Self-Retaining Retractor for Enhanced Surgical Visualization

Team 4 - MECHENG 450 - Fall 2024

Diego Montemayor, Arushi Narayanan, Aryan Rose & Audrey Safir
Dr. Julia Kramer
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Executive Summary

For over 100 years, Korle Bu Teaching Hospital has trained medical professionals in resource-constrained areas of Accra, Ghana. Through the Global Health Design Initiative (GHDI) at the University of Michigan, students traveled to Korle Bu to identify the hospital's needs within the Obstetrics and Gynecology (OB/GYN) department. One identified issue was difficulty viewing abdominal cavities during laparotomies. Our team of student engineers at Michigan was then employed to design a self-retaining retractor, which holds abdominal cavities open during surgeries.

Dr. Dhanu Thiyagarajan (Dr. Thiyag), an OB/GYN for Michigan Medicine working at Korle Bu, sponsors the project and has weighed in on design requirements including ease of use, limiting cavity closing during surgery, patient safety, and patient adaptability. We meet weekly with Dr. Thiyag via Zoom to share design updates and gain the perspective of an OB/GYN who would use the device. Furthermore, engineering professors facilitate us through the design process, including problem definition, concept generation, and solution verification.

The problem has been defined as creating a durable retractor that is self-retaining, easy to use, and inexpensive. We have benchmarked current retractors, including the Balfour and Thompson models, which are used at Korle Bu, and identified a conflict between affordability and functionality. To address both issues, we needed a design that could withstand the force of various cavity sizes while remaining within Korle Bu’s budgetary constraints. To quantify these objectives, we created a table of requirements and specifications. High-priority requirements were identified as ease of use, durability, and safety.

After defining our problem, we transitioned to concept generation. We started with individual brainstorming and developing a functional decomposition chart, with “retract tissue” defined as the primary retractor function and stability, surgical efficiency, and adjustability as important subfunctions. Next, we compared our ideas, which were placed into six categories based on their retractor methodologies. The categories were then presented to Dr. Thiyag, who indicated an inflatable, circular, or jig solution would be most useful to her and other OB/GYNs at Korle Bu. Using a Pugh chart, we selected the circular model for our alpha design, which included an inner rail system for adjusting blade positions.

After finding critical flaws in our alpha design, we moved to a “camera shutter” model that converts rotational motion into radial, linear motion and can retract eight blades with one movement. We then selected our most critical requirements and outlined methods for validation and verification, including hand calculations, finite element analyses, and manufacturing a build design. Our testing revealed that we met nearly all of our requirements and specifications, including safety, ease of deployment, and cost, remaining below $2 per use. However, our high priority ease of handle only minimally passed our requirements, and our vertical clamps proved difficult to manufacture and did not adequately constrain the plates. To address these issues, we outlined our recommendations for future works including new vertical constraints and locking mechanisms as well as testing methodologies that incorporate end users.

Abstract

During laparotomies (abdominal open surgeries) medical professionals struggle with clear and consistent cavity visibility, especially in resource-constrained environments. Current retractors enhance abdominal access but struggle with adaptability to patient sizes, easy sterilization, and low costs. We aim to enhance surgical efficacy by developing and testing a self-retaining device that is versatile, easy to use, and affordable. The device will reduce the necessary personnel while ensuring patient safety and simple sterilization. By addressing these issues, the retractor will be deployable in low and medium-income hospitals including Korle Bu Teaching Hospital in Accra, Ghana.

Project Summary

This project details the creation of a self-retaining retractor to increase surgical efficacy during laparotomies (abdominal surgeries) for the OB/GYN department at Korle Bu Teaching Hospital. During laparotomies, surgeons must cut incisions along the abdominal cavity. Surgeons employ retractors to hold the incisions open and enhance cavity visualization.

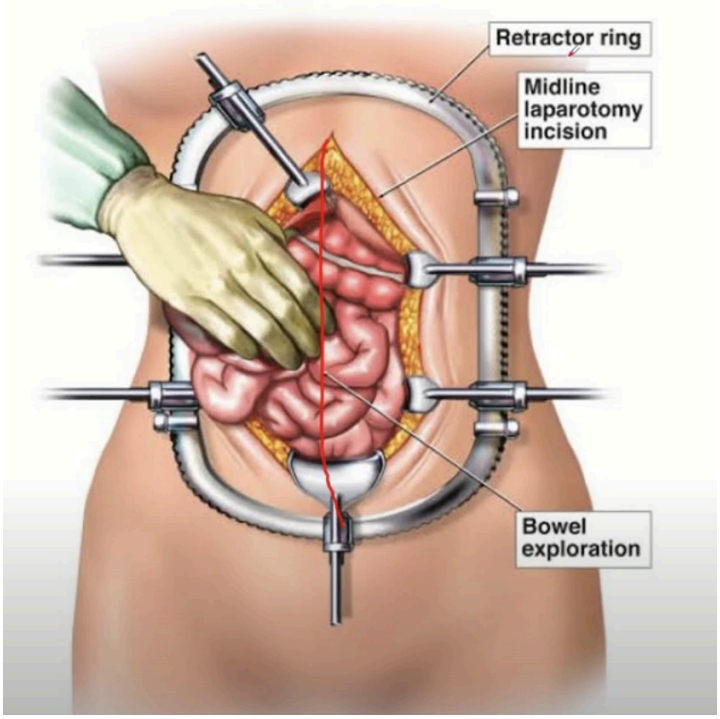


Figure 1. Laparotomy example with Bookwalter retractor [12]

While current solutions exist, they struggle with high prices and a lack of adaptability to patient sizes. These issues become particularly marked in resource-constrained hospitals, such as Korle Bu, which has limited retractors and staffing and a time-consuming sterilization process. Two current self-retaining designs are the Balfour and Thompson models.

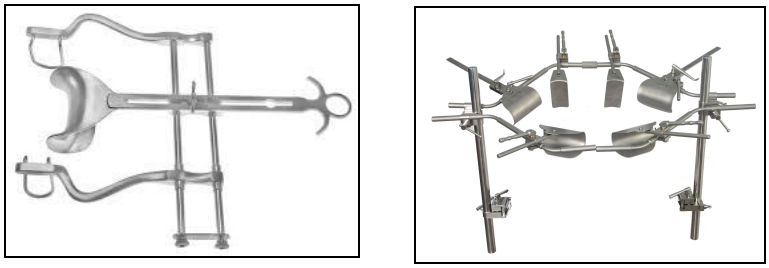


Figure 2. Balfour Retractor [33] (Left) and Thompson Retractor [34] (Right)

The Balfour retractor is free-standing and offers easy handling and deployment. However, the Balfour retractor struggles to adapt to larger patients due to shallow blades and often requires three medical professionals to use. By contrast, the Thompson retractor addresses the issue of patient size and reduces the needed personnel to two people, yet is difficult to assemble, costly, and takes four hours to sterilize [11]. Consequently, surgeons have communicated a need for a retractor that is cost-effective, adaptable, and easy to sterilize.

The new self-retaining retractor will accommodate unmet needs through interviews with medical professionals (including OB/GYNs at Korle Bu), exploration of innovative designs and materials, and prototyping concepts. Through these methods, the retractor will address the problem of adequate cavity visualization while also adapting to patient sizes and minimizing costs to resource-constrained hospitals.

Motivation

This project is motivated by the principle that healthcare is a human right [11]. However, disparities in class, support, time, and knowledge can bar patient treatment. To address this gap, Korle Bu Teaching Hospital trains medical professionals in understaffed and resource-constrained areas of Accra, Ghana. However, Korle Bu still struggles to meet patient needs due to understaffing, inadaptability of current surgical tools, and cost restraints. We seek to design a retractor that meets Korle Bu's functional challenges and expands healthcare access for everyone.



Figure 3. Korle Bu Teaching Hospital Staff [24]

Introduction

Our project is rooted in the relationship between a sponsor and a team of mechanical engineering students both seeking to promote equitable healthcare. Our sponsor is Dr. Dhanalakshmi Thiyagarajan (Dr. Dhanu Thiyag), an OB/GYN with Michigan Medicine currently working at Korle Bu Teaching Hospital in Accra, Ghana. Dr. Thiyag has communicated the need to improve the surgical outcomes of laparotomies at Korle Bu Teaching Hospital. Currently, Korle Bu only has five reusable retractors (including the Balfour and Thomspon models) which each take multiple hours to sterilize [11]. Furthermore, the current retractors require at least two people to hold a cavity open during surgery and often cannot accommodate patients with higher BMIs due to having shallow blades. However, Korle Bu OB/GYNs perform between five and fifteen surgeries daily, some of which are emergencies, and only have two to three staff members available for each procedure [11]. These surgeries can be further delayed due to difficulty deploying complex retractor mechanisms as well as face additional constraints if a retractor breaks after minimal usage and sterilization. Therefore, there is a need for a self-retaining retractor that is cost-effective, durable, easy to sterilize, and quickly deployable.

Our project will have succeeded if we can design a product that can last three to five years while remaining below Korle Bu's maximum budget of $450 [11]. To accomplish this, we first benchmarked currently used retractors and analyzed how they were and were not meeting the needs of OB/GYNs at Korle Bu. Next, we created a table of requirements and specifications to quantify how our retractor must perform, highlighting which requirements are most critical to the product's success. We then individually generated concepts to meet our requirements and specifications, shared and categorized our concepts, and then selected an alpha design to further refine and ultimately analyze and test in the future. While beginning our verification and validation process, we realized that our alpha design failed to meet the critical requirement of adaptability to patient sizes. Therefore, we transitioned to a final design that converts a single rotational motion into radial linear motion for eight attachable blades. We then created a table of validation and verification methods for our critical requirements and specifications, which includes hand-calculations, virtual finite element analyses, and 3D printed and manufactured models. To date, the final design has been verified as autoclavable and meeting ISO biocompatibility standards, meeting important safety requirements.

Background

Surgeons use retractors to maintain visualization of the surgical field (abdominal opening accessed by the surgeon) during laparotomies. A laparotomy is any surgical procedure that involves making a large incision along the abdomen. This incision can vary depending on what specific procedure is being performed, meaning the methods of holding the cavity open must adapt to various widths and body locations. For OB/GYNs, a safe and reliable retractor can be especially critical for procedures such as Cesarean sections, which involve engagement with infants. Our goal is to create a retractor that allows clear access to the surgical field, solving the current problem of inadequate visibility. Furthermore, our retractor aims to adapt to larger patients, reduce high retractor prices, and remain reusable over several years.

The retractor industry is largely populated with hundreds of surgical retractors addressing various procedures and surgical field positions. With so many available alternatives, we may encounter difficulty creating a unique solution. However, our project also considers adaptability to larger patients, which all hospitals struggle with regardless of available resources and is often disregarded as an irrelevant factor [10]. By understanding how a retractor can work for everyone, we hoped to relearn the fundamentals of what a retractor should do without dependence on current solutions. We used our understanding to inform a list of requirements and specifications that quantified the needs outlined by our sponsor. During our knowledge collection process, interviews with OB/GYNs were particularly critical to understanding their unique needs and safety considerations. These considerations helped guide us in generating and selecting concepts for new retractors to best meet user needs as well as determine how to verify our requirements.

Benchmarks

Before making our requirements and specifications list, we researched commonly used retractors. We found it helpful to understand how each retractor functioned, analyze their specific successes and failures, and see how they can inform or add context to our project. For our analysis, we considered retractors used at Korle Bu (Balfour and Thomspon models) as well as solutions employed at Michigan Medicine. The retractors below can be applied to different OB/GYN procedures; however, for more intensive surgeries, especially including larger patients, smaller retractors (Ex: Balfour, Weitlaner, Panniculus) will not be able to withstand the necessary force to hold the abdominal cavity open and must be assisted or replaced by larger retractors. Conversely, to account for potential patient injury and recovery time as well as ease of use, larger retractors (Ex: Thompson, Bookwalter, Titan) may be excessive for smaller surgeries. This tension emphasizes the importance of adaptable solutions that can be tailored to multiple surgeries (Ex: Alexis).

Alexis Retractor

The Alexis retractor serves as a simple yet effective laparotomy retractor [3]. Despite lacking reusability, it accommodates complex movements by implementing plastic wrap around a plastic ring that allows tightening and loosening. The Alexis keeps one ring inside the patient to keep the plastic wrap pressed against the walls of the opening, and one ring outside the patient to allow for adjustability. It provides 360-degree protection, allowing clear visualization with the transparent plastic and maximizing the size of the opening with even pressure across the opening. On average it costs around $75 but there are varying sizes.

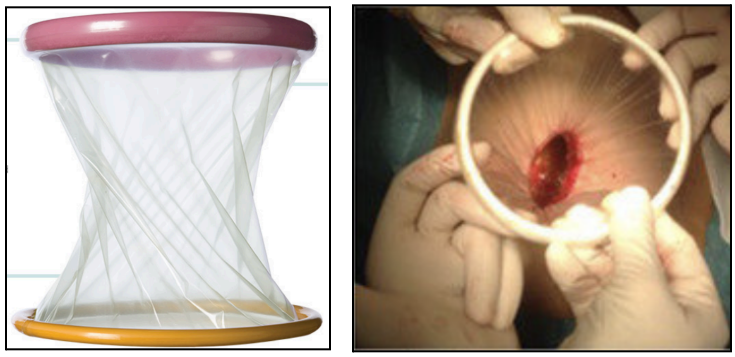


Figure 4. Alexis Retractor [3]

Balfour Retractor

The Balfour retractor serves as a baseline self-retaining retractor for the market, commonly thought of as a basic option for retractors [33]. With a $330 base cost, the Balfour offers three points of contact for the opening, with some blades fixed and others dynamically adjusted for the patient's needs. Balfour's typically have a 25 cm opening with 10 mm depth.

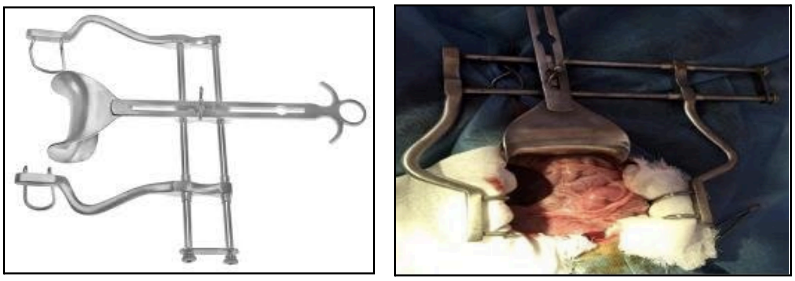


Figure 5 Balfour Retractor [33]

Thompson Retractor

The Thompson retractor is a large ring-like retractor that serves as a sort of rim for retractor blades to be fixed to maintain the opening of the patient [34]. It is much wider than the Balfour, boasting a 35 cm spread and 25 mm depth, which essentially covers the entirety of any patient. However, it struggles with installation as it needs to be fixed to a table for usage. A typical Thompson retractor will cost around $1700.

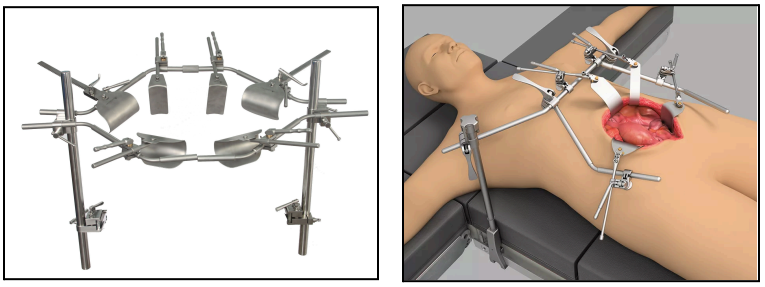


Figure 6. Thompson Retractor [34]

Bookwalter Retractor

The Bookwalter retractor is a self-retaining table mount retractor similar to the Thompson, maintaining a ring that fixes the surgical table and retractor blades that are fixed to that ring [6]. The Bookwalter uses a ratchet system to move the retractors up and down the ring base to allow for adjustment, and its single point of attachment to the table enables it to shift the location of the plane that it establishes. It provides roughly the same opening width as the Thompson and costs around $2000.

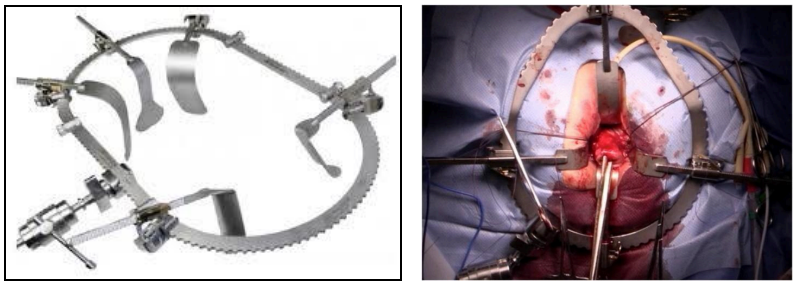


Figure 7. Bookwalter Retractor [6]

Weitlaner Retractor

The Weitlaner retractor is a self-retaining retractor that resembles a pair of scissors, with prongs at the end and a locking mechanism [38]. They are typically around 7 inches long with a 7-inch spread. The average cost is around $130, and the locking mechanism works with a ratchet to provide an easy self-retaining device.



Figure 8. Weitlaner Retractor [38]

Panniculus Retractor

The Panniculus (pannus) retractor is not specifically designed for incisions in laparotomies but works to shift the panniculus, which is the excess skin and fat below the abdomen that may interfere with post-operative wound healing [2]. It works as a sticky sheet of soft plastic that squishes the panniculus inwards, and due to the nature of it as a product, it works as a one-size-fits-all.

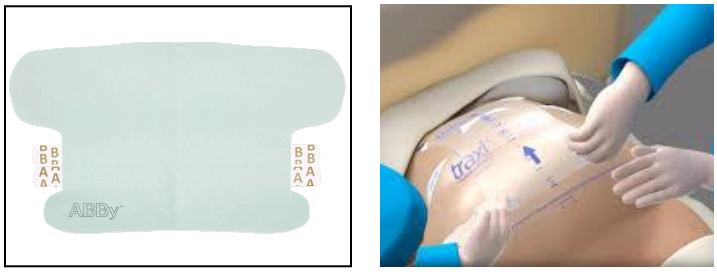


Figure 9. Pannus Retractor [2]

Titan Retractor

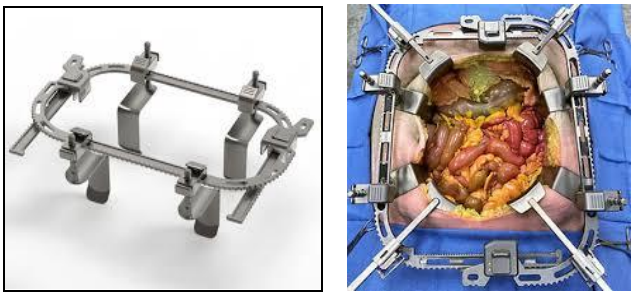


Figure 10. Titan Retractor [41]

The Titan retractor is a self-retaining retractor that fixes blades to an adjustable outer ring [41]. Four large, flat blades hold open the cavity, then attachable, smaller blades retract specific organs as needed. The blades are affixed to the outer ring using a clip mechanism, and the ring is compatible with Bookwalter attachments. The Titan retractor is additionally free-standing, eliminating complications associated with assembly and deployment with table-standing retractors. However, while the modularity of the Titan retractor is a strength, it can also create extra steps for the user to retract tissue. Furthermore, the retractor is made of titanium, while lighter than stainless steel is more costly per pound. The total Titan price is only available via appointment, but due to its size and modularity, we expect the price to be comparable to the Thompson and Bookwalter retractors.

Summary

These benchmarks serve as both a point of understanding for what retractors must accomplish as well as an industry standard for what is expected of retractors in a surgical setting. Whatever solution we have to the problem must not simply just do what these are doing, but to a degree, it should do it differently or better in some capacity. They help us establish our goals for this project, which is to improve on the ease of use and adjustability, while also hitting the sterilization and other standard targets that all current retractors meet.

Information Sources

Our sources are purposefully widespread with a few intentions behind that spread. The primary intention is that retractors are widely used, which means that many different people have encountered different issues and solutions, most of which we need to understand to properly solve the problem. The secondary intention is to access different kinds of information, primary sources are useful to answer specific questions but they may not always be ideal for measurable specifications and numbers, as well as engineering standards that need to be referenced. These standards are mostly related to medical devices, their weights, curvature, strength, and biocompatibility, later shown in our requirements and specifications.

Our primary sources are largely people related to the project handoff, specifically our sponsor Dr. Dhanu Thiyag who is a doctor with Michigan Medicine at Korle Bu Teaching Hospital who is ingrained in this problem currently and invested in seeing through a solution. Another primary source is some of the Michigan Medicine students who scoped out this project beforehand, developing the initial problem statement. Our secondary sources are online sites

from medical associations and organizations like the National Institute of Health or medical device companies that have created existing retractor solutions. These sources range from information about skin mechanics and biology to current retractor solutions and specifications about current retractors. There are also opinions, such as articles on different retractors and their benefits and needs. Finally, there are actual engineering specifications, such as ISO 10993 [15] and ISO 21920 [16], which outline medical device specifications and product surface profiles.

Between the first and third design reviews, new information sources have been specific to updating our engineering standards and verification/validation methods, while our holistic understanding of the problem, including the human impact, has been formed through discussions as a team and with our sponsor, Dr. Thiyag. We determined the feasibility of certain ideas through long-form discussions and pursued ideas based on sponsor preference to establish a set of ideas and alpha design as well as transition to our final prototype.

