To more fully define the scope of the problem, we explored the full spectrum of difficulties associated with the contraceptive removal process. Additionally, we investigated the different brands of contraceptive implants used in Ghana, along with their respective sizes and specifications, to better inform our potential solution.

Contraceptive Removal. With removal, there are two general categories of removal procedures: removals of properly placed, palpable implants and removals of improperly placed, impalpable implants [18], [19]. Palpable implants are those that can be touched or felt by hands, while impalpable implants are deeper underneath the skin and cannot be felt. For this project, we will only address the process of removing implants that are properly placed and palpable, as removal of improperly placed implants can have many complications and would be a more intensive procedure done in a hospital setting. Additionally, removal of improperly placed implants can vary widely from case to case, so through consultation with our project sponsor, we decided to focus specifically on addressing difficulties with removing properly placed implants.

Types of Contraceptive Arm Implants. Currently, the main types of implants used in Ghana are the Jadelle and Implanon [16]. The Jadelle is composed of two rod-shaped implants containing 75mg of levonorgestrel, whereas the Implanon is a single-rod implant containing 68 mg of etonogestrel [20], [21]. Figure 3 below shows the Implanon and Jadelle implants.

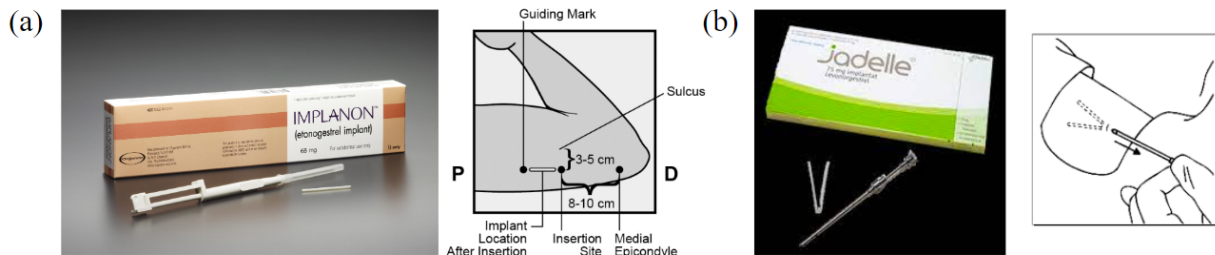


Figure 3. Comparison of Implanon and Jadelle implant designs. (a) Implanon is a single rod implant while (b) the Jadelle consists of two separate rods. Both are placed in the upper arm [20]–[23].

For the scope of this project, we will be focusing on the removal of the Implanon rather than the Jadelle, which was a choice made in consultation with our project sponsor [16]. Since there are currently no good alternative removal methods to current procedures, it made the most sense to begin by focusing on the simpler task of removing one rod. The removal for the Jadelle is relatively similar to the process for the Implanon, so solutions developed from this project can be later modified to also accommodate removal of two rods. Additionally, although both the Jadelle and Implanon are currently used, providers in Ghana are slowly transitioning to exclusively offering the Implanon, so considering the long-term, focusing only on the removal of Implanon is appropriate [24].

DESIGN PROCESS

The engineering design process is a method or series of steps for engineers to follow when working on a design project. The goal of a design process is to keep the engineer focused and to have a plan to follow, with stages or steps outlining the objectives in each section. There are many different types of engineering design processes, however they all have a similar purpose of outlining steps from a starting concept to a

final design or product. The following section outlines the design process we will follow and the way in which it will aid our project.

Design Process Categorization

We based our design process for this specific project on the Center for Socially Engaged Design (CSED) and ME 450 framework design processes. The CSED design process consists of exploration, definition, ideating, developing, and realizing stages, and places an emphasis on reflecting and analyzing upon power, privilege, identity, and motivations. Since this is a global health project, approaching this problem in a socially-engaged method is extremely important. The needs of the users and stakeholders are the driving force behind the project, so we must ensure we take their input into account during every stage of the design process.

We have done this so far by understanding that despite being the designers for this project, we have not been immersed in the environment where this product will be applied. To avoid bias and privilege, we have met with experts in Ghana and stakeholders that have worked in Ghana to have a better understanding of the context, expectations, and needs. Prior to making any large decisions, we asked for feedback from our sponsor and experts in Ghana as well. We have also reflected on the driving force of this project for us, which is that we are taking a course. However, this project has much larger implications than a one semester course, so we must research and document our progress to ensure it can be worked on or even implemented in the future.

Our design process is activity-based and problem-oriented, meaning that it is a very iterative, cyclical process, with a lot of rework and ideation during and across each stage. Activity based design processes are centered around the actions of the team or stakeholders in order to reach a goal. For many aspects of our project, we cannot move forward until we have completed certain activities, whether that means meeting with certain stakeholders or researching a specific topic. Rather than having set stages we must complete, the work in our project is split into certain actions we must do prior to moving forward. If we were unable to find the answer to a problem we have during one action, we went back and iterated upon our activity process. A visual of this process can be seen in Figure 4.

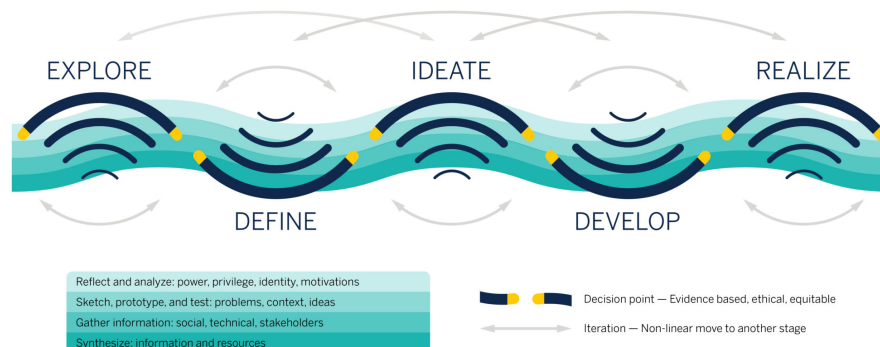


Figure 4. This graphic is the Center for Socially Engaged Design Process, off which we based our design process. This process is highly iterative and allows for several checkpoints across stages and activities [1].

This project is also problem-oriented, meaning that we discussed and studied the problem extensively prior to generating ideas. By approaching our design process in a problem-oriented manner, the scope of solutions is quite large, so we established set constraints and scopes in order to hone in on specific focuses moving forward. We developed a structured design process to create an effective product in the finite amount of time that we have. We defined the problem and needs early, because as time goes on, the possibility of change in design decreases. so we wanted to create a solution early that can address the needs of the stakeholders.

The ME 450 design process framework has five main stages as well, with need identification, problem definition, concept exploration, solution development and verification, and realization. This framework places a large emphasis on the front end-stages of the design process, which is not directly applicable to our design process. Due to the fact that our project was pre-established, with the needs assessment already completed, we were not responsible for as much of the front end aspect of the design process. Coming into the class, the problem was already somewhat defined, and the scope was generally there. We have had to improve upon the problem statement given to us, but we did not have to find the issue ourselves. Therefore, the “need identification” stage was condensed for us versus the ME 450 framework. However, we did make sure to take certain aspects of the ME 450 design process framework into consideration, especially the “ribbons.” We applied best design practices, synthesis of information, context assessments, and application of engineering principles throughout the design process. This project also has a greater emphasis on social engagement and public health, while the ME 450 design process is quite broad and general. When creating our design process, we incorporated aspects of the ME 450 framework with the CSED design process, and added individually aspects from our specific project, resulting in a design process that takes into account human-centered design and accessibility. A visual for this process can be seen in Figure 5.

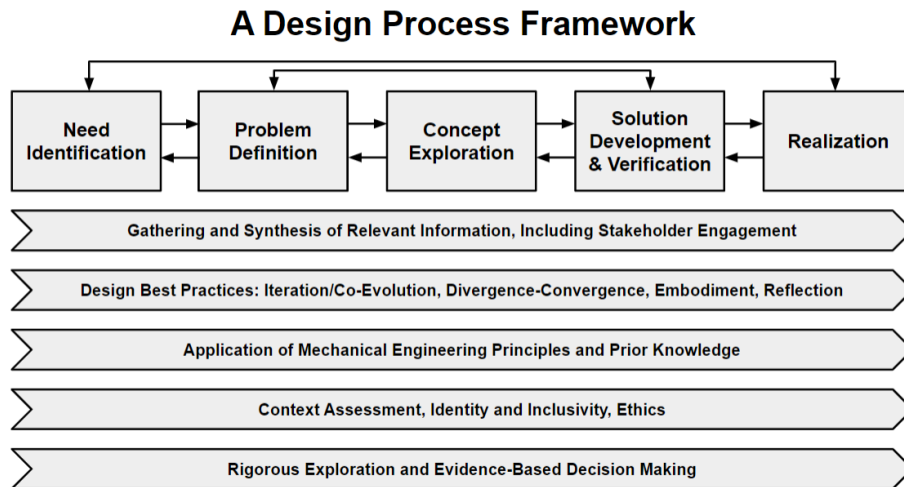


Figure 5. The ME 450 Design Process Framework is relatively straightforward, and places a large emphasis on the front-end design aspects [1, p. 450].

DESIGN CONTEXT

This project is being conducted in collaboration with the Global Health Design Initiative at the University of Michigan, whose goal is to address global health challenges in a design-centric method. In order to

effectively progress this project, it must be approached by incorporating social, environmental, political, economic, logistical, and cultural factors. These factors can be viewed in a variety of perspectives, and we took this into consideration when defining the design problem. Along with taking into account these factors, we must also address any issues or backlash that may occur as a result of these factors, as well as how a solution can be best implemented into the market. One factor we have to account for is that in Ghana, midwives are the individuals most likely to perform insertion and removal of arm implants. The training of midwives in Ghana is equivalent to the training of nurse practitioners [16] in the United States specifically for arm implant knowledge. In order to constructively understand the socio-economic impacts on technical solutions, we studied which stakeholders would have an impact on the problem, as well as benchmarked current solutions to the issue.

Stakeholders

When approaching our stakeholder analysis, we wanted to fully grasp the priority of stakeholders, as there are many individuals and organizations that may have an impact on the progress of this project. There are three levels of stakeholders: primary, secondary and tertiary. Primary stakeholders are individuals, groups, or organizations that are considered to be directly impacted by the issue, or will be directly affected by the implementation of a solution. Secondary stakeholders are those that are within the problem context, but may not be directly impacted by the problem or solution. Tertiary stakeholders are those who are outside of the problem context, however, they can still have influence on the problem or on the progress of a solution [1, p. 450].

Prior to choosing stakeholders, we met with our project sponsor and professor several times, and completed extensive background research. The stakeholders we decided upon were based on individuals or groups we believed would have an impact or be impacted by the problem and solution. We decided on stakeholders to be physicians, nurse practitioners, midwives, our sponsor Dr. Dhanu, manufacturers, patients, biomedical engineers, clinical administration, device manufacturers, RemovAid, and family planning centers. Although the National Health Insurance Scheme (NHIS) was considered while developing our list of stakeholders, they were ultimately not included because they do not cover family planning. The next step was to divide these stakeholders into primary, secondary, and tertiary levels, based on which groups we believed would have the most direct impact on the project. We also split stakeholders into groups based on the method of contribution they would have towards the project as shown in Figure 6 on the following page.

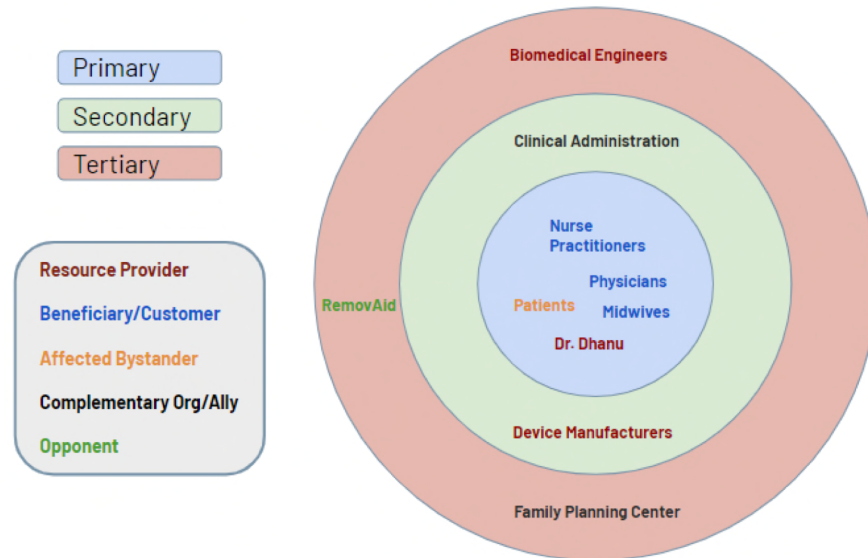


Figure 6. Stakeholder map of stakeholders that have an impact on the project. The stakeholders were grouped based on the type of contribution and level of influence.

Primary Stakeholders. Based on the scope and our problem statement, we decided to focus on physicians, nurse practitioners, midwives, patients, and Dr. Dhanu, as primary stakeholders. These medical practitioners are the individuals that will be directly using the solution, as they have experience recommending birth control methods and inserting and removing implants. Nurses are a group of individuals we considered as stakeholders; however, we learned that registered nurses are not permitted to complete the procedure themselves, so we mainly focused on nurse practitioners [16]. In Ghana, midwives are the individuals that most commonly insert and remove implants, so it is important that we include them as stakeholders in this project. Contacting and meeting with midwives in Ghana is a difficult process and was not feasible in the scope of this course and in the term of this semester. Since nurse practitioners have an equivalent amount of training to midwives in Ghana, they were included as stakeholders. As our goal is to assist providers with the removal process, the needs of these providers are some of the most important, therefore they are considered beneficiaries and customers. The implant removal experiences of these stakeholders is a driving force in this project, as we want to prioritize the input of these experts. They are the people most directly impacted by the problem and by a possible solution.

As a team, we met with Joanne Bailey, a midwife at Michigan Medicine. Bailey is the director of midwives at the hospital, and has ample knowledge on contraceptive implants. This meeting was extremely helpful in creating a more defined project scope and Bailey provided us with a lot of direct input on the current removal process. Bailey mentioned that there are often issues with skin fibers and tissues nagging on the implant, causing the provider to have to dig around underneath the patient's skin to extract the implant. The implant tends to get caught under the skin when it becomes unstable, and shifts around. She also explained that there is very minimal training for this procedure of insertion, but particularly, less training for the removal. Bailey elaborated on the fact that “removal is much more difficult than insertion” by explaining that it takes more time than expected, the location marking of the implant wipes off easily, and even after completing several removals herself, she does not feel comfortable completing them [17]. Bailey also put the team in contact with Mary McGuinness, the

primary midwife in charge of contraceptive arm implant insertion and removal at Michigan Medicine. We also met with her to discuss her perspective on the removal process. While McGuinness didn't have many aspects of the removal process that she herself struggles with she did provide us with more background information on the removal process as a whole.

Patients are a specific stakeholder that are a bit difficult to approach, as it is hard to gauge whether they should be primary or secondary stakeholders. Patients are defined as people with an implant or people that want to receive an implant. Further on in the development of this project, this definition may also expand to include people that are curious about methods of birth control. They are considered affected bystanders for this product, since they are impacted by the problem but are not the primary customer. We received mixed feedback from peers and sponsors as to whether they would be primary or secondary stakeholders, but following analysis of the problem scope, we decided that they would be considered primary. Our needs statement shows that there is a specific need to create a solution that assists providers with the removal process, but patients have the right to refuse treatment if they are not comfortable with the process, so even if the provider recommends it, that does not mean the patient will want the solution used on them. It was important that we took patients into consideration when brainstorming concepts, as we want this to be a process that they are comfortable with. The patient's comfort with using the device can depend on the aesthetic of the device, pain levels, as well as effectiveness and safety. The patient's perspective when it comes to these topics were taken into account when approaching requirements and specifications.

Dr. Dhanu, as our project sponsor, is an individual that we have consistent meetings with, and therefore, can provide us with a lot of information regarding this project. She is considered a resource provider, as Dr. Dhanu has extensive knowledge and experience on the topic, and has worked with the experts in Ghana at Korle-Bu.

Overall, these primary stakeholders have a significant amount of hidden power, as they heavily influence what considerations are prioritized in the decision-making process, especially during concept selection. Since we were only able to meet with a very limited number of people in each stakeholder group, it was important for us that we try to gather as much information as possible, and ask questions in a way that allows us to gather a diverse set of perspectives. Building from this, we also tried to keep in mind the way in which we are making decisions, especially because we do not have firsthand knowledge of this problem in the context of Ghana. Because of this, we tried to be mindful that we create more invited spaces, where stakeholders are asked to participate in decisions, rather than closed spaces, where decisions are made without stakeholder input [25].

Secondary Stakeholders. Secondary stakeholders for this project are clinical administration and device manufacturers. Clinical administration could be considered a complementary organization as well as an ally to the project, as these organizations are the ones that make financial decisions regarding hospitals and medical sectors. We focused on clinical administration as having the financial power in this project, as local health insurance organizations do not cover family planning [26]. The hospital or clinic would purchase the device, and the providers would then decide on who uses it. When it comes to motivating clinical administrators to purchase the device, the support of the government or a Non-Government Organization (NGO) will be critical. Our goal is to have the clinicians themselves not be responsible for the funding of the solution, but hospital administration must be aware that this device exists and works

well in order to be convinced to buy it. Therefore, there needs to be clear support and motivation from either government agencies or NGOs.

Device manufacturers are considered resource providers, as they will be able to locally source materials and labor for production of the solution. As an international project, focusing on resources that are available in the region is very important, as we want this to be an accessible and affordable device. The final selling price of the product depends greatly on the cost of manufacturing, so it is important to take labor, manufacturing processes, and material into account. However, by making the process more streamlined and comfortable, we hope to make this a more accessible and available procedure.

Tertiary Stakeholders. The tertiary stakeholders are family planning centers, RemovAid, and biomedical engineers. Family planning centers, such as Planned Parenthood, are complementary organizations, since they often do implant insertion and removals at family planning clinics. They also speak to patients and provide information about birth control methods, recommending methods of birth control based on a patient's background and health.

RemovAid is a competitor/opponent for this project, as they are the only other existing solution to this problem. RemovAid is an important stakeholder, as we are able to study their product and use it as a comparison tool to evaluate the pros and cons of our designs. Having more context on what is working with current solutions and what could use improvement is an important method of creating requirements and specifications for this project. The comparison between the current removal process and RemovAid was a part of the benchmarking section of the project, and is discussed further in this report.

Lastly, biomedical engineers are resource providers, as they have extensive experience, knowledge, and skills when it comes to biocompatible materials and the intersection between mechanics and human anatomy. There is a clear knowledge gap between the team, as mechanical engineering students, and a product that is focused on public health. It is extremely helpful that on the team, Sara Fernandez is studying both biomedical and mechanical engineering, as well as the fact that both Ella Samaha and Emi Yuki are interested in biomedical engineering. However, as students, we do not have in-depth knowledge on all of the biological aspects of this project, and it is important to speak to experts on the topic.

Information Sources

Throughout this project, and especially when considering perspectives from stakeholders, we have utilized a variety of sources to gather information. The difficulties in the removal of contraceptive implants is not very well studied in cases where implants are placed correctly, so we relied heavily on informational interviews with our sponsor and other healthcare professionals from both the US and Ghana to gain an understanding of the problem background and how to frame our problem definition. These interviews provided us with a lot of beneficial information that we integrated into our definition of the requirements and specifications. We engaged with the librarian to look for current solutions for the problem, which proved to be difficult, as they were limited in number. For information such as material properties, cleaning guidelines, and ergonomic guidelines, we turned to previous research, literature, and standards. Overall, the team had a lot of success in gathering information from interviews with stakeholders. However, as this problem is not widely studied, we found it difficult to gather information from sources such as previous literature.

Ethics

As engineers, it is also important to take into account the ethics involved in the project, and what ethical dilemmas may come up. As a whole, the group is aligned with the professional ethics outlined in codes from NSPE and ASME, along with the Engineering Honor Code from the University of Michigan. Throughout the project, we will aim to follow these codes to the best of our ability. As we are working in the context of a global health design project, the team has especially been cognizant of upholding the statement that engineers should “work for the advancement of the safety, health, and well-being of their community” [27]. Through our design work, and especially during our verification and validation, we aim to make an effective, safe product that will advance healthcare. However, an example of an ethical dilemma we faced is taking shortcuts on testing and verification due to rapidly approaching deadlines. This is something that we tried to mitigate through careful planning and time management. Additionally, we aim to follow the AdvaMed Code of Ethics, which is a code geared towards medical technology development. Within this code, we are particularly keeping in mind the need to “Engag[e] a Health Care Professional to Provide Consulting Services.” As discussed previously, as a group, we have no formal medical training, and therefore are heavily relying on our stakeholders to give us feedback, and have included them throughout the design process.

Intellectual Property

For this project, the intellectual property is shared between the team and the University of Michigan for the purpose of furthering the Global Health Mission.

Benchmarking

Benchmarking is a process in which current solutions are compared and evaluated to understand where there are gaps in the process or solutions. Benchmarking for this project in particular was somewhat difficult, as there is only one existing solution for the removal of contraceptive arm implants, called RemovAid. For this process, the team decided to compare the current removal process with the RemovAid, based on five metrics. The metrics we evaluated the processes on were: effectiveness, accessibility, extraction time, difficulty, and tools needed. These metrics were decided upon by comparing the biggest differences between the two methods. Following benchmarking, we found that the two most important metrics were effectiveness and difficulty, as the goal for this project is to create an assistive tool to make this process easier for the provider to complete. These benchmarking metrics were later used to designate requirements and specifications for this project.

Effectiveness is defined as the extent to which an implant is able to be removed on the first attempt with no complications. This does not include scenarios where the implant got stuck and was not removed. We defined accessibility as the ease with which someone can obtain or implement the device, especially in the context of Ghana. Extraction time is the length of time it takes to actively remove the implant, not including setup or cleanup of the process. Difficulty is whether or not the process is strenuous on the provider themselves, and tools needed is if any additional tools are necessary to complete the extraction process.

Current Removal Process. The current process is somewhat standardized globally, although there are regional, cultural, and technical factors that cause slight differences. The type of implant can make a big difference on the removal process as well. Figure 7 shows the current process, where an incision is made

at one end of the implant using a scalpel, and then forceps are used to pull the implant out while another tool is used to stabilize the implant.

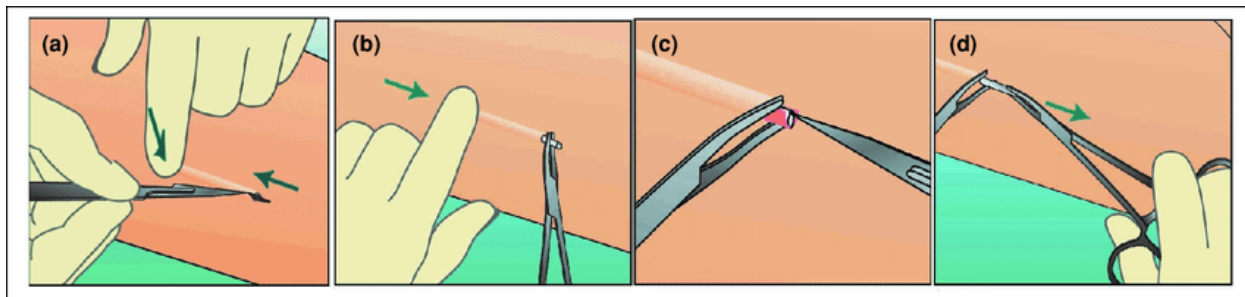


Figure 7. The current removal process requires both hands to make an incision using a scalpel prior to pulling the implant out of the skin. The steps are outlined above, assuming no complications [28].

Upon completing a literature review, it was found that the efficacy rate of the current removal process of the Implanon is between 77-100%. With a range this large, the data can be a bit misleading, so it is important to note that the efficacy can be impacted greatly on the situation. The measurement of what is considered to be a “one time removal” also differs across regions. However, to create a baseline, this data shows us that there is still a lot of improvement to be made regarding the efficacy of the removal process.

For the current process, standard surgical equipment is used, meaning it is quite accessible globally. Typical equipment, such as scalpels and forceps are available internationally, and although the equipment needed may depend on the situation, all equipment should be readily available.

The current removal process takes approximately 3.6 minutes to complete, and this is the time it takes simply to navigate the implant out of the skin and to pull it out [29]. This time frame does not account for setup of the procedure, locating the implant, or cleaning the incision following the procedure. Our goal was to focus on just the extraction time as this is the time frame in which providers have the most difficulty.

Extraction is when the patient's skin is cut into and the provider must dig underneath the skin to traverse the implant out of a small incision. After speaking with our sponsor, it was clear that we want to focus on extraction as a key requirement and intervention, as we do not want to increase the extraction time for providers. The difficulty of this procedure is explained to be quite strenuous and manual, which is why this process needs a solution. The difficulty of the removal procedure is found to be the primary reason providers in Ghana do not feel comfortable recommending the contraceptive arm implant to patients, so the objective is to make this process much less difficult for the medical practitioners.

As discussed earlier when explaining the accessibility aspect of the metrics, the tools that are needed for this process are standardized. However, oftentimes, the provider must switch between tools, increasing the tediousness of the procedure. By having to use one hand to hold the implant stable and having to switch tools with just one hand, there is a higher risk for complications. Since only one person completes the procedure, they must use both hands for the entire time, making it more difficult to navigate the procedure.

RemovAid. The RemovAid product is an all-in-one device that both makes an incision and removes the implant. This solution simplifies the process significantly, allowing for the entire procedure to make it faster and more efficient. The RemovAid, as shown in Figure 8, works by pinching the skin on the bicep and pulling up slightly, before making a horizontal incision in the middle of the length of the implant. The provider must then move the device so that it lays horizontally, still pulling on the skin. The device then pushes through the incision with small clamps and grabs onto the implant before pulling it out. While pulling it out, the implant is bent into a U-shape so that it can fit through the small incision [30].



Figure 8. Figure 8a (left) shows the RemovAid making the incision on the arm. The device is then shifted to sit horizontally, where Figure 8c (bottom right) shows the device pulling the implant out by grasping the center of the implant. The location of pulling leads to a higher likelihood of the implant breaking [30].

The RemovAid has a 73-92% efficacy with a device-only removal. This goes to show how this procedure is lacking, as it is not extremely common to remove the implant successfully after one use. This may be due to several reasons, however it was found that there is a higher rate of broken implants using the RemovAid compared to the current process. Although there is no quantifiable data available to the public regarding the number of broken implants, reports do show that the method with which the device cuts into the skin; it often goes too deep and cuts through the center of the incision, so when it is pulled out, it is much more fragile and can break. Due to the fragility of the implant, it can be snapped if one end of the implant gets caught under the skin or if the incision part cuts too deep.

We then evaluated the device based on accessibility. The product is only available in Europe, specifically on being applied in Norway. Due to the recent timeline and approval of this device, it has not yet been approved by any global organizations, so it cannot be used outside of the EU. This limits the audience significantly, allowing it to only be applied in regions it has been approved for. The device is also not reusable, which means it must be disposed of after every single use. This is due to the fact that it makes the incision and removes the implant, meaning it is likely interacting underneath the skin and may come into contact with blood, tissue, and other internal parts of the arm.

There is still very limited literature released about this product, as it just completed testing and trial runs in 2022, however, we did find that the extraction time is greater than that of the current removal process, meaning it is over 3.6 minutes [30]. Despite this, the statistic did not explain if this was including complications or assuming a best case scenario. This device has the capability to simplify the process, as

it would eliminate the multi-task aspect of the process, and instead it completes the entire procedure itself. However, if the implant breaks, or there are any complications, it makes the process much more difficult.

This also applies to the tools needed metric. If the procedure goes to plan, then no additional tools are needed, however providers must have tools available in the scenario that there are complications. The metrics of benchmarking are used to outline requirements and specifications for this project, and Table 1 outlines the benchmarking process completed.

Table 1. Benchmarking of RemovAid and the current removal process based on five metrics.

Metrics	RemovAid		Current Process	
Effectiveness	73-92% efficacy with device-only removal		77-100% efficacy removal	
Accessibility	Only available in Europe - Norway		Can be removed with standard surgical equipment	
	Not reusable			
Extraction Time	> Current removal process		Around 3.6 minutes	
Difficulty	Rate of broken implant is higher than current process, has the capability to be simple		Relatively manual procedure, may be strenuous	
Tools Needed	Best case scenario: Only device is needed, with no additional tools	Worse case scenario: Need additional surgical tools (scalpel, tweezers, and forceps)	Best case scenario: Scalpel, forceps, and needles	Worst case scenario: Surgery- forceps, dissectors, scalpels, scissors, etc.

REQUIREMENTS AND SPECIFICATIONS

When approaching our requirements and specifications we wanted to ensure that we were prioritizing the input of our primary stakeholders in their development. In order to ensure that all primary stakeholders opinions were being taken into consideration we used a combination of literature reviews, online social platforms, and zoom meetings with stakeholders to gather information. For patients, we were unable to meet with them due to patient privacy laws and thus focused our research on literature reviews and online social platforms in order to gain their perspective. However, for our other primary stakeholders we were able to coordinate zoom meetings in order to ask any questions we had and to better understand our problem through their perspective. Our project sponsor, Dr. Dhanu, was able to put us in touch with a nurse practitioner Joanne Bailey who is the Nurse Midwife Director at Michigan Medicine. Our meeting with Bailey gave us a lot of insight into the perspective of nurse practitioners and midwives who may be involved in the implant removal process; she was also able to give us the contact information for one of her colleagues, Mary McGuinness, who is a certified nurse midwife that provided an additional perspective. Additionally, Dr. Dhanu was able to get us in contact with an OBGYN from Ghana, Dr. Asah-Opoku, who was able to give us insight into the specific problems he faces in Ghana and how that might relate to potential requirements for our design.

From all of this research into our primary stakeholders we were able to determine our requirements and their specifications. We broke down our requirements into three main categories: high priority, medium priority, and low priority. Where we placed each requirement within those categories was determined through conversations with our stakeholders, specifically our project sponsor, Dr. Dhanu.

High Priority

The first category is the high priority category. The requirements included in this section were determined to be the most important by our stakeholders. It is crucial that these requirements are met in the development of our solution; if these requirements are not met, our solution will not be considered successful. Table 2 below includes all of the high priority requirements along with their minimum specifications and any goal specifications that may exist.

Table 2. High Priority Requirements and Specifications

User Requirement	Minimum Engineering Specifications	Ideal Engineering Specifications
Does not cause skin irritation, cytotoxicity, or sensitization	Meets the tests specified in the ISO 10993-1 [31] on safety for externally communicating medical devices including: <ul style="list-style-type: none"> - Cytotoxicity (ISO 10993-5) [32] - Sensitization (ISO 10993-10) [33] - Irritation or intracutaneous reactivity (ISO 10993-10) [33] - Material mediated pyrogenicity (ISO 10993-10) [33] - Acute systemic toxicity (10993-11) [34] 	-
Does not add additional complications	Can be operated by one person	-
	Requires ≤ 7 steps to complete extraction [29] *does not include setup	Requires ≤ 5 steps to complete extraction
Simplifies removal process	100 users report ≤ 5 out of 10 difficulty rating on average when surveyed	100 users report ≤ 3 out of 10 difficulty rating on average when surveyed
	Remove the need for the user to dedicate one hand to stabilizing the implant	-
Minimizes active removal procedure time	Removal time ≤ 3.1 mins	Removal time ≤ 2.6 mins
Durable	5 year shelf stable life when stored indoors with no sun exposure at 24-35 °C and 76%-89% humidity	8 year shelf stable life when stored indoors with no sun exposure at 24-35 °C and 76%-89% humidity
	Effective for 250 uses [35], [36]	Effective for 500 uses [35], [36]

	Able to be transported outdoors for 3 days	Able to be transported outdoors for 6 days
	Not easily corroded or impaired by medical grade cleaning solutions (95% alcohol)	-
Easy access to implant during the procedure	User should be able to view the implant and incision view should not be blocked by any solution	-
Does not increase incision size	Incision size is ≤ 3 mm [16]	-
Minimizes movement of the implant during procedure	Implant does not move ≥ 3 mm in any direction while using the device	-

Does not cause skin irritation, cytotoxicity, or sensitization. Patient safety is of the utmost importance, thus we must ensure that our device is not causing the patient any additional harm or unnecessary discomfort. We recognize that due to the very nature of the removal processes there will be some pain and discomfort for the patient but we want to make sure that our device is not exacerbating that discomfort. We chose to quantify this requirement through the use of ISO 2010993-1 [31] which establishes the standard for safety for short-duration skin contacting medical devices.

Does not add additional complications. The main issue that providers currently have with the removal process is how complicated and manual it is, thus it is important that we not add any additional complications as to not increase provider difficulty. The current removal process can be solely conducted by one provider, so we want to ensure that our device does not create the need for an additional provider to participate. Additionally, the current removal process only takes 7 steps in order to complete extraction of the implant (does not include setup) [29], thus we need to make sure that our device does not augment the steps for removal. Ideally we would like to reduce the amount of steps necessary to 5.

Simplifies removal process. In addition to not adding any complications, we would also like to simplify the procedure as a whole. The current removal process has been described as annoying, difficult, and tedious by all of the stakeholders that we have talked to thus far [16], [17], because of this we want our device to be ranked at least a 5 out of 10 difficulty on average by 100 surveyed users. Ideally we would like it to be a 3 out of 10 rating. These values were determined with feedback from our project sponsor. Additionally, Dr. Dhanu mentioned one of the main issues with the current removal process is that a provider must dedicate one of their hands purely to the stabilization of the implant and therefore only has one hand available to them when conducting the removal process, we would like to eliminate the need for this.

Minimizes active removal procedure time. We want to ensure that the addition to our device is not increasing the amount of time removal is taking. In fact, we would like for our device to reduce the total amount of active removal procedure time. The active removal procedure time is defined as the time it takes for the removal to be done after all of the setup steps have been completed. Currently the average active removal procedure time is 3.6 mins [29] and we would like to optimally reduce it by 0.5 min and ideally reduce it by 1 min.

Durable. Durability was one of the main requirements laid out by our project sponsor, Dr. Dhanu [16]. She informed us that for our product to be economically viable in Ghana it must have a long shelf life, be reusable, and be able to withstand travel. The first specification that we landed on was that our device must have a minimum shelf life of 5 years when stored indoors with no sun exposure (ideally 8 years). We determined this requirement based on what is standard storage life for medical devices. As far as the indoor condition specified, since Ghana might not have air conditioning in the building where our device will be stored we are defining the temperature and humidity requirements based on the outdoor average temperatures and humidities. These requirements are 24-34 °C and 76%-89% humidity; a safety factor of ± 2 has been added.

The next durability specification is that the device must be variable for a minimum of 250 uses, and ideally 500 used. This requirement was determined using the average population of Accra and the average number of patients getting implants removed on a yearly basis [35], [36]. We first found the total population in Ghana that uses the arm implant as their preferred method of birth control, and then found what percentage of the total population that constituted [36]. Next we used the population of Accra in order to find the percentage of likely users of the arm implant in the city by multiplying the found ratio by the population [35]. Finally we determined that approximately $\frac{1}{3}$ of users would need to get their implant removed yearly, as Implanon lasts 3 years, and that we would like for only 9 of our devices to be necessary to complete all of the implant removals that occur in one year. The number of devices used per year was determined based on an estimated cost analysis. We used our minimum requirement of cost, \$100/unit, and conversations with stakeholders to determine the maximum cost that can be dedicated to the production of our device annually. This math is what led to our value of 250 minimum uses per device; for our goal uses we simply multiplied the minimum uses by two to reach a value of 500.

The next specification was determined to be that the device could be transported outdoors for a minimum of 3 days and ideally for 6 days. This requirement is necessary because many midwives in Ghana will travel to more rural areas to conduct these removals and thus our device must be able to be taken with them. As far as how we decided in a minimum of 3 days, that was determined through conversations with our project sponsor, Dr. Dhanu.

The final specification was that the device is not corroded or impaired by cleaning solutions. To determine this, we want to make sure that the alcohol does not break down or dissolve the material in a set range of time. Medical devices are usually sanitized in alcohol by being placed for between twenty and ninety minutes according to CDC regulations [37]. We also want to make sure that the alcohol does not cause an increase in corrosion rate on the material due to dissolution of any protective layer on the machined device. In order for the product to be able to withstand multiple uses, the materials must be compatible with the medical grade cleaning solutions available in hospitals.

Easy access to implant during the procedure. We do not want our device to inhibit the removal process. If the implant is not accessible due to blockage by our device, this would not allow the user to remove the implant and would cause more complications during the removal process. In order to make sure that our device does not add to complications and only reduces them, we want to make sure that it maintains easy access to the implant during the procedure.

Does not increase incision size. Not increasing the incision size was a suggestion made by one of the Ghanaian physicians, Dr. Kwaku Doffoer, who provided feedback on our DR1 presentation. He brought up the stigma that could be associated with an easily identifiable birth control implant scar. After speaking with our project sponsor about this issue [16], we determined that our device must not increase the size of the incision beyond what is currently standard (2-3 mm). While all patients’ propensity for scarring is different, limiting the incision size minimizes the potential for a noticeable scar.

Minimizes movement of the implant during procedure. One of the main problems with the current removal procedure is the movement of the implant. In order to improve the removal procedure experience, this movement should be addressed by the device. Although there is no specific measure as to how much movement is “too much”, we decided based on discussion with our project sponsor that it should not move more than the size of the incision, which is 3mm, since we want the implant to be easily found by the provider.

Medium Priority

The next category is the medium priority category. While the requirements included in this category were deemed to be important by our stakeholders, they are not absolutely crucial in the development of our potential solution. These requirements are important in the long term development of a solution, but we recognize that our team may not be able to meet them within the constraints of a semester. Table 3 below includes all of the medium priority requirements along with their minimum specifications and any goal specifications that may exist.

Table 3. Medium Priority Requirements and Specifications

User Requirement	Minimum Engineering Specifications	Ideal Engineering Specifications
Minimize set up time	Set up time ≤ 7 mins	Set up time ≤ 5 mins
Easily hand held	0.197 inches \leq Height ≤ 4 inches, 0.079 inches \leq Length ≤ 10 inches 0.118 inches \leq Width ≤ 5 inches [32]	-
	Device ≤ 5.1 lbs and not attached to any stationary structures [38]	-
Low cost	Cost to manufacture \leq \$100/unit	Cost to manufacture \leq \$85/unit
Easy to clean	Made of materials that can be sterilized in ≤ 7 mins	Made of materials that can be sterilized in ≤ 5 mins
	Cleaning equipment is not product specific	-
Does not increase the risk of breaking the implant	73% of removals must be completed without the implant breaking [30]	92% of removals must be completed without the implant breaking [30]

Minimize set up time. The time to set up for the procedure is considered to be less important than the extraction time as there is no intrusive aspect to it. The set up time includes assembly of the solution, numbing the area, and finding the implant within the arm. After consulting with Dr. Dhanu and Joanne

Bailey, we understood that the setup time was not as important to the providers, but we still want this to be a straightforward, simpler procedure [16], [17]. Based on how long the current removal process takes, around 7 minutes, the team decided to keep the setup time around the same. As there may be additional products to set up with our solution, we wanted to account for this as well.

Easily hand held. Because we want to minimize the manual intensity of the removal process, we want the user to have both hands available for the extraction of the implant. By freeing up both hands, the user would then be able to use one hand to aid in extraction and maintain the need for only one person for the removal process. Because our device will be held for an extended period of time and should be usable for the majority of users, we found that the recommended size constraint would be between 0.197-4.0 inches in height, 0.079-10.0 inches in length, and 0.118-5.0 inches in width [38]. It should not weigh more than 5.1 lbs [38].

Low cost. When creating the requirements and specifications, incorporating aspects of cultural competency was important. After speaking with our sponsor, we decided that we want this product to be sourced and manufactured in Ghana, meaning most, if not all, materials are local [16]. This would reduce the costs of materials transportation, importation, and manufacturing. Another driving factor for low cost was accessibility of the device. We want this to be a product that can be afforded by local clinics, regardless of the amount of funding or subsidies. The RemovAid is currently sold at a price of \$15 per unit and is single use [39]. Based on this, we know that we will be creating a reusable product, and are aiming for a price of \$100/unit. This is based on the price of RemovAid and traditional cost of multi-use medical devices. We want this to be affordable, but realistically, as a device that can be used at least 250 times, this is a cost of around \$0.34-0.40/per use. Our goal is not to make a profit, so we are focused on just the price to manufacture. Creating a low cost solution will make it more accessible to providers, which is the goal of this project. When promoting the solution to the government or NGOs, a lower cost will be much more appealing, and therefore more likely for the solution to be implemented across the country.

Easy to clean. Another requirement we decided upon after speaking with Dr. Dhanu is that the product must be easily sterilized. Another aspect of cultural competency when approaching the problem is understanding that single use medical products create a lot of waste, and cost much more as the quantity that is purchased will be much higher. The healthcare industry is one of the most wasteful industries [40], and Ghana does not have the same disposing capabilities as the United States when it comes to waste [40]. For this purpose, we want to create a reusable product that is able to be cleaned between uses. Rather than having product specific cleaning products, the solution should be able to be sanitized by products the clinics or hospitals already have. Based on the number of implant removal procedures in Ghana, and the time in which most medical products can be cleaned, it must, at most, take less than 7 minutes to complete the sterilization process.

Does not increase the risk of breaking the implant. One of the main failure modes for the RemovAid is the implant breaking during the removal process. While there is no data for how often this specific failure mode is occurring, we do know that it makes up a decent portion of the failures noted in the clinical trial [30]. Due to this lack of data, we are choosing to use the RemovAid's overall failure rate as our standard for what percentage of removals the implant must not break during. The lower end of the RemovAid efficacy range is used for our minimum specification, while the top end is used for our goal specification.

Low Priority

The final category is the low priority category. These requirements were brought up by our stakeholders as wants and preferences. While these requirements would increase the success of our device, they don't have any impact on the actual efficacy of the device. Table 4 below includes all of the low priority requirements along with their minimum specifications and any goal specifications that may exist.

Table 4. Low Priority Requirements and Specifications

User Requirement	Minimum Engineering Specifications	Ideal Engineering Specifications
Made from locally available materials	All materials take ≤ 5 weeks to source	All materials take ≤ 3 weeks to source
Aesthetically pleasing to the patient	No visible needles or knives	-
	Appealing outer shell	-

Made from locally available materials. When speaking to our project sponsor, Dr. Dhanu, she informed us that in order for our device to have long term viability in Ghana, its materials must be locally sourced [16]. While the initial device may be successful with foreign materials, it is unlikely that providers would be able to either repair or replace the device if necessary if the materials are not locally sourced; it would be economically infeasible. We determined that it should take at most 5 weeks to source all materials, this was based on our conversations with Dr. Dhanu and some rough research into what is a normal timeline to source medical grade materials. We also determined an ideal of 3 weeks for sourcing. These numbers are still rough estimates as we do not know the types of materials we will be using. We expect to have a better understanding of what is an anticipated sourcing timeline locally once we have determined our alpha prototype in DR2.

Aesthetically pleasing to the patient. This requirement was developed based on feedback from our project sponsor, Dr. Dhanu [16]. She pointed out that while our device will mainly be interfacing with providers such as physicians, nurse practitioners and midwives, the patient's opinion must still be considered as they may refuse our device. We determined that there must be no additional needles or knives that are visible to the patient that may cause discomfort. We also determined that the device must have an appealing outer shell; this is mainly to ensure that we are covering up any of the inner workings of the device that may be jarring to patients.

CONCEPT GENERATION

After defining the need through requirements and specifications, we began concept generation. During the concept generation phase, we aimed to identify as many concepts as possible and fully explore the potential solution space [41]. In order to develop unique concepts that we may not have originally imagined, we used a variety of concept generation and development methods, which will be outlined in the following sections.

Individual Brainstorming

Before coming together as a group, we each conducted individual brainstorming to come up with some initial ideas. Each member of the group came up with as many ideas as they could think of, which we

later used as the basis for our other brainstorming activities, as well as a jumping off point for further discussion.

Brainwriting

Brainwriting is a technique where ideas are passed from person to person, where each person uses the previously written down ideas to use as inspiration and help trigger a new idea or a variation of the existing idea. We used this technique to bounce ideas off one another, and to help further develop some of the concepts we developed individually. This allowed for one design to turn into several different and unique designs in a short period of time. This technique also gave us a good opportunity to present our ideas to one another, and discuss the similarities and differences of the concepts we came up with.

Functional Decomposition and Morphological Chart

Since the current removal process follows a series of defined steps, we also used functional decomposition and a morphological matrix as the main tool to develop concepts that could specifically address key functions associated with removal. This was done in parallel with our brainwriting.

Functional decomposition. To begin, we started by defining the overall function that needs to be accomplished, which was derived from our problem definition. From there, we decomposed the overall function into subfunctions, with each sub-function being as fine as possible. Figure 9 below shows the decomposition of our overall function of “remove implant”.

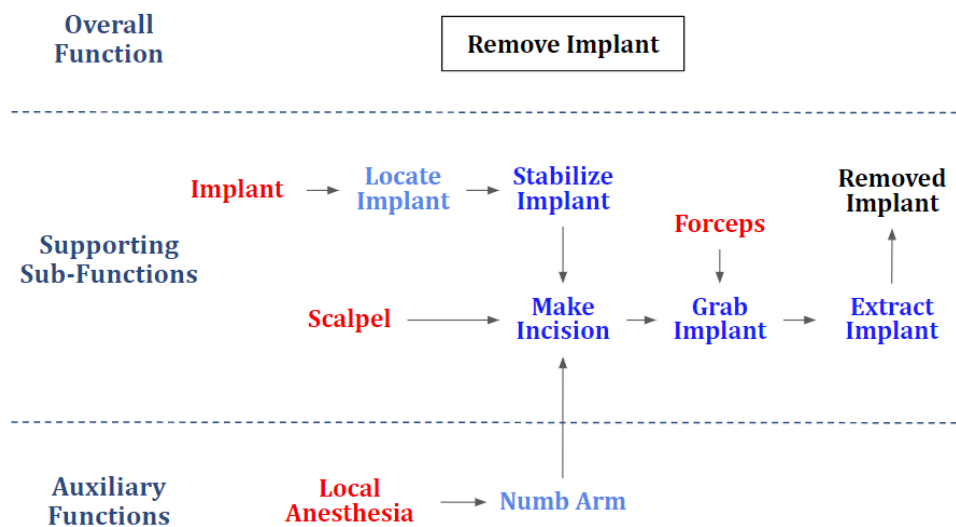


Figure 9. Functional decomposition of the function “Remove Implant.” The text in blue shows the sub-functions associated with the overall function. The light blue sub-functions are those we determined to be out of the scope for this project and the dark blue sub-functions are ones we will be focusing on. The text in red represents the tools necessary to carry out the sub-functions.

Morphological Chart. Based on the functional decomposition, we developed a morphological chart with the sub-functions “stabilize implant”, “make incision”, “grab implant”, and “extract implant” and their associated solutions. For this morphological analysis, we omitted the “numb arm” sub-function, as this was an auxiliary function that we did not consider for the scope of our project. We also omitted the

“locate implant” sub-function, as through discussion with our project sponsor, this part of the removal does not pose a significant challenge based on our project scope of only focusing on palpable implants. The resulting morphological chart is shown below in Table 5.

Table 5. Morphological Chart of Solution to Remove Implant

Subfunctions	Solutions →			
Stabilize Implant	Armband	Magnet	Adhesive	Block
Make Incision	Flat blade	Needle		
Grab Implant	Magnet	Grabber (similar to forceps)	Hook	
Extract Implant	Vibration Device	Slider (can push or pull)	Suction	

The solutions for each sub-function were determined based on ideas developed during our individual brainstorming, as well as through discussion during our collective group brainstorming. Table 5 displays a downselected, and narrowed down set of subfunction solutions. We came up with as many solutions as we could for each sub-function. Using this morphological chart, we combined a solution from each sub function to create one design concept. For some concepts, we only chose a subset of the subfunctions to combine (such as only choosing “stabilize implant” and “make incision”), since we were still unsure if we needed all sub-functions to be addressed to have a viable solution, or just some of them. While combining ideas, we also assessed the general feasibility of the combination, which lowered the number of total ideas we ended with. At the end of this brainstorming technique, we created around 15 additional ideas.

Design Heuristics

Design heuristics is an ideation tool used to help develop more novel and innovative ideas [42]. Since our solution space felt somewhat limited, we used design heuristics to help us better think outside the box, increase the creativity of our designs, and expand our original solution space. The ideas developed during brainwriting and functional decomposition were used for this activity. Figure 10 below shows an example of a design developed using Design Heuristic 15: “Attach product to user”.

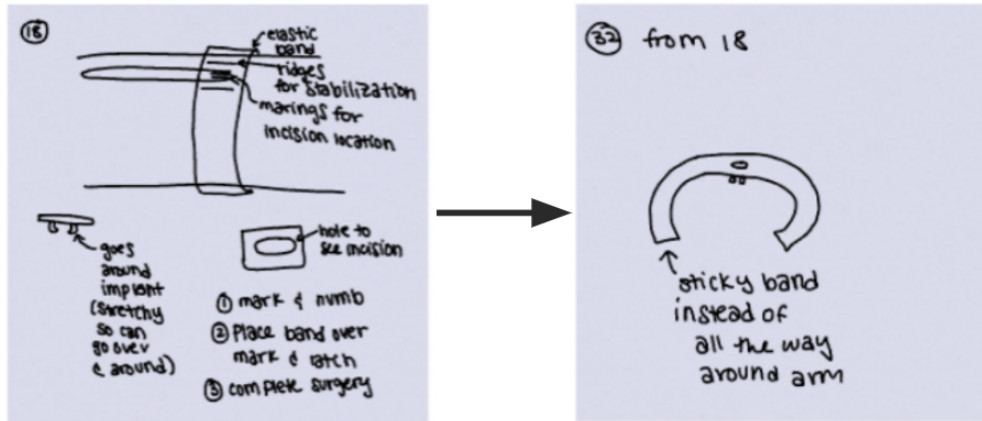


Figure 10. Design developed using Design Heuristic 15: “Attach product to user”. The original design on the left is a band used to guide the tip of the implant that stretches around the user’s arm. Using the Design Heuristic, a solution was developed where the band is attached to the user with an adhesive, rather than wrapping around the entire circumference of the arm.

Ideas that were selected for refinement were ideas that seemed relatively simple, as we thought those were the ones we could develop more. Although some of the design heuristics were not as applicable to the design problem, the prompting from the tool helped to push us further in our thinking and reimagine some of the designs we previously developed.

Concept Categorization

Through all of these concept generation methods, we were able to develop a total of ~160 different concepts. We then categorized these concepts to more effectively evaluate the completeness of our solution space. These categories were primarily based on the function of the concept, which we felt was the most important aspect to consider about our designs, as our solution aims to assist providers with the steps (or sub-functions) of the implant removal process. Within these categories, we noticed that some of the concepts grouped under the same function had quite different designs and forms. Because of this, we broke down some of the function categories into subcategories, based on form and the way in which the concept performs the function. In total, we generated concepts within 27 different categories, which are listed in Table 6 below.

Table 6. Complete list of categories for generated concepts

<ul style="list-style-type: none"> ● Implant Stabilizers ● Implant Pusher <ul style="list-style-type: none"> ○ Rubber-tipped pusher ○ Vibration Device ○ High-Pressure water ● Incision + Extraction Combination Device <ul style="list-style-type: none"> ○ Sharp forceps ○ Needle that grips ○ Sharp hook ○ Corkscrew ● End Guider 	<ul style="list-style-type: none"> ● Implant Extraction <ul style="list-style-type: none"> ○ Magnet ○ Lever ○ Needle ○ Gripper ● Incision Maker <ul style="list-style-type: none"> ○ Flat Blade ○ Circular Blade ○ Needle ● Marking + Incision Combination Device ● Location Marker ● Implant Location Visualizers 	<ul style="list-style-type: none"> ● Stabilization + Incision Combination Device ● Stabilization + Extraction Combination Device ● All-in-One Devices <ul style="list-style-type: none"> ○ Block stabilization with circular gripping blade ○ Pinching Removal ● Implant Dissolver ● Suction/Vacuum ● Skin-tensioner ● Miscellaneous
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Overall, the concepts covered the solution space, as we included solutions to solve all the steps of the removal, as well as different combinations of those steps. Additionally, we considered multiple forms to complete these functions, even if we later determined that the solution was infeasible.

Examples of Concepts Generated

The concepts generated throughout the 26 different categories covered a wide variety of solutions, some of which will be described in this section. A complete list of all of the generated concepts in each category is included in Appendix I.

Implant Stabilizer - Stabilization Device. The implant stabilizer concept was one of the first concepts that came to mind when thinking about solutions to this project. This design concept would stabilize the back of the implant, tilting the other end of the rod, which helps providers determine the location for the incision. The design consists of an arm band that wraps around the patient and exerts downward pressure onto the end of the implant. This concept was created to assist the provider during the “stabilize implant” sub-function. This concept is shown below in Figure 11.

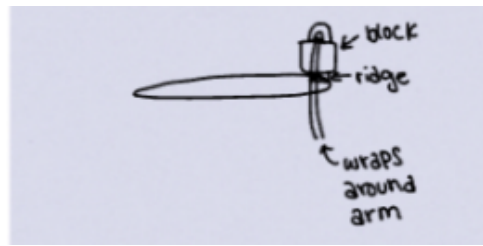


Figure 11. Implant stabilizer concept.

Implant Location Visualizer - Locator Device. The implant location visualizer is a concept that allows the provider to visualize the location of the implant within the arm throughout the entirety of the removal procedure. The design would utilize differences in light absorbency between the skin and the implant, so that the device would shine a specific wavelength of light, and highlight the implant rod in a darker color compared to the skin. This design was inspired by the vein finder devices that can locate veins using infrared light in order to assist providers during the placement of IVs. This was a concept that was developed based on an stakeholder interview with a family medicine physician in Ghana, who shared that the main difficulty he faces during the removal procedures is locating in the implant. We generated this idea during our initial brainstorming activities, prior to completing the functional decomposition and deciding that implant location was out of scope for our project. While we will not proceed with this solution category, this example is presented to show the extent of our explored solution space. This concept is shown in Figure 12.

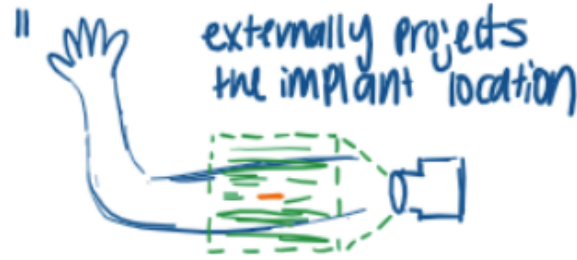


Figure 12. Implant location visualizer concept.