Design Process

Our design model utilizes elements from the Dym and Little definition of the design process [39]. According to Dym and Little, design models should be stage-based and linear. These stage-based ideals make Dym and Little's model problem-oriented; in the model, the designer must first define and understand a given problem before realizing any solutions. Similarly to Dym and Little, we follow the linear steps of problem definition, concept exploration, and solution development and verification as shown below:

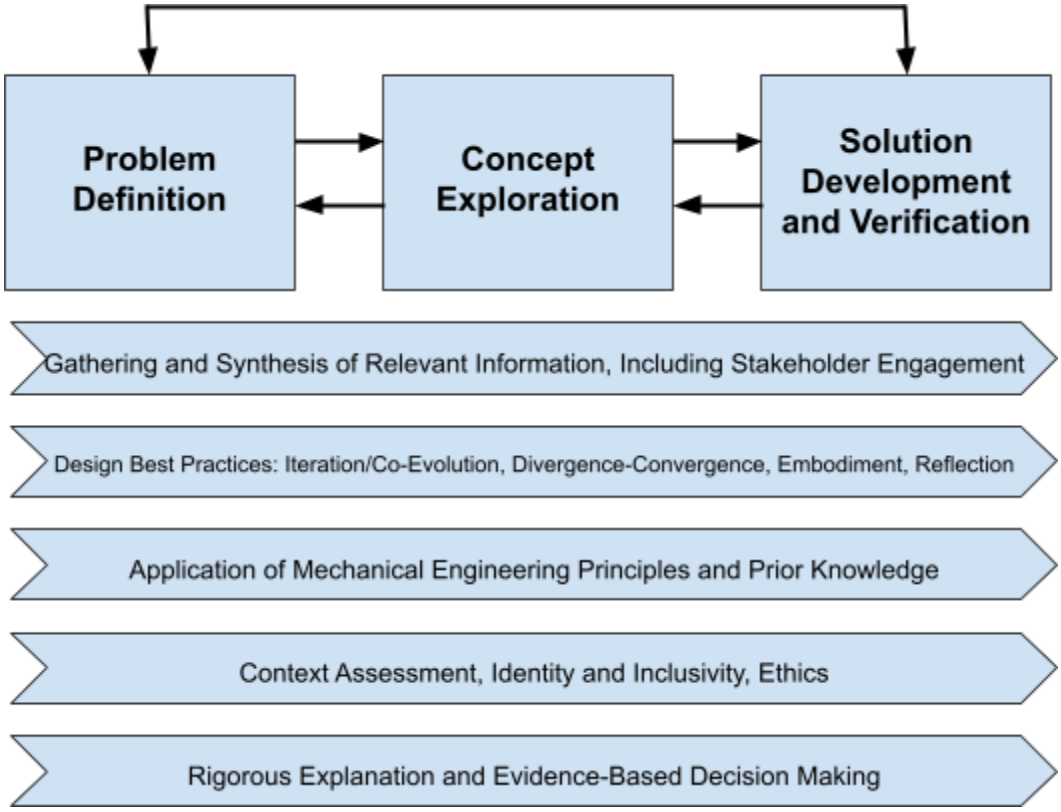


Figure 11. Design Process blocks for our project [44]

While our model's steps are similar to Dym and Little's, we also incorporated activity-based ideals that allow the ability to move between steps throughout the process. We believe that all steps in the design process should inform each other and not be limited to a specific time slot. There is always more to learn at any phase of the project, and testing failures can inform previously unconsidered problems. Therefore, while our model includes problem-solving as its first "linear" step, it ultimately encapsulates both solution-oriented and problem-oriented ideas as the design can be reconsidered throughout the engineering process, especially after receiving feedback.

Furthermore, our model acknowledges that with increased problem knowledge, there can be a decreased opportunity for making design changes, a critical flaw in the Dym and Little

model. This acknowledgement is accomplished by exploring concepts beyond an engineering scope including the identity, inclusivity, and ethics of our problem as well as having steps beyond the ability of problem definition that require evidence-based decision making. In fact, during our concept exploration phase, we presented preliminary ideas to other senior capstone teams with no prior knowledge of our project or its mission. Therefore, we were able to gain objective feedback on our engineering work without involving medical professionals who have previously worked with retractors.

After gaining new insights from lectures in our senior capstone class, we considered adding an extra step between problem definition and concept exploration called “Identify Constraints.” This step would mean that constraints would only be listed after the project had fully been defined with the intention of not letting those constraints guide our research. However, we found that especially in the context of an underfunded hospital, constraints such as funding and staffing were part of the problem definition itself and hence had to be understood in that section. Therefore, we stayed with the original capstone model and will continue to execute the steps outlined in the ribbons.

Our design process changed during our concept generation step by adapting to group preferences versus directly following what is written in the model. During problem definition, there was limited flexibility in how we researched the problem and engaged with our stakeholders; feasible possibilities were limited to reading articles and interviewing medical professionals. However, while we followed the brainstorming methodology of iteration/co-evolution and divergent and convergent thinking, we decided how we wanted to categorize our ideas and created our rating system for determining which solution to pursue. Therefore, while the capstone model still acts as an overarching guide for the project, we have now experienced creating sub-steps that expand beyond what was provided by the course.

For Solution Development and Verification, we returned to following our outlined design process as this phase requires substantive evidence that our product works as desired. We followed the ribbon of applying mechanical engineering principles and prior knowledge, including methods learned in previous engineering courses. Furthermore, we ensured our tests were extensive and evidence-based, allowing us to make informed decisions as we continued to iterate through the design process.

Design Context

Stakeholder Analysis

Retractors are very commonly used throughout most surgeries, which makes them a wide-scope product in use throughout the surgical industry. As a result, there are many stakeholders for our project as retractors are widely used and affect the lives of people who work in or engage with the healthcare industry, even if they are patients or experienced surgeons. While we have many stakeholders, each one holds a different stake in the project. Where surgeons may care about ease of use, patients may care more about safety and cost per use. On top of that, the addition of another retractor to the market can have negative effects on organizations such as medical device companies that are competing with us or hazardous disposal companies that may not be equipped to handle our new product which may subsequently have an environmental impact.

Besides the visual on the next page, our stakeholders can be categorized in a few different ways, but for this review, we will be categorizing them using influence and power within the project on a binary high/low scale. It is also worth noting that each stakeholder holds different importance to the project, which is why the following table has generally been ordered for relevance, with the most important stakeholders at the top of the list and the less important stakeholders closer to the bottom. This categorization serves as a useful metric for us to weigh concerns and considerations across different stakeholders, especially when we receive conflicting viewpoints or considerations about our potential solution and we have to decide if the advice we receive is worth incorporating or is simply worth consideration.

The following table is a stakeholder engagement and relevance chart that outlines our most relevant stakeholders and how they will contribute to our project.

Table 1. Stakeholder Impact Table

Stakeholder Name	Impact	Influence	Stakeholder Interests	Potential Contribution	Potential Resistance	Engagement Strategy
Dr. Thiyag (Sponsor)	High	High	Low-cost, versatile and functional end product	Provide knowledge and expertise	Adding requirements	Weekly meetings
Dr. Kramer (Mentor)	Low	High	Successful design process	Project guidance	Shifting project focus	Weekly meetings
Korle Bu OB/GYN Surgeons	High	Medium	Cost effective, easy to use end product	Problem understanding and end product evaluation	Some may prefer Status quo	Individual interviews
Maya, Syeda and Lauren (Students who traveled to Korle Bu)	Low	Low	Global health and equity at Korle Bu Teaching Hospital	Project reconnaissance and handoff	Differing beliefs on problem needs	Monthly check-ins
Surgeons	Medium	Low	Novel alternate retractor design	Solution feedback	Supporters of status quo	Individual interviews when testing
WHO	Low	Medium	Regulated and safe end product	Regulatory guidelines and specifications	Delay approvals or rejecting product launch	Literature review

Stakeholder Name	Impact	Influence	Stakeholder Interests	Potential Contribution	Potential Resistance	Engagement Strategy
Current Retractor Manufacturers and Companies	Medium	Low	Maintaining status quo	Manufacturing and design ideas	Against competing products	Literature review
Patients	High	Low	Low-cost and safe end product	Design specification generation	Design for edge cases	Literature review
Michigan Medicine	Low	Low	Novel product to promote Michigan Medicine's brand	Medical resources including current retractors	Minimal or delayed access to equipment	Email communications and in-person meetings
Resource Constrained Doctors & Hospitals	Medium	Low	Novel low-cost end product	Problem understand	Some may prefer status quo	Literature review

To further understand all possible stakeholders, we additionally created an ecosystem map that placed players into primary, secondary, and tertiary positions based on how significantly our product impacts them. The stakeholders are characterized according to the following color scheme: **Resource Providers (RP)**, **Supporters & Beneficiaries of the Status Quo (SB)**, **Complementary Organizations and Allies (CA)**, **Beneficiaries and Customers (BC)**, **Opponents and Problem Makers (OP)**, **and** **Affected or Influential Bystanders (AB)**.

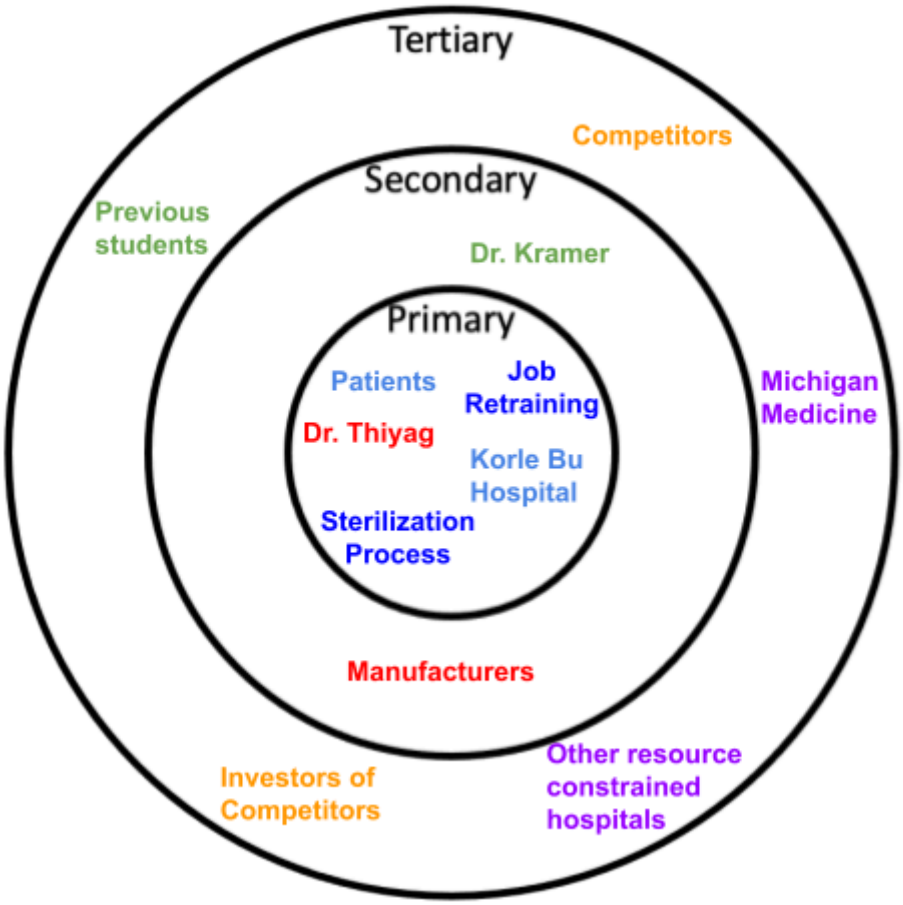


Figure 12: Stakeholder Ecosystem Map

While ultimately placed in hard categories, we recognized that some stakeholders could fulfill multiple roles; for example, Dr. Thiyag. Dr. Thiyag provides the resource of knowledge and connections to other medical professionals who can help us best frame the project problem. Additionally, she could be considered a complementary ally given her common support of providing equitable health care in resource-constrained environments. On a day-to-day basis, Dr. Thiyag will likely be a resource provider helping us refine our design process. However, her status as a complementary ally will also help instill a motivation to work for social change and allow us to understand what will be most helpful in a space unfamiliar to our team.

Other stakeholders can shift between roles such as someone benefiting from the status quo becoming an opponent of others achieving solutions. An example could be investors in a current solution/competitor. These investors may direct funding to continue to build their solution such as advertisements, making it difficult for other designs to become known/manufactured at the same rate.

Dr. Thiyag and Korle Bu Hospital are the primary stakeholders who will evaluate our project before deciding if they would like to implement our solution. Manufacturers, while secondary, may become decision-makers based on how they execute the design (if standard manufacturing practices are followed, what materials they indicate can be used/what they work with). The patients, while significantly impacted by the project, will have minimal decision abilities and are difficult to interview due to HIPAA compliances. Therefore, adequate research will have to be conducted to best understand the patient experience and try to best accommodate comfort levels. In addition, job retraining and new methods of sterilization will be directly impacted by the implementation of a new project and force new skills to be acquired in an already understaffed environment. While unavoidable, the design will be made with the consideration of easy training and sterilization.

Social Impact Analysis

The social aspect driving the need for a self-retaining retractor in Korle Bu Hospital stems from the challenges of resource-constrained healthcare environments. Overall, the project would contribute to enhancing healthcare access and equity. The implementation of the solution would result in allowing for smaller surgical teams (as no one will need to hold the retractor in place). Manufacturing locally would bolster the local economy whilst allowing for more affordable retractors.

Social impact ranks higher than other priorities due to the project's focus on improving healthcare delivery. A focus on social impact ensures the retractor is affordable, easy to use, and adaptable to local conditions. Prioritizing education would also ensure successful implementation while balancing profitability to ensure that the product is accessible to hospitals.

Besides these broad considerations, our team is prioritizing adjustability and patient safety, which also serve as our personal biggest design considerations. This is because they serve as our largest concerns in terms of achievability and we believe that these priorities will lead us to the most successful solution. Our sponsor has the priority of usability and patient safety, which serves as a good check and balance for us as we are not the end users and will not be directly affected by the outcomes.

In terms of the general social impact, while our project is being made for Korle Bu Teaching Hospital, it may serve as a solution to hospitals around the world, both in resource-constrained environments and not. The impact is difficult to measure as the very need to make it cheap enough for a resource-constrained environment like Korle Bu means that other resource-constrained environments will likely be able to benefit from it, and depending on how

our project compares to existing solutions, it may serve as a useful tool for more resource affluent environments.

Intellectual Property Impact

Before starting work on the project we had to sign a global health IP agreement. This agreement allows us to retain ownership of any inventions we develop while also granting the University of Michigan a nonexclusive license to use our inventions for furthering its Global Health Mission. This ensures that our work can contribute to improving healthcare access in other developing countries while still allowing any members of our team to continue developing and commercializing any inventions after the project ends in December.

If any innovation in the project is novel and non-obvious it can be filed for a patent to protect the design or process. Furthermore, any original documentation related to the project could also be protected under copyright law. This impact does not affect our solution past the consideration that we are allowed to continue its development and pursue it besides our current setting.

Sustainability Considerations

Disposal is a major consideration while using retractors. A material commonly used for medical devices is plastic, which on average makes up 25% of waste in hospitals and can contribute to damaging sea life [32]. In addition, some medical tools arrive wrapped in plastic to maintain sterility during transport. Another commonly used material is medical-grade steel, which is derived from iron, a finite element [32]. With a growing global population and frequent mining for a variety of commercial applications, reliance on a finite element could become unfeasible. Furthermore, regardless of the selected material, the manufacturing process will likely contribute to carbon emissions as it is difficult to configure the size and shape of a retractor without machining elements, which requires electrical power. In addition, the transportation of the retractor could lead to heavy gas emissions if transported to Ghana from the U.S. via a plane.

Our best countermeasure to these issues is to make our product as durable as possible. This consideration not only meets our sponsor’s need but also guarantees a long lifetime before disposal as well as limits manufacturing/transportation frequency. To further reduce emissions, we could also design our product with the consideration of being locally manufacturable so that the retractor would not have to be shipped over long distances, avoiding the use of planes. If we would like to further invest in recycling, we could ally with companies such as DuPont, which works with Michigan Medicine to recycle medical plastic into new products through comparable companies with missions for recycling our chosen material [32].

However, a drawback of making a long-lasting product is that the initial purchase could become costly versus a single-use retractor. While the single-use cost may ultimately add up to a

greater price, financially strained hospitals may not be able to afford more expensive retractors up front. In addition, the long-lasting product design would limit potential materials as the ones employed would have to be able to withstand stress tests over the desired lifecycle, causing potential options to be eliminated. Furthermore, making a product locally manufacturable limits the materials and machining to what is available in Ghana, preventing the application of other known methods. To address this conflict, we will refer to our requirements and specifications list, shown below, and guide the design to meet our highest priorities (Ex: cost or reusability). Additionally, given our knowledge of sustainability issues, we will attempt to guide our project toward reusability by continuing to research various materials and manufacturing methods including their respective costs.

Ethical Considerations

As we are working within the field of equitable public health, our problem is very person-focused. People will be using any solution we come up with on other people in surgery, and it will likely have a large impact on the surgical outcomes of the patient as well as the success of the hospital and the confidence of the surgeon to perform the surgery. Generally, this is a difficult problem to tackle, but realistically it can be boiled down to conform to a few dilemmas that must be addressed for the sake of the project. The first major ethical dilemma we must consider is our responsibility to make a safe, practical surgical tool that we realistically believe will not harm the patient before any human testing. Surgeries have risks of nerve damage associated with retractor strength, so it's important that we adhere to any ISO standards for medical devices, use common sense to make reasonable design decisions, and test and analyze our problem and solution for the safety of the patient and the surgeon.

This also ties into the ethical dilemma of our desire as students to want to finish something as fast as possible with the need for this project to be worked out and usable. Doctors have an oath that they must adhere to and an ethics board that they must follow, but mechanical engineering students only have their internal moral compass and an honor board that only cares if they plagiarize or submit work that isn't authentic. While there is an expectation from the University to best represent them with this project, there is not much holding our team accountable besides holistic meetings with our sponsor and mentor. However, there is motivation for our team to succeed, related to our success in MECHENG 450 with a high grade, our success at the University of Michigan as successful students, and our success with future employers for job prospects. Whatever work we complete is also inherently bound by the honor code, and while our internal moral compass may be higher or lower than that standard, the honor code serves as an important minimum specification for the authenticity of our project. That minimum specification is also important as the full implementation of this project will not happen within the scope of this semester, which means that whatever work we hand off must be authentically ours and must have gone through all the safety considerations necessary to ensure its usability.

Personal Identity, Ethics & Power Dynamics

This project team exists in a certain context just like everything else in our perceived world. A large part of that context is the fact that we are all students with a clear motivation to work for a result and a grade. This puts an interesting relationship at play, as our project mentor and sponsor are motivated to encourage us to create a solution to improve equitable healthcare and see us grow as students and engineers, even if that's not necessarily our motivation, and they have the means to motivate us by assessing our grade, something that we inherently care about as students. This creates a power dynamic that is important for two reasons. Primarily, it keeps us on track from a long-term schedule perspective and individual assignment deadline perspective. Secondarily, it ensures that we are producing results that contribute to the vision that our mentor and sponsor holistically maintain. We have certain individual contributions to make, but our sponsor and mentor hold power over us that guides those contributions and encourages us to make the best of our strengths as we collaborate.

Our team benefits from an imperfect diversity distribution that is clear in both racial and gender aspects, and while that does provide different viewpoints, beliefs, and styles of thinking, it is imperfect in the sense that we cannot be a perfectly diverse group just by the nature of groups as a whole. On the other hand, this is a good starting point for addressing part of the inclusivity that is necessary for this project. For context, three of four of our team members are people of color and our team is half women and half men. Inclusivity is important to this project as we are working with patients, who may come in different colors and contexts, so it matters that we represent a unified effort to have an inclusive mindset and be considerate, in this problem and any other that may arise. More specifically, how we tackle this problem and test it could prove to only work for specific groups if we are not careful with how we understand racial and gender differences in skin and body types.

Our final consideration is the power we generally hold as the engineers and designers of this project. Despite the thoughts and suggestions of our sponsor and mentor, we are the ones who decide what solution to pursue, how to define the problem, and what we make and test for the sake of the project. We hold almost all the power over the design, and how to proceed with each stage of the project, therefore it is our obligation to be responsible about how we consume information, seek it, and understand it. This is also directly related to what guidance we may receive from our sponsor or mentor, and how we choose to operate from there even though they have no true control over the project, simply influence on our opinions.

User Requirements & Engineering Specifications

The engineering targets for our self-retaining retractor were determined through a combination of interviews with surgeons and literature reviews of similar medical devices, and research into laparotomies. Interviews with surgeons helped define critical requirements while competitive products and medical journals were analyzed for benchmarking performance metrics.

We prioritize our requirements from 1 to 3, where Rank 1 is the highest priority necessary for the success of the prototype. Rank 2 covers moderately important requirements which are essential but not critical to function. Rank 3 are wishes that are not likely to be fulfilled within our time constraint of 3 months. Rankings were primarily determined through interviews with our stakeholders, who specified the most critical retractor needs for OB/GYNs at Korle Bu. Additionally, ethical considerations informed priority rankings such as patient safety, a principle that was reaffirmed by Dr. Thiyag. Ethics were further used to update our requirements and specifications as we realized that the product should withstand 100 N of force versus our originally determined 80 N after learning of retractors snapping inside patients and causing bodily damage.

All the requirements are stated in the table below with the corresponding engineering specifications and justification. The Problem Analysis and Iteration section below details the validation methods for each specification. The engineering specifications are quantified and have a minimum and optimum specification where the minimum is the base specification the requirement should meet while the optimum is the improvement beyond current retractor capabilities in all cases but the ones concerning material choice.

Table 2. Requirements and Specifications for defined problem

Ease of Deployment (placing the retractor in the surgical cavity)				
Rank	Requirement	Minimum Specification	Optimal Specification	Justification
1	Product should be easy to carry and quick to deploy for operation with surgical gloves on	Product should weigh < 4 kilograms	Product should weigh < 2.5 kilograms	Based on the weight of bookwalter retractor and Titan CSR retractor [14]
		Product deployment should take < 5 minutes	Product configuration for operation should take < 30 seconds	Slowest and fastest times of retractors used at Korle Blu [11]
2	Self-retaining mechanism can be deployed with minimal personnel	Mechanism should be able to be deployed into the open cavity with two hands	Mechanism should be able to be deployed into open cavity with one hand	Support minimal presence at Korle Bu [26] [11]

Ease of Assembly and Disassembly (to sanitize the separate parts outside of the surgical suite)				
Rank	Requirement	Minimum Specification	Optimal Specification	Justification
1	Product can be disassembled and assembled using basic, easily accessible and non-powered hand tools	Requires less than two common tools to assemble	Requires no tools to assemble	Requirements specifications expressed by Dr Thiyag [11]
2	Product must be easy and quick to disassemble for sterilization	Product disassembly < 5 min	Product disassembly < 3 min	Requirements specifications expressed by Dr Thiyag [11]

2	Product must be easy and quick to assemble for operation	Product assembly < 7 min	Product assembly < 5 min	Requirements specifications expressed by Dr Thiyag [11]

Durability/ Reliable				
Rank	Requirement	Minimum Specification	Optimal Specification	Justification
1	Product should limit the closing of the abdominal cavity opening with sufficient force during operation	The product should restrict the closing of an 80N force to 5 cm^2 in 2 hours	The product should restrict the closing of a 100N force to 1 cm^2 in 2 hours	Forces based on tension load from skin layers[4] Time based on average surgery length at Korle Bu [26] Area based on size of laparoscopic tools [26]
2	Product should be mechanically functional over time	Product should should be able to withstand 80N force after a minimum of 2200 uses over 3 years	Product should be able to withstand 100N force after a minimum of 3650 uses over 5 years	Forces based on tension load from skin layers[4] Two uses everyday for the number of years [26][11]

Adjustability				
Rank	Requirement	Minimum Specification	Optimal Specification	Justification
1	Product dimensions can be adjusted to meet the 1st to the 99th percentile of patient body dimensions	Product retracts a range of 8 cm to 15cm	Product retracts a range of 8cm to 30 cm	Based on cut size* for a myomectomy[13] and hysterectomy[19] with optimal addressing the 99th percentile
1	Product should account for different patient cavity depths	Depth > 25 mm	Depth > 60 mm	Based on skin, fat, and muscle thickness of women of average BMI and high BMI [18] with optimal addressing 99th percentile

*The reason for basing the horizontal dimensions just being based on cut sizes of different operations is because the higher BMI sizes affect the depth the blade should reach, not the cavity area or cut size [11] .