Skin tensioner - Locator and Stabilization Device. The skin tensioner concept is a design that pulls the skin around the implant, with the purpose of isolating the implant, locating the implant, and preventing its movement. In many of the removal videos we looked at, the provider uses their fingers to tension the skin around the implant, so this concept would be aimed at replacing that action. Figure 13 below shows this concept.



Figure 13. Skin tensioner concept.

Suction - Extraction Device. The suction concept is a design that uses suction or some type of vacuum to remove the implant from the arm and addresses the “extract implant” sub-function. This concept is intended to be used after the provider has already made an incision, and would replace the need to use forceps or dig around the incision to locate and grab the implant. Figure 14 below shows this concept.

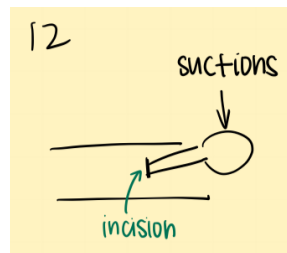


Figure 14. Suction concept.

Incision and Extraction Combination Device - Gripping Needle. The incision and extraction combination device is a concept that addresses the “make incision”, “grab implant”, and “extract implant” sub-functions from the functional decomposition. The gripping needle concept is a design that consists of a sharp hollow needle that pierces the skin and encircles the circumference of the implant. It then tightens around the implant, so that the provider is able to pull and remove the implant. Figure 15 below shows this concept.

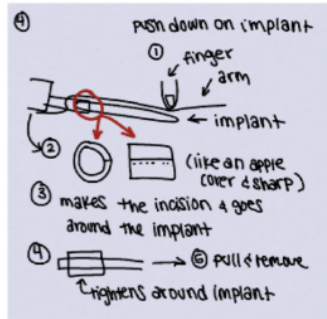


Figure 15. Incision and Extraction Combination Device - Gripping Needle.

Block Stabilization with Circular Gripping Blade - All-in-One Device . This concept aims to address the entire removal procedure, from stabilization to extraction. The stabilization is done with a rigid L-shaped bar that pushes on one end of the implant, while the incision is done with a blade that is attached to the same bar. The blade component is also able to enclose the incision end of the implant and grasp it, and then pull out the implant. Figure 16 below shows this concept.

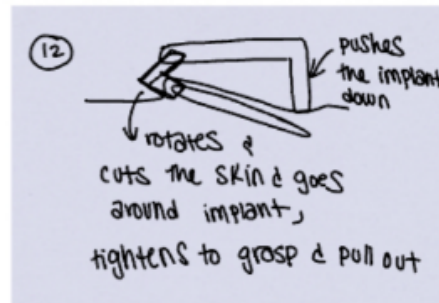


Figure 16. All-in-One Device - Block Stabilization with Circular Gripping Blade.

CONCEPT SELECTION PROCESS

Once we developed solutions covering all of the sub-functions from the functional decomposition, as well as every possible combination of sub-function, we could move on to the process of narrowing those ideas down in order to select our alpha prototype. This was a multi-step process during which we used various tools to evaluate the categories outlined above in order to arrive at our final design.

Go/No-Go Process

The first narrowing technique used was a simple Go-No-Go based on the viability and feasibility of the solution. We chose this method in order to rapidly filter through the 27 concept categories, as trying to weigh all the categories against each other would be quite time consuming. We did this by sitting down and determining all of the potential ways in which a particular solution category could be infeasible and only moving forward with the categories that seemed to have the most likelihood of success, determined through a group consensus. When considering these designs, feasibility was mainly based on the safety of the concept for the patient. From the 27 initial categories determined in the concept generation section, we narrowed down to 10; this can be seen in Table 7 below.

Table 7. Reduction in concept categories from 27 to 10

<ul style="list-style-type: none"> ● Implant Stabilizers ● Implant Pusher <ul style="list-style-type: none"> ○ Rubber-tipped pusher ○ Vibration Device ○ High-Pressure water ● Incision + Extraction Combination Device <ul style="list-style-type: none"> ○ Sharp forceps ○ Needle that Grips ○ Sharp hook ○ Corkscrew ● End Guider 	<ul style="list-style-type: none"> ● Implant Extraction <ul style="list-style-type: none"> ○ Magnet ○ Lever ○ Needle ○ Gripper ● Incision Maker <ul style="list-style-type: none"> ○ Flat Blade ○ Circular Blade ○ Needle ● Marking + Incision Combination Device ● Location Marker ● Implant Location Visualizers 	<ul style="list-style-type: none"> ● Stabilization + Incision Combination Device ● Stabilization + Extraction Combination Device ● All-in-One Devices <ul style="list-style-type: none"> ○ Block stabilization with circular gripping blade ○ Pinching Removal ● Implant Dissolver ● Skin-tensioner ● Suction/Vacuum ● Miscellaneous
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Although we eliminated these categories, we did not eliminate the possibility of incorporating aspects of the designs later in the design process. In addition, we tried to create categories that were narrow so that there wasn't too much variability between designs. Therefore, we felt confident that we could narrow our concept categories in this way.

After that initial reduction we made a further reduction based on one of the requirements of our project sponsor. Dr. Dhanu informed us that stabilization is of the utmost priority and must be a function that our device is capable of addressing [16]. From the 10 categories we previously narrowed down to, we further reduced the amount of viable categories to 4 based on this requirement. These categories and their reduction is shown below in Figure 17.

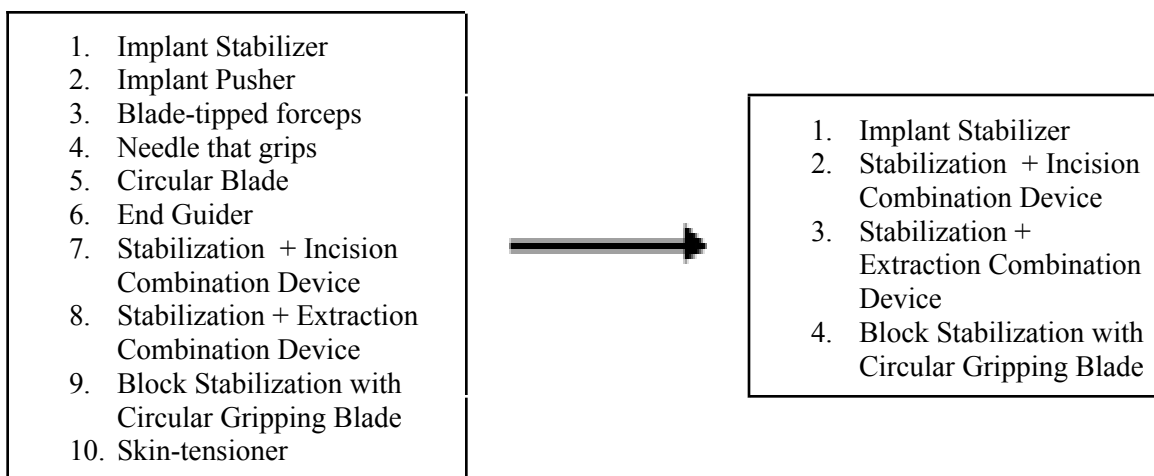


Figure 17. Reduction in concept categories from 10 to 4

Pugh Chart

After arriving at our final 4 categories, we then used a pugh chart to evaluate how well each category met the high priority requirements we had outlined. We only looked at our high priority requirements, as those are the requirements that we define as “needs”, whereas the medium and low priority requirements are “nice to haves”. The concepts for these four categories are shown in Figure 18 below.

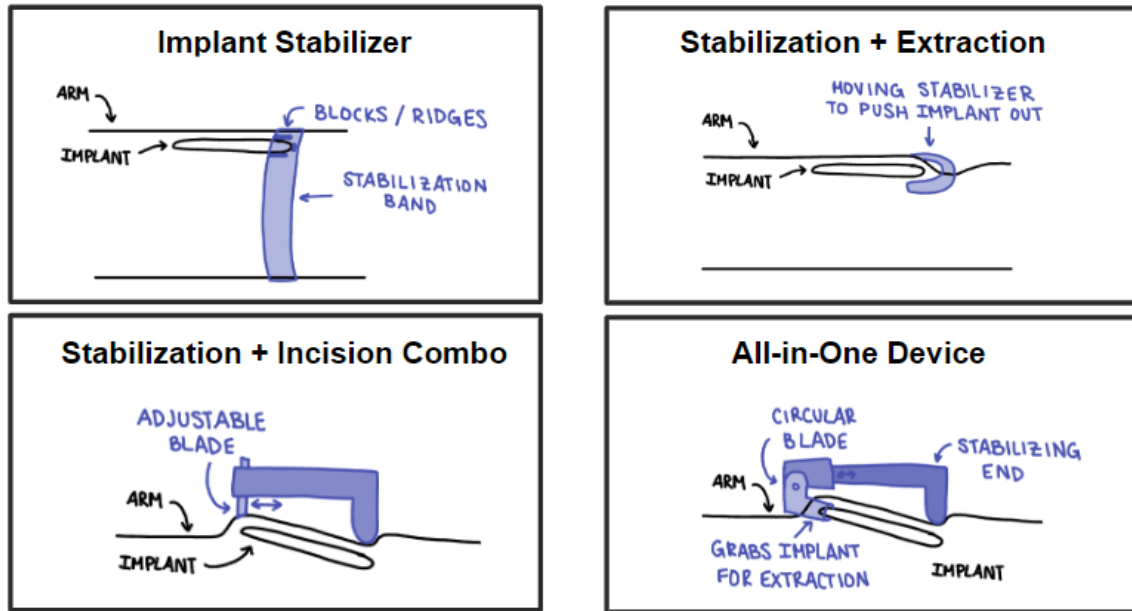


Figure 18. Top 4 concepts from concept filtering

Because the requirements are all high priority and we want our designs to meet every one, we decided that they all have equal importance. Because of this, we gave each requirement a weight of 1, and evaluated each category as either a +1, 0, or -1. The category received a +1 if it would perform better than the current removal process in that specific requirement, a 0 if it would perform the same, and a -1 if it would perform worse. The resulting pugh chart can be seen below in Table 8.

Table 8. Pugh Chart

	Implant Stabilizer	Stabilization + Incision	Stabilization + Extraction	All-in-one Block Stabilization	Current Removal Process
Does not cause skin irritation, cytotoxicity, or sensitization	0	0	0	0	0
Does not add additional complications	+1	-1	-1	-1	0
Simplifies removal process	+1	+1	+1	+1	0
Minimizes active removal procedure time	+1	+1	+1	+1	0
Durable	+1	-1	+1	-1	0
Does not increase incision size	+1	+1	0	-1	0
Does not increase the risk of breaking the implant	0	-1	0	-1	0
Total	5	0	2	-2	0

For the “Does not add additional complications” requirement, the concepts other than the implant stabilizer received a -1 value since they all could add additional steps to the procedure.

For the “Durable” requirement, the Stabilization + Incision and All-in-one Block Stabilization concepts received a -1 value due to the many small parts involved in the design, which are more prone to breaking with many uses. The other two concepts received a +1 rating because their relatively simple designs are likely to be able to withstand continuous use.

For the “Does not increase incision size” requirement, the All-in-one Block concept is likely to widen the incision due to the nature of its grabbing mechanism and thus its the only category that received a -1.

Finally, for the “Does not increase the risk of breaking the implant” requirement, the two concepts involving incisions were given a -1 value due to the possibility of slicing into the implant accidentally. This slicing of the implant is the main failure mechanism of the RemovAid and thus is something we wish to avoid in our design.

As can be seen in the table, the implant stabilizer performed the best out of all the solution categories. Thus this is the category that we have decided to pursue for our alpha design. Although the other concepts also have benefits, we believe that pursuing a more simplistic design, rather than a complex design attempting to complete multiple functions, will create a more effective final product. In addition to the results garnered from the pugh chart, we also spoke to Dr. Dhanu about what she inherently felt would be the best method. This mentor conversation resulted in the same ideal solution category as the pugh chart. Because of these lining up, we can move forward confidently with our design choice.

Internal vs External Stabilization

Within our chosen category of device stabilization, there are two main methods: internal stabilization and external stabilization. After initial concept generation and convergence, we decided to focus on external

stabilization. During the concept selection process, we spoke with sponsor Dr. Dhanu. Through this discussion with our sponsor, we found that external stabilization alone through our current methods would not be effective. Dr. Dhanu explained that the issue with external stabilization is that the amount of continuous pressure needed to push the implant down and out would hurt the patient. The variation of the laxity or looseness of the skin makes it difficult to stabilize the device enough without requiring too much pressure on the skin and would most likely cause significant bruising. Elevating the implant directly from the front is not feasible for most cases without interfering with the provider or causing discomfort to the patient, which contradicts our high priority requirement of: does not cause skin irritation, cytotoxicity, or sensitization. Tenting is the act of pushing the implant down on one end and allowing for the other end to push up against the skin. This shows where the tip of the implant is located, making it easier to locate and remove the implant. She also told us that it would be helpful for the medical practitioner to be able to see inside the incision as the implant is stabilized. Because of this, we determined that some component of internal stabilization would be necessary. With this idea in mind, we could move forward with either a device that solely focuses on internal stabilization or a device that combines internal and external stabilization.

After deciding to also address internal stabilization, we each came up with concepts on how to accomplish this, and presented them to Dr. Dhanu. This concept generation was done by each of us attempting to develop 2 CAD models of potential solutions without discussing our ideas with each other in order to preserve some semblance of uniqueness between our models. We chose to use CAD models rather than sketches for this stage in design due to our team's lack of artistic skills, we wanted to make sure the images were clear enough for Dhanu to understand their function and felt we could most easily do this using CAD. Dr. Dhanu explained which aspects of each design that she liked and believed would work well, and we took this feedback into consideration when creating our Alpha Design. Dhanu also allowed us to watch a live arm implant removal that she was conducting, and we noticed that it was important that the implant is tented during removal. Watching the procedure motivated us to decide on a two part solution, with both internal and external stabilization. From this, we combined two designs we created in order to have an external device that pushes the implant down to tent it, as well as the primary internal stabilization device that goes through the incision.

The main modes of internal stabilization that we analyzed were passive stabilization (i.e. the use of a hollow tube that goes around the implant) and active stabilization (i.e. a clamping mechanism). For now we have chosen to move forward with the passive method of stabilization, however after speaking to Dr. Dhanu, we would consider incorporating an active stabilization component to our device moving forward.

THE “ALPHA DESIGN”

As mentioned in the Concept Selection portion of the report, we developed designs for both internal and external stabilization that can both be used at the same time to aid in removal. For internal stabilization, we decided to use a funnel-like design that can be inserted through the premade incision and around the implant. For external stabilization, we used a dynamic block design that can tent up the implant while providing support in the back (opposite side of the incision) of the implant. These two designs are discussed in detail in the following subsections.

Internal Stabilization

Based on conversation with our sponsor, we focused on a design that keeps the implant from moving in all directions, can allow for easy access of the implant, and does not cause discomfort for the patient. To fit these requirements, we developed the internal stabilization design that can be seen in Figure 19.

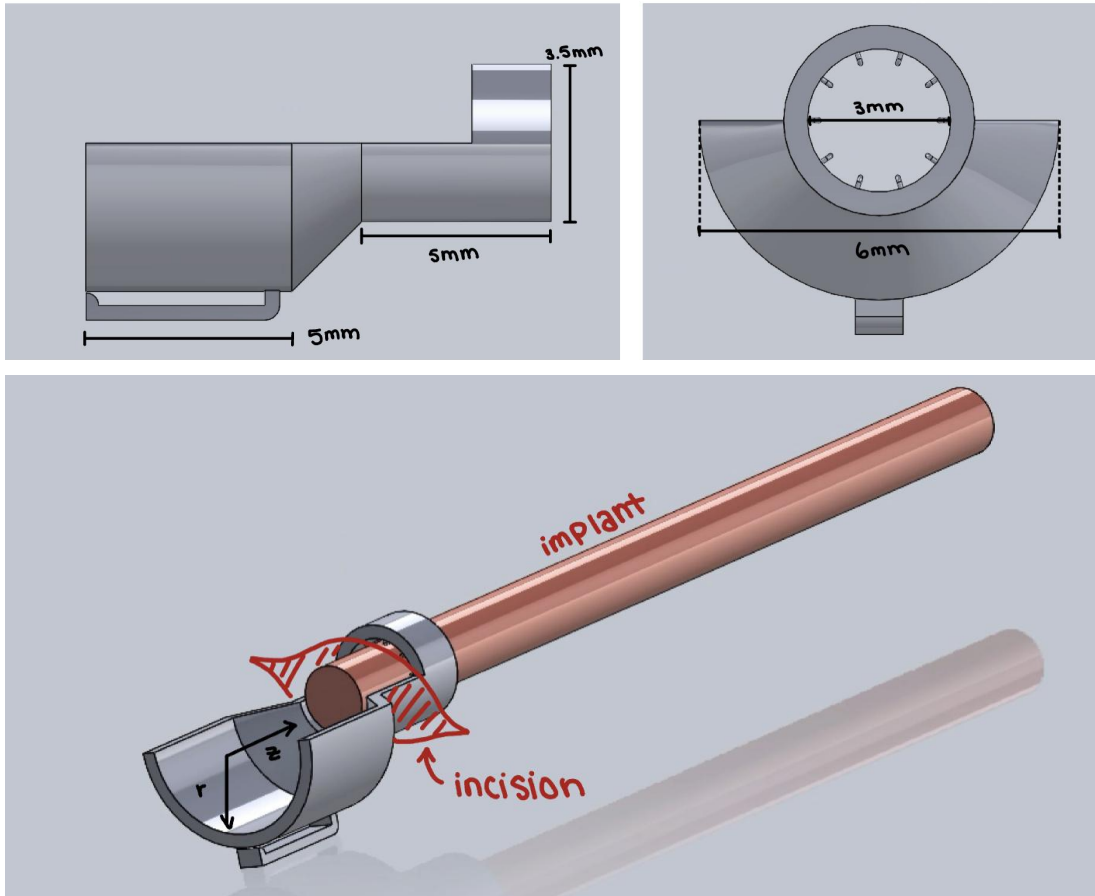


Figure 19. The internal stabilization design from the side view, front view, and isometric view respectively.

The design takes the form of an open funnel where the smaller diameter portion can fit around the implant to keep it from moving in the radial direction. The drafted portion of the funnel has multiple purposes. Firstly, it allows the user to hold the device and gives leverage to push the device through the incision and around the implant. Secondly, it keeps the device from moving too far into the body through the incision while using the incision to stabilize itself.

Additionally, there are small, spring-like rods around the inner circumference of the tip of the device, which will help grip the implant and keep it from moving forward or backward, as shown in Figure 20.

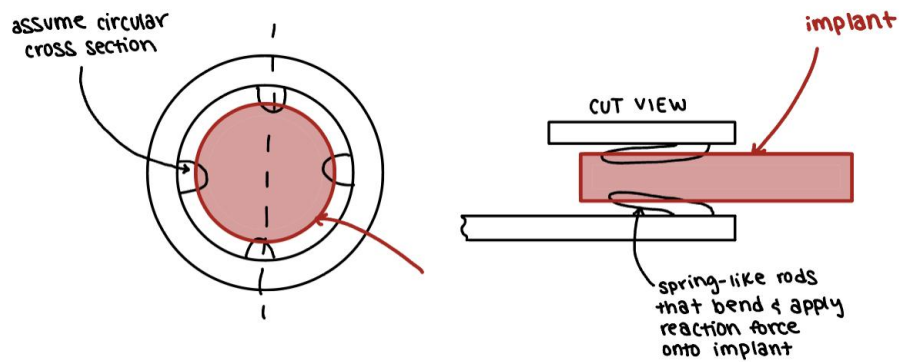


Figure 20. Diagram of internal spring-like rod functionality. They will provide force around the implant to stabilize the implant longitudinally. The implant will slide into the device and compress the rods. The rods would then elastically deform to create a reaction force on the implant to keep it in place.

External Stabilization

The initial design for external stabilization can be seen in Figure 21. The purpose of this design was to tent the implant using pressure that was transferred from an arm band to a plunger at a set height. This design focused on lateral stabilization of the implant and the use of a plunger mechanism to push the implant forward in the longitudinal direction when needed. We hoped to achieve the most stabilization possible with both of our devices being used, so we believed that longitudinal stabilization would be beneficial.

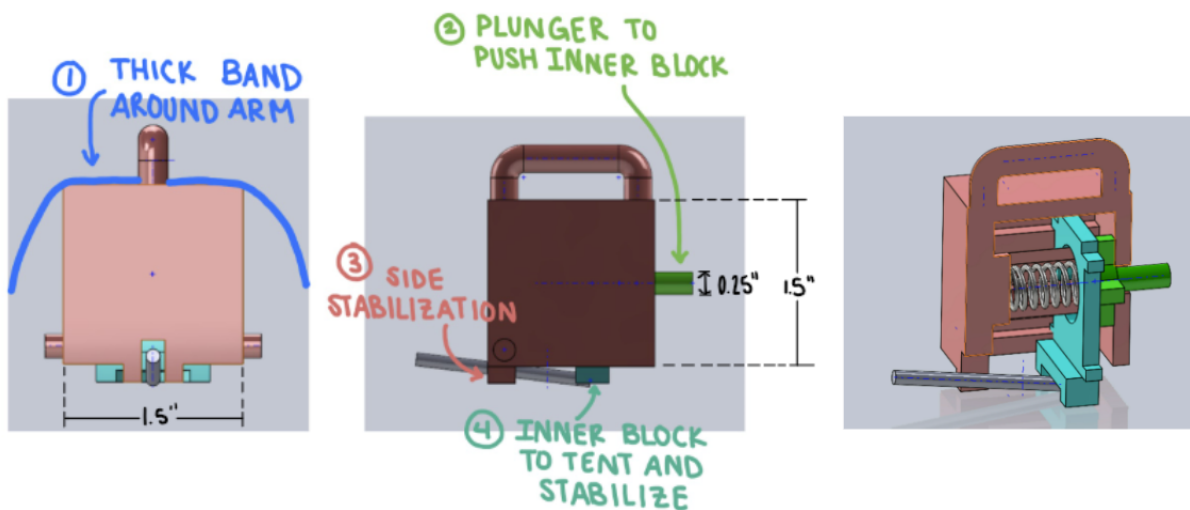


Figure 21. Assembly of our initial external design. This is an external device that pushes the implant down as well as preventing the implant from moving further into the skin during the removal process. It is made up of three parts: the housing (pink), the pusher (blue), and the plunger (green).

Our design consists of three parts. The housing (pink) surrounds the moving parts and will be strapped into the patient's arm via a band (a tourniquet, velcro band, cloth band, etc.). The pusher (blue) will be aligned with the back end of the implant (opposite side of incision). Using the force applied onto the

housing by the band, the pusher will be able to tent up the implant while providing support to the back end of the implant. The plunger (green) is spring loaded and can be pressed to push the pusher back and forth. When the pusher moves forward, the implant can be pushed out of the incision.

Combination of Internal and External Stabilization

Although we are considering a two part solution, our goal is for the internal stabilizing device to be the primary solution, while the external device is an advised secondary device. The goal of two devices is for the medical practitioner to have both hands free in order to extract the implant as it is tented and movement is isolated. However, the internal device is able to be used independently, and the practitioner is able to push the implant themselves if they would prefer that method. The external device is able to replace the need for the medical practitioner to push the implant down and out of the incision, but this is not intended to be the primary solution that meets our requirements and specifications. The movement of the implant along with the positioning of the devices can be visualized in Figure 22.

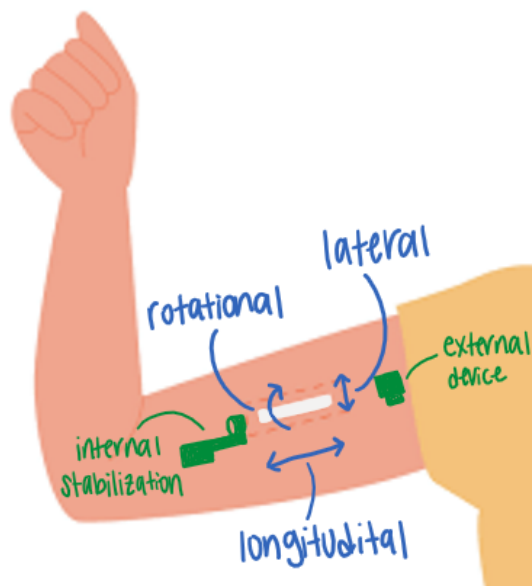


Figure 22. The three degrees of freedom are shown relative to an implant. The internal stabilization is able to isolate the rotational and lateral movement, while the external device isolates longitudinal motion [43].

With either combining the devices or focusing on internal stabilization, we are able to meet most of our physical requirements and specifications. The device(s) can be used by one person, and would remove the need for a user to dedicate one hand to stabilization.

Benefits and Drawbacks

One benefit to this design is that there is a gripping mechanism in the internal device that could hold onto the implant. This could make sure the implant will not slide back into the incision, which makes it easier for the user to perform the removal. Another benefit is that the internal device could be easily accessible to the provider with its clip feature.

Some drawbacks to the design include the possibility of discomfort with the plunger mechanism. Pushing on the plunger could cause a lot of friction and rubbing on the skin, which could cause a lot of patient

discomfort. Another drawback is how difficult this geometry would be to manufacture. With the small spring-like rods in the inside of the internal device, this would mean that some sort of precision manufacturing would have to be utilized to make the device, which could be very costly.

ENGINEERING ANALYSIS

After developing our alpha design, we used various engineering analysis methods to evaluate and optimize the design to make sure that it meets the requirements and specifications outlined for the solution. The analysis conducted was used to determine design parameters such as dimensions, shape, and materials. The applications of these methods in relation to our specifications are discussed in the following sections.

Empirical Testing of Alpha Prototype

To test the efficacy and practicality of our initial alpha design, we 3D printed a model and assembled it. We then tested it on the arm model by placing it over the implant that was situated under the skin of the model. Through this initial use, we found some issues that needed to be addressed. We found that the size of 1.5 inches would be too large to fit comfortably on a patient's arm. This size of the housing caused the device to be too heavy and unstable. This size also made it difficult to align the device properly with the implant. After trying the device in different scaling, we found that the most stable size that can be held by an arm band was about 0.5-1 inches. We used this size to set the size constraints for future designs. We are also looking into different ways to apply markings to the future designs to aid in alignment between the device and the implant.

We also found that the set inner block height was not tall enough to tent the implant sufficiently without applying more pressure than would be comfortably applied by an arm band. Furthermore, we found that it did not support the implant from moving laterally despite having a ridge at the end of the plunger. These issues became more prominent as we considered the need to take into account varying skin elasticity and thickness of subcutaneous fat. The tenting and lateral support applied by the device would need to vary to take into account these issues. These issues were addressed in future iterations and made us change from the static block to press on the end of the implant to a vertical plunger that could be adjusted for variable depths. This is further explained in the Build Design and Final Design section of this report. The final model can be compared to the 1.5" and 0.5" alpha models as seen in Figure 23.



**1.5” Alpha
Model**

**0.87” Final
Model**

**0.5” alpha
model**

Figure 23. Comparison between alpha and final design size. Through empirical testing, we found it to be most beneficial to keep the final design size between 0.5” to 1”. For our final design for the external device, we meet this specification.

After printing the internal device, we also realized that the clip and internal gripping rods were extremely small and impractical. Talking to staff at the machine shop, we determined that these components would be extremely difficult to manufacture. After discussion with our project sponsor, we decided to eliminate these components from our design since they were not serving critical functions.

Human Factors and Ergonomics Analysis

Since our internal device is quite small, we wanted to make sure to consider its dimensions, especially in relation to ergonomic principles, so that it is comfortable for providers to use. For this analysis, the main dimension we considered was the larger outer diameter, shown in Figure 24 below. This was chosen as the main design driver as it is the main grip point for providers picking up the device.

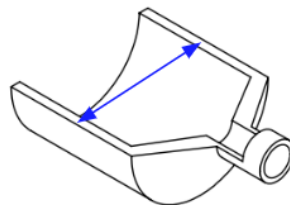


Figure 24. Internal device design with an arrow denoting dimension considered for ergonomic analysis.

With a device this small, we found that most people picked up the component using a “pinch grip”, which is a grip where an individual uses their thumb and forefinger to grab an object. Based on literature, the optimal diameter of an object to be picked up using this type of grip is between 8-16mm [44]. Since the interior area of this section will be where forceps are inserted to grasp the implant, we also wanted to make this diameter as large as possible, leading us to choose the larger end of this range. Ultimately, we

chose an outer diameter of 15.875mm (equivalent to 5/8 in) since it was the closest available stock diameter to 16mm.

Spring Analysis

One major mechanical aspect of our chosen design is the spring force. In order to analyze the spring constant needed for a hand held device with a plunger method, we made the assumption that the force needed to push down would be similar to that of a pen. In order to analyze this problem, we created a free body diagram (FBD) based on the spring mechanics of a ballpoint pen. This FBD and basic static equilibrium calculations allowed us to find the force needed to push against the spring of a pen. Hooke's Law tells us that the strain of an object is proportional to the applied stress within the elastic limit of the object [45]. This law permits us to solve for the spring constant with the force and displacement. Assuming the device must be compressed in around 1.5 inches, the spring constant is found to be approximately 131.23 N/m. Equation 1 shows the equation for Hooke's Law, with F being the force applied over a distance x in newtons, and x being the displacement by the spring in meters.

$$\text{Hooke's Law: } k = \frac{-F}{x} \quad \text{Eq. 1}$$

$$k = \frac{5N}{0.0381m} = 131.23 \text{ N/m} \quad \text{Eq. 2}$$

This information grants us the opportunity to find and implement a spring with a spring constant around 131.23 N/m which helps us meet some of our requirements and specifications. With the proper spring constant, our external mechanism can be the most effective, as it applies enough force to keep the plunger retracted while allowing the screw to be turned easily. This allows for a variable pressure that can be applied by the external device. This would replace the need for the user to use their hand to tent the implant themselves.

Implant Elevation Analysis

One of the main aspects that failed on the alpha design was the mechanism used to tent the implant, which is when one end of the implant is elevated, as the block was not able to press down deep enough to elevate the implant. To make sure that problem is resolved for this iteration of the device, we analyzed how deep a plunger must press to fully elevate the implant. We tested this empirically, through pushing on an arm model and measuring the depth needed to elevate the implant. Figure 25 shows the method we used [46].



Figure 25. Depth testing test method. The implant was inserted underneath the “skin” and the force gauge pushed down on one end

Before completing this test, we wanted to find the most accurate material to represent the subcutaneous fat that would surround the implant. After speaking with Dr. Kramer, we found that there have been initial tests to model subcutaneous tissue using varying foams or sponges. From this, we used foams and sponges of varying elasticity and hardness (Airtex High Density Upholstery Foam, Scotch-Brite® Sponges, Melamine Sponge) of sizes 3x6 sheets with thicknesses of 1”. After talking with our sponsor and other participants, we found that the Airtec foam had the most accurate feel compared to the upper arm when inserted into our model.

From this, we completed the test using the Airtec foam. We used the ImageJ software, which is a software that is used to measure distances within images, to measure the depth and the height that the implant was tented, and found that the maximum depth needed was around 7mm. We used this depth as a reference for the length of our plunger, and made sure that the plunger was longer than 7mm.

We also made a model correlating pressure and tenting height. From this model, we can ensure that our device will be able to tent the implant sufficiently. We made a scatter plot relating the pressure and the change in height on the opposite end. This correlation can be seen in Figure 26.

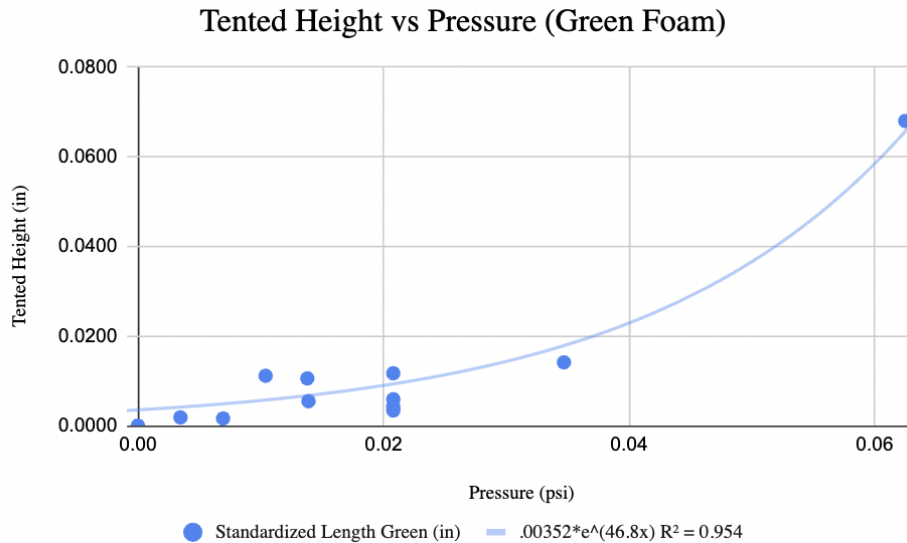


Figure 26. The correlation between pressure applied and the change in height follows the equation $0.00352e^{46.8x}$. This equation will be used in verification later this term.

We also met with Dr. Dhanu again to gain a better understanding of the current tenting procedure, and to determine the average pressure our device needs to apply. We asked Dr. Dhanu to tent the implant as she normally would by hand, and then had her compare it to the external device. We were able to compare the amount of tenting and relative pressure on the skin visually. One important factor we realized was that when Dr. Dhanu was using her hands for tenting, she would not apply single point pressure at just the tip, she rather, used two fingers to press around the area of the tip. This increased the surface area over which pressure is being added, leading to a lower pressure on the skin. Dr. Dhanu explained that based on this, some medical practitioners may be more comfortable tenting the implant by hand rather than using a device, however it is good to have the external device as an option for less experienced practitioners. This process was repeated a few times, to ensure repeated results.

Material Selection Analysis

To meet the requirements that are highly based on material properties, we used a systematic approach to determine the most optimal material for our design. This analysis is also important for the feasibility of design implementation in regards to the cost and the possibility of local manufacturing.

Material selection for internal component. The internal component of our device is a funnel shaped piece that will be inserted into the incision, with the tip encircling one end of the implant, meaning that it will make contact with tissue. To begin the selection process, we looked at materials under the “biomedical materials” category in the GRANTA software, as these have been validated for use within healthcare. Out of a list of 4261 total materials, 387 materials passed this filter.

We then filtered materials based on durability to medical grade alcohol and sterilizability using the steam autoclave, as these are the two main cleaning methods that will be used [16]. This left us with 186 total possible materials.

From these materials, we sorted the materials from lowest to highest price per unit cost, as we are aiming to make the cost as low as possible. We finally selected 316 Stainless Steel as our material, since it has a low price per unit cost, and as a very common grade of steel, it will also be accessible in Ghana.

Material selection for external component. The external component of our device is responsible for tenting the implant by applying pressure on its proximal end. When looking at what materials could be used for the external component, we had a few requirements to consider.

We decided to do all of our prototyping for the external component through 3D printing in order to simplify the iterative process and to allow for changes in design early and often. However, we hope to be able to injection mold all of the parts long term. We know that a shift towards injection molding would drastically reduce the price point for our stakeholders as well as making it a more standardized manufacturing process. Therefore, when looking at what materials we could use we wanted to ensure that the material could be used for both 3D printing and injection molding. The two materials we felt met this requirement were PLA and Standard Photopolymer Resin.

The next requirement that we considered was that the material chosen must be able to withstand constant exposure to cleaning agents such as 95% alcohol. Since PLA might degrade a bit through constant exposure to alcohol, we chose to move forward with Standard Photopolymer Resin as our material of choice [47].

BUILD DESIGN AND FINAL DESIGN

This section will outline the device design for both the external and internal components including dimensions and scaled drawings.

Build Design

The build design is the design we prototyped to use for during our verification and validation testing. This prototype is a to-scale build of our previous final design, and is made out of the same materials. After much of the testing was completed, we modified the design to our current final design. Some of the verification and validation testing will need to be redone, but most of the testing can be translated to the final design.

Internal device design. The internal device is a funnel-shaped stainless steel device that is inserted into the incision made by the provider around the end of the implant to prevent lateral movement. Its corresponding dimensions and geometry are shown in Figure 27 below.

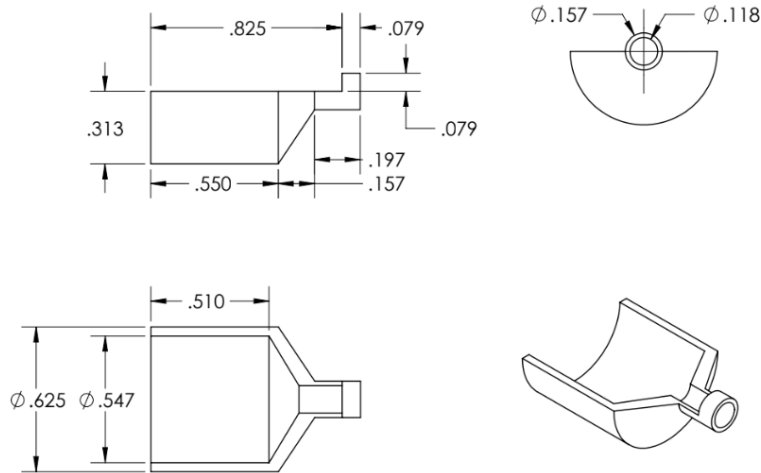


Figure 27. Engineering drawing of the internal device. All dimensions listed are in inches.

This internal device is manufactured using machining. This machining method was selected through a selection process that considered factors including shape, mass, section thickness, tolerance, surface roughness, and economic batch size. Tolerance was based on the allowable difference for the internal tip diameter. The difference between the diameter of the implant and the internal hole of the tip is 1mm, so we divided this by 10 to be conservative. Economic batch size was determined by multiplying the number of clinics in the country of Ghana by the number of devices per clinic [48]. For a conservative number, we will pick 3 as the number of devices per clinic, and assume they will be replaced on an annual basis based on calculations from our minimum use durability criteria. Based on the selection matrices outlined from ME452 lecture slides, a selection table was developed, which is further outlined in Appendix III [49].

Based on this selection table, machining is the only method compatible with all our filters. Since machining is a method that is accessible within the X50 machine shop, we were able to create a prototype with stainless steel. The detailed list of machine tools and operations used are outlined in Appendix IV. The final machined prototype can be seen in Figure 28.



Figure 28. Machined internal device made out of 316 stainless steel.

The most critical dimensions for this device are the tip dimensions. Both the internal and external diameter of the tip must have a tight tolerance, as the implant must fit within the internal circumference, and the tip must fit within the incision that is made. In addition, the surface on the tip must be quite smooth to ensure that there are no sharp features that unintentionally hurt the patient.

External Device Design. The external device is a block-shaped device which straps to a patient’s arm, and consists of an adjustable plunger that helps to elevate the incision end of the implant.

To address the issues of our alpha design (mentioned in the Empirical Testing of Alpha Prototype section of this report), we decided that it would be more beneficial to focus on tenting the implant with an external device that could apply the variable pressure itself. We iterated through the initial design by removing the lateral plunger and replacing it with a plunger that would apply direct downwards pressure on the end of the implant. We also decreased the size to 20x21x20mm (0.79x0.83x0.79 in). Lastly, we tested different end types based on comfort on the arm and ability to tent on the arm model. The end types consisted of different foam materials and flat and extruded ends. Through this iteration process, we finalized the design that can be seen in Figure 29 below.

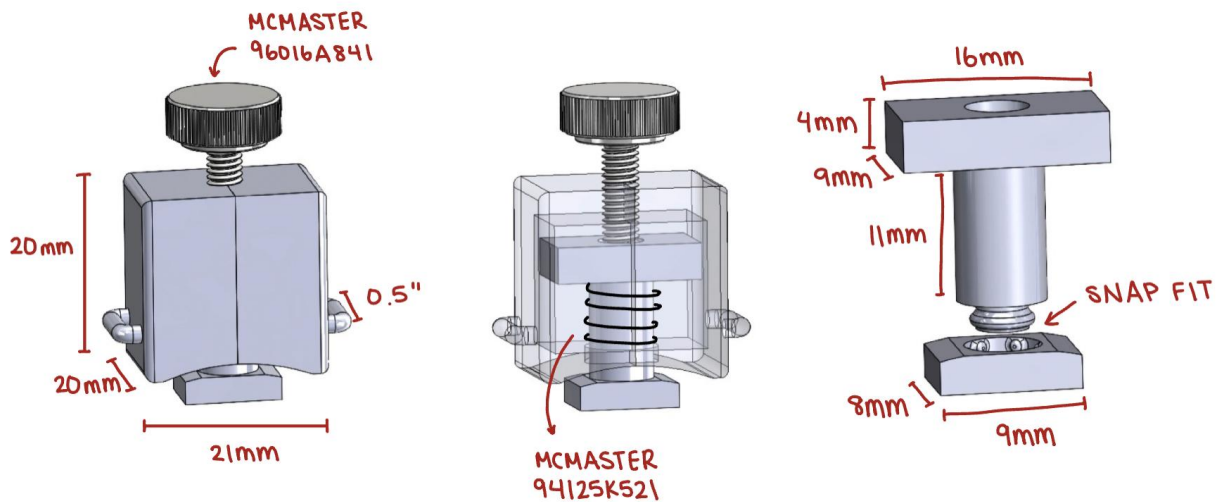


Figure 29. Assembly of our final external design. This design consists of two main parts: the housing and the plunger. The housing is 20x21x20mm and has extrusions on the side to pass the arm band through. The plunger is held up by a spring and can be pushed down by a hand screw to allow for variable pressure. The end of the plunger can be snapped on during assembly after the spring is placed around the shaft. The snap-fit end also allows for variable angle of the end if needed. We also used this feature to test out different end types during the iterative phase.

Although it increases the number of parts needed and the cost for the device, we made the plunger and screw two separate pieces because we wanted to make sure that the plunger would not spin while the depth was being adjusted. If the screw was directly attached to the plunger, the friction on a patient's skin from the plunger rotating would be uncomfortable, so we designed the device to prevent that from occurring. Assembly for the device is outline in Appendix V.

This device was manufactured using additive manufacturing (stereolithography 3D printing) for prototyping. Utilizing 3D printed resin for testing the second part offered flexibility for small-scale manufacturing, allowing for rapid prototyping and iterative improvements. To lower the cost of manufacturing, injection molding would be recommended for the future design, as this method is better suited for larger batch sizes. The shift to injection molding for larger-scale production acknowledges the need for efficient mass manufacturing. This method optimizes production output while maintaining product consistency and quality. However, the material will stay consistent between both manufacturing methods, allowing us to accurately evaluate the performance of our final design during verification and validation testing.

Figure 30 below shows how the device works, and the interaction between the external and internal components.

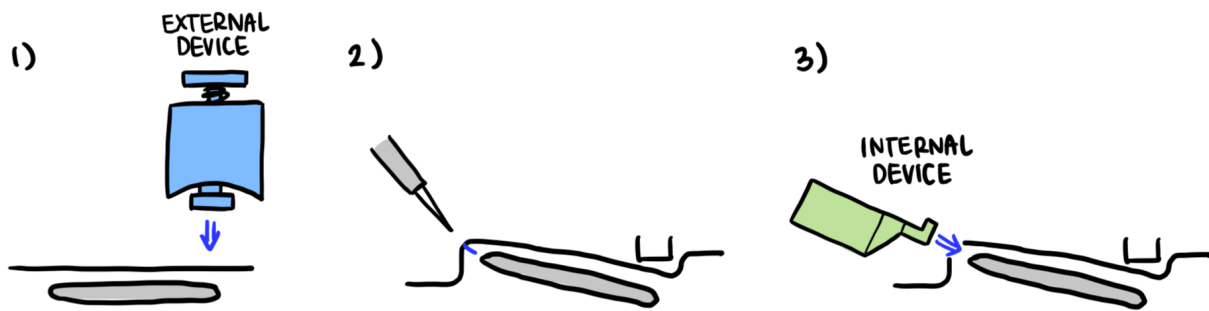


Figure 30. Function of internal and external devices during removal procedure. Step 1: Prior to making an incision, the provider places the external device on the arm with the attached arm band to tent the implant. Step 2: Provider makes an incision at the elevated tip of the implant. Step 3: Provider inserts the internal device into the incision, with the tip encompassing the implant. Then removal proceeds as normal, with the provider removing the implant.

Total Device Cost. Based on the selected materials, along with their corresponding manufacturing methods, we can estimate the total cost of materials for one unit of the device. Our device consisted of both in-house and off-the-shelf parts, which are listed in Table 9 below.

Table 9. Bill of Materials for the different components of our build design.

Item	Part Name	Quantity	Price	Vendor	Notes	Component
1	316 Stainless Steel, 5/8 OD, 3" Length	1	\$5.70	ALRO	Machined in X50 Shop	Internal Device
2	Standard Photopolymer Resin	18 grams	\$0.36	ELEGOO	3D Printed	External Device
3	Plastic-Head Thumb Screws, Knurled, M4 x 0.7 mm Thread, 8 mm Long	1	\$0.60	McMaster-Carr	96016A558	
4	Compression Spring, 0.781" Long, 0.375" OD, 0.291" ID	1	\$1.79	McMaster-Carr	9657K86	
5	VELCRO Brand Extra Narrow Straps, 1' Length	1	\$0.29	Amazon	VEL-30765-A MS	External Device - Armband
Total			\$8.73			

Since our “low cost” requirement also considers manufacturing costs, we determined the costs to manufacture our device using machining for the internal device and injection molding for the external device. In this case, we only analyzed the costs for injection molding, as this is the method that will be used in the long-term. The cost of manufacturing the internal component is \$8.20 and the cost of manufacturing the external component is \$2.46. Calculations for these costs are outlined in Appendix VI.

The total price of the device should be around \$19.39. If parts such as the thumb screw and compression spring are bulk ordered, the final design cost will likely decrease. In addition, the labor cost was assumed to be \$60/hr, based on average labor costs in the United States, but could be lower if manufacturing occurs in Ghana, which could also reduce the total cost.

Final Design

After meeting with Dr. Dhanu and getting feedback from her regarding our build design, we had to make a few alterations for our final design.

Internal device design changes. For our internal device we needed to make some changes to the larger portion of the funnel in order to make visualizing the implant easier for providers. This change consisted of removing a segment of the funnel in order for it to lay flatter against the patient's skin during the removal process. This new design is shown below in Figure 31.

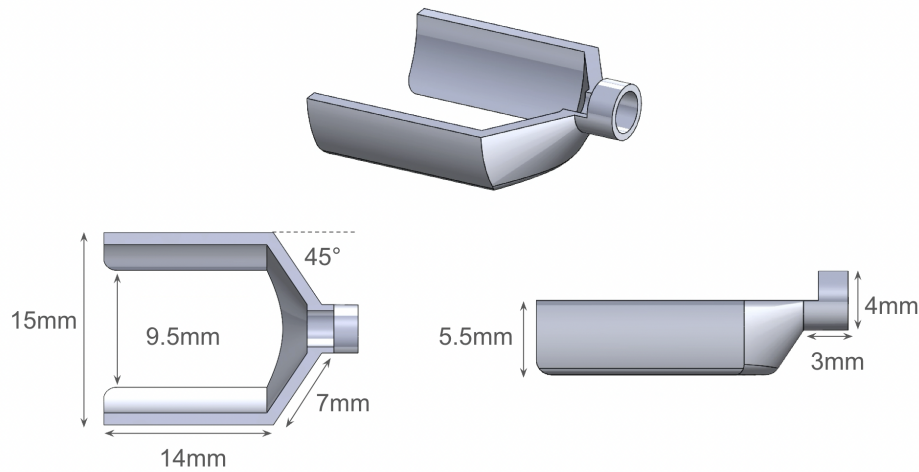























Figure 31: Final iteration of the internal device. The bottom was reduced by half while maintaining the width of the original device.

Due to this change there are a few verification and validation tests that need to be reconducted, specifically the does not increase incision size and easy access the implant during the procedure. Our plans for addressing these changes are included in the validation and verification section for these specific plans. Unfortunately due to the time constraints of this project we were unable to manufacture a prototype of the updated final design. This is due to the time consuming process of machining stainless steel.

External device design changes. For our external device Dr. Dhanu suggested we add a small piece of silicone to the end of the plunger in order to decrease the likelihood of the patient feeling any discomfort due to our device. We looked into the possibility of including this improvement and determined that it is not currently possible. All of the silicone and rubber materials we were able to find were not suggested to be used with an alcohol cleaner. Since this is the method currently used in Ghana to clean reusable medical devices and the method we have rated our device to, we have chosen to not move forward with a silicone tip.

Since the final design is very similar to the build design, we can feel confident that testing done on our build design will translate to meaningful verification and validation results for our final product in most cases. Any verification and validation tests we feel might require additional inspection due to differences in our build and final designs will be outlined in the verification and validation section. Table 10 below summarizes the status of our verification and validation testing for each requirement and specification.

Table 10. Validation and Verification of Requirements and Specifications

Key			
 Passed V&V	 Met by Design Choices	 In Progress	 Future Work
Requirements	Priority	Engineering Specification	Progress
Does not cause skin irritation, cytotoxicity, or sensitization	H	Meets the tests specified in the ISO 10993-1 [30] on safety for externally communicating medical devices including: <ul style="list-style-type: none"> - Cytotoxicity (ISO 10993-5) - Sensitization (ISO 10993-10) - Irritation or intracutaneous reactivity (ISO 10993-10) - Material mediated pyrogenicity (ISO 10993-10) - Acute systemic toxicity (10993-11) 	
Does not add additional complications	H	Can be operated by one person	
		Requires ≤ 7 steps to complete extraction *does not include setup	
Simplifies removal process	H	100 users report ≤ 5 out of 10 difficulty rating on average when surveyed	 
		Remove the need for the user to dedicate one hand to stabilizing the implant	
Minimizes active removal procedure time	H	Removal time ≤ 3.1 mins	
Durable	H	5 year shelf stable life when stored indoors with no sun exposure at 24-35 °C and 76%-89% humidity	
		Effective for 250 uses	
		Able to be transported outdoors for 3 days	
		Not corroded or impaired by medical grade cleaning solutions (95% alcohol)	
Does not increase incision size	H	Incision size is ≤ 3 mm	
Easy access to implant during the procedure	H	User should be able to view the implant and incision view should not be blocked by any solution	
Minimizes movement of the implant during procedure	H	Implant does not move ≥ 3 mm in any direction while using the device	
Easy to clean	H	Made of materials that can be sterilized in ≤ 7 mins	
		Cleaning equipment is not product specific	
Does not increase the risk of breaking the implant	M	73% of removals must be completed without the implant breaking	

Minimize set up time	M	Set up time ≤ 7 mins	
Easily hand held	M	0.197 inches \leq Height \leq 4 inches, 0.079 inches \leq Length \leq 10 inches 0.118 inches \leq Width \leq 5 inches	
		Device \leq 5.1 lbs and not attached to any rigid structures	
Low cost	M	Cost to manufacture \leq \$100/unit	
Made from locally available materials	L	All materials take \leq 5 weeks to source	
Aesthetically pleasing to the patient	L	No visible needles or knives	
		Appealing outer shell	

VERIFICATION & VALIDATION

Verification is the process through which a design is evaluated on whether a system or component meets the specified requirements and fulfills its intended purpose. Verification involves activities such as reviews, inspections, and testing at different stages of development to ensure that each phase produces the expected outputs [1]. It focuses on ensuring that the product matches the given specifications. Validation assesses whether a product or system meets the user's actual needs and expectations. Validation ensures that the end product satisfies the customer's requirements and is suitable for its intended use. It involves activities like user acceptance testing, field trials, and demonstrations to validate that the final product meets the customer's needs. In order to verify and validate our design, we analyzed our high, medium, and low priority requirements against the minimum specifications.

High Priority

Our main focus for verification was our high priority requirements, as these are requirements that must be met for a solution to be deemed successful. The following section outlines our verification methodology for each requirement and specification.

Does not cause skin irritation, cytotoxicity, or sensitization. For the skin irritation requirement, we specified that the design must meet the tests specified in the ISO 10993-1 on safety for short duration skin contact medical devices. This specification did not require additional tests, as our material selection was dependent on the ISO tests. The materials that were chosen for both of our devices have been previously approved by the FDA for similar biomedical applications and were deemed to have passed the ISO standard. Therefore, this requirement was already verified through design decisions.

Does not add additional complications. The first specification for this requirement is that the solution is able to be operated by just one person. We designed both parts of this design, internal and external, to be set up and used by just one person. We then validated usability with Dr. Dhanu on November 20, 2023. Prior to these tests, Dr. Dhanu believes that it can be used and established by just one person, and in the future, we recommend conducting this test so that it can be verified by more medical practitioners, especially one in Ghana.

This solution is also expected to require less than or equal to seven steps for extraction. This does not include set up of the external device. For extraction, this includes tenting up until the implant is removed.

The current method takes seven steps, so our goal is to not increase the number of steps necessary for extraction, in order to make this a simpler procedure. This was verified through user testing with our sponsor. We asked our sponsor to count the number of steps that they took while counting steps ourselves. We wanted to ensure there is no discrepancy about what is considered a step, and will therefore always have at least two people keeping track.

After meeting with Dr. Dhanu in person on November 20, 2023, we found that with the internal device, it takes exactly seven steps to complete extraction, meaning it meets our design specifications. The seven steps were: to locate and mark the implant, make the incision, tent the implant, cut through subcutaneous skin and fat, insert the internal device, push the implant through the internal device, and lastly to pull the implant out with forceps. Dr. Dhanu said this number of steps is reasonable and expected, it did not add any additional complications or steps to the removal process.

We chose to conduct empirical testing for this as in-person testing is the only way to accurately gauge the steps taken in a real-life setting. One limitation of our method is that we have a small sample size, but since the procedure is quite standardized, the steps should not vary greatly between people. In the future, we hope to test this with multiple providers for greater confidence.

Minimizes active removal time. The specification for this requirement is for the removal time to be less than 3.1 minutes. This test is somewhat difficult to test as we are unable to run through actual implant removals while using our device. Therefore, for the scope of this project, we are verifying that the active removal time remains 3.1 minutes or less by using the arm model. We conducted three different tests with our sponsor on the arm model: (a) full extraction with current procedure, (b) full extraction with only the internal device, and (c) full extraction with both the internal and external device. Each test followed a set of instructions and was timed. On November 20, 2023, Dr. Dhanu conducted all three tests on the arm model and we compared it to the implants she has completed in the past, to understand if the timing is around the same, more or less.

For the current procedure (test a), we had our sponsor perform the following steps:

- (1) Palpate the implant and mark the location of the incision.
- (2) Tent the implant using your index and middle fingers
- (3) Make the initial incision and carefully cut through any skin and/or fat until tip is located
- (4) Gently push the implant towards the incision until the tip is visible
- (5) If the implant is encapsulated, make an incision into the capsule
- (6) Attempt to pull the implant out with forceps

For test (b) using only the internal device, we followed similar steps to test (a) with the addition of inserting the internal device.