Safety				
Rank	Requirement	Minimum Specification	Optimal Specification	Justification
1	Product must withstand sanitation and fit in an autoclave	–	Material can withstand 134°C and 30 psi without change in shape or color	Needs to withstand being run through an autoclave [37]
		Each part must fit in 140 cm x 46 cm x 46 cm	All parts must fit together in 140 cm x 46 cm x 46 cm [47]	Needs to fit in an autoclave [42]
1	Material performance and appearance should resist deterioration after use	No cracking over 1 mm after 3 years (2200 uses) with 100N compressive stress Likert scale > 3.5 for ideal state (looking good as new)	No cracking over 0.5 mm after 5 years (2200 uses) with 80N compressive stress Likert scale > 4 for ideal state (looking good as new)	Need to handle general wear and tear without chance of splintering or breaking.

Safety				
Rank	Requirement	Minimum Specification	Optimal Specification	Justification
1	Product should be made out of materials that meet biocompatibility standards ISO 10993 [15]	—	Select a material from a list of materials used for orthopedic implants [9]	Orthopedic implants need to follow the same biocompatibility standards as retractors
2	Product should achieve a safe surface roughness and finish as per ISO 21920 [16]	surface roughness < 6µm	surface roughness < 0.8µm	Avoid injury upon running finger along project as per the standard
2	Product prevents potential nerve damage to patients***	Product can be loosened during surgery < 1cm off from their intended distance Likert > 3.5 for feeling to the user	Product can be loosened and tightened during surgery < 1cm off from their desired distance Likert > 3.5 for feeling to the user	Requirement specifications expressed by Dr. Thiyag [11]
1	Surgeons should have an adequate field of view not obscured by the product	The product can be set to obstruct < 5% of the surgical field at the start of surgery Likert > 3.5 for ideal state	The product can be continually set to obstruct < 5% of the surgical field during surgery Likert > 3.5 for ideal state	Surgeons need as much visibility [11] mostly due to sudden blackouts in Ghana [26]
2	Surgeon should have an adequate space for movement not obstructed by the product	Surgeons feel they have adequate space to move around the surgical site. Likert > 3.5 for	Likert > 4 for ideal state	The product should not constrict the surgeon from maneuvering themselves around the patient.

Cost				
Rank	Requirement	Minimum Specification	Optimal Specification	Justification
2	Product should be cost-effective over its lifetime	The product's cost per use should be < $2	The product's cost per use should be < $0.12	Based on cost of product and estimation of lifetime [11]
2	Product should be low-cost for purchase	The acquisition cost of the product should be < $450 [11]	The acquisition cost of the product should be < $300 [33]	Based on requirement stated by sponsor [11] and cost of balfour retractor [33]

Manufacturing/ Local Maintenance				
Rank	Requirement	Minimum Specification	Optimal Specification	Justification
3	Product should be locally manufactured as much as possible	< 2 parts are needed to be sourced/manufactured from outside Ghana	All parts can be sourced/manufactured in Ghana	It minimizes travel time and cost
3	Product should be able to be maintained and repaired close to the KBTH site	< 2 maintenance and repair parts are needed from outside Ghana	Maintenance and repair parts are available all within Ghana	It minimizes repair time and cost
3	Product should have a short lead time (manufacturing order to deliver) to account for demand spikes	The total lead time should be < 50 hours	The total lead time should be < 26 hours	Maximize efficiency

Concept Generation

Our team started concept generation by starting individually and then later moving into our whole group. We began brainstorming on our own, doing our best to think of a wide range of ideas, even if they were not in the realm of possibility. We followed the format outlined in Figure 13 below.

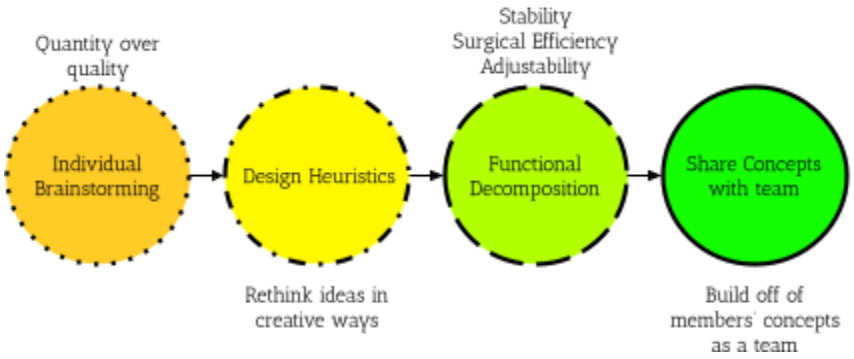


Figure 13. Concept generation flow chart

After generating whatever we could in a “brain drain”, we took those ideas, still individually, and looked at them to see how they could be changed using a list of design heuristics [44]. These heuristics served as a metric to modify each design, such as adding levels, combining, twisting, unity, bending, changing geometry, reducing material, and modularity.

From there, we were able to look at these designs and, while still alone rather than in a group, decompose them into the functions that the designs need to achieve and how they can go about achieving them. After comparing our functional decomposition ideas, we decided on a final chart to help drive our concept generation. Our final chart allowed us to mix and match certain aspects of the locking, adjustability, and durability functions.

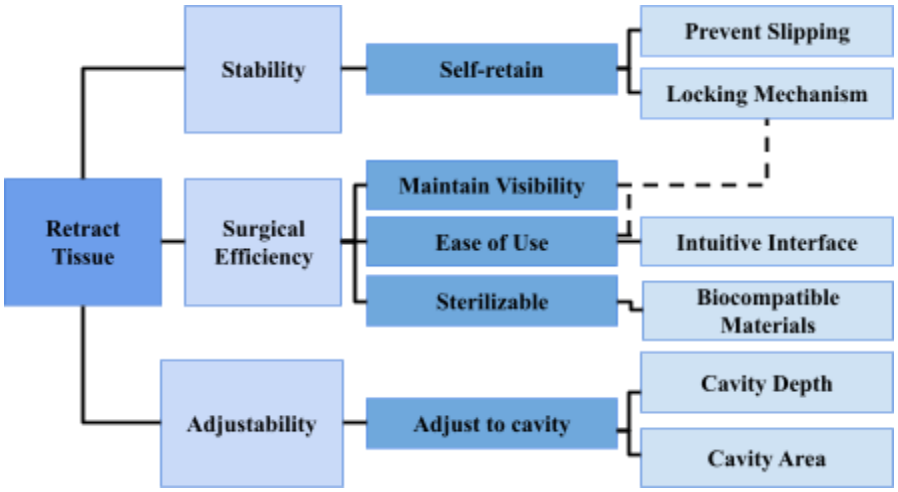


Figure 14. Functional decomposition chart

After using the communal decomposition chart to exhaust individual ideas, we rejoined as a group. We then observed each other's ideas, coming up with new ones and redeveloping individual ideas using the design heuristics and the functional decomposition. Feeling we had exhausted our group's imagination, we organized our ideas to ensure none were lost. A sample of our ideas is included below in a rough categorization we determined. These categories included jig designs, inflatable designs, linkages, circular designs, table attachments, designs with creative openings, and unrealistic ideas. All of our generated ideas can be found in Appendix B.

Inflatable.

The set of inflatable designs attempts to use the idea that balloons get bigger as they inflate to bake adjustability into the design. The basic idea it forms is that you use varying diameters and strengths depending on the need. Some sort of hand pump to inflate a ring-shaped balloon to get varying diameters and strengths depending on the need.

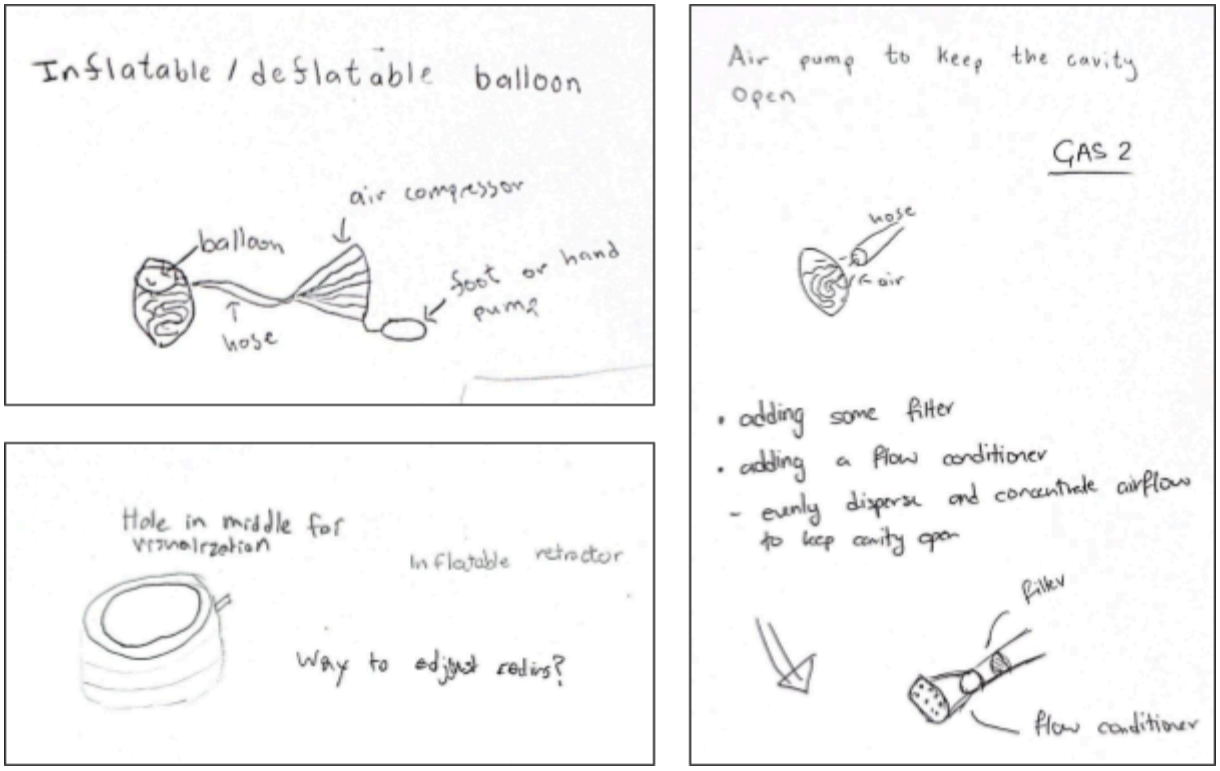


Figure 15: Inflatable Design Ideas

Linkage.

The linkage designs use the idea that you can have multiple bars to act as the main body of the retractor and only adjust them at the joints. The joints would have some sort of friction to them that would only enable humans to move them with their physical strength, but would not allow for simply the tension of retracting tissue to move it.

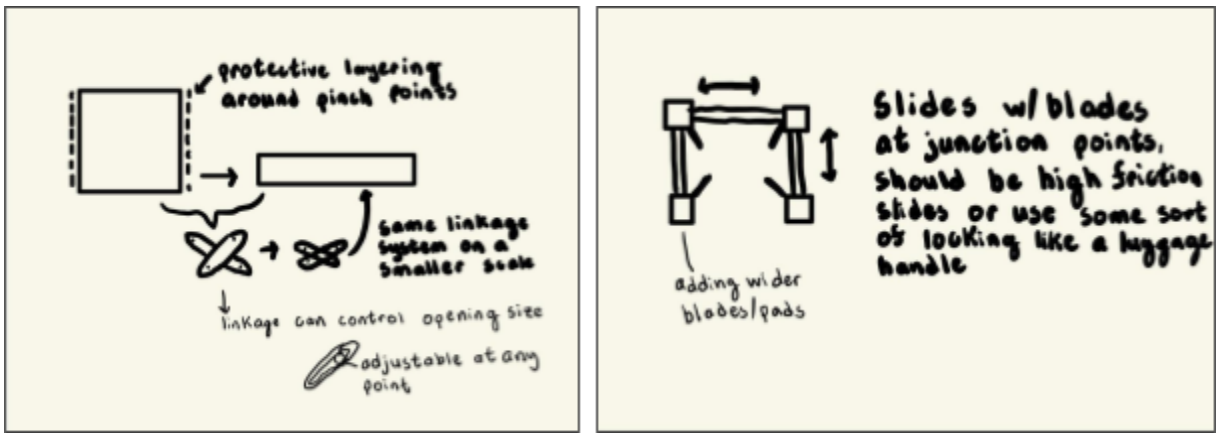


Figure 16: Linkage Design Ideas

Jig.

The jig uses the material's strength and a simplified design to produce a quickly manufacturable and simple design, while generally sacrificing the dynamic adjustability for static support. These designs use pins in metal plates to achieve this. At its core, it can be two unique parts that would rely on the surgeon to place creatively to get the cavity shape they desire, and allow for as many pins as desired to be placed to enhance the strength.

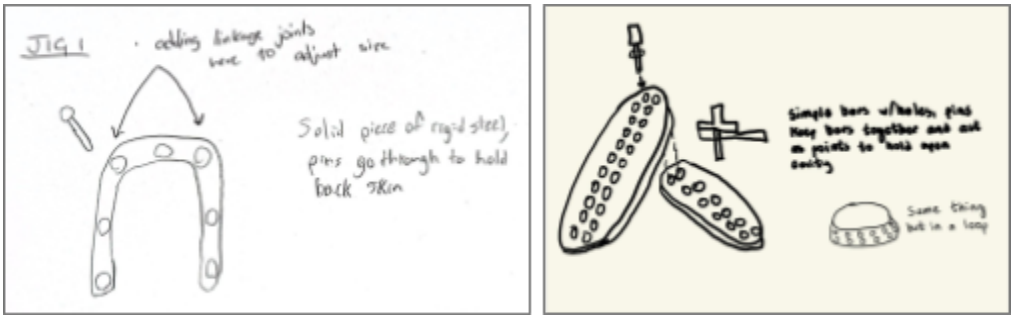


Figure 17: Jig Design Ideas

Circular.

The circular designs mimic a lot of current retractors on the market, attempting to improve upon them for usability, adjustability, and strength. They try to take advantage of the fact that many surgeons are already comfortable with the retractors on the market, and may not necessarily want something "new" so much as "better". The circular design has the further benefit of allowing for specific blade placement, unlike retractors with defined sides.

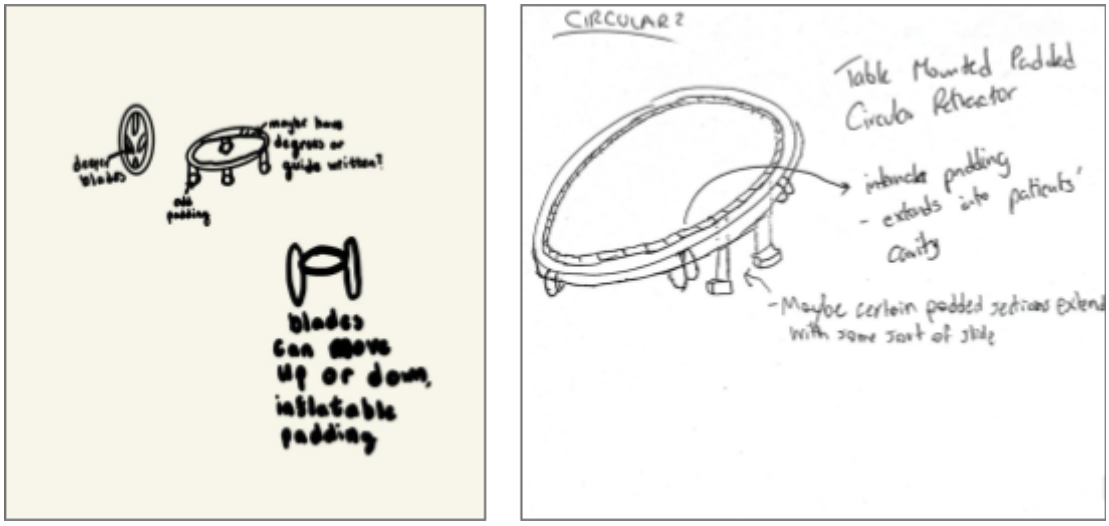


Figure 18: Circular Design Ideas

Table Attachment.

The table attachment designs do exactly what their name implies, they attach to the table in some form or another and use the rigidity of the table to retract human tissue. These designs are partially inspired by the Thompson retractor, which similarly attaches to the table but has been noted as occasionally inconvenient to use and costly.

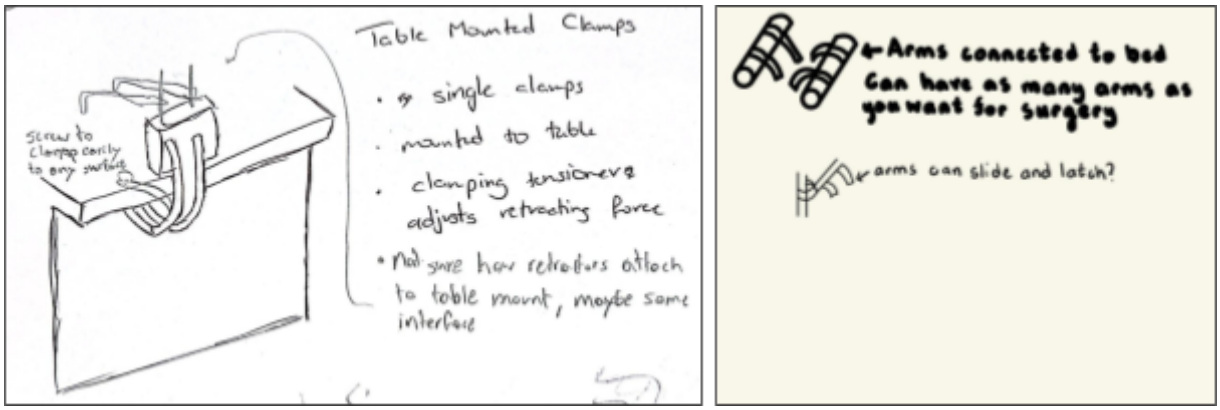


Figure 19: Table Attachment Design Ideas

Opening.

The opening designs are categorized as such because of their creativity in making an opening. They largely use a mechanism similar to that of a camera aperture to go from a small opening to a larger one. These solve the problem most creatively and use pins to go into the body cavity, similar to the jig designs.

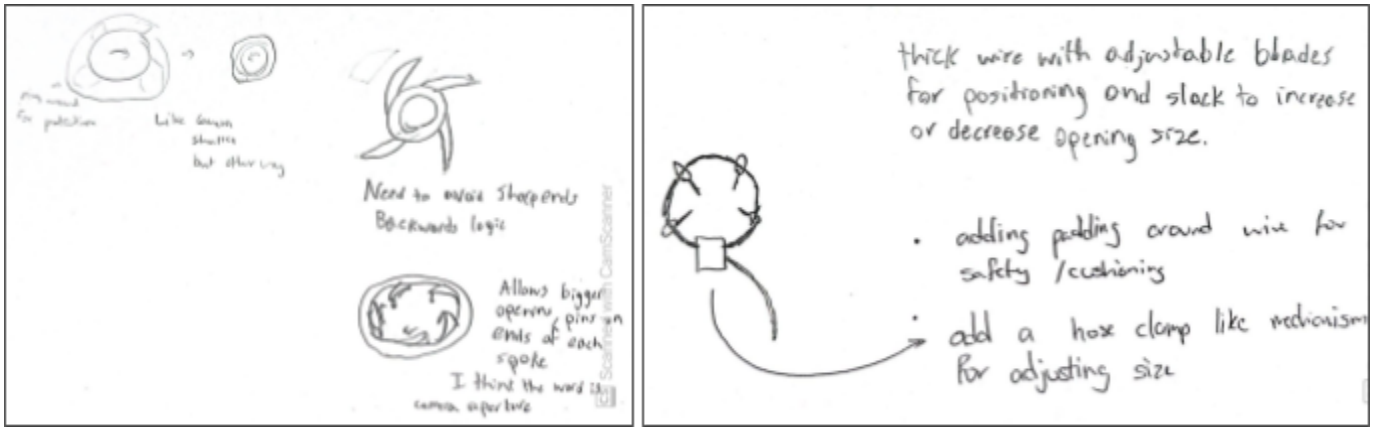


Figure 20: Opening Design Ideas

After gaining this plethora of ideas, we decided to combine the ideas in each category into singular, refined designs that utilized the best elements within each category.

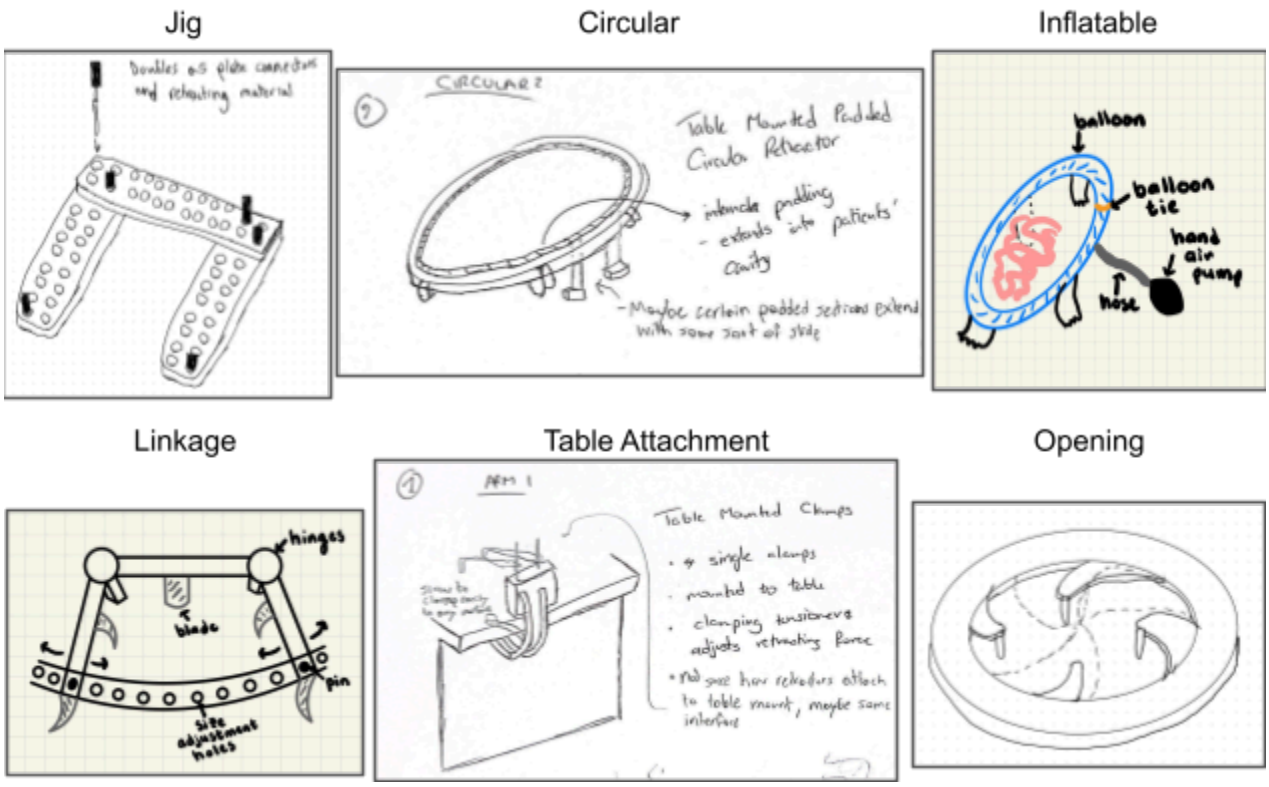


Figure 21. Combined ideas from within each category

We then discussed with our sponsor what she would like to see and what she thinks the surgeons at Korle Bu Teaching Hospital would like to see from a new retractor. This, on top of an initial gut check, led to the elimination of three category concepts: the linkage, the table attachment, and the opening. The linkage was eliminated due to complexity and lack of usability as it seemed to be difficult to maneuver. The table attachment was eliminated since it would require more setup than other ideas and doesn't differentiate too much from current industry benchmarks. Finally, the opening was eliminated due to complexity and not solving the problem as it would be difficult to sterilize and open as a surgeon. Dr. Thiyag sounded much more passionate about the remaining three ideas as well, pointing out some of the issues with the linkage and table attachment as well. Therefore, the process selection was continued with the jig, balloon, and circular categories.