- (1) Palpate the implant and mark the location of the incision.
- (2) Tent the implant using your index and middle fingers
- (3) Make the initial incision and carefully cut through any skin and/or fat until tip is located
- (4) Insert the internal device through the incision
- (5) Gently push the implant through the internal device until the tip is visible

- (6) If the implant is encapsulated, make an incision into the capsule
- (7) Attempt to pull the implant out with forceps

For test (c) using both the internal and external devices, we followed similar steps as test (b) but using the external device to tent the implant.

- (1) Palpate the implant and mark the location of the incision.
- (2) Place the external device around arm and use it to tent the implant
- (3) Make the initial incision and carefully cut through any skin and/or fat until tip is located
- (4) Insert the internal device through the incision
- (5) Gently push the implant through the internal device until the tip is visible
- (6) If the implant is encapsulated, make an incision into the capsule
- (7) Attempt to pull the implant out with forceps

It was found that with just the internal device, it took Dr. Dhanu approximately 2 minutes and 36 seconds, which is less than the current procedure. The timing is a slightly more ambiguous measurement when using the arm model however, as the complications that may occur during an actual removal do not exist, for example there is no capsule to consider. For the timings, we ensured that Dr. Dhanu followed the same steps for both procedures, with the only addition being to insert the internal device.

This method was used as there is no other effective way to simulate the time it takes for removal. Any theoretical calculation would not accurately capture removal, as too many simplifications and assumptions would have to be made. Some limitations of this testing include the accuracy of the arm model. The arm simulator does not include a capsule, the fibrous tissue that usually makes removals more difficult, so testing on this device will not completely model removal on a real patient. Therefore, all of our measured timings will be evaluated against the time it takes for removal on the arm model, rather than the time during real procedures.

Durable. The specifications for this requirement are that it is 1) 5 year shelf stable life when stored indoors with no sun exposure at 24-35 °C and 76%-89% humidity, 2) effective for 250 uses, 3) able to be transported outdoors for 3 days, and 4) not corroded or impaired by medical grade cleaning solutions (95% alcohol). The durable requirements and specifications had varying testing based on the internal and external components of our design. The material selection of our internal component being stainless steel helps mitigate several durability concerns. Stainless steel has a shelf life of over 50 years, so the internal component meets the first specification of a 5 year shelf life at 24-35 °C and 76%-89% humidity. For the external component, we studied the material properties of both PLA and resin. Since we finally decided on resin as our 3D printed material, we found that resins can get dissolved by harsher solvents so medical grade alcohol is not likely to affect the shelf life of the device. The guidelines for shelf life of a material is shown in Equation 3, with $A_{F(T)}$ being the acceleration factor between natural and accelerated weathering under temperature control, Q is the reaction rate coefficient; T_{aw} is the temperature used in accelerated weathering (given in °C), and T_r being the room temperature. The external part will most likely not last 8 years, which is our ideal specification, however it will meet the minimum specification of 5 years [50].

$$A_{F(T)} = Q10^{\left(\frac{T_{aw}-T_r}{10}\right)} \quad \text{Eq. 3}$$

The second specification is that the device is effective for up to 250 uses. In order to validate this specification, we applied pinching to the thin ends of the device. We decided that the thin edge of the internal device would be the area most vulnerable to failure, as stainless steel has a higher yield strength. While pinching the device 250 times, we switched between members after every 30 pinches to have a variety of forces. For the external device we decided that the primary failure mode would be internal movements of the mechanism. In order to validate this, we will screw and unscrew the device up and down 250 times. For both of these tests, we will observe whether there is any deformation or damage done to the devices. These tests are able to be run while completing other tests since only members need to be testing at one time. Although 250 tests sounds high, due to the simple nature of these tests, it did not take long. This method was chosen because empirical testing is more accurate than theoretical calculations, and since the tests did not take long to conduct, they gave valuable information.

In order to ensure durability, the device must also be able to be transported outdoors for 3 days. This specification is a more ambiguous test, as it is difficult to test transportation tests. Material selection tells us the devices should last in environmental ambient conditions. To test the durability of transportation, we put the devices in our bags and carried them around for three days each trial and observed little to no deformation or damage. We chose to test the device in this way since we thought it best simulates what transportation could look like in a real life scenario, and would be more accurate than trying to simulate what movements the device might encounter in a lab setting. It also could be easily done in conjunction with other tests.

The last durability specification is that the solution is not easily corrosive or impaired by medical grade cleaning solutions of at least 95% alcohol. This requirement was met by the material selection for our devices. Medical-grade alcohol is not corrosive nor does it impair cured photopolymer resin [51] nor 316 stainless steel [52].

Does not increase incision size. For this requirement, the specification is that the incision size remains less than or equal to 3mm. We tested this specification by creating a 3mm incision on the arm model and inserting the internal device and removing the implant. We measured the incision before and after that internal component was inserted, and we repeated the process twenty times. After completing this test, we found that there was no correlation between the internal component and increasing incision size. The incision stayed at 3 mm throughout all twenty tests. This was an initial test based on our design functionality. A visual of the test can be seen in Figure 32.

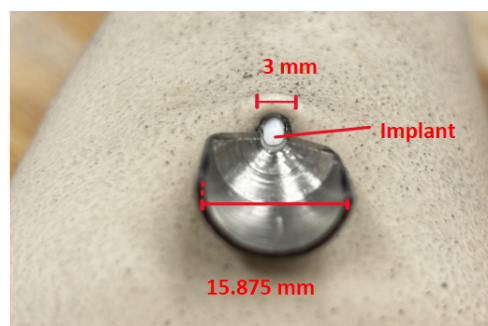


Figure 32. The internal device is able to be inserted into a 3 mm long incision without causing the incision to increase at all.

Due to changes in our final design from our build design, this test will need to be reconducted. Unfortunately, due to the time constraints of this semester we were unable to remanufacture a prototype to include the design changes and thus were unable to conduct this follow up testing. We recommend any team taking this project on to repeat this test with a prototype of the final design. We also recommend using a material with an elasticity closer to human skin [53] (using either chicken breast [54] or silicone [55]) rather than the latex skin on the model to more accurately verify this test.

Easy access to implant during procedure. The specification for this requirement is that the user should be able to view the implant and the incision view should not be blocked by any solution. In this case, the user is the medical practitioner that would be removing the implant. This specification had a large influence on our design decisions, as we decided on a half-tube design that allows for clear visibility from the top view. There is a tapered end, with a wide end diameter compared to the tip in order for the user to fit in forceps to grab the implant as it is being held stable. This open faced and gradient design gives the medical practitioner a clear view of the implant during the procedure, and access to the implant as the device increases stability of the implant. Figure 32 above shows that the implant is clearly visible while the internal device is in place. This specification will also be verified by user testing when conducting testing and mock implant removal trials. Due to the time and personnel constraints associated with this project we focused on Dr. Dhanu as our primary user, and ran these tests with her.

After meeting with Dr. Dhanu on Monday, November 20th, we spoke about how the design could be improved. While Dr. Dhanu was simulating the removal procedure using our internal device, she found that the device tended to tilt upward due to the curvature of the design, shown in Figure 33 below. Another issue she seemed to be having was that there was too much of a buffer between the hollowed section and the cylindrical hole. This tilt made it slightly difficult to access the implant with forceps to pull it out. We spoke about possible methods to fix this issue and have decided to create another design with a thinner chamfer and no cylindrical aspect to the hole. These improvements were included in the final design.

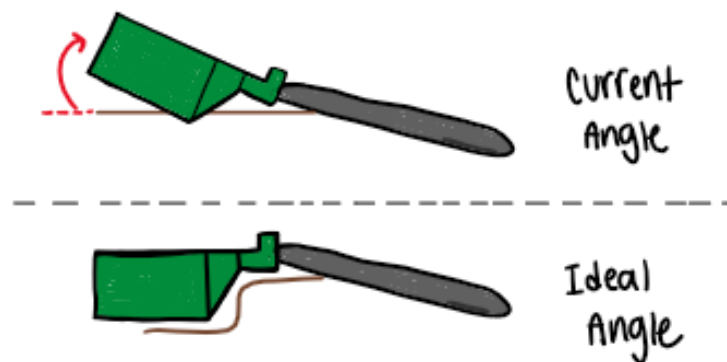


Figure 33. As can be seen above, the internal device was tilting upwards at the far end, making it more difficult to access the implant with forceps and other tools. The angle also made it difficult to see the implant during the removal process.

Due to changes in our final design from our build design, this test will need to be reconducted. Unfortunately, due to the time constraints of this semester we were unable to remanufacture a prototype including the design changes we hope to include in our final device and thus were unable to conduct this follow up testing. We recommend any team taking this project on to repeat this test with a prototype of the final design.

Simplifies removal process. There are two specifications outlined for the simplifies removal process requirements; these are that 100 users report ≤ 5 out of 10 difficulty rating on average when surveyed and that the device removes the need for the user to dedicate both hands to stabilizing the implant.

The first specification will be measured at using a Likert scale. Within the scope of this class, we were not able to survey 100 users, but we aimed to survey as many people as possible. We decided to conduct this test during the design expo; we had a person conduct two removals, one following the current removal process, and one with the help of the assisted devices. After the individual had conducted the two removals, they were surveyed about their experience. Listed below are the questions that we included.

1) How would you rate the difficulty of the current implant removal procedure?

Extremely easy	1	2	3	4	5	6	7	8	9	10	Very difficult
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2) How would you rate the experience of performing the current removal procedure?

Very poor	1	2	3	4	5	6	7	8	9	10	Excellent
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3) How would you rate the difficulty of the implant removal procedure while using the assistive devices?

Extremely easy	1	2	3	4	5	6	7	8	9	10	Very difficult
-------------------	---	---	---	---	---	---	---	---	---	----	-------------------

4) How would you rate the experience of performing the removal procedure with the assistive devices?

Very poor	1	2	3	4	5	6	7	8	9	10	Excellent
-----------	---	---	---	---	---	---	---	---	---	----	-----------

5) How would you rate the experience of performing the removal procedure while using the assistive devices compared to without the devices?

Much worse	1	2	3	4	5	Much better
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We were able to have 7 people go through the removal process and rate their experience. For Question #1 we on average received a 6.43 out of 10, for Question #2 we on average received a 4.14 out of 10, for Question #3 we on average received a 4.47 out of 10, for Question #4 we on average received a 6.43 out of 10, and for Question #5 we on average received a 4.57 out of 5. These results make it clear that overall users felt that our device made the removal process easier and more enjoyable. Additionally, the average difficulty given to the removal process with the assistance of our device was less than 5 which meets the specification laid out.

Although healthcare providers who have previously conducted removals would be the ideal population to survey, we have limited access to this group of people. Therefore, we conducted these surveys with non-healthcare providers for initial evaluation, and compared the results to see if there was a decrease in difficulty reported. In the future, we would like to conduct this survey with a larger population of people, as well as with providers in Ghana, to get a more accurate sample size and population.

The second specification, removes the need for the user to dedicate both hands to stabilizing the implant, was tested by having Dhanu conduct a removal while using our device. She was able to successfully remove the implant without needing to dedicate both of her hands to stabilization and thus we consider this a successful meeting of the specification.

Minimizes movement of the implant during procedure. To conduct this test, we needed to use a transparent skin on our arm model. We used cling wrap to simulate the transparent skin. We recognize that there may be better transparent skin options, this was the most time efficient option. Once we decide on the best material, we performed the following test:

- (1) Place the implant (encased in ziploc) between the transparent skin layer and the foam.
- (2) Set up a camera/phone so that it can record the test. Make sure the full implant is in frame. Place a ruler so it is in frame as well. Mark two small lines on the exterior of the transparent layer about 3mm from each side of the implant. (The ruler and the markings will be used by the ImageJ software for measurements)
- (3) Start recording
- (4) Complete the full procedure with just the internal device (test b highlighted in the Minimizes Active Removal Time subsection of this report)
- (5) Stop the recording. Determine where the most movement occurs in the procedure or if at any point the implant moves across the marked lines. Using ImageJ, determine how much the implant moved at these times.
- (6) Repeat this test with both the internal and external device (test c highlighted in the Minimizes Active Removal Time subsection of this report)

We used green foam, a 3D printed colored implant for an ease of visualization, and a transparent outer layer (cling wrap). With this test, we determine that our device does not move more than 3 mm in any direction while conducting the removal process with the help of our device.

Easy to clean. After discussion with our sponsor and physicians in Ghana, we learned that the typical cleaning process for devices like ours was to soak them in alcohol-based cleaning solution. We wanted to make sure that our device could be cleaned within 7 minutes using this method. To do so, we applied GloGerm to our devices prior to the alcohol soak. We chose to use GloGerm as it is frequently used in industry to teach aseptic technique and also has been used as a proxy to bacteria in previous research [56]. We then soaked our devices in 97% alcohol at varying times from 1 minute to 7 minutes. After each duration, we used a UV light to check how much GloGerm was left on the devices after soaking them. The result for each time can be shown in Figure 34 and Figure 35 below.

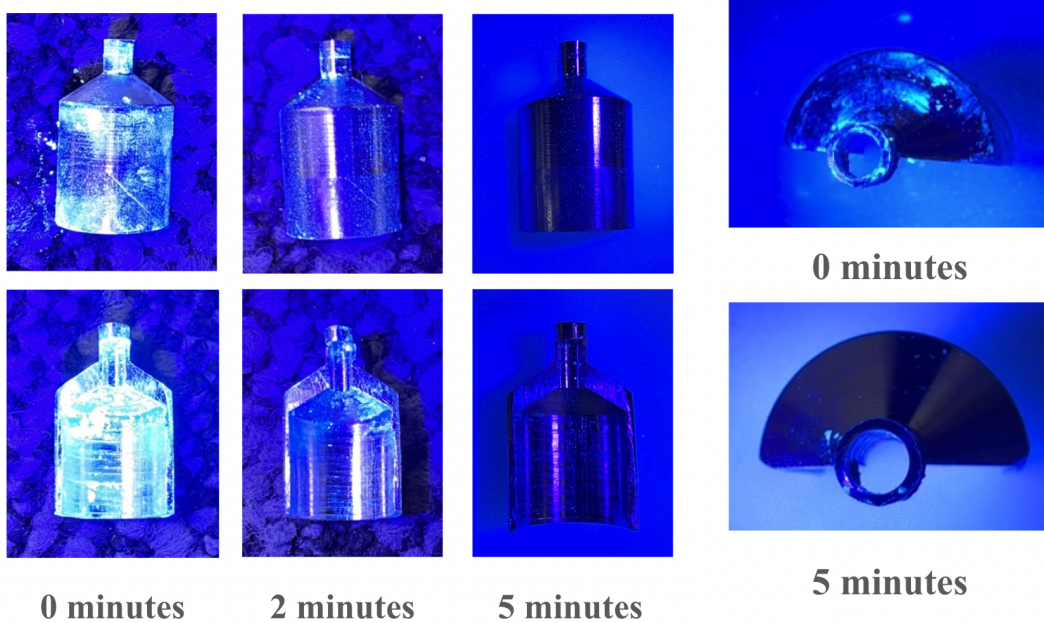


Figure 34. The internal device was sufficiently cleaned with little to no visible GermGlo after 5 minutes of soaking. The most concerning portion for sterilization prior to this test was the smaller diameter hole due to its size. However, as seen on the right, the GloGerm was sufficiently cleaned off with the soak and a slight wipe.

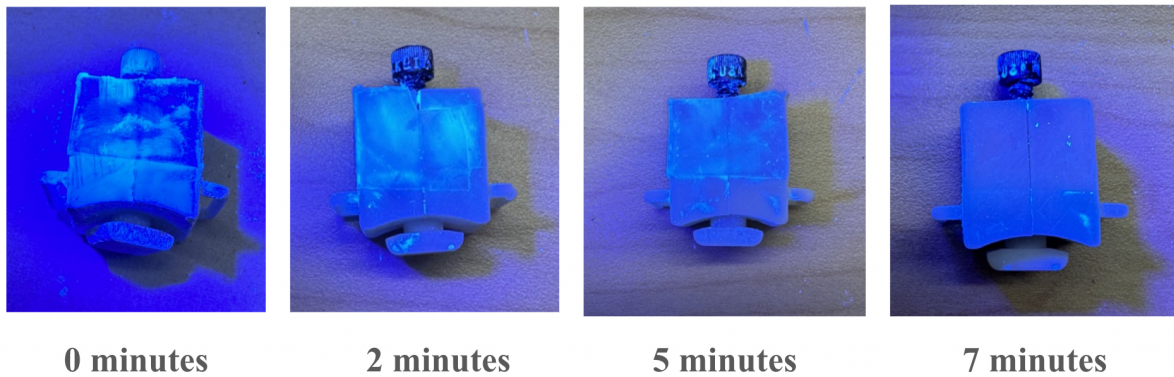


Figure 35. The external device had about 99% of the GermGlo removed after 7 minutes of soaking. This is considered sufficient in our testing. The most concerning area for sterilization was found to be the screw to provide the downward push on the plunger. To address this, we found a different screw with smoother edges and that is cheap enough to be replaced when needed.

The same alcohol-based cleaning solution was used on both devices, which means that they meet the specification where the devices do not need any special cleaning solution for proper sterilization. From this test, we recommend soaking the devices for 5-7 minutes and wiping down after the soak. We also recommend using a tool similar to a flosser toothpick to clean the smaller diameter hole of the internal device. This is recommended but not needed. This test shows that our device meets both specifications for

the Easy to Clean requirement, as it was able to be cleaned within 7 minutes and used standard cleaning solution and equipment.

This method of testing was done for its simplicity and accuracy. An even more accurate method would be to swab parts after cleaning for bacteria and grow out the colonies over time, but this takes significantly more time and resources. Due to the fast timeline of our testing, we chose not to do this, and went with a method that was easier to conduct, but could give us almost the same information.

Medium and Low Priority

This section outlines the verification methods for the medium and low priority requirements. Although these requirements have not been deemed crucial, they are still important to consider for successful implementation of this device.

Does not increase the risk of breaking the implant. The specification for this requirement is to ensure that 73% of the removals must be completed without breaking the implant. To test this, we conducted the full removal procedure including setup and extraction 20 times. Since no implants were broken in the 20 trials we are fairly confident that our device falls within the 73% specification.

Minimizes setup time. Based on our definition of the steps of extraction highlighted in the Minimizes Active Removal Time subsection of this report, there are no additional steps required for setup of our internal device. Because our specifications for setup time were defined based on the current procedure and the internal device does not need any extra setup, we can confirm that the internal device meets this specification. To determine if our overall solution meets this specification, we need to find the setup time needed for the external device. To do so, we found the amount of time needed to place the external device on our own biceps. To do so, we followed these steps:

- (1) Mark the spot where the external device should be placed
- (2) Place the device on the participants arm
- (3) Wrap the strap around the arm
- (4) Secure the device in the correct position

We completed these steps 5 times and timed each test resulting in setup times of 5, 4.5, 4.8, 5.1, and 4.8 minutes. These average out to a set up time of 4.84 minutes which is far below the specification of 7 minutes.

Easily handheld. This requirement consists of two specifications that are based on the physical properties of our devices. During our design phase, we wanted to meet the size specification by keeping our design less than 4 inches tall, 10 inches long and 5 inches wide for both devices. With their small size, they were inherently less than the weight constraint of 5.1lbs and were not attached to any rigid structures. In addition to the maximum size constraint, we also had to decide the minimum size that our devices could be through empirical testing and setting new needs of our devices.

For the internal device, we wanted to ensure that the opening would be large enough to fit forceps or tweezers so that the user can easily remove the implant. We found that the minimum size needed to hold the implant based on an ergonomic study on “pinch grip”, we found that the minimum size would need to be 8mm. [44]. In order to make it large enough to hold the device and fit the tools to extract the implant,

we decided on a final size of $\frac{5}{8}$ ". With this size, it would meet the required size specification while maintaining functionality. Testing of the efficacy of this size was done with Dr. Dhanu, and provided us with an understanding of whether or not the device is comfortably and easily held by medical practitioners. It was determined that our device is easily hand held. Since our overarching goal is to make the removal process easier for practitioners, it is important to ensure that they are able to grasp the internal device with either hand or forceps.

For the external device, we wanted to make sure that the size was smaller than the specifications but also wanted to make sure it was going to stay stable on the arm. We used empirical testing from our initial alpha design to test sizes of 1.5" cubic, 1" cubic, and 0.5" cubic for their stability and comfort. We found that, while these sizes met the size specification, the 1.5" was too large to fit comfortably and stable on the arm. We also found that the size of 0.5" was too small to have a plunger large enough to apply pressure that was not painful. From this, we found that a size between 0.5-1" cubic would be the best size of our device to meet the handheld specifications while maintaining functionality.

Low cost. The specification outlined for low cost is that the cost to manufacture the device is less than \$100. Based on our Bill of Materials and manufacturing cost calculations, the total cost of manufacturing both the internal and external device is \$19.39. This meets both our minimum requirements, as well as our ideal specification, which was to be less than \$85.

Made from locally available materials. For this requirement we needed to ensure that all materials could be sourced in Ghana within 5 weeks. In order to determine this, we looked at the materials that we chose and looked into vendors in Ghana. Through a basic search of online ordering sites available in Ghana we were able to determine that all materials chosen, including stainless steel and Standard Photopolymer Resin, are available for purchase through Ghanaian vendors. Thus all of the materials used should be able to be sourced in under 5 weeks excluding extenuating circumstances.

Aesthetically pleasing to patient. There are two specifications outlined for the aesthetically pleasing requirements; these are that the device must not have any visible needles or knives and that the outer shell of the device is appealing. The first specification is met through the design choices made for both our external and internal components. Neither component contains any type of knife or needle and thus that specification is met implicitly.

The next specification will be looked at using a Unipolar Likert scale. We used the Design Expo as a forum to obtain a random sampling of people to rate our devices aesthetics. We gave each participant time to view and touch both the internal and external components of our device and then asked them to fill out a questionnaire as honestly as possible. This questionnaire included four questions related to the participants overall impression of our device and their likelihood to be ok with a practitioner using the device on them. The questions included in the questionnaire are listed below.

(1) How would you describe the physical appearance of the internal stabilization component?

Not At All Appealing 1 2 3 4 5 Extremely Appealing

(2) How would you describe the physical appearance of the external stabilization component?

Not At All Appealing 1 2 3 4 5 Extremely Appealing

(3) How likely are you to be ok with a provider using our internal stabilization component in order to remove your arm implant based on its appearance?

Not At All Likely 1 2 3 4 5 Extremely Likely

(4) How likely are you to be ok with a provider using our external stabilization component in order to remove your arm implant based on its appearance?

Not At All Likely 1 2 3 4 5 Extremely Likely

In total we had 23 people who rated our device's aesthetics during the design expo. For Question #1 (in reference to the physical appearance of our internal component) we on average received a 4.26 rating out of 5, for Question #2 (in reference to the physical appearance of our external component) we on average received a 4.22 rating out of 5, for Question #3 (in reference to the participants' likelihood to allow our internal device to be used on them) we on average received a 4.22 rating out of 5, and finally for Question #4 (in reference to the participants' likelihood to allow our external device to be used on them) we on average received a 4.26 rating out of 5. Additionally, we had no participants rank our device below a 3 out of 5 in any of the categories.

We are considering these results as sufficient to establish that we have met the aesthetically pleasing requirement. Ideally we would have liked to conduct this test with women in Ghana as we acknowledge that their perspective may differ from the results that we have acquired in our limited setting; unfortunately, this was not possible due to the constraints of ME450. Moving forward, we recommend that any teams taking on this project pursue testing of this requirement in Ghana.

DISCUSSION

Creating a final, marketable product takes many iterations of the design process, which could take months or even years to complete. Due to the constraints of this class, we are unable to complete those many iterations, but have considered potential future avenues and directions. In this section, we will analyze our current design and outline potential areas of improvement.

Refining the Problem Definition

The main foundation of our design is the problem definition. By developing and shifting our problem definition, we can define the problem, as well as its associated requirements and specifications. As such, this is a critical aspect to the success of our solution.

If we had more time, we would gather more input on the exact points of difficulty during the procedure from stakeholders, specifically the healthcare providers in Ghana. Much of our information on the exact points of difficulty came from talking with our sponsor, Dr. Dhanu, as it was difficult to get in contact with Ghanaian providers, but ideally, we would gather more information from the true users of the device. Instead of solely conducting informational interviews, which have the potential to be biased due to

perceptions or differences in recall, with more resources, we would have liked to observe the procedure done in Ghana, so that we could take note of points of difficulty in real time and ask specific questions.

In addition, with more time and resources, we would have liked to explore the question of “what is an acceptable cost?” further. As a global health project, this would be an important factor that needs to be adequately considered for the solution to be viable when implemented. From our literature review and interviews, it was difficult to determine what a reasonable cost would be for this device, so we would have liked to conduct surveys with hospital administrations in Ghana to understand what they typically spend on similar devices.

Device Strengths

Our device has multiple strengths that set it apart from other potential solutions that currently exist or may be developed. These strengths give our device a competitive advantage against other potential competitors.

Adaptable to provider preferences. The biggest strength of our device comes from the two component form factor. The device consists of an external and internal component, which can be used independently based on a provider’s preference. Both devices are designed to be used together, but for providers who just want additional support with elevating the end of the implant with external stabilization, they can use the external device even without using the internal device. For providers who want more assistance keeping the implant from moving side to side, but prefer using their own hand to stabilize the end of implant, they can solely use the internal device. This flexibility allows the provider to have an assistive device that is most catered towards their needs. Through this user-focused design, the device hones in on the problem of needing to make removal easier for providers.

Adjustability. Another strength of our design is its ability to be adjustable. The external component of our device includes a plunger that allows the provider to adjust the depth at which the implant is being pushed; this can assist a provider in tailoring the removal procedure to a specific patient. Differing levels of subcutaneous fat or differing implant insertion depth may impact the amount of pressure necessary to tent the implant, thus including a level of adjustability ensures that our device can be used for a wide range of patients.

Simplicity. The final strength that really sets our device apart is its simplicity. Our device, while nuanced in its design, is rather simple to produce and assemble. This simplicity ensures that it can be produced around the world without the need of specialized equipment. This is particularly relevant when looking at a setting like Ghana, as it could be very costly to produce our device in the United States and ship it out. Ensuring that our device is simple enough to be produced anywhere in the world makes it accessible to countries and patients that may otherwise be priced out of accessing a device such as ours.

Device Critiques

As all designs do, our device also has some drawbacks that should be addressed. Addressing these drawbacks would improve the possibility of implementation of this device in the future.

Pressure on localized spot for an extended period of time. When conducting user testing with our sponsor, an aspect that she pointed out is that since the plunger remains in the same spot for the entire procedure, the pinpointed pressure on the spot for the extended period of time can feel slightly uncomfortable. Although a provider also exerts a similar pressure with their finger during the procedure, they also have the ability to move the position of their finger around slightly, more evenly exerting the pressure.

One way to avoid this uncomfortability would be to redesign the external device to allow for the plunger to move horizontally to different positions. This should be done without needing to remove and reattach the armband, so a potential way to approach this would be to put the plunger on a x-y slide system.

An alternative method could be to increase the surface area of the tip of the plunger, so that the downward force is distributed over a larger surface area. This could mitigate some of the uncomfortability, as the pressure felt by a point on the skin would decrease.

Device tilts upward. As described in the verification and validation section, the device tilted upward when inserted into the incision, making it more difficult to access the implant. We made modifications to our build design to attempt to solve this problem, but were unable to make a full prototype to validate the design. This would need to be explored further to fully solve the problem, but we believe that this can be resolved with the modification we proposed.

Must be diligently sanitized. There is a small concern in regards to the potential for transfer of bodily fluids when using our device. The internal device is used inside of the body, but is also reusable, meaning that if it is not sufficiently sanitized, there is the potential for blood or other biological matter to be transferred between patients, which could be extremely harmful. We do not currently have any indicators on the device that could signal when the device is sufficiently cleaned, so it would be up to the providers to determine when they feel it is clean. Based on our preliminary “Easy to Clean” testing, it takes around 5 minutes to clean the device. In the future, the device could potentially come with a color-changing sticker, or some sort of other visual indicator that changes color at the 5 minute mark.

Requires training to use. A small downside to our design is that it is not necessarily intuitive to use. When people picked up our design, they were not able to figure out how to use the device without previous instruction. Therefore, some sort of brief training would need to be conducted. This training could potentially be added on to the end of the training on inserting the implant, so that providers could practice using the device on the arm model prior to using the device with a patient.

Risks

One of the main challenges we encountered during our design process was the inability to properly model what an implant removal would look like. The arm model available for our use was not sufficient in modeling what a removal would be like on an actual person. This challenge posed serious risks to the integrity of our solution and to our verification and validation process. In order to combat these risks we had multiple checks in place. The first and most important check was to continually discuss our testing plans and design choices with our sponsor Dr. Dhanu. Dr. Dhanu has intimate knowledge of the actual removal process and by continually checking in with her, we ensured that our tests were as similar to a

true removal as possible. Additionally, we attempted to modify some tests to account for the arm model. For our difficult to use test, we used the arm model as a baseline rather than the actual removal in order to ensure that the test results once our device was used would not be skewed one direction or the other.

Another risk is that we were not able to complete user testing with multiple providers. Although user testing with Dr. Dhanu was extremely helpful, she could have specific biases or preferences with the removal procedure. Due to the constraints of the class, we were unable to conduct testing with other healthcare providers, so some testing was done with individuals with no background in healthcare. This is a significant limitation, so future work should include a larger sample size of users.

REFLECTION

When our team first was tasked with this project, we were told to consider the global and societal impacts this project could have. Throughout the course of this semester, these elements influenced every stage of the design process, from problem exploration and stakeholder analysis to concept generation and verification and validation. It was vital for the team to be cognizant of how the design context of the project impacts a solution's goal as well as the steps to get there. In this section, we vocalize the shifts in our perspectives over the course of the semester, specifically regarding the public health, global context, ethics, and cultural identities of ourselves as a team and our stakeholders. It is almost impossible to eliminate bias and personal beliefs from engineering and design projects, but we have attempted to be aware of the perspectives we each bring to the project and have influenced our identities to progress this project throughout the semester.

Design Context

The design context in an engineering project refers to the broader framework or environment within which the design is conceived, developed, and implemented. It encompasses various elements such as user needs, technological constraints, market trends, cultural influences, economic considerations, and environmental impacts. Understanding the design context is crucial for engineers as it provides the necessary insights and parameters to create effective and relevant solutions. The design context serves as a guiding framework that helps engineers make informed decisions throughout the project lifecycle. It ensures that the final product not only meets technical specifications but also addresses real-world challenges, enhances user experiences, minimizes negative impacts, and remains adaptable to changing conditions.

External Factors. Human centered factors will inevitably have a large impact on this project, especially due to the fact that it is a Global Health Initiative project. Being cognizant of the public health, safety, and welfare of the consumers as well as any stakeholders is incredibly important, and we attempted to keep this in mind throughout the course of the semester. This project and solution will directly impact the accessibility and safety of contraceptives for women, affecting their health and well-being. The difficulty in the current removal process creates a barrier to widespread availability in regions like Ghana. Addressing the cumbersome removal procedure is essential for ensuring the public health aspect of this project. An easier removal process will enhance the welfare of the women relying on this contraceptive method. In addition, the project's success in simplifying the removal process has potential global implications, especially in regions with limited healthcare access, similar to rural areas in Ghana. Although our scope is focused in Ghana, in the future, this solution could be expanded to help with the

removal of global arm contraceptives, like Nexlanon. Simplifying the removal process could make this contraceptive method more feasible and accessible in various global settings, aligning with the UN's goal of improving access to family planning worldwide. There are definite social impacts associated with the manufacturing, usage, and disposal of the solution we have created, however we have been purposeful in accounting for the fact that we want this to be an affordable product. These factors are critical to consider, as changes in the removal process may affect societal acceptance, usage rates, and cultural perceptions regarding contraceptive methods. During the design process, the team made sure to utilize stakeholder maps and analysis and life cycle costs to characterize societal impacts of a solution. We routinely met with primary stakeholders, attempting to hear from different perspectives. We also did materials analysis to understand what materials would be feasible to manufacture within the environmental context of Ghana. Modifications to the implant's removal might influence its uptake within societies. Considering social implications can ensure the design aligns with cultural norms and user preferences. In order to take into account these social implications Streamlining the removal process could affect production costs, affordability, and overall economic feasibility. A more efficient process might positively impact the economic aspects of manufacturing, use, and disposal.

Team Dynamics. The influence of cultural, privilege, identity, and stylistic similarities and differences among team members has been substantial throughout our project's journey. Our diverse cultural backgrounds have enriched our perspectives, offering a comprehensive lens to comprehend Ghana's contraceptive landscape. However, navigating varying cultural norms and communication styles among us posed challenges, demanding concerted efforts to ensure effective collaboration. Additionally, disparities in privilege affect decision-making and resource allocation within the team, urging us to actively address and balance these dynamics for a more equitable working environment. Varied work styles impacted task approaches and solutions proposed, necessitating a delicate balance to harness creativity without causing friction. Moreover, regarding our sponsor, cultural and power differences influenced our design processes profoundly. Since we are working on a project for Dr. Dhanu, we regarded her input as highly important, and she has worked with medical practitioners and patients in Ghana. However, Dr. Dhanu being a doctor in the United States, influenced our approach, as we were only able to test with her, not medical practitioners in Ghana. Understanding cultural perspectives and power dynamics with the sponsor was pivotal in aligning our designs with the local context and preferences. Acknowledging identity disparities and leveraging stylistic similarities facilitated a more cohesive and effective design process, ensuring our final design resonates with both the cultural context and sponsor expectations for improved contraceptive accessibility in Ghana.

The cultural dynamics between our team and the sponsor have played a pivotal role in our design process. Understanding the perspectives rooted in cultural differences has shaped how our design ideas are perceived and accepted. The sponsor's cultural background significantly influences their expectations and preferences, directly impacting the trajectory of the design process and the ultimate outcome. Moreover, acknowledging power dynamics stemming from privilege and identity differences with the sponsor has been crucial. Variances in power might sway decision-making, potentially directing the project based on the sponsor's inclinations. Striking a balance in these dynamics while upholding the project's integrity has been paramount. Additionally, aligning stylistic preferences has been a key challenge. The sponsor's preferences and stylistic choices are influential in determining the final design direction. This necessitates a delicate integration of these preferences with our team's expertise and the project's objectives to ensure a

successful collaboration yielding a design that resonates with both the sponsor's inclinations and the project's goals.

Inclusion and Equity. The power dynamics in our project were multi-faceted. With stakeholders, there was a notable hierarchical power structure, where their input and decisions held significant weight in shaping the project's direction. End users possessed the power of influence through their needs and experiences, driving our understanding of the problem's urgency and impact. Among team members, power dynamics were more equitable, but differing expertise and roles led to varied influences on decision-making. Our own identity and experience, compared to the end users, provided a different lens. As designers involved in the project, our perspective was influenced by research and collaboration, while the end users' experiences were firsthand and deeply rooted in the actual challenges faced.

Regarding diverse viewpoints, our approach emphasized inclusive meetings where stakeholders, including experts from Ghana, shared insights. Regular feedback loops ensured everyone's perspectives were considered and integrated into the project's evolution. Balancing ideas from stakeholders and team members involved an objective evaluation of each viewpoint's alignment with project goals, feasibility, and potential impact on end users. Cultural similarities and differences among team members influenced our approaches significantly. While diverse cultural backgrounds enriched our problem-solving perspectives, it also presented communication challenges. We addressed this by establishing open communication channels and fostering an environment that valued varied viewpoints. With the sponsor, cultural differences affected design processes by necessitating an understanding of their preferences and aligning these with project objectives. It required a balanced integration of their cultural preferences with the team's expertise for a cohesive design.

In essence, cultural dynamics among team members and with the sponsor impacted our collaboration and decision-making processes. We aimed to leverage cultural diversity for enriched perspectives while mitigating communication barriers. Engaging stakeholders and considering diverse viewpoints ensured a more inclusive and comprehensive approach to solving the challenge of contraceptive accessibility in Ghana. The project's approach so far has been proactive in mitigating bias and privilege by engaging with local experts and stakeholders from Ghana. Seeking feedback from these experts and stakeholders, as well as the sponsor, before making significant decisions helps in aligning the project with the needs and expectations of the target population. Reflection on the project's driving force beyond just a semester course demonstrates an understanding of the project's larger implications and emphasizes the need for thorough research and documentation to ensure its viability for future implementation. Acknowledging and navigating these cultural, privilege, identity, and stylistic differences within the team and with the sponsor is crucial for fostering an inclusive and effective design process that addresses the specific needs and challenges related to contraceptive accessibility in Ghana.

Engineering Ethics. In the design process of a contraceptive implant aimed at enhancing accessibility, ethical dilemmas surfaced, including concerns regarding informed consent, equity in healthcare access, and cultural sensitivity. These were managed through comprehensive consultations with stakeholders, transparent education on the product's implications, and adherence to ethical guidelines. In order to receive culturally competent feedback from stakeholders, we met with medical practitioners in Ghana. These perspectives allowed us to hone in on the specific issues with the removal process in Ghana, rather

than making it a global issue. It was continuously a challenge to balance the input from location specific stakeholders with stakeholders we met with more frequently, such as Dr. Dhanu. As our sponsor, it was important to us that we followed the process Dr. Dhanu perceived as most useful as she has been in the field. However, we wanted to make sure we also incorporated aspects of the Ghanaian removal process. Most often, all of our primary sponsors ended up providing us with very similar feedback, which gave us a good direction with our project, but it is definitely important to continue to listen to all perspectives as the project progresses.

If introduced into the marketplace, potential ethical issues might involve market dominance affecting access, continuous monitoring of long-term effects, and considering environmental impact. Personal ethics, while often aligned with professional ethics, may differ in scope and subjectivity; however, maintaining alignment between personal values and professional ethics is pivotal for ensuring integrity and ethical decision-making throughout the design and market entry phases. Understanding that when it comes to large scale project and engineering designs, it is important to separate personal ethics with engineering ethics. It is very common to have our own personal ethics and beliefs impact our approach to an issue and solution, so an important stage of the design process is discussing the ethics with the team and stakeholders. Ethics for a project may vary greatly depending on company, industry, and even manager, but understanding where your personal beliefs stand is vital. A huge aspect of this project was ensuring the removal process was made earlier in order to have providers be more comfortable with the procedure.

RECOMMENDATIONS

Based on our experiences with the project, there are a few recommendations that can be made for the future. This section will outline important future work and recommendations to consider for those who may continue to work on this project in the future.

User Testing With More Providers

Due to the limitations of ME450 and the short timeline of this semester we were only able to conduct user testing with our sponsor, Dr. Dhanu. We believe that it is very important to also obtain feedback from other providers at varying skill levels in order to truly understand what improvements can be made to this device. We recommend that anyone who takes on this project focuses on getting feedback from nurse practitioners and midwives, as well as from doctors, who may be less experienced in the removal process than Dr. Dhanu. User testing should also be done in Ghana in similar conditions to how removals are usually done, to best simulate the context in which this device would be used

Accuracy of Arm Models

A large challenge we faced this semester was regarding the biofidelity of our arm model. One of the most time consuming steps and main challenges involved in the removal process is cutting away the capsule, the fibrous tissue that surrounds the implant. However, all of the arm models currently available only simulate the skin, fat, and muscle in the arm, and do not account for any of the fibrous tissue that surrounds the implant. Because of this it has been a challenge to conduct verification and validation testing with the greatest possible accuracy. While we have tried to find ways to simulate the capsule, they are still not quite accurate to the feel of the capsule. We suggest that future teams work to find a more accurate way to model the capsule to better meet the needs of verification and validation testing.

Clinical Testing

Due to time and resources constraints we were not able to pursue this project to the point of clinical testing. We recognize that it is truly impossible to fully know how successful this device will be without testing it in a real life removal application. Because of this we recommend that anyone who pursues this project obtain an Investigational Device Exemption (IDE) in order to conduct clinical testing. This will allow for further insight into potential improvements to the design as well as more in depth validation and verification.

CONCLUSION

In this project, we are addressing the difficulty of the contraceptive arm implant removal procedure. The implantable arm contraception is the most effective, reversible contraceptive method and it prevents pregnancy for up to 3-5 years after administration, with no need for routine clinical follow-ups or maintenance, making this contraceptive method convenient and appealing to many patients. Although the placement of the implant is a very quick, relatively simple process, the removal process is difficult for both experienced and inexperienced providers, as they must find and maneuver the implant through an extremely small incision. As a result, providers are less willing to conduct removals and feel discouraged from offering this type of contraceptives to patients. Although there are other contraceptive methods available, the importance of having different methods of contraception is that each method has benefits and drawbacks, so the more options that are available, the more likely the patient will find a contraceptive method that fits their needs. For that reason, it is important to create a solution that can make the process easier and quicker for providers to perform. We hope that as a result, this will improve the overall availability of modern contraceptives in sub-Saharan Africa.

To initially approach the problem, the first step was to understand the problem scope before generating our own problem statement based. Based on our needs statement, we outlined our primary, secondary, and tertiary stakeholders which provides us with the understanding of the problem breadth and objectives. Our primary stakeholders are physicians, nurse practitioners, midwives, Dr. Dhanu (project sponsor), and patients. We met with stakeholders throughout the various stages of the project to ensure that we had a fuller understanding on the specific focus of the problem we are aiming to solve. We also conducted benchmarking, where we compared the current removal process to the one existing solution, RemovAid. We evaluated the two methods based on five metrics: effectiveness, accessibility, tools needed, difficulty, and extraction time.

These metrics helped us decide on our project requirements and specifications. In order to accurately evaluate the requirements and specifications, we sorted them into high, middle, and low priority, with the highest priority being: does not cause skin irritation, cytotoxicity, or sensitization, does not add additional complications, simplifies removal process, minimizes active removal procedure time, durable, does not increase incision size, easy access to implant during the procedure, minimizes movement of the implant during procedure, and easy to clean. The high priority requirements are the main requirements we considered throughout the rest of the process, as these are the ones we deemed as “need to haves” for the solution to be successful.

Following this groundwork, we initiated the concept generation phase. In this phase, our primary objective was to explore as many concepts as possible and thoroughly investigate potential solutions. To foster creativity and uniqueness, we employed a variety of concept generation and development

techniques, including brainwriting, functional decomposition, morphological chart, and design heuristics. These methods collectively yielded approximately 160 distinct concepts, which were subsequently categorized based on their function and form, resulting in 27 distinct categories.

Once a substantial pool of distinctive ideas was generated, we transitioned to the process of narrowing down these concepts to select our alpha prototype. This involved a multi-step procedure, incorporating a go/no-go approach and a Pugh chart to converge on a design. Throughout this phase, we maintained an open channel of communication with our project sponsor to gather feedback on our concepts, which played a pivotal role in shaping our alpha design.

Our alpha design comprises two main components: one for internal stabilization and one for external stabilization of the implant. The internal stabilization component takes the form of a funnel-shaped design, which can be inserted through a pre-made incision and encircle the implant's circumference. The external stabilization component features a dynamic block design capable of tenting up the implant while providing support on the side opposite to the incision.

With this design in place, we conducted preliminary engineering analyses across various aspects of the design, including empirical testing on the arm model. Based on our initial engineering analysis of our alpha design, we made new iterations to address size and efficacy issues for both the internal and external devices. For the internal device, we decided to remove the internal springs within the inner diameter and the external clip on the larger diameter due to size and lack of efficacy. We also decided that the ideal width of the larger diameter was about $\frac{5}{8}$ ". For the external device, we reduced the size from about 1.5 to 0.87 cubic inches. We also changed the plunger design from the initial lateral direction to a downward direction. This would allow for variable pressure on the proximal end of the implant.

We then conducted various design analyses based on manufacturability, material selection, and empirical testing. The internal mechanism dimensions and spring coefficient were determined through tenting tests and engineering analysis (FBD and Hooke's Law) respectively. The material of the internal device was determined using the GRANTA software, with which we found that L316 stainless steel was the best option. Our internal device will be manufactured through machining. We found that standard photopolymer resin was the best material choice for the external device based on current design iteration needs and future mass manufacturing. Based on our design and manufacturing costs, we found the total cost of both devices was \$19.39.

Once a final design was established and manufactured, we initiated the verification and validation step of the design process. These tests ensure alignment with previously established requirements and specifications. Most tests have been completed by this stage, confirming that our design meets the specified criteria. The methods and outcomes of these tests have been documented and outlined in this report.

We also analyzed the benefits and drawbacks of our design, which were used to determine avenues for further development. Some benefits of our design include its adaptability to provider preferences, adjustability, and simplicity. There are some usability and comfort drawbacks which include the extended amount of pressure on the arm from the external device, the position of the internal device makes it difficult to access the implant, and the devices must be trained on and diligently sanitized. Furthermore,

we recommended next steps for individuals taking on this project in the future. With our new final design, it is recommended to reconduct the verification tests for Does Not Increase Incision Size and Easy Access of the Implant. We also recommend conducting user tests with multiple providers of varying skill sets and with an improved arm model that includes a simulation of the capsule. With these tests, we would hope our design can be fully improved and verified for use in clinical settings to aid in the removal process and accessibility to contraceptive arm implants.

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TEAM BIOGRAPHIES

Shreya Jain



Shreya is a senior studying mechanical engineering with the certification in sustainable engineering (PiSE). She is originally from Atlanta, Georgia, where she grew up with both parents and older sister. Shreya has an interest in mechanical engineering because she loves to approach design problems from a technical viewpoint and hopes to make an impact through socially engaged and sustainable engineering projects. Here at Michigan, she completed research in the Wooldridge Lab working on flare combustion, is Vice President of BLUElab, and President of Michigan Seismic. Working on project teams and doing research have been one of Shreya's favorite opportunities at Michigan, as she was able to apply her skills from classes in a hands-on environment. Shreya interned at Whirlpool this past summer, where she was working in KitchenAid on a sustainable engineering project using Six Sigma methodology. She will be working at bp following graduation in May 2024, in a full time rotational program. The summer before, she had the opportunity to study abroad in Prague, and she hopes to work internationally at some point in the future to understand the importance of approaching engineering problems from a global mindset. Shreya went skydiving this summer, which has been a goal of hers for years, and hopes to reach her goal of traveling to 20 countries by the end of 2024.

Emi Yuki



Emi is a senior studying mechanical engineering with a minor in biology. She is originally from Lexington, Massachusetts, but has also lived abroad in Japan. Emi has an interest in mechanical engineering, as she loves to apply theoretical knowledge to solve complex problems. Additionally, the versatility of mechanical engineering and the diversity of applications it has is also appealing to Emi, as she has a variety of interests. At Michigan, she is the Vice President of Michigan RoboSub (a project team dedicated to building an autonomous submarine), an instructional assistant for ME 235 (Intro to Thermodynamics), and runs a community service organization called Redefined. Emi is especially interested in the applications of engineering to the medical devices and pharmaceutical industries and interned at Merck this past summer, where she worked in antibiotic manufacturing creating a process monitoring dashboard for the filling line. She will be returning to Merck full-time as a process engineer after graduation in May 2024. In her free time, Emi likes to bake, cross stitch, and try new restaurants.

Ella Samaha



Ella is a senior studying mechanical engineering with a minor in computer science. She is originally from Cincinnati, Ohio where she lived with her parents, three siblings and two dogs. She enjoys applying her experience in mechanical engineering to the biomedical field. On campus, she is a research assistant in the Rehabilitation Biomechanics Laboratory where she aids in designing testing fixtures for stance perturbation testing and conducts data collection and analysis. She also worked at Ethicon, the surgical department of Johnson and Johnson, as a co-op in Summer 2022 and 2023. During her time there, she conducted tests on surgical device verification, analyzed data, and designed and produced models and fixtures for testing. Following graduation in the Winter of 2024, Ella plans on pursuing a masters in biomedical engineering through the SUGS program at the University of Michigan. One of her personal goals is to become fluent in French and Spanish in 7 years and to begin learning Arabic. Ella also enjoys weightlifting, sports, and making clothes by crocheting or sewing.

Sara Fernandez

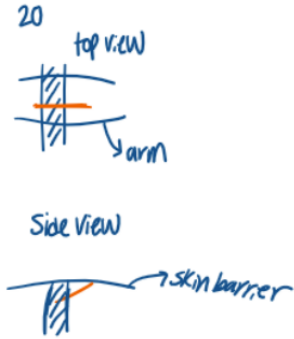


Sara is a fifth year student getting a dual degree in Mechanical Engineering and Biomedical Engineering. She was born in Venezuela but was raised in Weston, FL. Here at Michigan Sara has worked as a learning assistant for Physics 140X since her sophomore year, she also used to be a campus tour guide. Additionally Sara has been a member of the university club volleyball team since her freshman year, she has taken on the role of fundraising chair, and most recently, president. Outside of school, Sara has spent two summers interning for Anheuser-Busch, working with their can manufacturing division. One summer was spent in their corporate office in St. Louis mainly focusing on data analysis, automation and spoilage reduction. The following summer was spent in one of Anheuser-Busch's manufacturing plants in Jacksonville focusing on root cause analysis and quality analysis. Some of Sara's extracurricular passions include knitting, binge watching TV shows, and trying as many Ann Arbor restaurants as possible. Sara plans to graduate this December and start working with Eli Lilly as a manufacturing process engineer in Indianapolis.

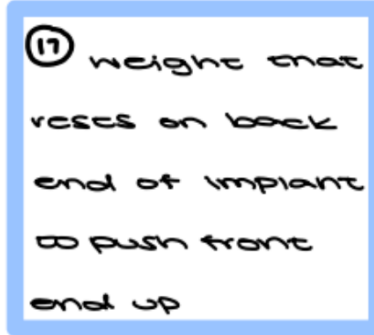
Appendix I: Concepts Generated from Brainstorming

1. Implant Stabilization

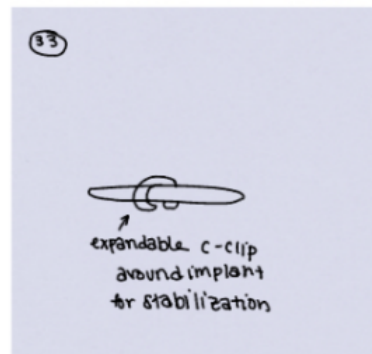
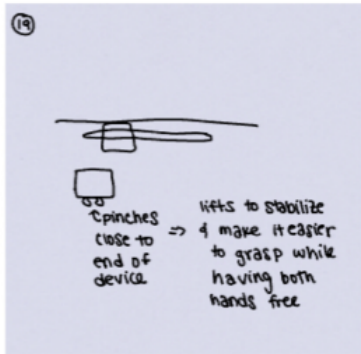
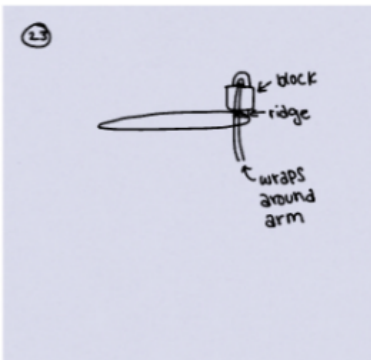
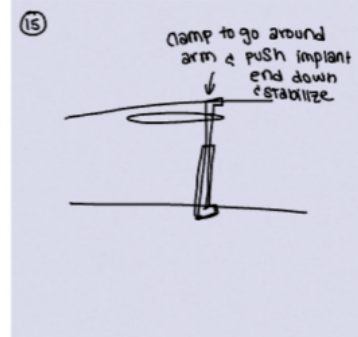
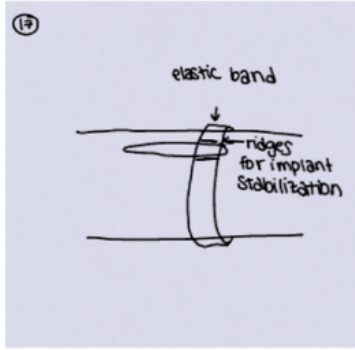
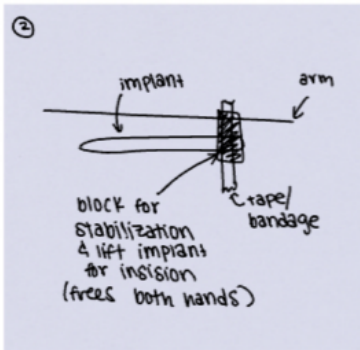
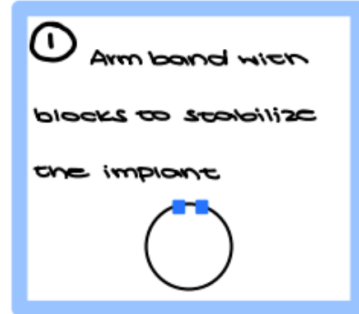
Object that pushes one side of the implant up