Concept Selection

After our discussion with Dr. Thiyag, we pursued 3D models for the three preferred ideas, incorporating a rail system into the circular model, renaming it ‘rail.’ The models for these ideas are shown below.

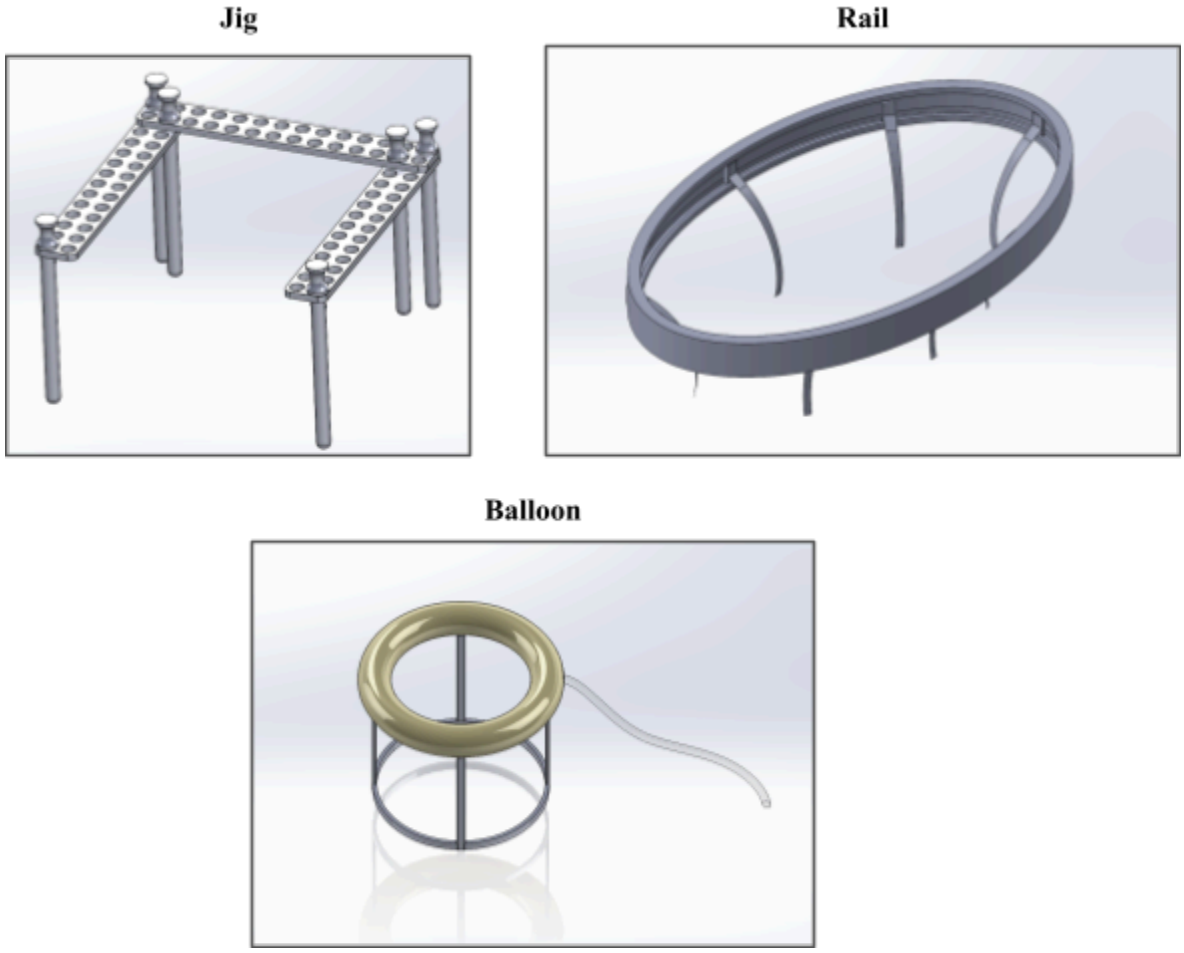
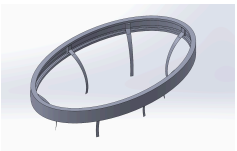
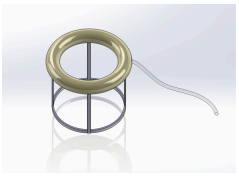
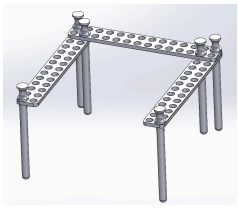


Figure 22. Models developed for the top 3 ideas based on conversations with our sponsor

Once we developed these models, we presented them to groups of four students working on other projects related to global public health. The ideas were presented to have new people, who are unfamiliar with our generation process and overall selection of ideas, decide which idea was the easiest to understand, which one felt the most creative, which felt doable, and what they were excited to see us develop into a solution. After further researching balloon materials and shapes, we found that few inflatable materials met safe medical standards, and once inflated, would be difficult to remold. On the other hand, the jig and rail ideas produced a lot more conversation related to what could be modified or improved. From there, we had a better understanding of the failures and successes of each design, and with

that, we created a pugh chart for a final ranking and to choose which idea we would work with. We used our requirements as categories within the Pugh chart to determine how effective these solutions would be. Our pugh chart is shown below in Table 3.

Table 3. Pugh chart weighing potential success of each remaining idea across requirements

Criteria	Weight (1-3)			
Ease of Use	3	0	1	0
Safety	3	0	-1	-1
Adjustability	3	0	1	-1
Complexity	2	0	-1	1
Durability	2	0	-1	0
Accessibility	1	0	0	-1
Manufacturability	1	0	-1	1
Total		0	-2	-4

Our list of criteria was adapted from our user requirements, with the critical requirements being assigned higher weights as they are most crucial to our design's success. Safety, ease of use, and adjustability were notably given the highest weight as these factors were critical to the success of our project. The Rail design was set as the baseline and the Jig and Balloon were then evaluated against the Rail design, being assigned a score of -1, 0, or 1 if the design performed worse, equal to, or better than the Rail design in each criterion. The assigned number was then multiplied by its criteria weight and added to a total score.

As can be seen from the chart, our circular rail design had the highest score, indicating that it was the best solution out of the three concepts for tackling our requirements. This enabled us to pick the circular rail design as our alpha design.

Initial Selected Concept - “Alpha Design”

Our concept generation process led to us developing an Initial Alpha design that served as the basis for future design improvements and verification at that time. Figure 23 below provides a high-level CAD overview of the alpha design, while Figure 24 shows an approximate scale of a human body.

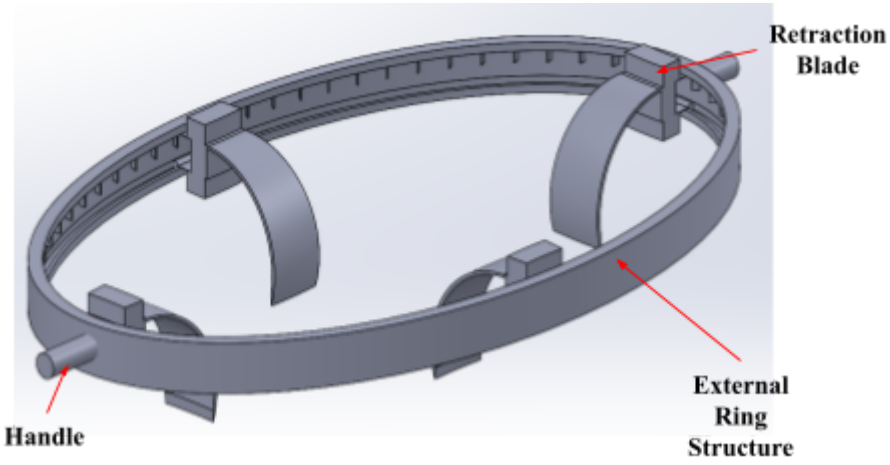


Figure 23. Labeled, isometric view of the current Alpha design in CAD representation, made on SolidWorks.

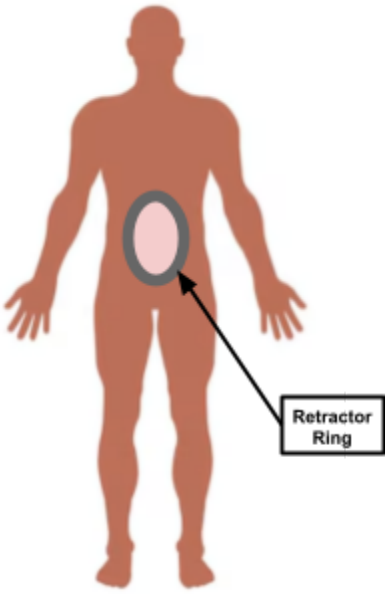


Figure 24: Relative size of Alpha design retractor to 50th percentile human human body size

Our Initial Alpha design was separated into two sub-components: external ring structure and retraction blades.

External Ring Structure

This sub-component is the main structural component of our design that controls overall retractor adjustability and blade placement. The external ring structure has an elliptical shape and extends outward horizontally to form an elliptical shape, as shown in Figure 25.

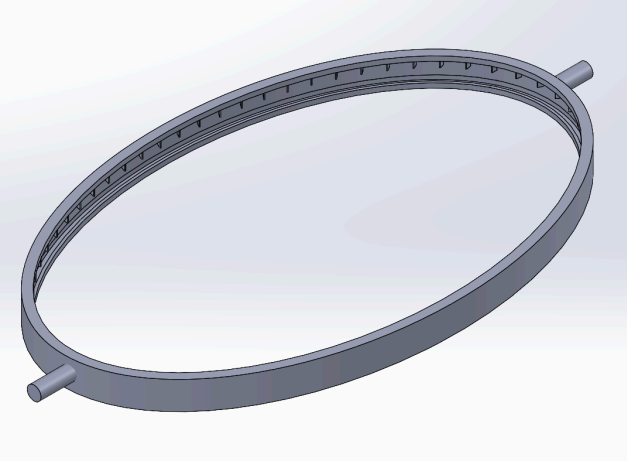


Figure 25: Isometric of elliptical-shaped external ring structure with handles for adjustability.

This external ring structure has been motivated by a conventional and functional shape commonly used in existing retractors. The elliptical shape of the ring structure is driven by the majority of patient cavities resembling an elliptical shape. This ring structure is intended to sit on top of a patient's cavity during use.

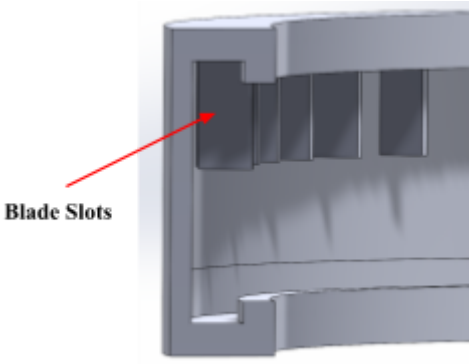


Figure 26. Inner profile view of the external ring structure labeled with blade slots for locking blades into position along the ring.

The ring structure has an inner profile that allows the blades used for cavity retraction to be placed. As shown in Figure 26, the inner profile has a slot in which the blades can be placed. Furthermore, the ring structure has designated blade slots that are periodically placed around the inner profile and are designed to keep attached blades fixed and rigid to the ring structure. These slots are intended to be a snug fit (H7 refers to the tolerance grade in the ISO system as having a maximum of 25.021 mm deviation from an initial 25 mm) as this allows for a secure blade fitting that can be easily moved with moderate hand pressure.

Retraction Blades

These blades are meant to provide the initial retraction that keeps the abdominal cavity open. Figure 27 below shows the primary retraction blade design.

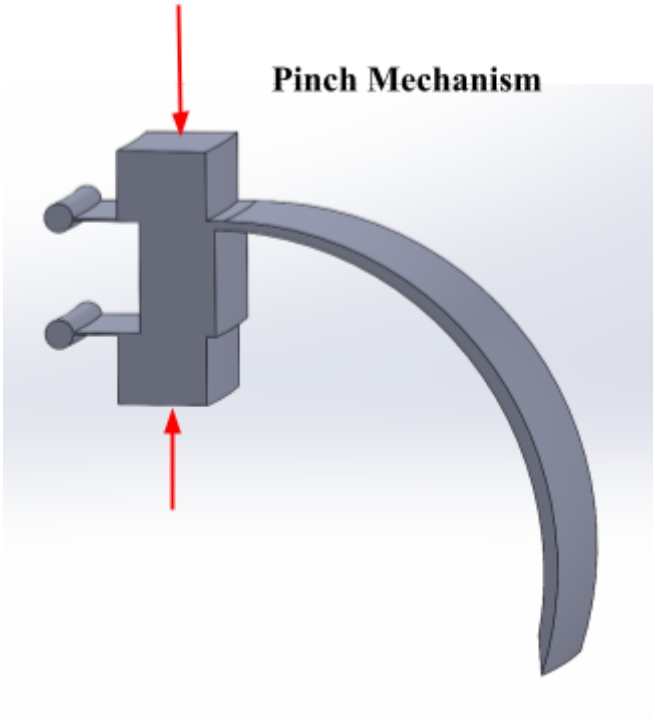


Figure 27. Isometric view of retraction blade with pinch mechanism for attaching blade to external ring structure.

These blades are designed to be wide and curved to adapt to patient body contours for secure and stable retraction. These blades are designed to have a standard, fixed shape and size that will be applicable to all patients. They model existing blades used on current retractors, ensuring our safety requirement is met. These blades are designed to be made out of medical grade Stainless Steel 316L as it meets ISO 10993 standards and has the relevant material properties that make it safe for autoclave sterilization and reusability.

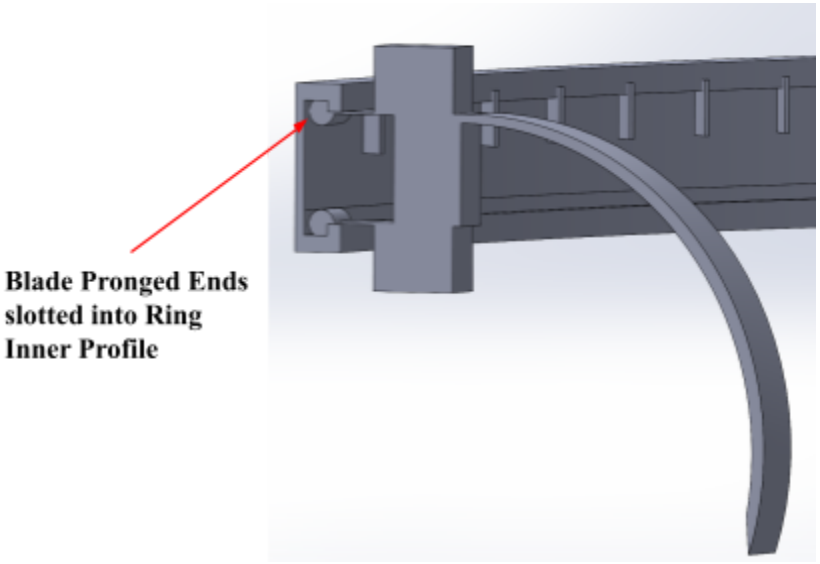


Figure 28. CAD inner profile view of retraction blade slotted into the inner profile of external ring structure and kept fixed by blade slots.

These blades have a pinching mechanism that is used to compress the pronged ends of the blade into the inner profile of the ring structure shown in Figure 28. This pinching mechanism component is intended to be made out of medical-grade spring steel for its increased elasticity that would allow surgeons to easily press down at the pinch point and place the blade into slots on the ring structure.

The pinching mechanism of these blades works in tandem with the blade slots along the inner profile of the ring structure to offer surgeons the flexibility and modularity to place as many blades as needed for primary retraction at any location along the ring, offering further adjustability.

Concerns

The primary concern with the alpha concept was meeting the adjustability requirement and ease of deployment requirements. After looking at our alpha design, we conducted a simplified design for manufacturability (DFM) analysis to validate the feasibility of our design. This analysis can be seen in Table 4 below.

Table 4. Simplified design for manufacturing (DFM) analysis conducted evaluating design and manufacturing of proposed "Alpha" design

	External Ring Structure	**Retraction Blades**
Potential Manufacturing Process	CNC Mill, Injection Molding, Additive Manufacturing	CNC Mill, Injection Molding, Additive Manufacturing
Manufacturing Feasibility	Expensive, time-consuming to manufacture, requires specific machinery, skilled labour	Expensive to manufacture, requires specific machinery, skilled labour
Design Complexity & Evaluation	Very large part, complex inner profile, tightly toleranced. Could be very heavy, difficult to use	Complex shape, tightly toleranced. Pinch mechanism might be too small to comply with design
Desired Material Properties	High strength, low-density, high melting point, chemically resistant, biocompatible	High strength, flexible, biocompatible, chemically resistant, high melting point
Cost	Expensive to manufacture and maintain	Expensive to manufacture, unnecessary to develop a different blade - can utilize pre-existing blades (Thompson, Bookwalter)

Through conducting a DFM (design for manufacturing) analysis, we realized many obstacles that made the "Alpha" design infeasible. Some key issues were:

1. Pinch Mechanism - Required a material that would be flexible enough to bend when handled but not too flexible that bent under the compressive forces applied by fat, skin, and tissue on the blade. Ideally, we hoped to use stainless steel for the pinching mechanism due to its high yield strength and low ductility, as it is the connection between the blade and rail and would experience high bending stresses. However, this strength would also make the pinching mechanism difficult to squeeze as its yield strength is above the average human pinching strength of five to ten pounds [48].

2. Ease of Use & Deployment - Required multiple hands to deploy as it would be difficult for a single person to perform the dexterous pinching while simultaneously holding open the cavity.

Due to these concerns, we revisited our concept generation phase and selected a different final design.

Final Design

After identifying issues in our “Alpha” design, we revisited the concept exploration phase to ideate new ways to solve the design problem. We particularly emphasized ease of manufacturing to promote lower costs and make a locally buildable product. With this focus, we revisited our other two finalized design concepts. Based on our Pugh chart evaluation (Table 3), we found that both designs either lacked robust functionality or would have been difficult to manufacture. Hence, we decided to isolate the strengths and weaknesses of each design and combine the strengths of our ideas. From this activity, we concluded that our design should:

1. Use a conventional mechanism for adjusting the size of the retraction
2. Create surgical visualization from an opening in the middle of the retractor
3. Have modular blade attachments that do not require complex geometries.

Based on these criteria, we ideated circular opening retractors that would use a conventional mechanism to create retraction. From this, our team developed initial sketches to visualize our concept, as shown in Figure 29.

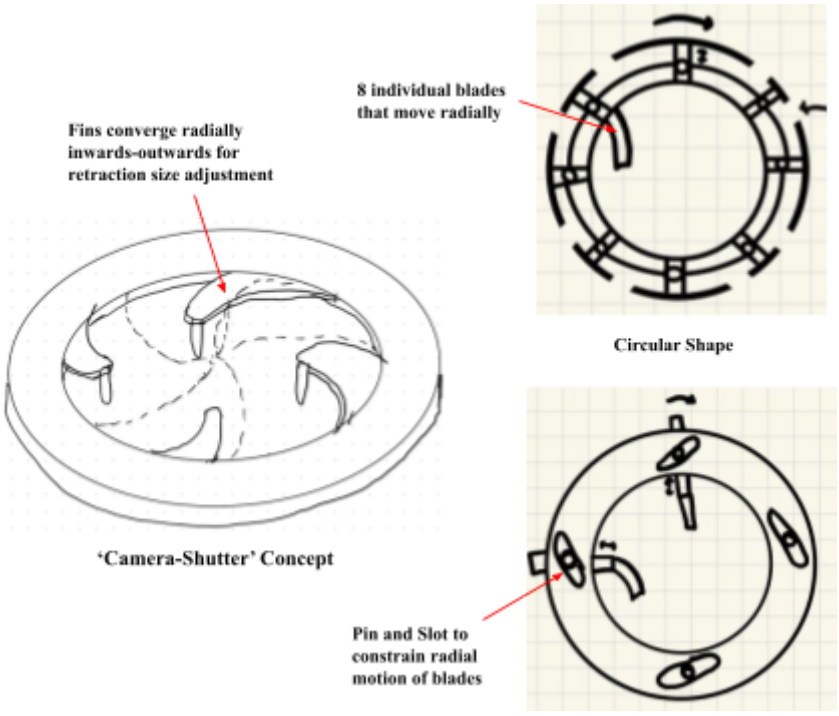


Figure 29. Initial sketches of camera-aperture styled mechanism

Based on the ideas from Figure 29, our team continued to develop and refine the design, consulting Dr. Thiyag and Dr. Kramer, for their biomedical and mechanical design expertise. This led to our final design presented in Figure 30.

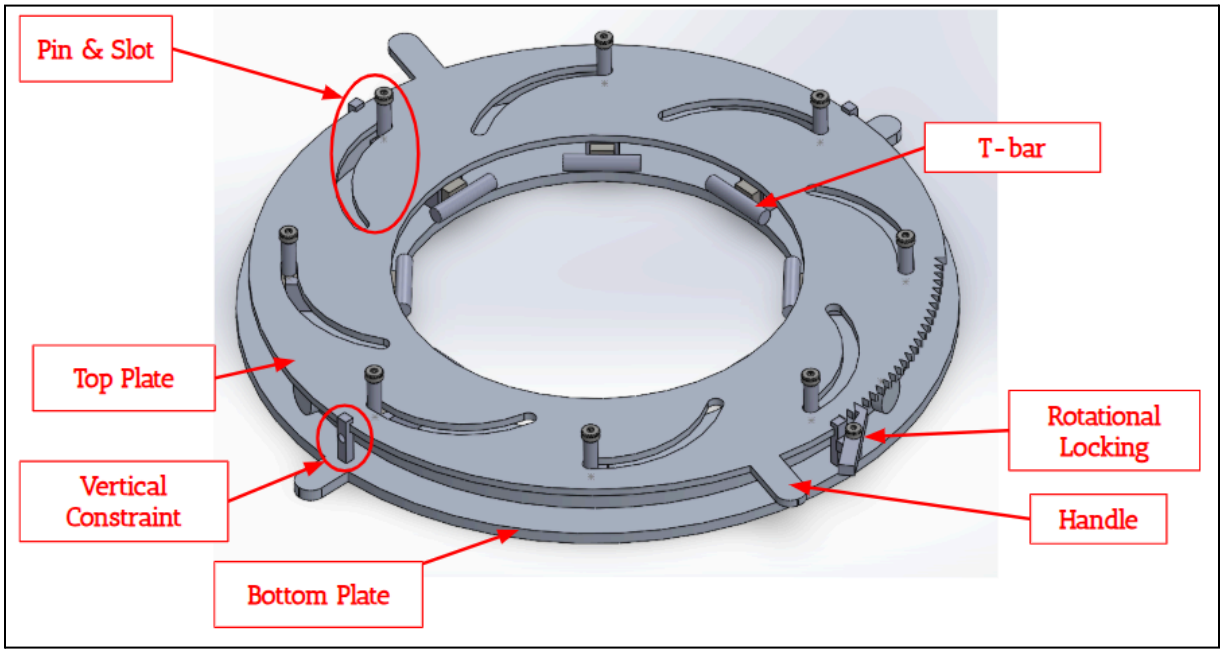


Figure 30. Overview CAD assembly of Final Design (before verification) with labeled critical components.