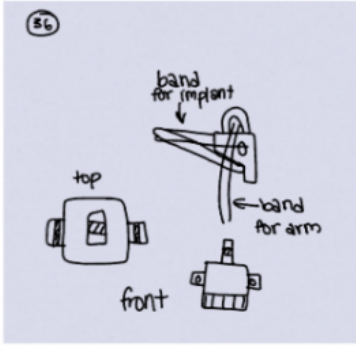


Arm strap that pushes implant up and holds stable

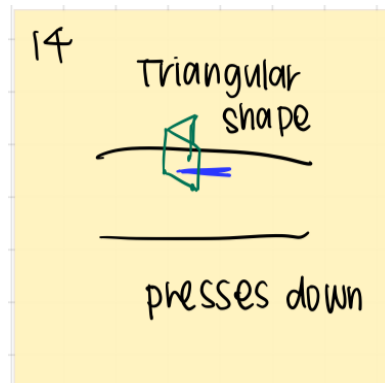
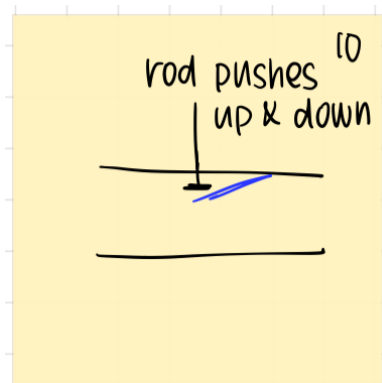
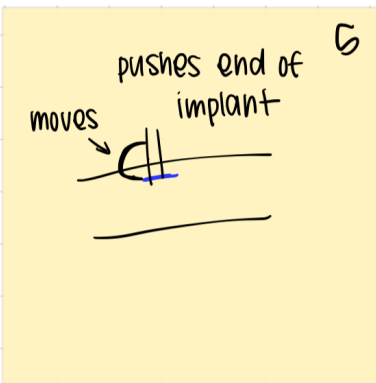
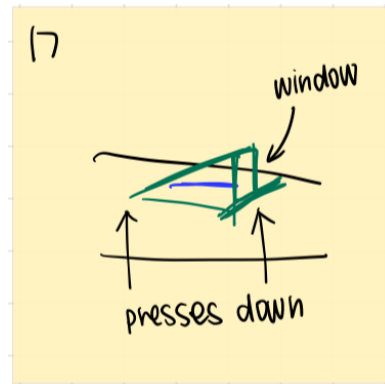
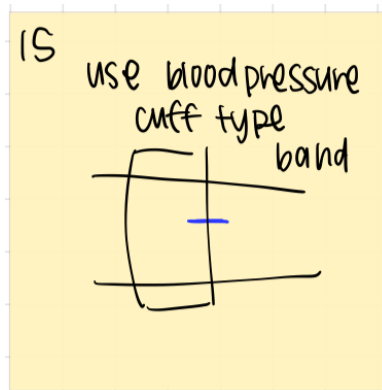
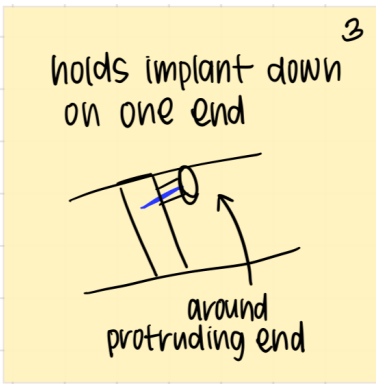
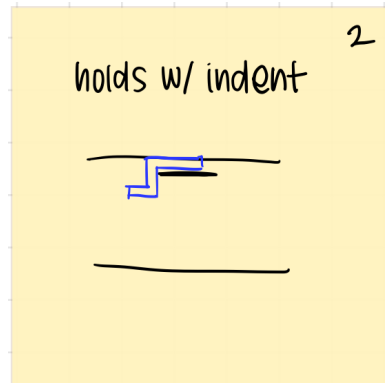
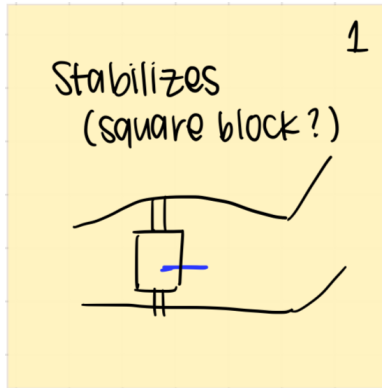
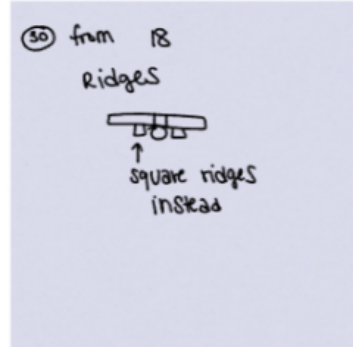


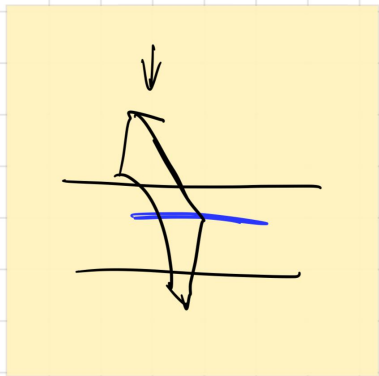
Strap that numbs the area for the patient and holds implant stable



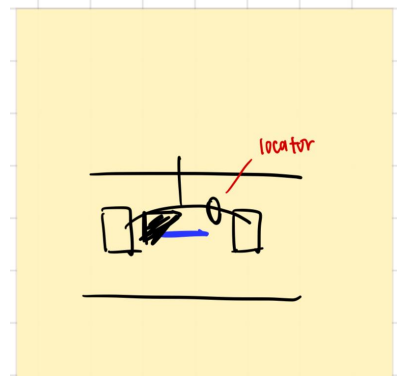
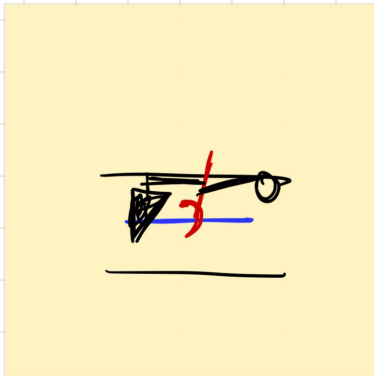
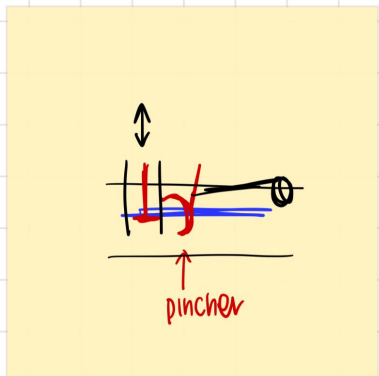
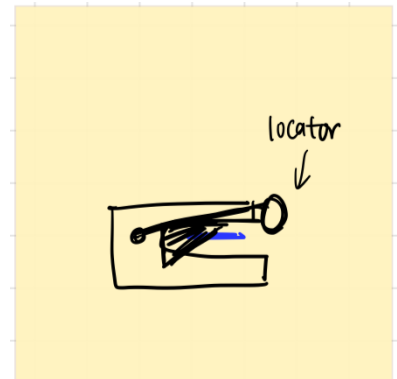
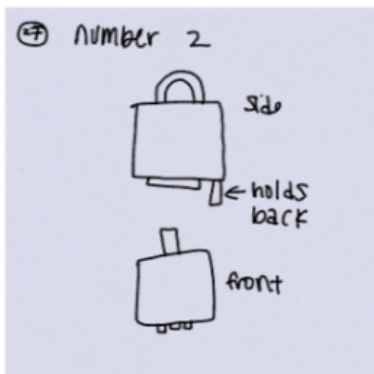
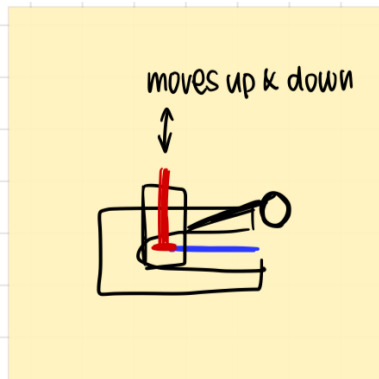
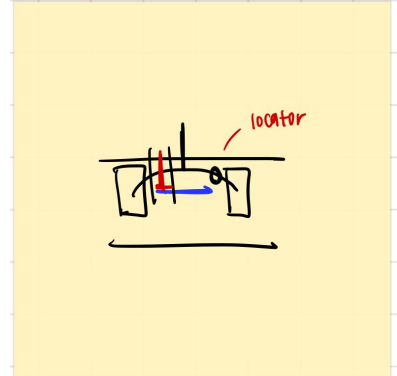
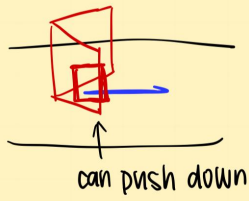


20 Device that is placed on arm & uses moving parts locate & stabilize

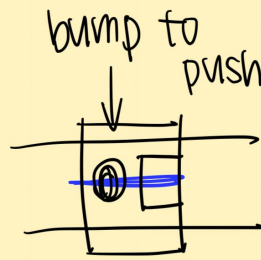
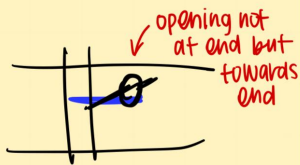




reference 14 → DH 79



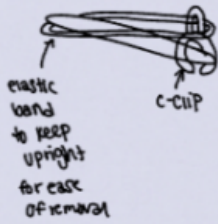
ref 3 → DH 13



from 15
ridges

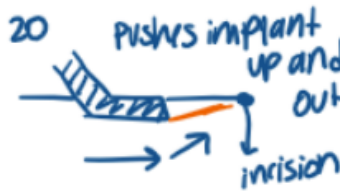


35



2. Implant Pusher - Rubber Tipped Pusher

Pushes one end of the implant out of incision

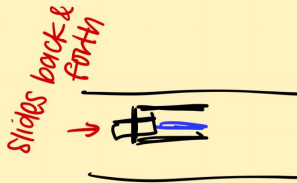


Uses soft edge (silicone/rubber) and pushes implant out of incision

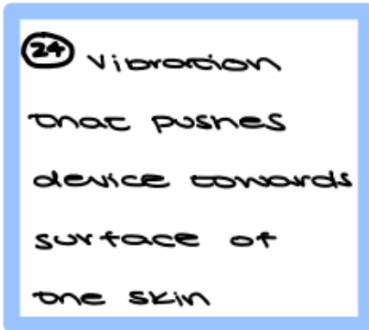
19



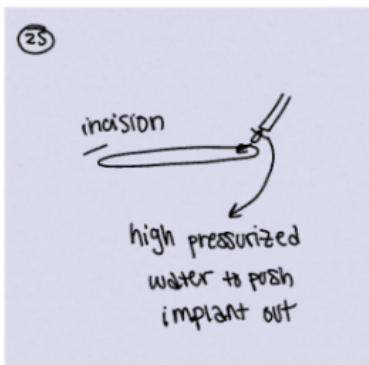
ref 6 → DH 61



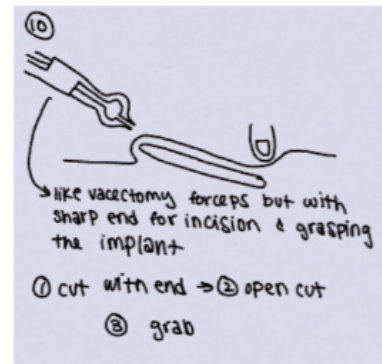
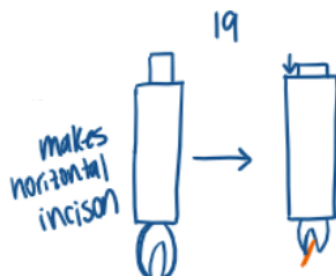
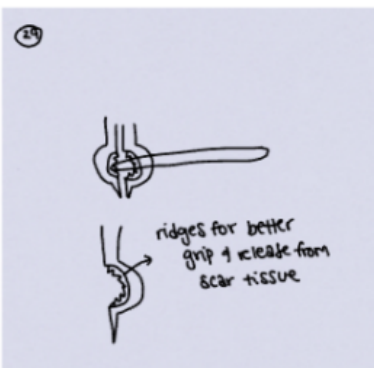
3. Implant Pusher - Vibration Device

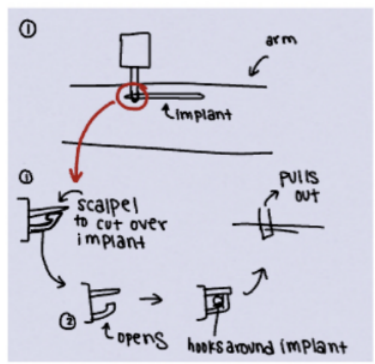
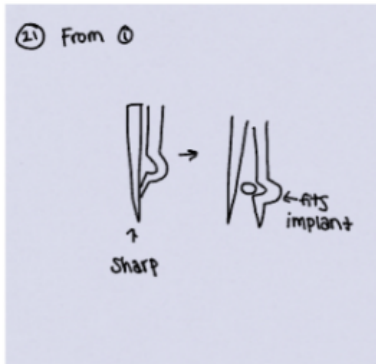
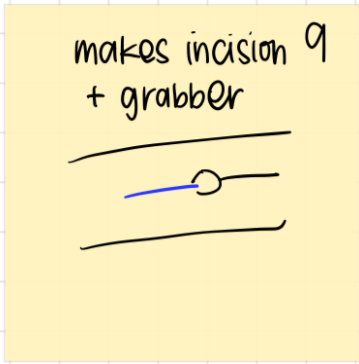


4. Implant Pusher - High-Pressure Water

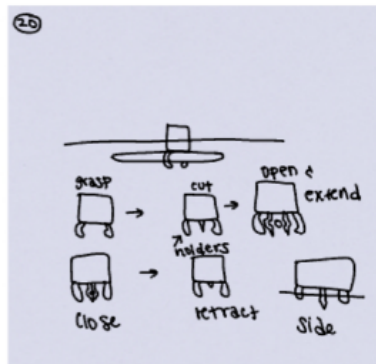


5. Combination Device (Incision + Implant Extraction) - Sharp Forceps

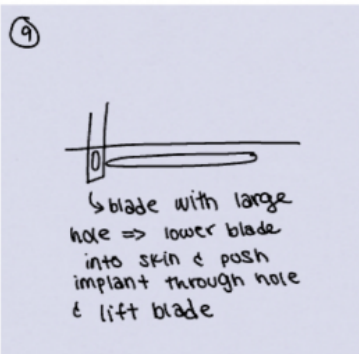
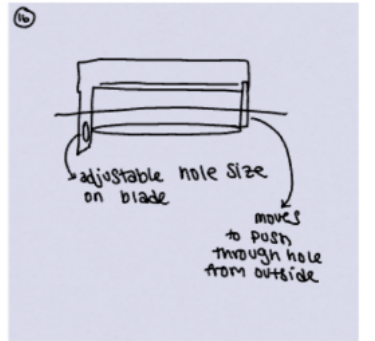
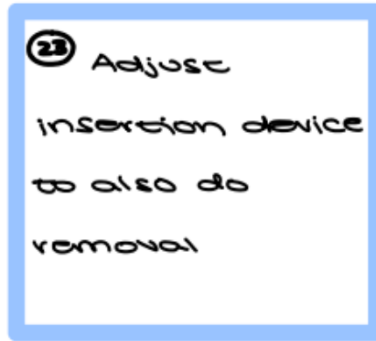
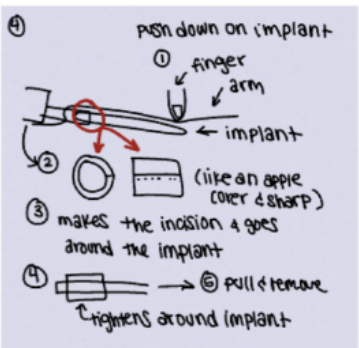




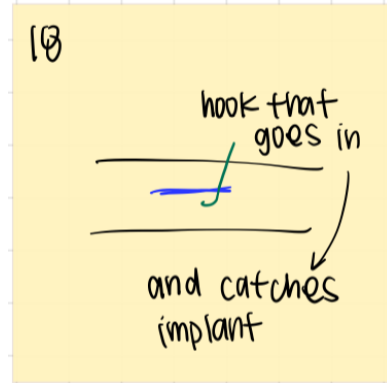
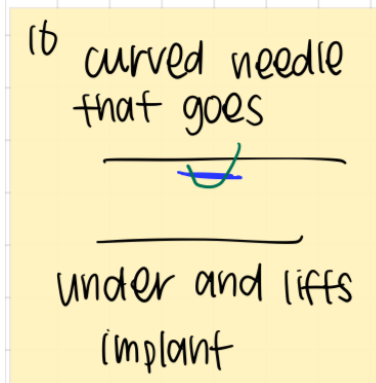
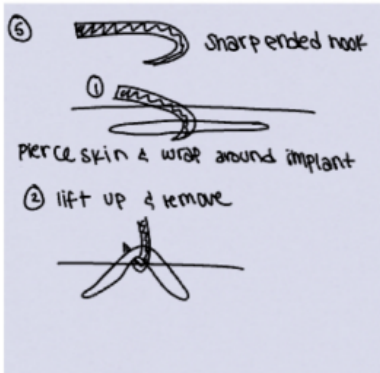
Incision-like clamps that gently grasp onto the implant and pull it out



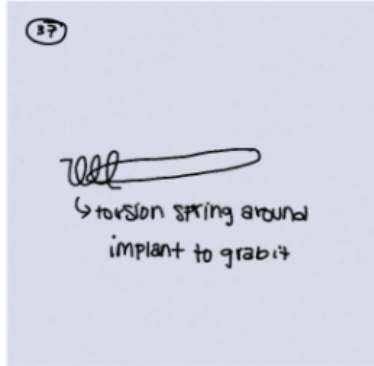
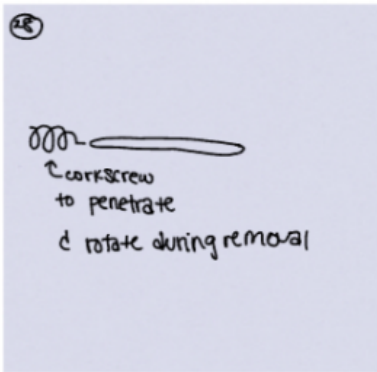
6. Combination Device (Incision + Implant Extraction) - Needle that Grips



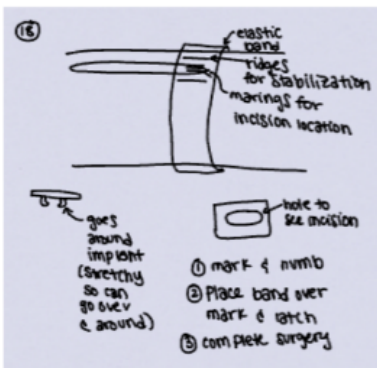
7. Combination Device (Incision + Implant Extraction) - Sharp Hook



8. Combination Device (Incision + Implant Extraction) - Corkscrew



9. End Guider

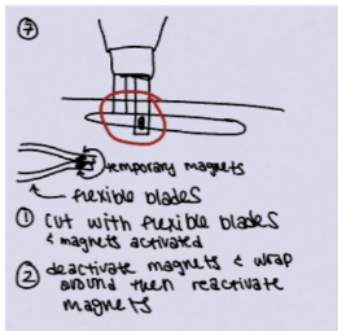


10. Implant Extraction - Magnet

Magnet-like device that is able to gradually pull the implant out of the incision

⑮ Grippy gloves that attach to the implant

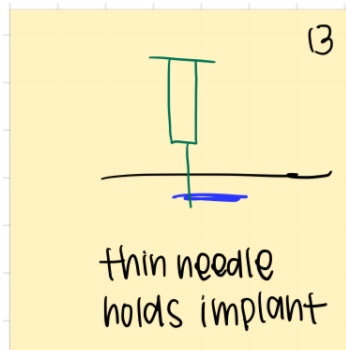
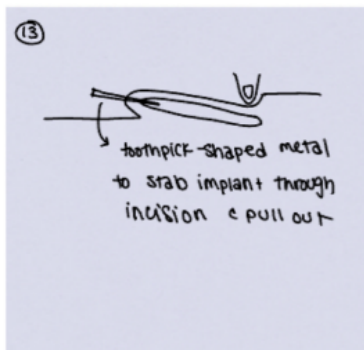
④ Magnet that pulls implant out once the incision has been made



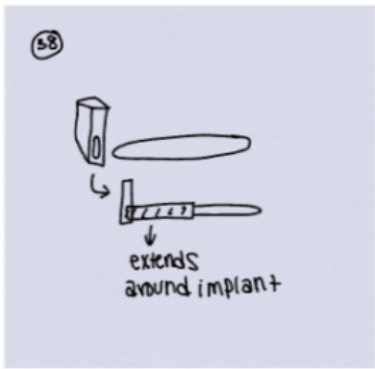
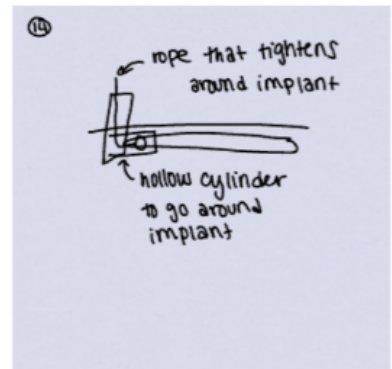
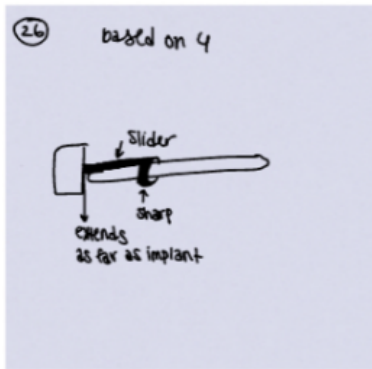
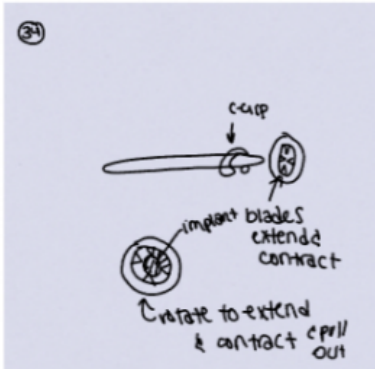
11. Implant Extraction - Lever

⑨ Lever that pulls implant out

12. Implant Extraction - Needle



13. Implant Extraction - Gripper



14. Incision Maker - Flat blade

Solution that cuts a precise incision

Glove that has a scalpel attached

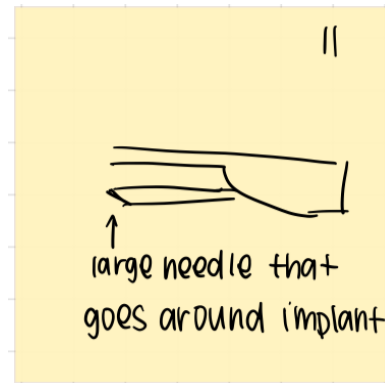


10 special scalpel that feels implant location & cuts in the right spot

15. Incision Maker - Circular blade



16 Circular blade that goes around implant & cuts surrounding skin



16. Incision Maker - Needle

Device with needle prick to make incision to pull implant out of

17. Combination Device (Marking + Incision)

Marks one end of the implant with a pen and makes incision

Dual device that on one side makes a marking and blade can be slid over

18. Location Marking

Needle that can poke a precision marking

Marker that is not wiped off by sterilization substances

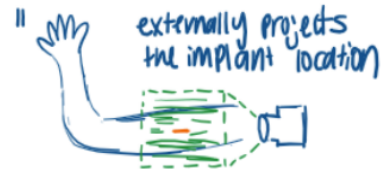
Allows patient to mark the implant and numb the area themselves

19 special marking tool that doesn't wipe away with betadine

19. Implant Location Visualizers

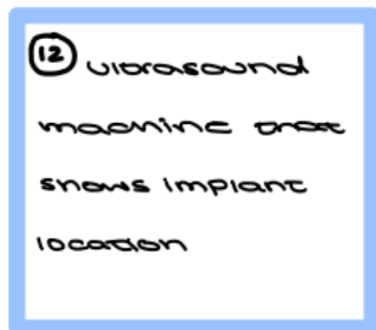
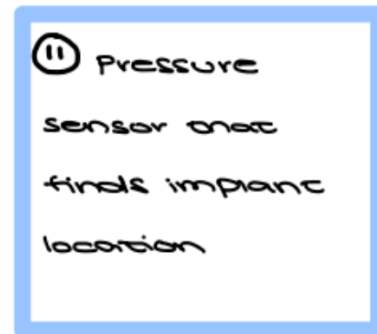
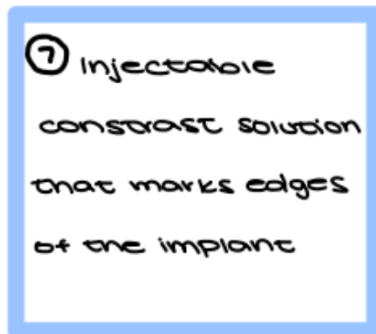
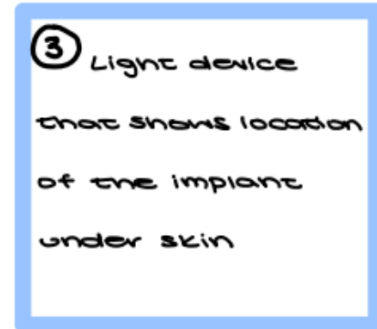
Magnet that is able to locate the implant

Infrared machine that locates the implant

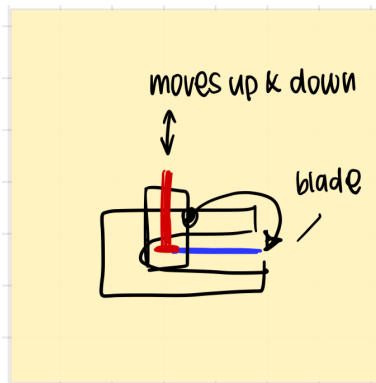
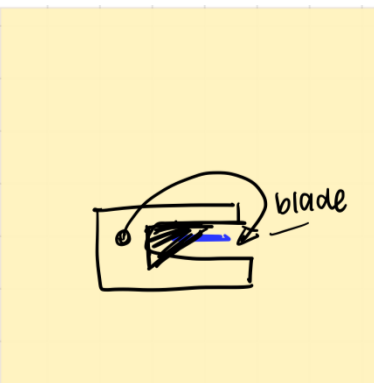
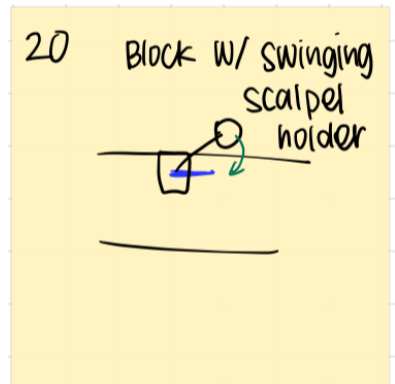
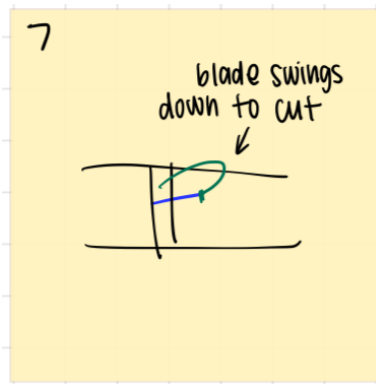
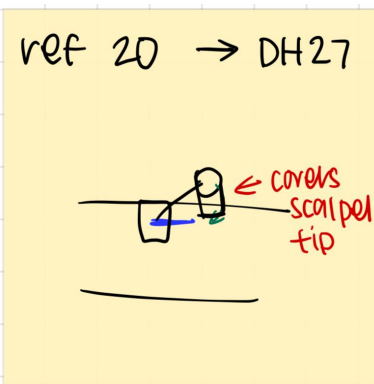
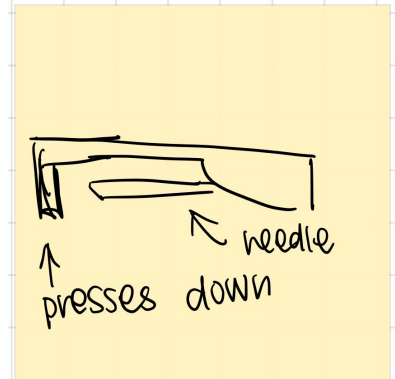
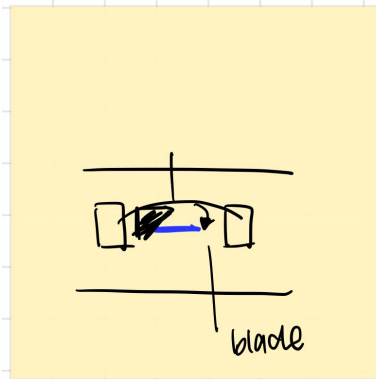
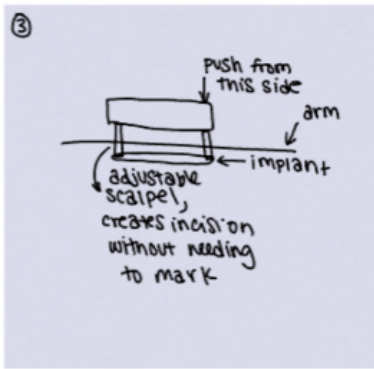