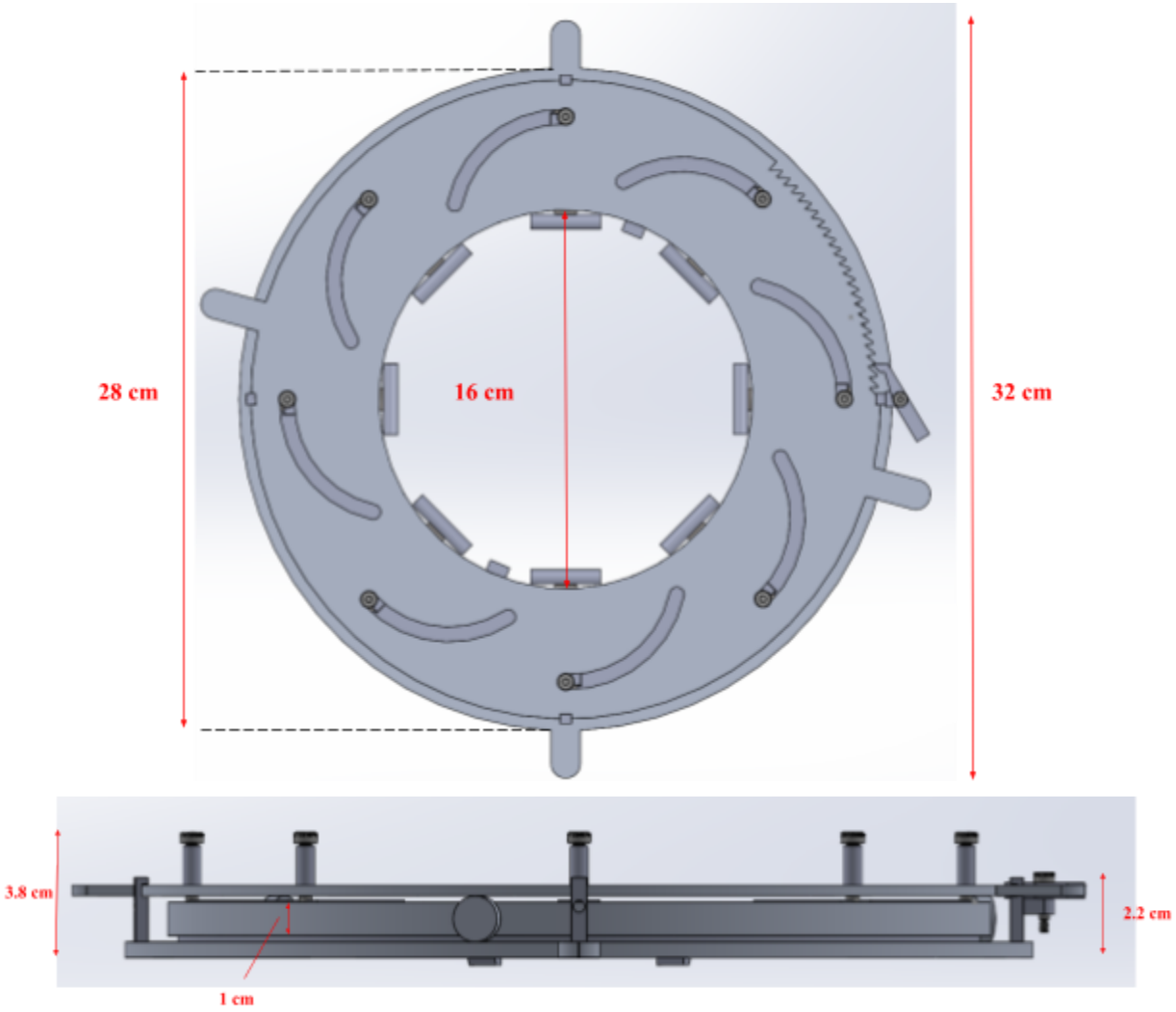


Figure 31. Key Dimensions of Final Design CAD Assembly

Our new final design converts rotational motion into radial linear motion through constrained pins and slots. This enables us to enact rapid, evenly distributed retraction when deployed. The moving parts, called T-slots, are linearly constrained to a circular base piece and move into and away from the center of the circular base. The T-slots are attached to pins that fit into slots in the circular top plate. These pins rotate about the center of its circle, allowing the T-slots' pins to move forward and backward and creating the desired radial linear motion. The T-slot ends interface with Thompson retractor blades to minimize cost given that Korle Bu already possess these blades.

There are two types of mechanisms incorporated to constrain the vertical and rotational movement of the plates to secure the retractor:

Vertical Constraint

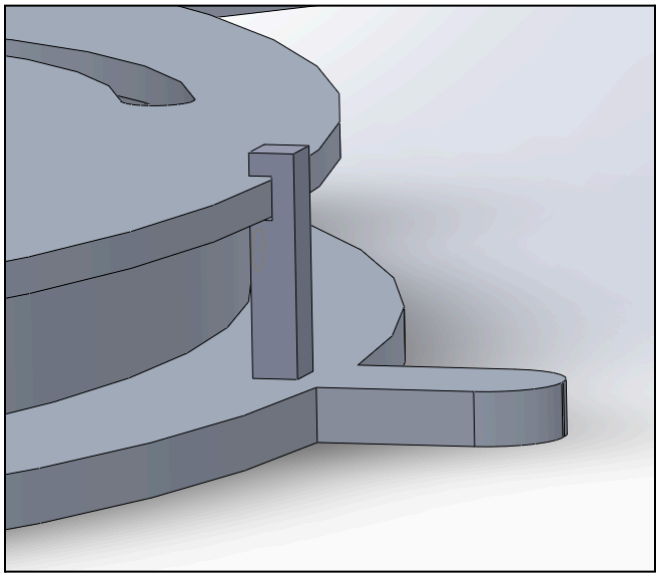


Figure 32. Vertical Clamping piece screwed into the bottom plate and constraining the top plate

We designed a vertical clamping piece that is screwed into the bottom plate and has an etch on the side and locks onto the top plate. This piece is at four points around the outside of the plates as seen in Figure 32.

Rotational Locking

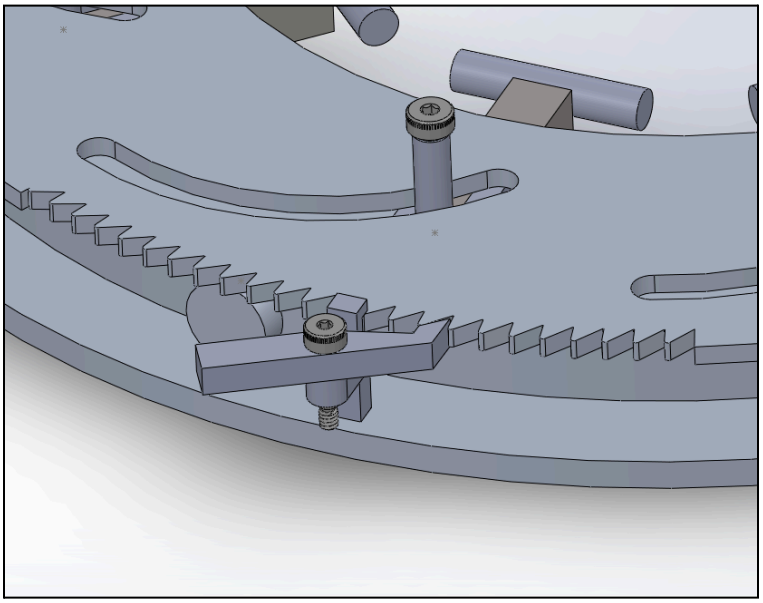


Figure 33. Rotational locking with a ratcheting mechanism

As detailed in the final design, we researched several rotational locking mechanisms, electing a ratcheting mechanism due to its smooth rotation while turning the retractor and strong hold when activated. The mechanism incorporates ratchet teeth on a top plate and a pawl attached to a clamp on the bottom plate that is tensioned with a torsion spring. This allows the top plate to rotate counterclockwise freely but the pawl has to be toggled to rotate the top plate clockwise.

We ultimately selected this design due to its feasibility, even retraction, and novelty. The design was easy to understand beyond theoretical ideation and has already been executed for other purposes. Additionally, the design evenly combats tissue compression, preventing one blade from taking an excess load that could contribute to tissue damage. Finally, we believe that our design is different from current market options. While we could pursue a solution similar to current retractor benchmarks, due to the market's oversaturation, we would be unlikely to create something different enough to constitute a new invention and would run into the struggles we were selected to address such as adjustability to patient sizes.

Build Design

Our build design differed from our final design due to our limited manufacturing timeline, but maintains the same "camera shutter" mechanism. In addition, the build design has the same critical functional elements as the final design but with simplified manufacturing processes that were time-efficient and low-cost. A more comprehensive overview of the differences between our build and final design is detailed at the end of this section.

The purpose of this build design was to perform verification and preliminary validation testing. The sub-section below details each sub-component of our build design.

Top Plate

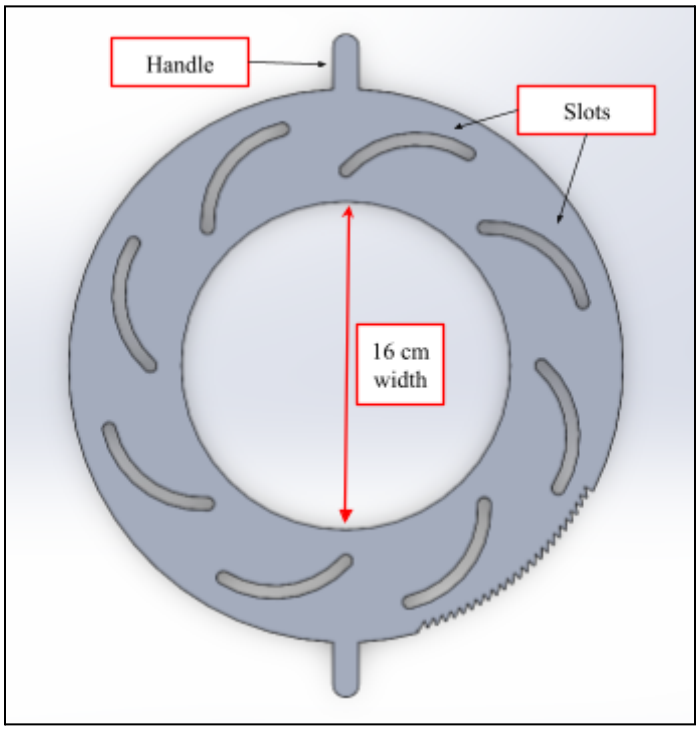


Figure 34. Top plate CAD

The top plate of our design features circular slots that help constrain the motion of the T-Slot bars radially for cavity retraction. The build design is consistent with the final design with regard to material and dimension. For our build design, we waterjetted Aluminium 6061 sheet stock, which did not need to be modified from the final design.

Bottom Plate

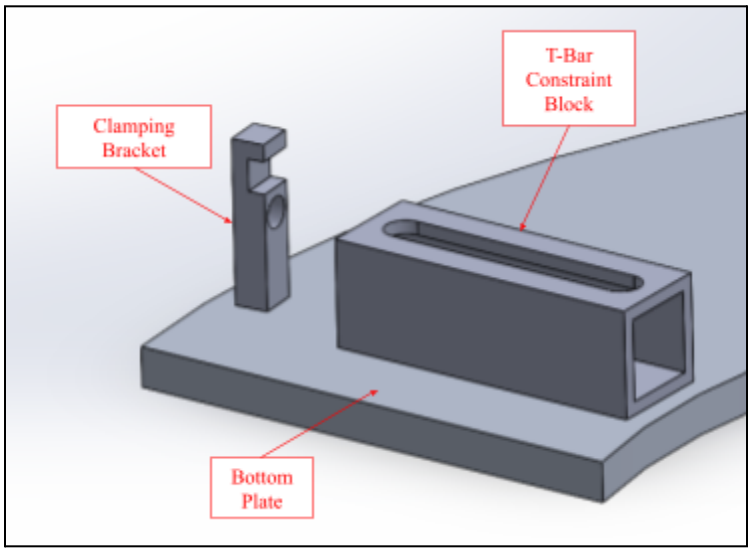


Figure 35. Cross-section view of bottom plate sub-assembly. T-Bar Constrain Block is 1.5 inches long.

The bottom plate serves the key purpose of housing the constraints for the T-bars. Its sub-assembly consists of the vertical clamping bracket and T-bar constraint blocks. The clamping bracket serves as a safety mechanism for preventing the top plate from falling beyond the bounding geometry of the full product. The constraint blocks help restrict motion of the T-bars in a single direction to allow for closing and opening of the cavity during use. This design relies on waterjet cutting all parts and milling countersink holes for #6 screws to mount the bracket and blocks to the bottom plate. The bottom constraint blocks are designed to be press-fit into geometrically similar rectangular cutouts on the bottom plate.

Vertical Clamping Mechanism

The vertical clamping brackets (seen in Figure 35) were used to provide a vertical constraint between the top and bottom plates. It was designed to prevent the top plate from accidentally slipping off the side or being lifted off during use. Since the bottom plate would be completely waterjet cut, the clamping bracket was designed to have a tapped hole through its bottom for a bolt to thread into after passing through a clearance hole in the bottom plate.

T-Bars

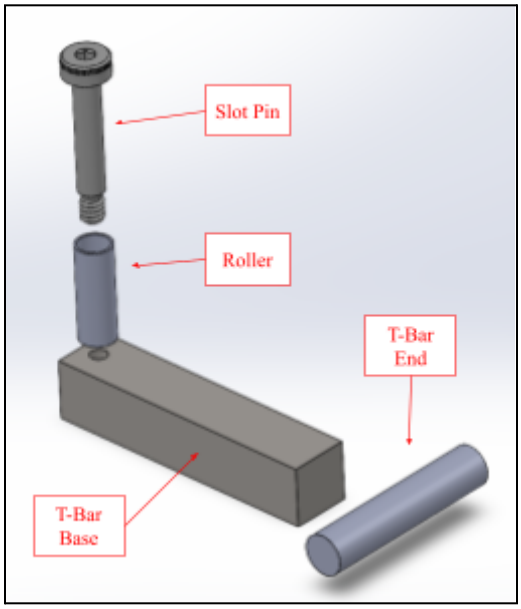


Figure 33. T-bar exploded assembly with all constituent parts. T-bar length is 1.75 inches.

The T-bars consisted of 4 different components: a base, circular end, shoulder bolt, and a roller. This assembly was designed for simple manufacturing to optimize time-efficiency. The base outline was waterjet, then a hole was milled for the shoulder bolt to be bolted into. The shoulder bolt acted as the pin that slides along the slot on the top plate. The circular end is a round stock part that was cut to length and welded onto the end of the base. The housing is a square stock part that has an inner square profile and provides a transition fit with the base, allowing it to move with sufficient freedom along the length of the housing.

We used the shoulder bolt as the pin because the well-machined surface of the shoulder section of the screw would provide a low-cost solution for minimal friction between the shoulder and slot. As a precaution, we also added a plastic roller to minimize potential wearing from the bolt rubbing against the slots.

Turntable



Figure 34. Purchased turntable for build design with a 25.4 cm diameter

For the build design, we used a turntable we procured from Amazon [46] instead of manufacturing the Aluminum stock we elected for the Final Design. Notably, the procured turntable differs from the Final Design as our Build Design has a smaller circumference than the Final Design.

Handles

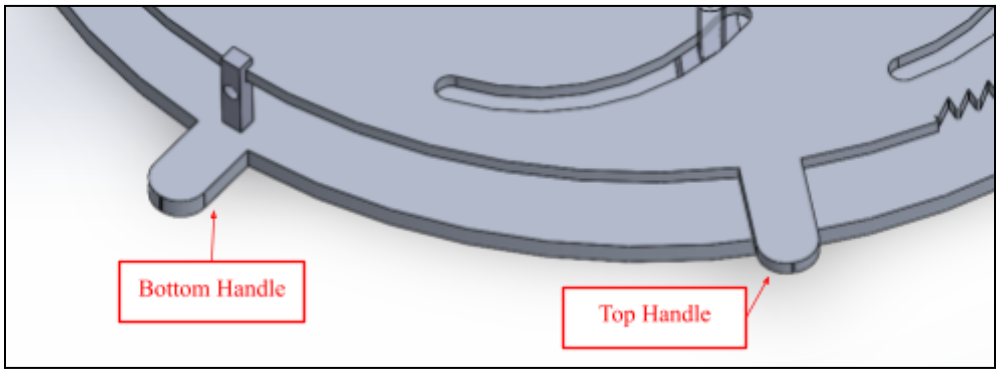


Figure 35. Close view of the build design handles.

The handles for the design are placed on opposite ends of the top and bottom plates. They have a hemi-elliptical shape and were made on the same waterjetted part as the top and bottom plates. The handles were designed to be large enough for surgeons and nurses to grip the handle with two fingers. If there is adequate personnel, the handles on the bottom plate can be held while the top handles can rotate the device to open and close the opening. If only one staff member is available, the top plate can be individually rotated.

Blade Attachments

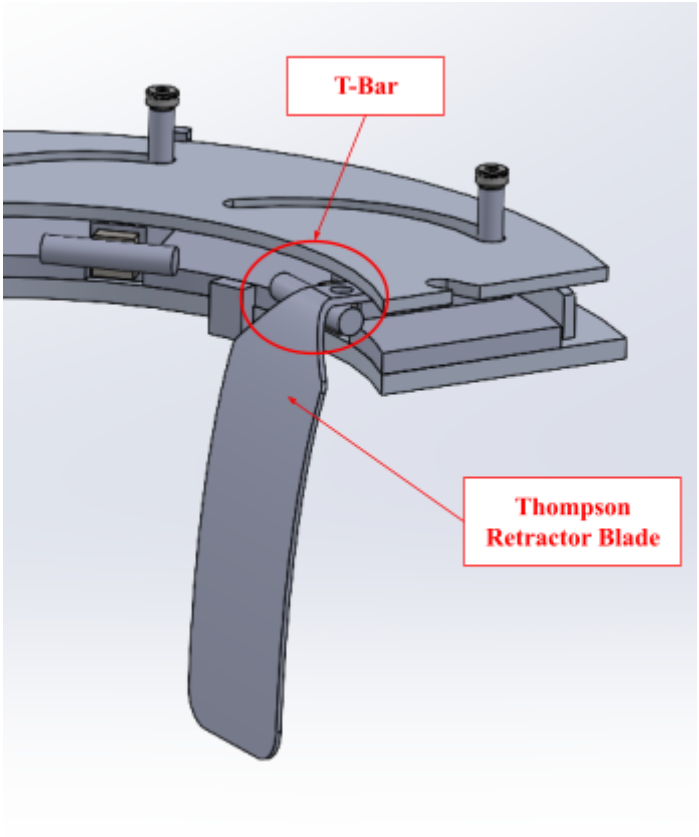


Figure 36. Visualization of Thompson Retractor Blade attached onto T-Bar

Continuing our "Alpha" design methodology, we made our retractor compatible with currently existing retractor blades. Based on Dr. Thiyag's advice, we designed our T-bars to be compatible with the Thompson retractor blades, as these attachments are already being used at Korle Bu. This design choice helps reduce the cost of the device and makes the design easier for surgeons and nurses to use due to its familiarity. The Thompson blades can be seen in the figure below:

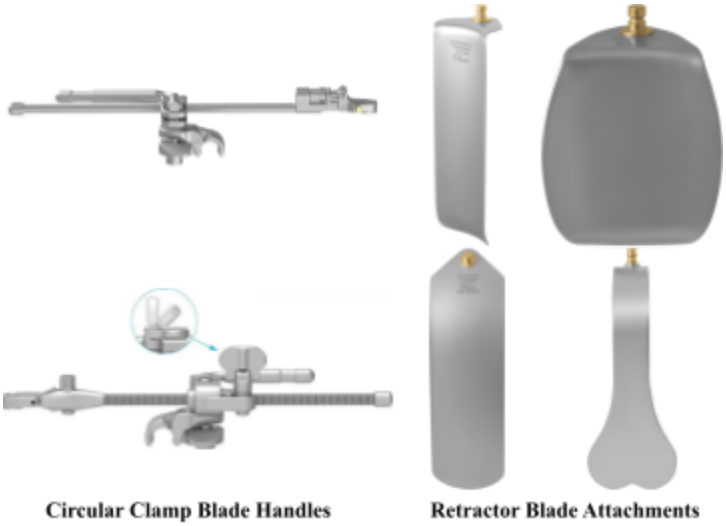


Figure 37 (A & B). (A) Types of circular clamp blade handles that mount onto the circular ends of the T-bars and connect to the Thomspon blades. (B) Types of Thompson Retractor blades that connect to the blade handles.

Figure 37 shows the Thompson retractor's blade handles and the retractor blades. Our T-slot ends mimic the Thompson's clamp blade handles, allowing our retractor interface with the Thompson blades. As seen above, there are many different Thompson blades that can be used for a variety of surgeries. By making our retractor compatible with these blades, surgeons will be able to perform multiple procedures using the blades that meet that procedure's unique needs.

Rotation Locking Mechanism

We initially identified 3 mechanisms for rotationally locking our retractor that we have detailed below:

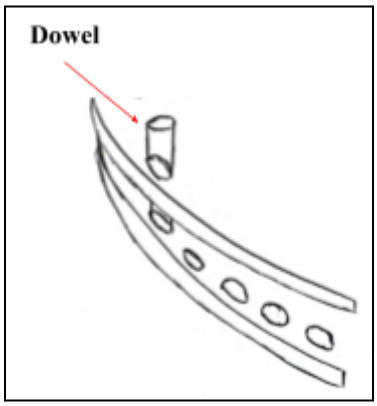


Figure 38. Dowel Pin locking mechanism.

Figure 38 shows a dowel pin locking mechanism that involves surgeons placing a dowel through a hole on the top plate and then through the bottom plate to rotationally lock it. This design would involve purchasing round stock for the dowel pin, cutting it to the appropriate length, and adding holes to the waterjet cut process for both plates.

The strength of this concept is its ease of manufacturability. However, the small dowel pin size may be difficult for surgeons to grasp, and it poses the risk of falling into an open cavity or being lost during the assembly process.

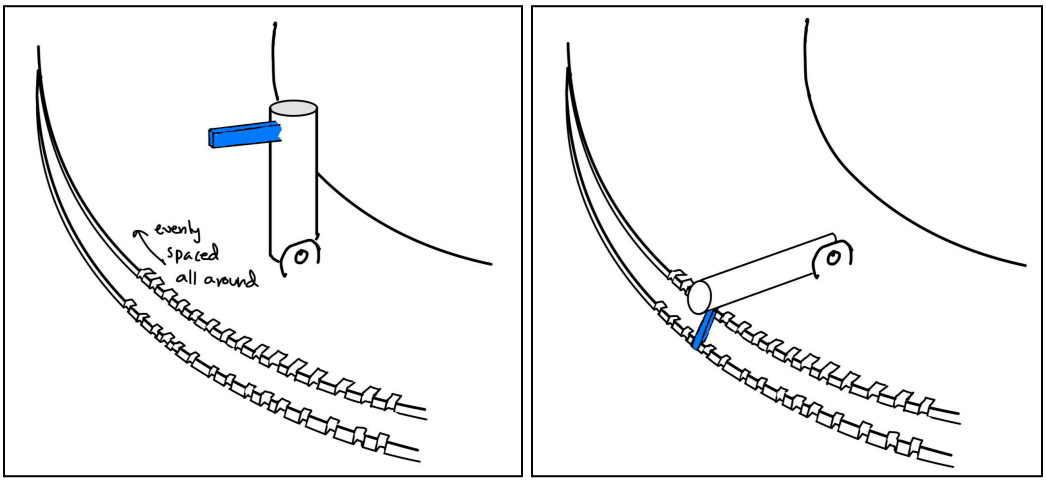


Figure 39. Handle-Tab locking mechanism idea.

An alternate idea is for the vertical handles to be mounted to a pivoting joint that would allow the handle to be folded down and fastened onto the side edges of the top and bottom plate. This design idea involves adding a tab that is perpendicular to the handle, as shown in blue in Figure 39, and adding jigsaw-like, rectangular-shaped slots to the sides of the plates. When the handle is vertical, surgeons will be able to use it to adjust the size of the retractor. Once they have adjusted the retractor to their desired size, the handle can be lowered, and the tab will press fit into the slots on the sides of the plates. Once the tab is fit into the slots, this will rotationally lock the device and create greater surgical visualization since the handle is folded. This design would require manufacturing the tab by water jetting and then either welder or fastening the tab onto the handle. We would need to manufacture a pivot joint and drill a hole through the handle.

This design provides a very robust solution to rotationally locking that is complemented with a folding handle that would improve surgical visualization. However, this concept would have been very difficult to manufacture and would require frequent maintenance of the pivoting joint to ensure it is sufficiently lubricated for easy handle rotation.

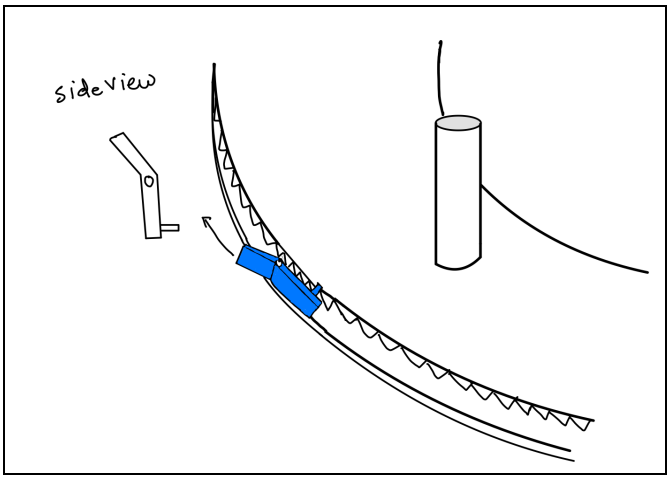


Figure 40. Ratchet locking mechanism idea.

Another potential idea is to use a ratcheting mechanism to rotationally lock the top and bottom plates. The ratcheting clamp would be mounted onto the bottom plate and use a spring to tension the clamp. To adjust the size of the retractor, surgeons would have to disengage the ratcheting clamp and then lock it into grooves to fix the retractor. The clamp and the mount could be waterjet cut and there would need to be a tapped hole through the mount to fasten a bolt through the bottom plate into the mount. Another vertical mount would be needed to waterjet to attach a spring onto that is connected to the ratcheting clamp.

This concept offers an interesting approach to rotational locking. The ratcheting mechanism is also common with biomedical instruments like repositioning forceps which adds to the ease of use factor as surgeons would be comfortable with the mechanism. The weakness of this concept is that there are many additional components to manufacture.

Based on a brief evaluation of each rotational locking concept, our team decided to move ahead with the ratcheting mechanism as it offered a familiar approach for surgeons for robust locking and did not require complex manufacturing. This design choice is reflected in the Build Design are team made for verification and validation testing that is detailed later in the report.

In summary, our build design was devised as a way of building a low-cost prototype that would allow us to verify key operating mechanisms of our design and evaluate their feasibility for the final design.

Differences between Build and Final Design

Our build design differs from our final design in several ways. Primarily, it is smaller than our final design, which is intended to be large enough to meet our specification. We reduced the size of our build design so we could easily waterjet it with our available resources. Our build design also simplifies many of the parts for the sake of rapid

manufacturing right now, avoiding milling and lathing options where possible in favor of water jetting. In a manufacturing setting, more complex parts can be casted or CNC machined in mass. The build is intended to validate some of the general usage ideas behind the design in an attempt to address the problem below scale and below cost.

Engineering Analysis & Iteration

Relevant Engineering Fundamentals

Our engineering specifications address the key categories our design needs to achieve to be successful: safety, durability, low cost, adequate surgical visualization, ease of use, ease of assembly, and disassembly and manufacturability. The requirements encompass various design considerations highlighted in our project description, secondary research into abdominal retractors and informed by interviews with our project mentor, Dr. Dhanu Thiyag, and other key stakeholders.

Achieving our design specifications and requirements involves incorporating core engineering fundamentals into our design process when generating and validating designs. Figure 41 below identifies the core engineering concepts in tackling our engineering specifications and requirements.

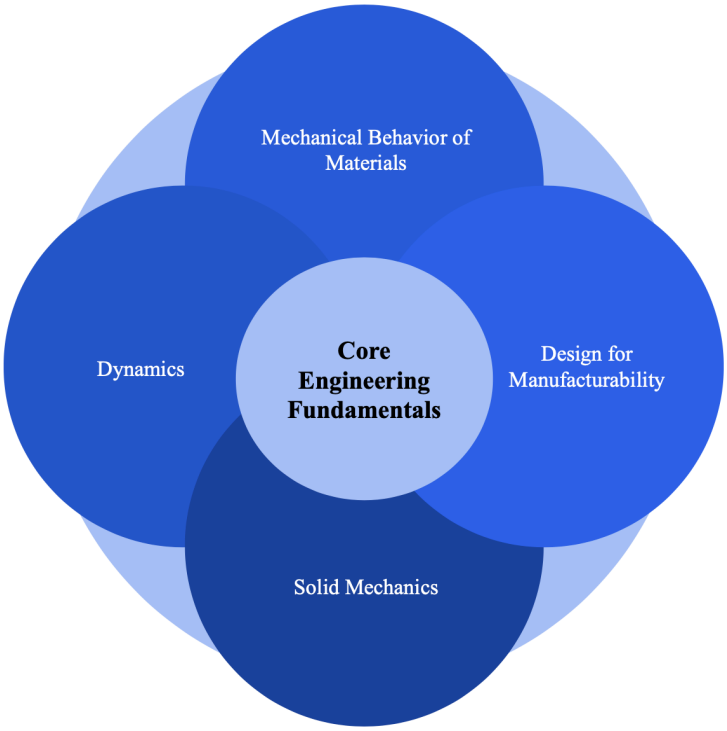


Figure 41. The core engineering fundamentals that are essential to our project. These fundamentals include dynamics, mechanical behavior of materials, design for manufacturability and solid mechanics.

Mechanical behavior of materials.

This core principle will help inform our material selection between biocompatible plastics or metals which will influence the reusability and manufacturability of our product. It will also help in identifying our product's modes of failure - yield, cracking or fatigue, etc. This will help us determine appropriate shapes and sizes to mitigate failure.

Design for manufacturability.

Designing for manufacturability will be key in helping us address manufacturing costs as well as exploring the potential of making the product manufacturable with resources and facilities regional to Ghana and the Korle Bu Teaching Hospital. By optimizing our design's manufacturability, we can reduce the amount of material used in products, simplify the final design by eliminating redundant parts, and deliver a low-cost solution.

Solid Mechanics.

Solid mechanics will help with determining the appropriate geometries of our retractor that will allow it to handle the expected stresses and compressive forces imposed by the patient's skin, tissue, and fat. Further into our design process, we can utilize finite element analysis (FEA) to digitally simulate how our design performs and behaves under loads to validate designs.

Dynamics.

Dynamic analysis will be a useful tool in the design of any moving part of our design. It will help us identify the relevant range of motion that our product needs to achieve. It will also help us analyze the impact of vibrations on the structural integrity of the product that may arise from accidental and sudden movements.

The diagram below, Figure 42, illustrates the engineering tests that can be performed to validate the functions of the retractor from our functional decomposition. These are the precursor tests that can be run on parts of the product before finalizing the concept to suggest that it will fit with most of our requirements.



Figure 42. Diagram that details the engineering analysis for functional decomposed functions. Boxes in red indicate tests we would like to run to verify the function requirement but due to time constraints we will opt for faster verification methods.

Below we will detail the analysis (including the analysis in the above diagram) that we use for our final design and its successive iterations to each specification for validation and verification. We will first focus on the high (1) priority requirements in each category and discuss how we plan to test them and contingency in case the first tests prove inconclusive. This will be followed by the medium priority and then lower priority specifications. We aim to use the quickest and easiest methods of validating our requirements without having to manufacture a final prototype before we start testing.

We aim to ensure that our prototype will satisfy at least the minimum specifications of our high priorities. Iterations will be prioritized in the interest of satisfying optimal specifications.

Analysis techniques for medium priority specifications

Ease of Deployment.

The medium priority specification is the ability for the retractor to be deployed with minimal hands. We can verify if a certain concept might work through inspection of our virtual model (CAD). However, we can also 3D print the various parts to validate deploying the retractor in a simulated circumstance such as a cardboard box with a foam opening at the top to mimic a cavity opening.

Ease of Assembly and Disassembly.

Two medium-priority specifications cover the speed and ease for disassembling and assembling the retractor respectively. Both of these specifications can be tested with 3D printing parts of our concept that volunteers can be timed to put together and take apart. Since the parts are plastic and will not have a clean finish they will be more difficult to fit seamlessly together and validating the specifications with them will overestimate their validation for a furnished final product.

Durability/ Reliability.

There is a single medium-priority specification that requires the retractor to withstand force over the years of potential use. This requirement would need analysis through solid mechanics. The weak joint that would cause the retractor to close prematurely is the attachment connecting the two sides, therefore that will be what we analyze the compressive stress from the cavity over multiple uses. This can be estimated using cyclic fatigue FEA.

Adjustability.

There are two medium priority specifications that detail the horizontal adjustability of the retractor frame and the depth that the blades can reach. We can validate both with inspection and measuring of the design against virtual cavities modeled into virtual bodies. This will inform us of if the frame adjustability of blade length has to be increased.

Safety.

Three medium-priority specifications focus on the retractor finish, patient safety, and surgeon convenience.

Roughness - The finish of the product should have a clean finish with no pointy edges that could injure the user or patient. We can ensure minimized roughness by choosing materials that are capable of clean finishes either with physical or chemical polishing. If our

chosen material is not compatible with either method we will have to select another for our concept. In terms of our current final design, both stainless steel and aluminum are capable of being polished to a clean finish with physical and chemical polishing respectively. Therefore, we can conclude that our current concept is capable of passing this specification.

Prevent potential nerve damage - This specification is our most vague due to it varying for each patient's requirement during surgery and surgeons subjectively loosening and tightening the retractor at their discretion. Therefore, we would want to validate this requirement by 3D printing (if full manufacturing is not possible) the retractor frame and primary blades.

Minimize obstruction to surgeon space - We will validate this requirement with an inspection of our virtual model against a cavity in a virtual human model[45]. With measurement and inspection, we will be able to validate our concept.

Cost

There are two-medium priority specifications for cost one for acquisition cost and another for lifetime cost. We can estimate an upfront cost with estimates from 'hubs.com' for CNC manufactured parts. This will be an overestimation of the cost of manufacturing since costs are greater in the United States than in Ghana. With Granta EduPack we can estimate the lifetime cost of the product if manufactured in Ghana (within a certain square mile radius) for a lifetime of 3 to 5 years that we want the product to last for.

Analysis techniques for low priority specifications

Manufacturing/ Local Maintenance.

There are three low specifications that relate to having local and swift manufacturing and maintenance. All of these can be estimated based on manufacturing companies close to Korle-Bu. We would have to contact these companies for specific quotes and timelines to get accurate estimates which will be out of scope for this project. We will be providing the sponsor with a list of possible manufacturers and maintenance contacts that could be of service to them when they further this project for mass production.

We have currently narrowed it down to a material selection, 304 stainless steel, and that is most likely to adhere to our safety specifications related to material selection. Our current alpha design suggests use of this material will pass the current minimum specifications for weight. Our next steps would be to concurrently run FEA tests on the relative specifications that require it and 3D printing of the parts for tests to continue the validation of our current design or to identify necessary places for iteration.

Verification and Validation

We developed a set of verification and validation plans to ensure that we met all our requirements, including statics calculations, finite element analysis, and testing our build design. The tables below outline our specifications and their corresponding verification plans. Some of our tests required user testing for twenty individuals so we could receive a baseline yet manageable amount of data. However, given the semester's short timeline, we did not execute these tests, and instead recommend them for future work. All the testing statuses labeled "N/A" are tests that we additionally could not verify due to time constraints.

While the majority of our tests proved successful, we failed our adjustability requirement and only met our minimum specification of the critical ease of assembly section. However, we believe some of our failures during verification were related to manufacturing issues in our build design, such as the vertical clamp failing to constrain the top plate and interfering with our locking mechanism.

Further information regarding the tests including our statics calculations is provided in Appendix C.

Table 5. Verification Plans for all User Requirements and Engineering Specifications

Ease of Deployment (placing the retractor in the surgical cavity)					
Requirement	Minimum Specification	Optimal Specification	Verification method	Priority	Status
Product easy to carry and quick to deploy	Product should weigh **< 4 kilograms**	Product should weigh **< 2.5 kilograms**	Modeling - gather volume from SolidWorks Materials - decide based on predicted weights from part volumes	High	Optimal Pass
	Product deployment should take **< 5 minutes**	Product configuration for operation should take **< 30 seconds**	Testing - collect data on 20 people deploying the product with gloves on.	High	N/A
Self-retaining mechanism can be deployed with minimal personnel	Mechanism should be able to be deployed into the open cavity with **two hands**	Mechanism should be able to be deployed into open cavity with **one hand**		Medium	N/A

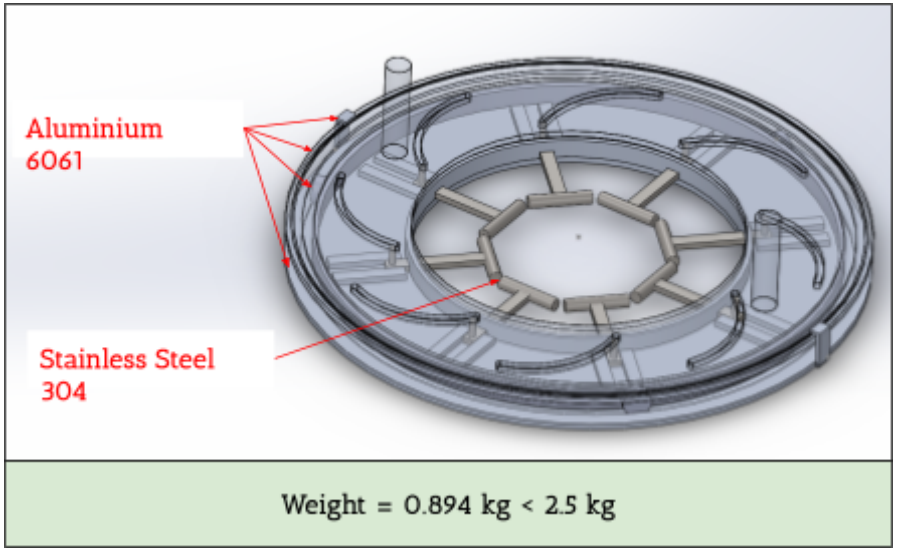


Figure 43. Weight specification determined from CAD

Ease of Assembly and Disassembly (to sanitize the separate parts outside of the surgical suite)					
Requirement	Minimum Specification	Optimal Specification	Verification method	Priority	Status
Product can be disassembled and assembled using readily available hand tools or nothing	Requires **< 2 common tools** to assemble and disassemble	Requires **no tools** to assemble and disassemble	Build design assembly	High	Minimum Pass
			Testing - collect data on 20 people assembling and disassembling the product as fast as possible.		N/A
Product must be easy and quick to disassemble for sterilization	Product disassembly **< 5 min**	Product disassembly **< 3 min**		Medium	N/A
Product must be easy and quick to assemble for operation	Product assembly **< 7 min**	Product assembly **< 5 min**		Medium	N/A

Durability/ Reliable					
Requirement	Minimum Specification	Optimal Specification	Verification Method	Priority	Status
Product should limit the closing of the abdominal cavity opening with sufficient force during operation	The product should restrict the closing of an **40N** force per blade to **5 cm^2** in **2 hours**	The product should restrict the closing of a **50N** force per blade to **1 cm^2** in **2 hours**	Testing - compressive test rig with loads on either side	High	N/A
Product should be mechanically functional over time	Product should should be able to withstand **40N** force per blade after a minimum of **2200 uses** over 3 years	Product should be be able to withstand **50N** force per blade after a minimum of **3650 uses** over 5 years	Testing - figure out cycles of use before fatigue	Medium	N/A

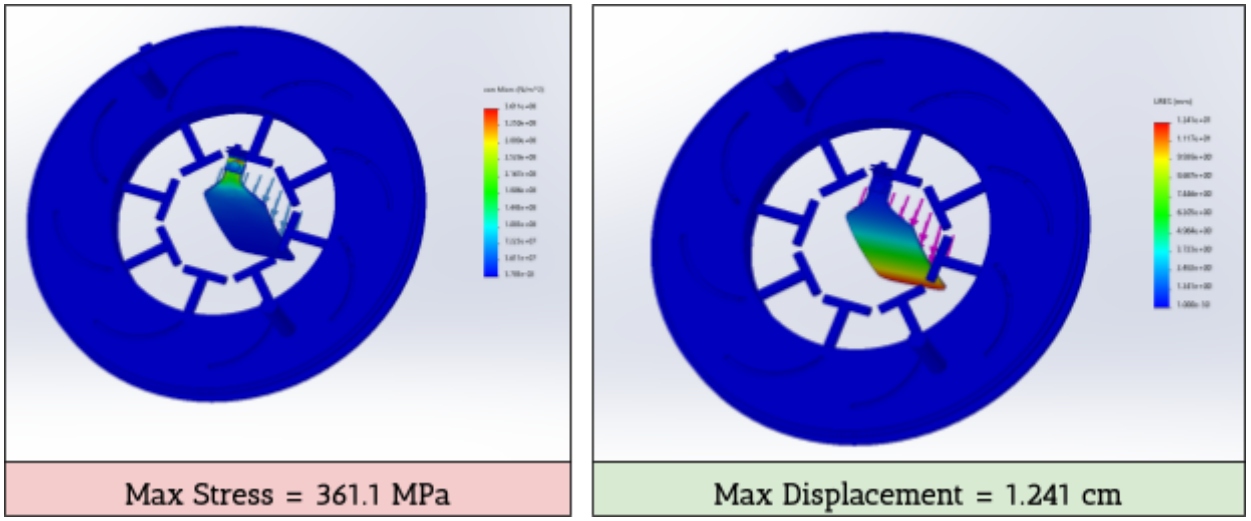


Figure 44. FEA with 20 N load on retractor blades as part of our initial specifications.
The maximum stress is high at the joint due to small geometry that no longer exists in our design.

Adjustability					
Requirement	Minimum Specification	Optimal Specification	Verification Method	Priority	Status
Product dimensions can be adjusted to meet the 1st to the 99th percentile of patient body dimensions	Product retracts a range of **70 cm^2 to 178cm^2**	Product retracts a range of **70cm^2 to 353 cm^2**	Build design inspection and measurement	Medium	Fail
Product should account for different patient cavity depths	Depth range of **15 to 25 mm**	Depth range of **15 to 60 mm**	Build design inspection and measurement with Thompson blades	Medium	N/A

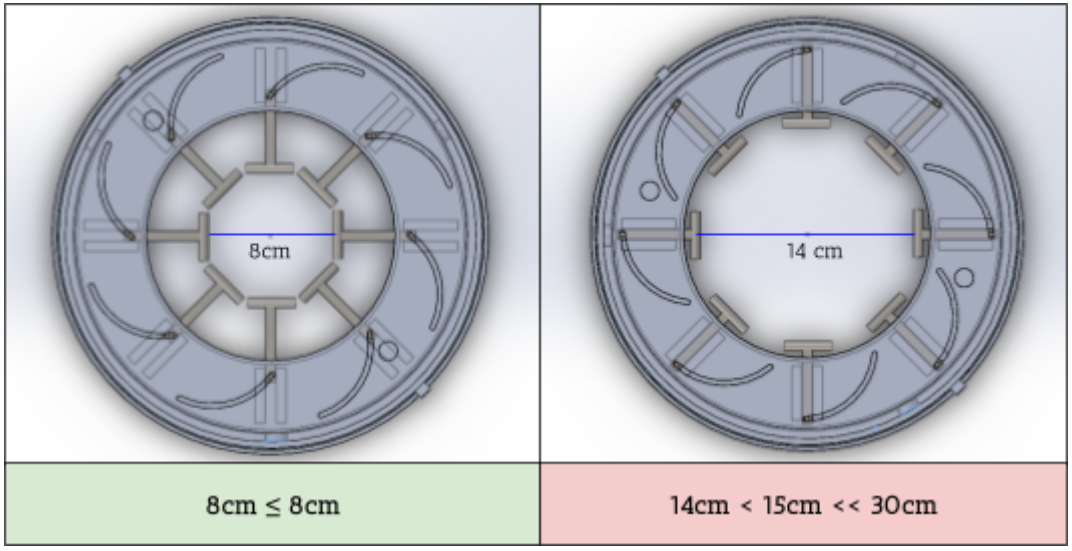


Figure 45. Adjustability from initial version. Verification has shown that it is currently not viable. Design must be scaled for usage, across different people and different surgeries.