Infrared projection that stays on during the procedure

Solution that shows the start and end of the implant



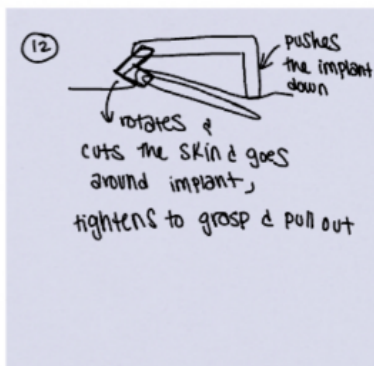
20. Combination Device (Stabilization + Incision)



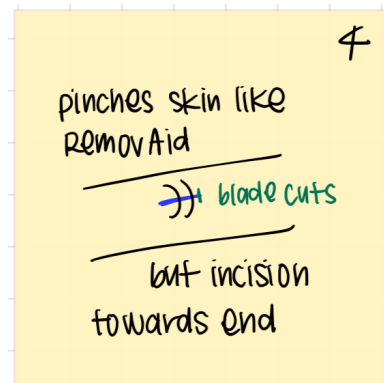
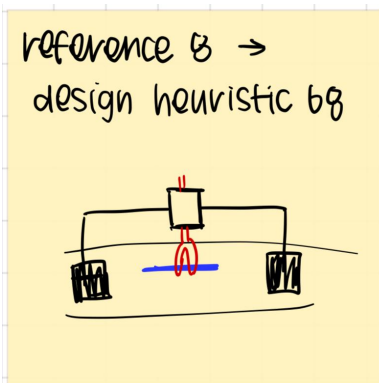
21. Combination Device (Stabilization + Extraction)

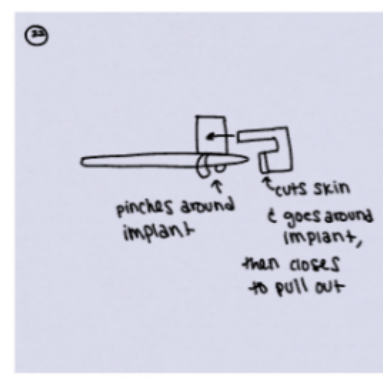
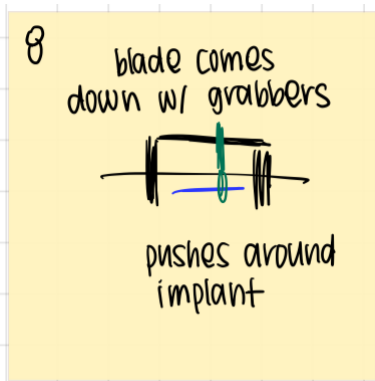
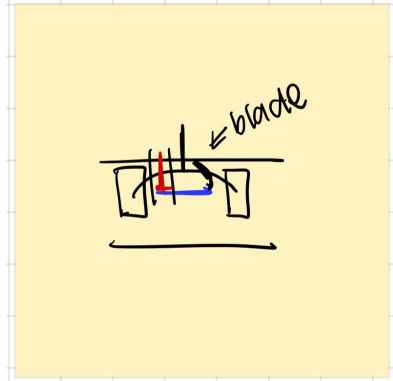
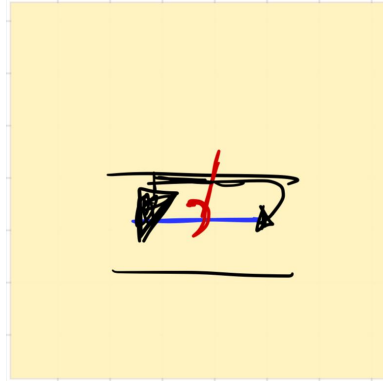
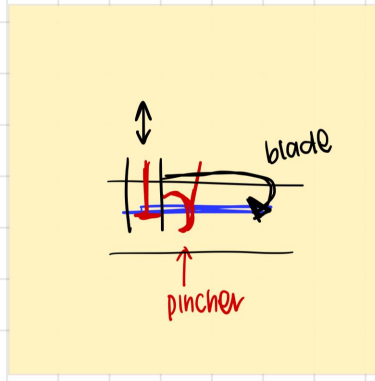


22. All-in-One Devices - Block Stabilization with Circular Gripping Blade



23. All-in-One Devices - Pinching Removal





24. Implant Dissolver

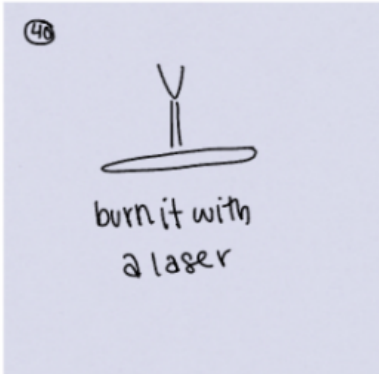
13 Injection
 that dissolves
 implant so body
 can dispose of
 it

12

dissolve with chemicals

flush out with water
 (or remove entire arm)

14 Laser that
 breaks implant
 into small pieces
 that body can
 digest

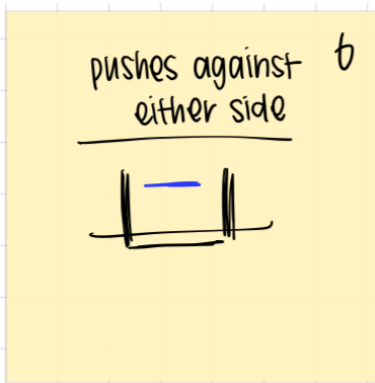


25. Implant Isolator/Skin Tension



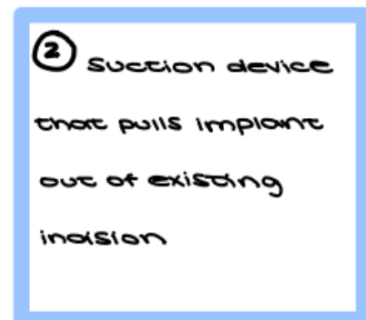
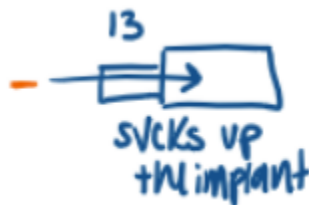
Device that pulls patients skin around the bicep tight

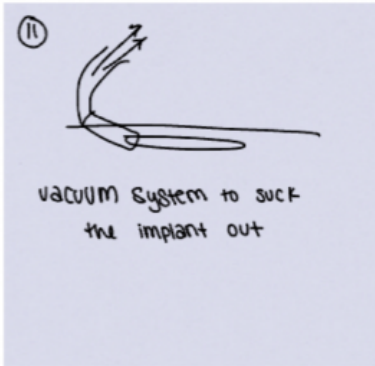
Isolates movement of the implant



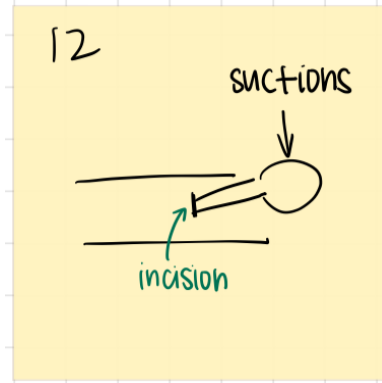
26. Suction

Makes small incision and has vacuum-like function to pull out implant





21 suction device that does one incision as well



27. Miscellaneous

Rubber part can be easily removed and sanitized

Solution that is compatible with/in hemp packaging (3"x3"x3")

Device made out of stainless steel to allow for sterility and reusability

18 change to making incision @ middle of implant

19 squeeze implant out of skin like a pimple



Numbs area in a non-painful method

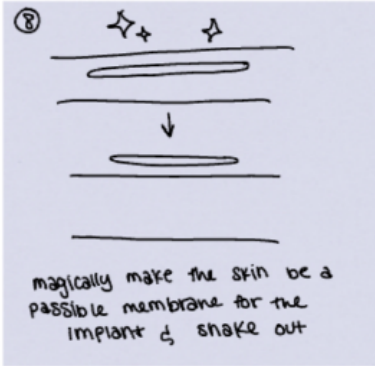
Resting platform for medical professionals hands

Arm strap that keeps patients arm stable

Platform to hold one of the medical professionals arms (the one making the incision)

Create adhesive solution to stick surgical equipment on

22 Remove device using * Magic *



Appendix II: Internal Device Concept 1

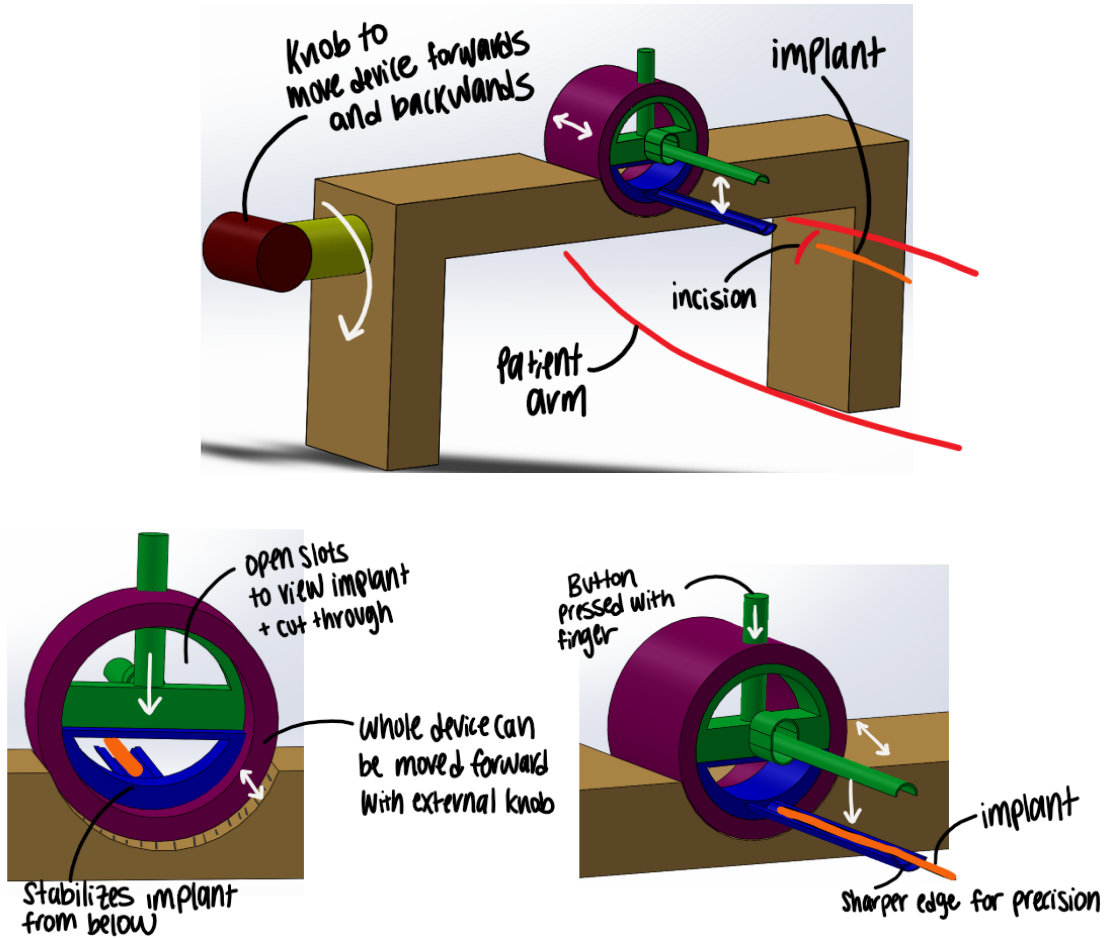


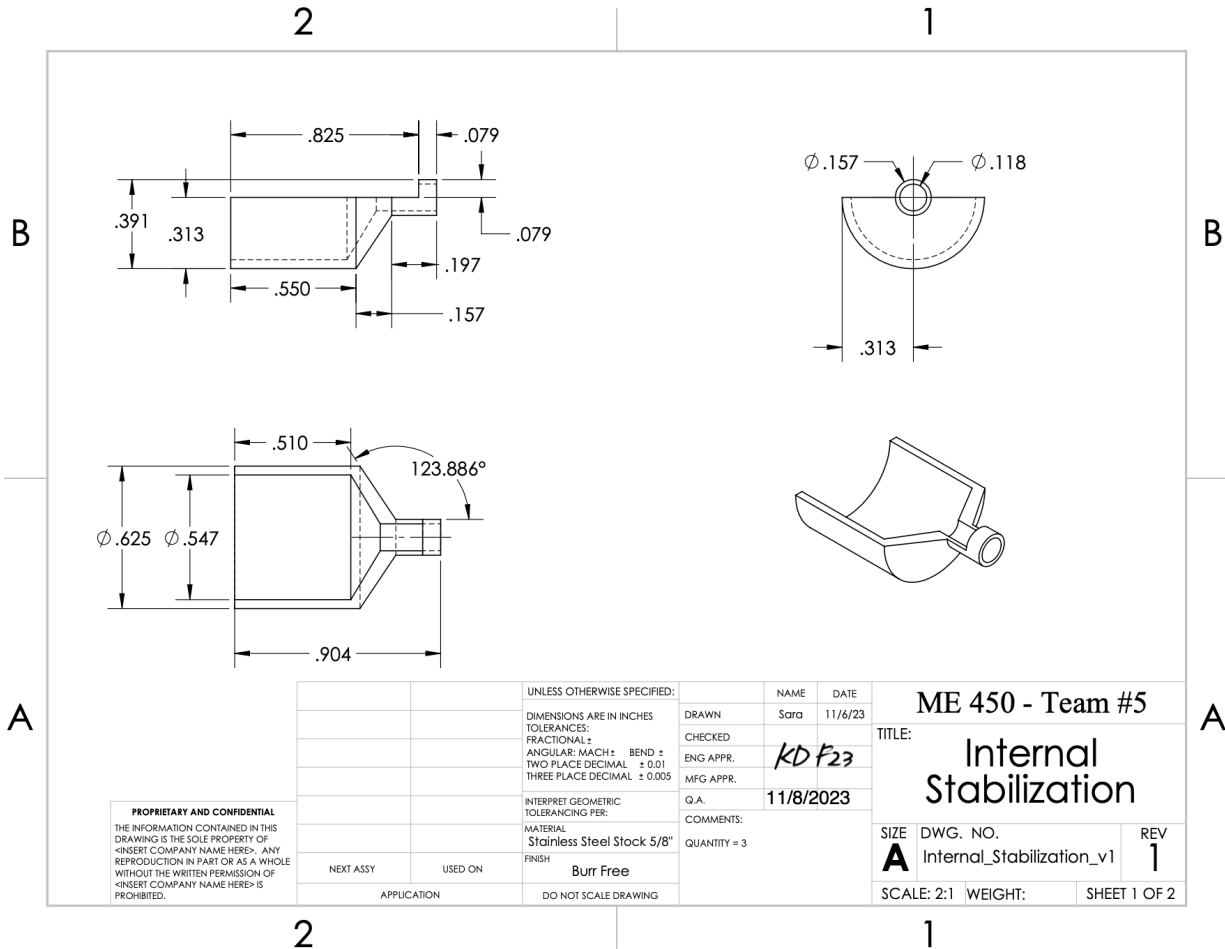
Figure 36. Shreya's internal stabilization concept CAD rendering. This concept is able to make a small incision and is able to clamp down on the implant while still underneath the skin.

Appendix III: Manufacturing Process Selection - Internal Device

The material is 316 stainless steel, mass is less than 0.05kg, minimum section thickness is 1mm, tolerance is 0.05mm, and economic batch size is 5000. Surface roughness is negligible.

Processes compatible with material	Shape	Mass	Section thickness	Tolerance	Surface roughness	Economic batch size
Sand casting		Fails				
Investment casting			Fails			
Centrifugal casting		Fails				
Forging		Fails				
Sheet metal working			Fails			
Powder methods			Fails			
Electro-machining						Fails
Machining						
Additive manufacturing			Fails			

Appendix IV: Manufacturing Plan - Internal Device



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		UNLESS OTHERWISE SPECIFIED:	NAME	DATE	ME 450 - Team #5
		DIMENSIONS ARE IN INCHES	Sara	11/6/23	
		TOLERANCES:			
		FRACTIONAL ±			
		ANGULAR: MACH ± BEND ±	CHECKED		TITLE:
		TWO PLACE DECIMAL ± 0.01	<i>KD F23</i>		Internal Stabilization
		THREE PLACE DECIMAL ± 0.005	ENG APPR.		
		INTERPRET GEOMETRIC TOLERANCING PER:	MFG APPR.		
		MATERIAL	Q.A.	11/8/2023	SIZE DWG. NO.
		Stainless Steel Stock 5/8"	COMMENTS:		A Internal_Stabilization_v1
		FINISH	QUANTITY = 3		REV
		Burr Free			1
NEXT ASSY	USED ON	APPLICATION	DO NOT SCALE DRAWING		SCALE: 2:1 WEIGHT: SHEET 1 OF 2

2

1

MANUFACTURING PLAN

RAW MATERIAL STOCK: Stainless Steel Stock 5/8"

STEP	PROCESS DESCRIPTION	MACHINE	FIXTURE	TOOL(S)	SPEED (RPM)
1	Cut stock to > 1.5" of finish length and deburr (extra length is for mill grip later)	Horizontal Band Saw	-	Deburring Tools	100 ft/min
2	Attatch stock to lathe and clamp with collet	Lathe	5/8" Collet	-	-
3	Reduce length of part to exactly 1.5" more than the final part length	Lathe	5/8" Collet	Turning and Facing Tools	600
4	Use center drill to make inital hole	Lathe	5/8" Collet	Center Drill No. 3	1200
5	Drill hole using peck method to a depth of 2.01" (1.5" excess length + 0.51" hole depth on final part)	Lathe	5/8" Collet	Drill No. 35/64	400
6	Flip part and reattach to lathe and clap with collet	Lathe	5/8" Collet	-	-
7	Reduce outer diameter to 0.157" over a length of 0.197"	Lathe	5/8" Collet	Turning and Facing Tools	600
8	Reduce outer diamer of the subsequent 0.157" of length on a gradient from 0.157" to 0.625" by setting the compound rest at a angle of 56.114 deg and moving it out as we move back on the part	Lathe	5/8" Collet	Turning and Facing Tools	600
9	Use center drill to make inital hole	Lathe	5/8" Collet	Center Drill No. 3	1200
10	Drill hole using peck method through all	Lathe	5/8" Collet	Drill No. M3	600
11	Deburr all holes and the rest of the part	Lathe	5/8" Collet	Deburring Tools	600
12	Attatch part to mill and find datum	Mill	Vise	Edge Finder	1000
13	Mill down one side of the part leaving a 0.79" lip on the small end	Mill	Vise	Shaft Fixture, End Mill	1100
14	Cut down excess 1.5"	Horizontal Band Saw	-	-	100
15	Deburr the entire part	-	-	Deburring Tools	-

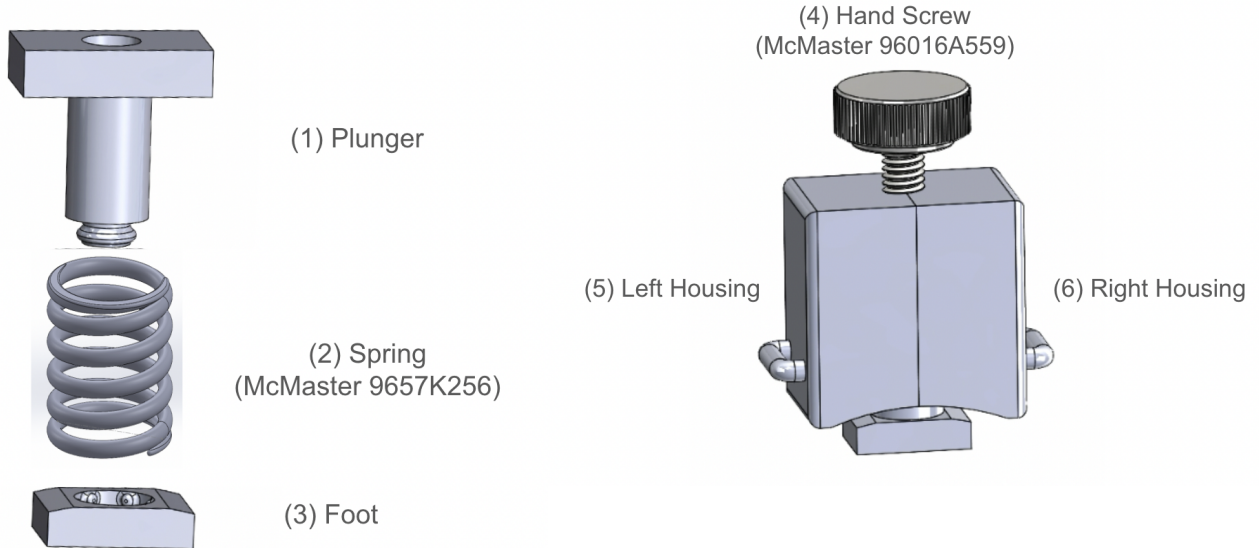
SHEET 2 OF 2

2

1

Appendix V: Assembly of External Device

After printing the parts, the assembly of the external device with the following 6 parts can be completed as follows:



- i) Slide the spring (2) onto the shaft of the plunger (1).
- ii) Snap-fit the foot (3) onto the base of the plunger (1).
- iii) Fit the plunger assembly (includes the plunger, spring, and foot) into the left housing (5) internal cavity. Make sure the end of the spring is inside the cavity.
- iv) Use epoxy in the press-fit holes of the housing. Press fit the right housing (6) over the plunger assembly and into the left housing.
- v) While clamping the housings together, thread the hand screw (4) into the top hole. Ensure that the hand screw can be screwed and can move the plunger.

Appendix VI: Device Manufacturing Cost Calculations

All calculations were done based on ME452 slides [57], [58].

Internal Device Machining Costs:

$$C_m = R \left(\sum_{j=1}^{N_{\text{setup}}} t_{S_j} + \sum_{j=1}^{N_{\text{feature}}} t_{m_j} \right) \quad \text{Assume 5000 created}$$

Machine / Operator Cost:

$$R = \$0.0167 / \text{s} \rightarrow \text{based on a } \$60 / \text{hr price}$$

Non-productive time:

Workpiece weight: 0.165 lb \rightarrow work within 0 - 0.2 lb range

Loading / Unloading time:

Collet: 10.3s

Chuck: 16.0s \rightarrow Total: 39.8s

Vise: 13.6s

Time for tool engagement:

$$9 \text{ (manual lathe)} \cdot 8 \text{ (operation steps)} = 72\text{s} \quad \Rightarrow \quad 132\text{s}$$

$$30 \text{ (milling machine)} \cdot 2 \text{ (operation steps)} = 60\text{s}$$

Basic + additional setup time:

$$1.2 \text{ h (lathe)} + 0.2 \text{ h} \cdot 4 \text{ (tool switch)} + 1.5 \text{ h (mill)} + 0.17 \text{ (bandsaw)} = 3.67 \text{ h}$$

$$t_s = 39.8 + 132 + 3.67 \cdot 3600 / 5000 = 174.44\text{s}$$

Feature machining time:

Operation	Tool Type (HCD)	Dimension (in.) <i>hw</i>	Dimension (in.) <i>da</i>	Dimension (in.) <i>db</i>	Volume (in ³) <i>vm</i>	Specific Cutting Energy (hp min/in ³) <i>ps</i>	Available Power (hp) <i>Pm</i>	Machining Time Max Power (s) <i>tmp</i>	Rate of Surface Generation (in ² /min) <i>vf</i>	Milling Feed Speed <i>vf</i>	Area (in. ²) <i>Am</i>	Machining Time Recommended conditions (s) <i>tmc</i>	Time Corrected for Tool Wear (s) <i>tm</i>	Time Corrected for Extra Tool Travel (s) <i>t'm</i>
Drill	C	1.904	0.625	0.625	0.120	1.35	0.103	94.58	5.64	-	0.235	2.50	94.5757627	152.5265977
Rough lathe	C	1.904	0.625	0.16	0.056	1.55	0.103	51.17	-	48	-	0.25	51.17074246	82.52536407
Finish lathe	C	1.904	0.16	0.157	0.00015	1.55	0.103	0.13	-	28.8	-	0.41	4.124849099	6.652330165
Drill	C	1.904	0.157	0.157	0.004	1.35	0.103	3.05	1.786	-	0.019	0.65	3.057028538	4.930207789
Taper	C	1.904	1.57	0.157	0.02256	1.55	0.103	20.44	-	48	-	0.20	20.44349511	32.97014652
Mill	C	1.904	0.625	0.313	0.025	1.55	0.103	23.00	-	41	-	1.21	22.99564603	37.08611541
Total														316.6907617

$$t_m = 316.69\text{s}$$

$$C_m = R(t_s + t_m) = 0.0167(174.44 + 316.69) = \$8.20$$

External Device Injection Molding Cost:

$$C_{im} = \frac{C_r t_s}{3600n} + \frac{C_{md}}{N_t}$$

Machine Operating Cost:

$$n = 1, V = 8.4 \text{ cm}^3$$

$$f_r = 145.63 V^{-0.485} = 145.63 \cdot 8.4^{-0.485} = 51.88$$

$$A_p = 2.4 + 1.55 = 9.55$$

$$P_j = 965, D = 1 \text{ cm}$$

$$F \geq 0.01 A_p (1 + f_r) n \cdot 0.5 P_j = 70$$

$$V_s \geq V (1 + f_r) n = 12.75$$

$$L_s \geq 2D + 5 = 7 \text{ cm}$$

Pick 300 kW machine

$$\rightarrow C_r = \$28/\text{h}$$

Cycle time:

$$t_s = t_f + t_c + t_r$$

$$t_f = 0.0002 V (1 + f_r) n \cdot P_j / P_j = 0.447$$

$$t_c = \max \left\{ 3, k \frac{h_{\max}^2}{\pi^2 \alpha} \ln \frac{4(T_i - T_m)}{\pi(T_x - T_m)} \right\} = 84.5$$

$$t_r = 1 + 1.75 t_d \sqrt{(2D + 5) / L_s} = 2.76$$

$$P_j = 5.5 \text{ kW} \quad k = 1$$

$$h_{\max} = 5 \text{ mm}$$

$$T_i = 218 \quad t_d = 1.7$$

$$T_m = 38 \quad L_s = 20$$

$$T_x = 88$$

$$\alpha = 0.08$$

$$t_s = 87.658$$

Mold Cost:

$$C_{md} = C_b + C_{cl} n^{0.7}$$

$$A_d = 19 \cdot 17.5 = 332.5, h_d = 16$$

$$C_b = 1000 + 0.45 A_d h_d^{0.4} = 1453.58$$

$$C_{cl} = R(M_e + M_{po} + M_x + 65 n_s + 150 n_i + 250 n_u + M_s + M_t + M_{tex} + M_p)$$

$$R = \$60/\text{hr}$$

$$n_s = 1, n_i = 0, n_u = 0$$

$$M_e = 2.5 A_p^{0.5} = 7.72$$

$$M_{po} = 5 + 0.085 A_p^{1.2} = 6.275$$

$$M_x = 5.83 (X_i + X_o)^{1.27} = 33.91$$

$$X_i = 0.1 N_{sp} = 2$$

$$X_o = 0.1 N_{cp} = 2$$

$$M_s = f_s (M_e + M_{po} + M_x) = 4.79$$

$$M_t = 0$$

$$M_{tex} = 0.05 (M_e + M_{po} + M_x) = 2.395$$

$$M_p = f_p A_p^{0.5} = 3.86$$

$$C_{cl} = 7437 \rightarrow C_{md} = 8890.98$$

$$N_t = 5000$$

$$C_{im} = \$2.46$$