Safety					
Requirement	Minimum Specification	Optimal Specification	Verification Method	Priority	Status
Product must withstand sanitation in an autoclave	—	Material can withstand **134°C** and **30 psi**	Material Selection	High	Pass
	Each part must fit in **140 cm** x **46 cm** x **46 cm**	All parts must fit together in **140 cm** x **46 cm** x **46 cm**	Inspection - measure volume of each part		Pass
Materials must not change in strength across multiple usages	No cracking over **1 mm** after 3 years (**2200 uses**) with **100N** compressive stress Likert scale > 3.5 for ideal state (looking good as new)	No cracking over **0.5 mm** after 5 years (**2200 uses**) with **80N** compressive stress Likert scale > 4 for ideal state (looking good as new)	Compressive test rig with checking for any deformations or cracking after total uses. 20 users rate visual condition based on before and after images.	High	N/A
Product should meet ISO 10993 - biocompatibility standards [15]	—	Select a material from a list of materials used for orthopedic implants [9]	Material Selection	High	Pass
Surgeons should have an adequate field of view not obscured by the product	The product can be set to **obstruct < 5%** of the surgical field **at the start of surgery**	The product can be continually set to **obstruct < 5%** of the surgical field **during surgery**	Testing - collect data on various people, asking them to rate if they think more or less than 5% of the surgical field has been obstructed by the product	High	N/A
Product should meet ISO 21920 - safe surface roughness[16]	surface roughness **< 6µm**	surface roughness **< 0.8µm**	Testing - Avoid injury upon running finger along project as per the standard Material - select materials with ability of having physical or chemical smoothe finishes	Medium	Pass

Safety					
Requirement	Minimum Specification	Optimal Specification	Verification Method	Priority	Status
Product prevents potential nerve damage to patients***	Product can be **loosened** during surgery off **< 1 cm** from their intended distance Likert > 3.5 for feeling to the user	Product can be **loosened and tightened** during surgery **< 1 cm** off from their desired distance Likert > 3.5 for feeling to the user)	Testing - collect data on various populations of people loosening and Tightening the retractor to their wanted dimension.	Medium	N/A
Surgeon should have an adequate space for movement not obstructed by the product	Surgeons feel they have adequate space to move around the surgical site. Likert > 3.5 for sufficient space	Likert > 4 for sufficient space	Testing - collect data on different people, not necessarily doctors	Medium	N/A

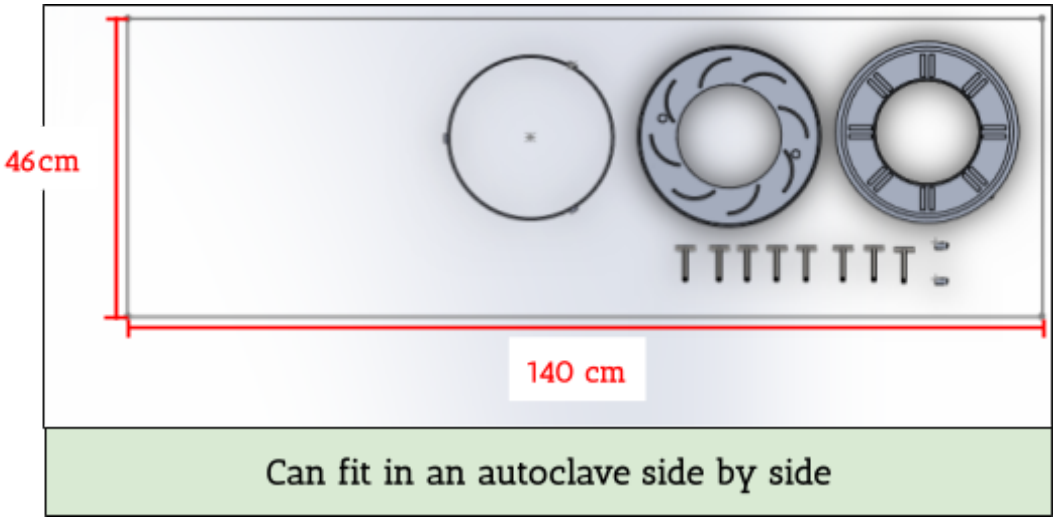


Figure 46. Autoclavability of our final design based on size.

Cost					
Requirement	Minimum Specification	Optimal Specification	Verification Method	Priority	Status
Product should be cost-effective over its lifetime	The product's cost per use should be **< $2**	The product's cost per use should be **< $0.12**	Cost estimation - with GRANTA EduPack	Medium	Pass
Product should be low-cost for purchase	The acquisition cost of the product should be **< $450** [11]	The acquisition cost of the product should be **< $300** [33]	Cost estimation - with Xometry	Medium	N/A

Manufacturing/ Local Maintenance					
Requirement	Minimum Specification	Optimal Specification	**Analysis** Method	Priority	Status
Product should be locally manufactured as much as possible	**< 2 parts** are needed to be sourced/manufactured from outside Ghana	All parts can be sourced/manufactured in Ghana	Research - find manufacturing plant in Ghana capable of sourcing and manufacturing our materials	Low	Optimal Pass
Product should be able to be maintained and repaired close to the KBTH site	**< 2 parts** need maintenance and repair from outside of Ghana	Maintenance and repair for all parts are available all within Ghana	Research - find repair service in Ghana capable of maintaining our product	Low	N/A
Product should have a short lead time (manufacturing order to deliver) to account for demand spikes	The total lead time should be **< 50 hours**	The total lead time should be **< 26 hours**	Research - find manufacturing plant capable of sourcing and manufacturing our materials close within 10 mile radius of Korle Bu	Low	N/A

Testing Summary

The results of our testing were primarily positive or untestable due to issues with the build design. We were able to test very simple items, such as assembly and weight; however, most of our specifications related to the usability and functionality have not been addressed by neither this build design nor the initial final design. The main considerations that should be acknowledged from these results are as follows:

1. Firstly, this build and initial final design are the result of a shift in concept halfway through our solution development. Our alpha design is notably different, which forced this design to operate on a half intentionally allotted schedule.

2. Secondly, throughout the build, no requirements were weighed to be more important than any others for testing. If there had been more intentionality behind which specific requirements we wanted to address with the build, we likely could have collected results for a couple more of the critical specifications.

3. Finally, the build design was not adequately functional, which has guided us through redesign efforts, allowing the build to serve its purpose of guiding the final design.

Final Design - Post-Validation

Based on results from verification testing of our build design we identified problem areas, particularly in the handles, vertical clamps, and rotational locking mechanism. Detailed below are the changes made for these specific problem areas.

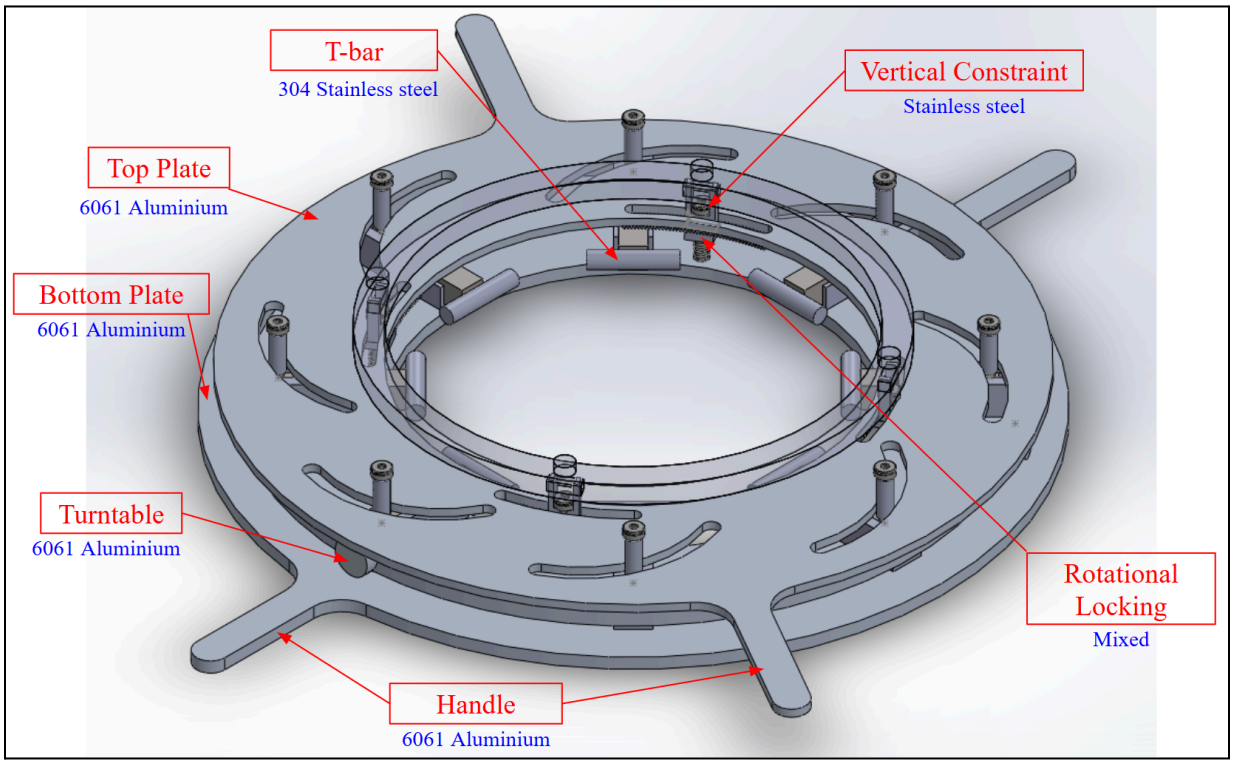


Figure 47. Overview CAD assembly of Final Design (after verification) with labeled critical components

Handles

The build design (Figure 30) had smaller handles on the side that proved difficult to grip. The new handles, as shown in Figure 47, are 2 inches longer and should allow adequate grip with two fingers and a thumb while still not interfering with the user's space.

Vertical Locking

Our main point of failure in our earlier design were the clamping brackets that vertically constrained the plates. We attributed that failure to the small size and material of the parts as well as their position on the outside of the plates. We had not accounted for the force exerted on the parts from the plates trying to translate over one another, not just rotate.

For a redesign, we chose to use stainless steel (higher tensile strength than aluminum) head screws that attach to the bottom plate closer to the center at four points (Figure 48.A). The top plate has slots that allow it to rotate across the body of the screws (Figure 48.B). The positioning assists with stopping the plates from translating over each other in addition to their rotational motions.

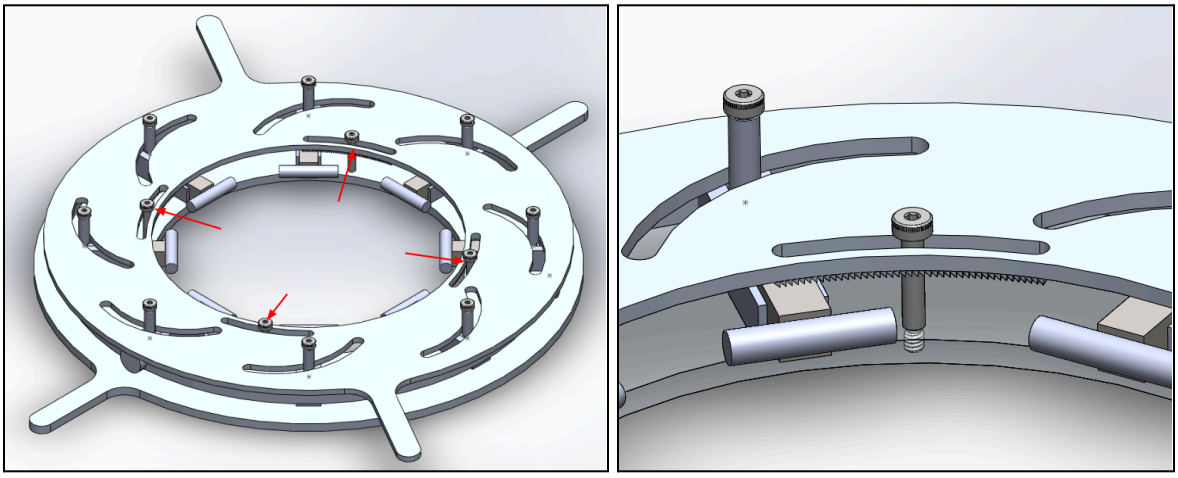


Figure 48. (A) CAD Model of retractor frame with arrows indicating the screws vertically constraining the plates (B) Close up view of a vertical costraining screw

Rotational Locking

During testing of the initial design, a key failure point of our rotational locking mechanism was that it was constrained at only one location on the outside of the plates and was difficult to tension given.

In the redesigned version, we implemented four linear ratchet contacts. These ratchet contacts allow the top plate to move freely in the counterclockwise direction, thereby separating the T-bars. A spring mechanism pushes each locking contact upward to prevent the top plate from rotating clockwise (Figure 49.A). To enable clockwise rotation, we designed a round plastic ring that fits over the bottom ratchet teeth contacts. We indicated raised surfaces on the ring to indicate how to orient it to the bottom ratchet contacts. Pressing down on this ring separates the teeth, allowing smooth clockwise rotation (Figure 49.B).

The plastic top ring is removable, which makes it difficult to disengage all the ratchet connections simultaneously. This design minimizes the risk of accidental closure during surgery, improving both reliability and safety.

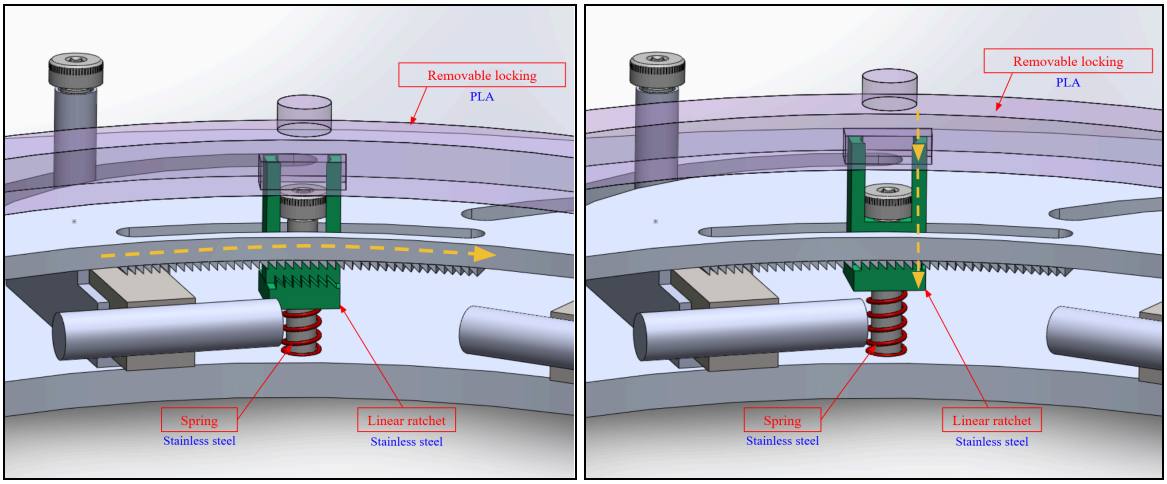


Figure 49. (A) CAD of the rotational locking mechanism with the ratchet teeth meshed (B) CAD of the rotational locking mechanism with the top ring pressing down on the locking contact separating the teeth

We designed these changes after the build design broke during testing therefore these changes may not still validate our requirements but we assume that they will improve the chances. A few issues to look out for are friction due to more interacting parts when rotating the top plate, ergonomics of the new handles, and reliability of the new locking in simulated test conditions.

Problem Domain Analysis & Reflection

Deliverables

At the end of the project, we aim to have a final design as a virtual model (CAD), a built design (that validates the physical specification tests), and a document that details the next step considerations for furthering this project to a final physical product that can be mass manufactured.

We are confident that we can at least finish a first round of verification of the high-priority specifications and that our final design as a virtual model will reflect the changes needed to surpass these specifications if they did not do so in the first tests. We are also confident that we will be able to deliver a final list of the next steps for further progression of this idea. Our built design will be to validate the physical tests we have set. While we hope to have a manufactured version of our design, if time constraints prove too difficult, we will use 3D printing or other materials we use for rapid prototyping.

The primary “drivers” behind our design decisions include adjustability, patient safety, and blade locking. The upper plate of the design requires a suitable mechanism for adjustability and locking. Therefore, we must design a safe and durable locking mechanism to hold the plate in place once it has been rotated to the desired position. Furthermore, patient safety is a concern given the inability to test patients and regulations prohibiting interviews. To address this, we will execute static calculations by hand to find maximum bending moments based on quantified forces from skin, tissue, and muscle using equations taught in Michigan Engineering’s solid mechanics class. We will additionally simulate interactions between our CAD model and a virtual, 3D model of the human body using Solidworks static testing methods. When the prototype is built, we may test it on materials similar to the human body such as pig skin.

Anticipated Challenges

Patient Safety.

For our project, we anticipate various technical difficulties in assessing our engineering specifications. Clinical trials and patient testing are out of the scope of our project due to time and budget constraints inherently imposed by the class structure. To combat this, we plan on simulating a developed CAD model of our design in Solidworks. This will help us understand how our design interacts with patients and serve as a verification method for our product's safety requirements.

Modeling Effects of Skin and Tissues Mechanics.

Another issue we anticipate is simulating or replicating the effects of skin and tissue mechanics on the retractor. This arises from our limited ability to empirically test our concepts and alpha design as highlighted above. To overcome this, we plan on creating low to high-fidelity FEA simulations throughout our design process to model the impact of skin and tissue elasticity. Furthermore, we may consult Biomedical and/or Mechanical Engineering professors at the University of Michigan who specialize in modeling and studying human skin and tissue mechanics.

Standards and Regulations.

Ensuring our design adheres to ISO, WHO and other relevant biomedical device standards and regulations is an essential part of our design process. The potential issues with this are meeting the surface roughness and finish standards which will be difficult to validate with limited availability of metrology equipment and may be an expensive cost in the manufacturing process. This can be overcome by establishing manufacturing standards that need to be met and satisfy regulations and analyzing the costs associated to help with estimating costs of production.

Estimating Costs of Manufacturing.

We anticipate difficulty in estimating the cost per use of our design with limited understanding of manufacturing and labor capabilities and costs in Ghana which prevents us from evaluating manufacturing locally against internationally. Since manufacturability is a low-priority user requirement, we only plan on contacting facilities staff at the Korle Bu Teaching Hospital community to better understand regional biomedical device manufacturers to get more accurate estimates of the local costs of production and the manufacturing capacity..

Prototyping Time

Our finalized model is admittedly fairly complex, mostly from the perspective of how little time is left in the semester to rework it and create a prototype for our build design. We've found that 3D printing worked as a general proof of concept alongside the CAD model itself. However, to reach some of our verification goals and maybe some of the simpler validation goals, we must make a prototype or build that attempts to perform the tasks or requirements we set out instead of remaining theoretical. This is largely difficult due to the little time left in the semester and the complex shapes of the parts. We expect to try and break down these parts into subcomponents for rapid prototyping, however, this will be directly against our easy-to-assemble specification as it will likely have many parts as a result. For the sake of an initial build, however, that has been descoped.

Even Distribution of Pressure as a Hindrance

By the very nature of the design, each retractor must pull as it is opened. While the typical standard operating procedure we envisioned as a team involves putting in initial retractors, and then adding and rotating other retractors as desired to get more or less compression at certain points, this introduces a potential for difficulty or impossibility of use. If a cavity shape needs to change into some shape that cannot easily be encompassed by the sizing requirements of our retractor, it could cause the whole system to become useless in the middle of the surgery. To counteract this, we hope to verify that there is still added adjustability in the rotation of each blade that can provide a sufficient level of added customization for the surgery.

Blade Connector Strength

The final concern in our design is the blade connector component that interfaces with the adjustability mechanism. This connection point is the most clear point of failure in our design, so ensuring that it is strong enough to meet our specifications and prototyping it quickly is fairly important to us. We are redeveloping certain aspects of the design before prototyping but we will try to pursue this component in parallel with the whole design to try and get ahead of this concern.

Discussion

With the completion of the semester, we can now review our design and design process including how we defined our given problem, the functionality of our design, and the risks we faced as well as potential risks that could be experienced by product users.

Problem Definition

If we had more time to better define our problem, we would further research if rusting is a significant issue during sterilization. One of the expressed issues with the Balfour retractor was that it degraded quickly from autoclaving. To combat this, we stipulated in our requirements that our selected material must withstand 134 degrees Celsius and 30 psi without changing color or shape. However, we did not research nuances such as how much the part can rust, if the part rusts, if it is still usable if the rust is removed (or if a rust-removing product is available at Korle Bu). If we were to redo the project, we would search for potential articles on rusting in an autoclave (or under similar conditions) as well as interview our sponsor about her experiences with rusting.

Additionally, we would further study body mechanics including how much rubbing skin can safely withstand from a device resting on it. We focused on more urgent safety concerns such as preventing infection from harmful materials or protecting against nerve damage due to blades slipping. However, since our retractor has a greater surface contact with the patient's skin compared to other models, this rubbing would be more significant for us to investigate. To accomplish this, we would research the friction coefficients of skin and our selected materials as well as if there are any significant differences in skin sensitivities. Furthermore, we could research potential interfaces between skin and metal that would help protect the patient such as a medical rubber. While rubbers are known for their high friction coefficients, the material is softer and may prevent slipping which could potentially result in injury.

Design Critiques

The main strength of our design is its camera shutter mechanism, which translates rotational motion into linear motion. Given the understaffed conditions at Korle Bu, creating a retractor that a single person can deploy is a significant triumph, especially since current models commonly require several people to use. In addition, our retractor is free-standing, overriding the issue of difficulty of deployment with table-standing retractors. Furthermore, unlike other free-standing retractors such as the Balfour, it can still withstand the force of high BMI patients without collapsing.

On the other hand, weaknesses include our locking mechanisms and sources of unwanted friction. Specifically, our vertical locking mechanism was difficult to tap given its small size and partially hollowed structure, resulting in breaking and its failure to hold onto the two plates. Axial locking in general proved difficult given that it had to be executed on the outside of the plates since the inside was occupied by the T-slot housing and T-slots. In future designs, we

would investigate alternative slot shapes that do not require such tight tolerances. Furthermore, due to there being eight slots and tight tolerances between the T-slots and shoulder bolts, we had many sources of friction in unideal locations. Through both hand calculations and prototype testing, we found that this could add unwanted difficulties in turning the retractor. If we were to redesign our product, we would address these issues by testing alternative slot shapes that do not require such tight tolerances.

Risk

Our design process prevented risk by remaining design-neutral, allowing us to remain safe and on schedule when we quickly changed our design. After we selected one idea, we were still in the concept generation mindset, limiting us from fully committing to and exploring our verification and validation tests. When we had a second, very different idea, we transitioned to execute it quickly due to its novel conversion of radial to linear motion. Fortunately, due to our design-independent requirements, the verification and validation measures remained the same for both designs, such as if the product could fit in an autoclave. By outlining design-neutral steps to determine the success of our product, we ensured that conceptual changes would not derail our design process.

Risks associated with the end user include the freedom of blade placement. An intended strength of our design was to create eight locations where blades could be placed, allowing for different incision shapes to be held open. However, more freedom could result in a greater chance of injury. There may be nonoptimal blade positions that inexperienced doctors use, resulting in longer recovery times and increasing injury potential for the patient. Furthermore, another potential risk to the user is blistering or skin irritation from turning the handles. While ideally, turning the plates should only last seconds, if surgeries become more frequent or in the unlikely case that the locking mechanism fails, holding the metal handles could become potentially irritating.

Reflection

Project Factors

Public Health, Safety, and Welfare

Public health is crucial to our project as its targeted users, OB/GYNs, are in the medical field. Our requirements and specifications had a section dedicated to safety, with each requirement ranked as either the highest or second highest priority. Our project serves to keep medical professionals and patients safe and is inoperable if it does not meet critical safety standards set by the medical field. Our overarching motivation is to promote equitable healthcare and make the world safer by assisting critical surgical procedures in resource-constrained environments.

Global Context

Our design, through its connection between an American university and a Ghanaian hospital, is based on international relations. During our problem definition phase, we specifically interviewed Korle Bu doctors to understand how we could tailor our product to their needs. In particular, we were mindful of Korle Bu's resource constraints, and how our design would need to address their unique difficulties. Hopefully, by addressing these resource constraints at Korle Bu, our product will be deployable in similar environments around the world.

Social and Economic Impacts of Manufacturing, Use, and Disposal

Through our research and interviews with Korle Bu's biomedical department, we determined that our product is buildable and maintainable in Ghana. Therefore, funding for manufacturing would remain local, helping bolster Ghanaian businesses and eliminating hefty fees associated with shipping. Additionally, by eliminating shipping steps such as flying or sailing our product, the pollution associated with travel will be reduced. However, there are still environmental concerns, especially around the disposal of our product. Our product is made primarily of metal, which is often discarded in scrap yards. Furthermore, there is pollution associated with manufacturing, which disproportionately affects lower-income populations; for example, raising the acidity level of fishing waters. While the reduced cost of the retractor and its simple deployment are positive societal gains, the impacts of manufacturing and disposal are important factors to consider in the design.

Societal Impacts

Tools we used to characterize the social impacts of our design included Stakeholder Impact Tables and a Stakeholder Ecosystem Map. These tools were especially useful during the concept generation phase by helping us converge our ideas and eliminate infeasible concepts.

Culture, Privilege, and Identity

Our team shared the common identity of being University of Michigan students with access to well-funded research and manufacturing opportunities. This privilege allowed us to fully explore our ideas within an impressive maker space, even if our material budget was limited. Therefore, tensions that may have arisen from space constraints or travel times/access to manufacturing shops were avoided. In addition, our sponsor had an engineering background, meaning that we did not have to explain basic physics principles and could use technical language if necessary.

Differences in our team included three out of four team members being people of color and two being women. Despite these identity differences, we remain mostly respectful of each other's ideas, creating an inclusive environment for executing the design process. The greatest conflicts came from heavy course loads, delaying our timeline for working on reports; however, we rallied together during high-stress times to finish our coursework together.

Our greatest differences arose between our team and our sponsor, Dr. Thiyag. Dr. Thiyag works at Korle Bu and therefore had insights into what would be most helpful for her and the OB/GYN department. As we were physically removed from Ghana, it was our job to listen to the needs and constraints of Korle Bu's unique environment. Unknown cultural differences such as the professional hierarchy for interviews proved crucial to developing a solution while remaining respectful of their processes.

While it is important to remain aware and respectful of role differences, they can enhance the design process by bringing unique perspectives to an issue. Dr. Thiyag set objectives and constraints based on her experiences, and we innovated using our own backgrounds and academic training. Therefore, as long as both groups remain respectful of each other, sharing different identities and perspectives can facilitate a positive engineering design process, especially when allied in promoting social justice such as equitable healthcare for all.

Inclusion and Equity

Power Dynamics

Our primary power dynamic was between our sponsor and our group, as she set the project goals and could reject or accept ideas based on what was most useful to her. On the other hand, we were still designers who had ultimately made engineering choices even if influenced by her wants. If providing financial income, Dr. Thiyag's power would be elevated, as that money could be withdrawn, but due to the structure of the class, we maintained a working relationship that we found to be professional and inspiring. On the other hand, patients for whom the retractor would be used have no say in what the hospital purchases or how surgeons choose to use the retractor. Yet while personally, patient power is limited, there are international organizations such as the World Health Association (WHO) that have set safety standards to ensure this power imbalance cannot be abused. Within the team itself, we were on equal ground as Michigan engineering students, yet had differences in gender and race, with some groups traditionally

being associated with engineering more than others. We addressed this by having systematic work sessions in which everyone was given access to a whiteboard or scratch paper, as well as positioning ourselves to sit in a square so that everyone had the same tools and potential to be heard. In fostering sensitivity and respect for each other, our empathy continued into our work as we researched several articles and interviewed many medical professionals to ensure the lower-powered patients were safe.

Idea Balances

We balanced project ideas by creating design-independent requirements and remaining true to them. For example, our sponsor encouraged a balloon-based retractor which, while a creative solution, after research was found to be unsafe due to its easy puncturing. Furthermore, we created a Pugh chart based on our requirements, in which the balloon design was lost to our alpha concept, which we communicated to our sponsor. These strategies also proved helpful within our team as we could point directly to our utilized tools to settle any disagreements.

Cultural Impacts

Cultural differences between our team and sponsor included differences in the engineering and medical cultures. Engineers are more fluid, with bachelor's degrees able to progress far into the field without question. On the other hand, every step of the medical process, including the ranking of graduated doctors, was important to acknowledge and respect to facilitate the best cooperation between us and Korle Bu. Dr. Thiyag, who also has a background in engineering, helped navigate this dynamic as she has experienced both worlds. When presenting an engineering concept, we could speak in engineering “lingo” if required, yet she also informed us about the care we had to take when addressing medical professionals. This dynamic allowed Dr. Thiyag to have a heavy influence on our final product as we would discuss meeting with other professionals before interviews.

Within our team, we had members representing three countries, which allowed us to bring our unique perspectives into the design process. However, we had a common understanding of a camera shutter mechanism, having all used cameras ourselves, which was the inspiration for the final design. Therefore, when a camera shutter idea was proposed, we all understood the general concept and were able to research improvements. Yet regardless of how we had known the device itself, engineering principles are universal, with designs being comprehensible through proper documentation and listening. We believe that the beauty of engineering itself is that it can be shared across cultures and used for the common good.

Ethics

During the design of our project, we faced ethical dilemmas such as abiding by patent laws and ensuring our product was safe for both surgeons and patients. Since the retractor market is so saturated, it was difficult to generate our ideas without discovering that they had already been built and patented. The research process could be frustrating, and given our heavy course

load, there is a temptation to use an existing invention with a finished design report. However, we were determined to create something novel and instead utilized concept generation tools such as organized brainstorming sessions to find our solution.

Moving beyond the design process, if our project were to enter into the marketplace, ethical issues that may arise include mitigating pollution from manufacturing and transport. Additionally, if we expanded our market to serve several middle and low-income locations, resources and manufacturing capabilities could become constrained. In the medical world, where time can be a factor in saving lives, deciding who has priority to receive medical devices is a difficult conflict.

For academic conflicts, our ethics differed from the University of Michigan's by remaining intuitive versus explicit. Entering the project, we understood concepts such as patient safety, yet through Michigan's class structure, were forced to document all ethical considerations, encouraging us to investigate nuances in the design process such as material roughness versus preventing nerve damage. Other than this difference, we found that our ethics remained aligned with Michigan's. For future employers, ethics may become a greater issue as salaries can impact our lives significantly more than grades. In an academic setting, we can take risks and challenge norms we find unethical. However, if an employer demands a reduced timeline or insufficient testing to increase profit, this can have profound impacts on the safety of the user as well as incur personal harm from refuting these demands. When budgets and stakeholders increase, design dynamics can become more difficult to navigate even if a designer's moral principles remain the same. Therefore, it is important to reflect and incorporate the ethics lessons we have learned at Michigan into the workforce.

Recommendations

Manufacturing and Design

We would recommend updating the build design to mimic the vertical and rotational constraints in our Final Design before any testing or iteration. As we iterated before, a lot of our verification failed due to not having proper constraints for vertical and lateral translation. Addressing this issue may result in more accurate and practical physical test outcomes that can be analyzed to improve the design further.

Additionally, we suggest implementing the following updates to the build design that would require remanufacturing the two plates and procuring/manufacturing a few more parts:

- Implement the new handle and locking designs by recutting the new plate using the waterjet. The top plate may have to be manufactured through CNC to cut out the ratchet teeth
- Manufacture and integrate the new locking mechanism to improve rotational control and stability.
- Consider removing the turntable component if it no longer adds value to the current system.
- Consider adding further rollers for the vertical constraint to reduce friction and allow for smooth rotation of the top plate.

Testing Recommendations

To streamline the testing process and improve data collection efficiency, we recommend the following:

- Likert Scale and Population-Based Testing: Conduct all user tests in a single session per participant. This approach could maximize the data collected per individual and reduce logistical challenges.
- Ergonomic Testing: Perform focused tests to evaluate the ergonomics of the handle design and the overall ease of handling the retractor. These tests can include user feedback on comfort, grip stability, and rotational effort during simulated use.
- Surgeon and Clinical Feedback: Conduct usability trials with surgeons and operating room staff to collect qualitative and quantitative data on the device's performance, ergonomics, and ease of use in simulated surgical environments. Compare their experiences with the Thompson retractor (or another common retractor) to have a standard that you rate this design better or worse against.

- Safety features and intuitive testing: Conduct a test with surgeons in training by giving them the retractor with no instructions in simulated circumstances (with a cardboard box or dummy) to interact with the retractor. Collect information on confusion or incorrect use of the retractor. Use the feedback to add visual or tactile indicators to mitigate incorrect use of the retractor. A final iteration of a retractor could also be supplemented with a comprehensive user manual and training materials for surgeons and technicians to ensure proper operation and maintenance of the device.
- Slipping test and mitigation: Conduct multiple tests with different that simulate the slipping of the bottom plate against the body. Use different levels of viscous liquid to mimic blood beneath. Rubber coating on the base or a different shape of the base plate to contour it to the body could help mitigate slipping.

Conclusion

Korle Bu Teaching Hospital promotes equitable healthcare by training medical professionals in resource-constrained areas of Accra, Ghana. Dr. Dhanu Thiyagarajan (Dr. Thiyag), an OB/GYN at Korle Bu has assigned our team of Michigan Engineering students to design a self-retaining retractor for our capstone design class. The retractor will address the lack of a low-cost solution that provides adequate visualization during laparotomies. It will also account for Korle Bu's constraints with time, staffing, and tool access as well as the availability of sterilized retractors for surgery, patient safety associated with current retractor use, and current retractors' inability to accommodate high BMI patients. By following the design process of problem definition, concept generation, and solution verification, we aim to design a self-retaining abdominal retractor product that meets Korle Bu's needs over four months.

Throughout our report, we detailed the pros and cons of current retractor models, clarified our design process, analyzed the greater context of our project, defined user requirements and engineering specifications, generated solutions, created an alpha sign, analyzed and reflected upon potential problems, and outlined a future schedule. While benchmarking, we found a tension between cost and durability in current retractor models as the cheaper models could not withstand higher forces, yet the stronger models were unattainably expensive. Given our most significant stakeholders (in both impact and power) were identified as Dr. Thiyag and additional OB/GYNs at Korle Bu, this tension becomes particularly crucial to resolve as the OB/GYNs need a reliable product that does not have an expensive upfront cost and a high cost per use.

Furthermore, understanding the design context of our project revealed a cultural gap between Michigan and Korle Bu, encouraging us to conduct as many interviews as possible to understand what will be most helpful to patients in Ghana. In addition, we learned that medical waste can have negative environmental impacts, reaffirming our need for a durable product that minimizes the frequency of disposal. We factored these considerations into our list of requirements and specifications.

The requirements found to be most important were ease of assembly, ease of deployment, durability, and patient safety. We quantified these critical requirements by setting the minimum specifications of the product weighing less than 4 kg and taking less than 5 minutes to assemble, restricting closing to 5 cm2 over 2 hours under 100 Newtons of force, withstanding autoclaves over a 3-year lifetime, and the product itself obscuring less than 5% of the cavity at the beginning of surgery. Finally, we identified the issue of patient safety as the most crucial to address and will combat limited patient interactions by medical professionals, especially OB/GYNs, who have an understanding of tissue and skin dynamics during surgery.

Transitioning to concept generation, we used tools outlined in the capstone class lectures to conduct purposeful brainstorming sessions that allowed us to generate a wide array of ideas for evaluation and prototyping. Collaborative brainstorming led to three categories of solutions: jig, inflatable, and circular. Through interviews with our stakeholders and a Pugh chart, we

selected the circular category for an alpha design and built a 3D CAD model. From there, we determined that we were not reaching our requirements with this idea and held another round of concept evaluation, settling on a design that resembled a camera shutter with linear motion modifications, allowing for improved linear adjustability and blade placement options in locations exerting the highest compressive force versus the current, static models.

We then selected our most critical requirements and outlined methods for validation and verification, including hand calculations, finite element analyses, and manufacturing a build design. Our testing revealed that we met nearly all of our requirements and specifications, including safety, ease of deployment, and cost, remaining below $2 per use. However, our high-priority ease of handling only minimally passed our requirements, and our vertical clamps proved difficult to manufacture and did not adequately constrain the plates. To address these issues, we outlined our recommendations for future works including new vertical constraints and locking mechanisms as well as testing methodologies that incorporate end users.

Acknowledgements

Thank you to Dr. Thiyag and Korle Bu Teaching Hospital for sponsoring the project. Thank you to Professor Kramer and the MECHENG 450 teaching team for assisting our design process. Thank you to Dr. Kim for providing her medical expertise. Thank you to our peers for your insights and reviews.

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Appendix A: Bios

Audrey Safir



My name is Audrey Safir, and I am a senior mechanical engineering student at the University of Michigan. I am from Ridgefield, Connecticut, a small, revolutionary war town an hour outside New York City. Growing up, I always loved to build things from legos to fake instruments to model rockets, and was excited to learn I could get paid to do it. While at Michigan, I have enjoyed taking classes that help translate my ideas into possibilities and gaining a better understanding of how the world works. While at Michigan, I have been part of the Mars Rover team, the Michigan chapter president of the mental health organization IfYoureReadingThis, and treasurer of the Michigan Quadball team. Additionally, I have spent two summers in Seattle as an intern for the additive manufacturing department at Boeing. Some fun facts about me are that I am double-jointed in my elbow, and I have a brother studying at Michigan who is coincidentally studying medicine.

Arushi Narayanan



My name is Arushi, and I am a senior mechanical engineering student. I was born in Singapore where I lived for a bit before moving to India, and then the UK before coming to Michigan for college. I would say that my affinity for engineering started when I was 10 and tried to rewire my AC from the wall switch and accidentally caused it to short circuit (that may have started a mini fire). I like to understand how things work and how they can be modified or improved. Since coming to Umich I have been a part of MAAV (Michigan autonomous aerial vehicles) and engineering honors. I have also done a few year-long projects through umich like MDP and techlab. The last few summers I have interned with a forklift manufacturer, a data storage company, and a startup that makes safety equipment for motorcyclists. Some fun facts about me, past my (very) brief history with pyrotechnics, are that I can play any song in paramore's album Brand New Eyes on the drums and I can bake a mean quiche lorraine.

Aryan Rose



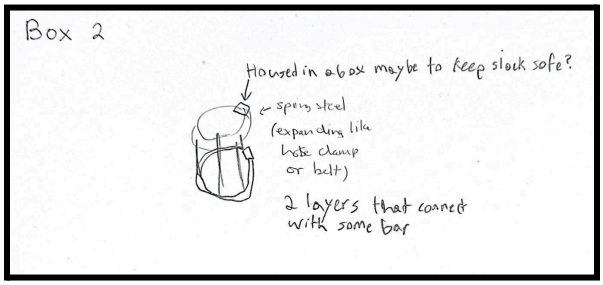
My name is Aryan and I am from India but was born and grew up in Dubai, UAE all my life before coming to Michigan to study Mech E. I was always interested in learning how things work about everyday objects around me which lead me to wanting to study engineering. While at Michigan, I have been a member of Pi Tau Sigma, the Mech E honor society, served as the mechanical systems lead of the Supermileage project team where we build concept cars for hyper energy-efficiency and served as an Instructional Aide for two introductory engineering classes for freshmen. I have spent my summers interning at a metrology company as an applications engineer and recently, at a mobile carbon capture startup helping design the structures for their carbon capture system. A few fun facts about me are that I have visited 22 countries and that I can read and write Arabic.

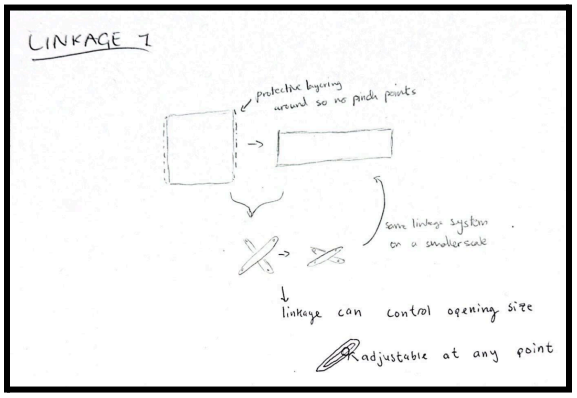
Diego Montemayor

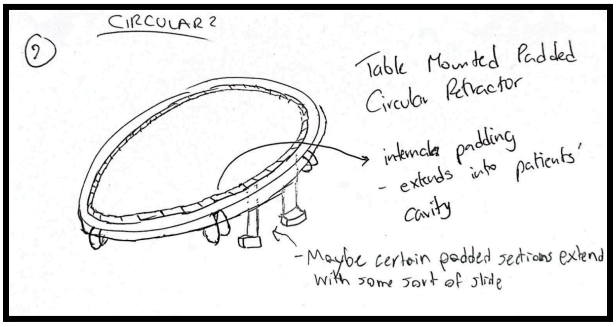


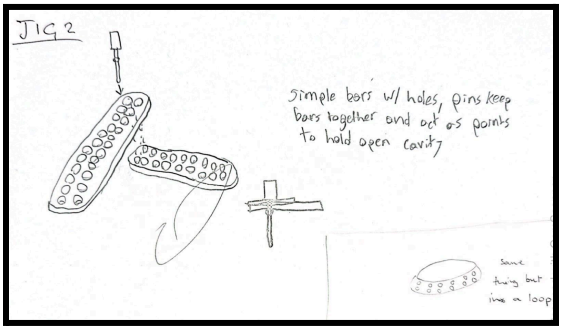
I'm Diego, I'm obviously a senior in Mechanical Engineering at the University of Michigan. I'm from Ellicott City, Maryland, a small suburb just outside of the Baltimore Metropolitan area with a small downtown area that gets flooded every few years. I've always been interested in making things and how complex systems and machines work. I first properly got into engineering in middle school during a tech ed course that my school offered, where I got to make magnetic toy cars to race on a track. Later on in high school, I joined a FIRST robotics team and enrolled in Project: Lead The Way engineering courses. Here at the University of Michigan I was the mechanical lead for the Michigan Robotic Submarine project team, and I'm a part of the Society of Hispanic Professional Engineers. I've interned twice at SpaceX these past couple summers. A few fun facts about me, I'm often caught in public wearing yellow, I enjoy trying new restaurants and cafes despite not drinking coffee, and I like going to the Ann Arbor farmers' market every Saturday.

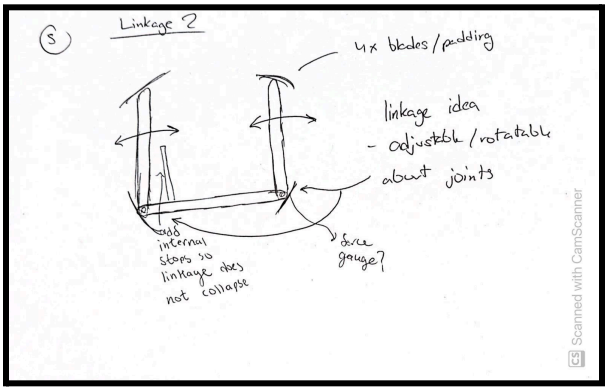
Appendix B: Concepts Generated

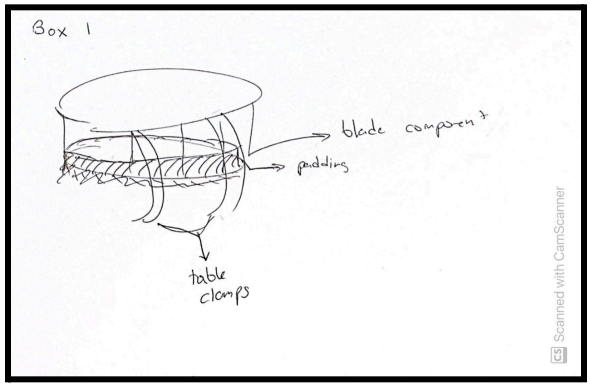










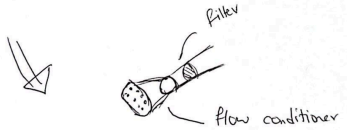


Air pump to keep the cavity open

GAS 2



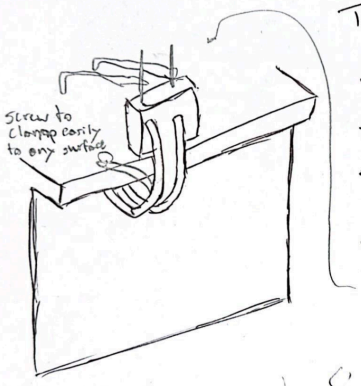
- adding some filter
- adding a flow conditioner
  - evenly disperse and concentrate airflow to keep cavity open



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(1) ARM 1

Table Mounted Clamps



- single clamps
- mounted to table
- clamping tensioner? adjusts retracting force
- Not sure how retractors attach to table mount, maybe some interface

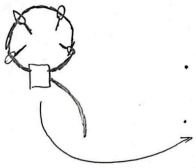




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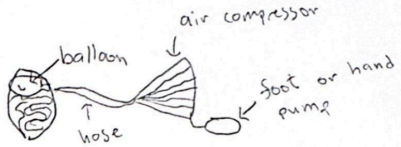
Opening 2

thick wire with adjustable blades for positioning and stack to increase or decrease opening size.



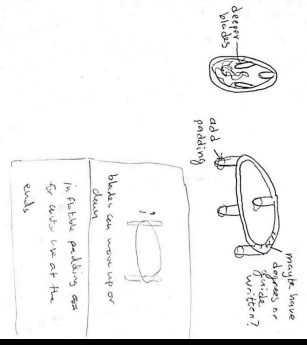
- adding padding around wire for safety / cushioning
- add a hose clamp like mechanism for adjusting size

Inflatable / deflatable balloon



GAS 3

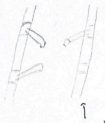
CIRCULAR 1



Classic retractor design with deeper blades

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ARM 2



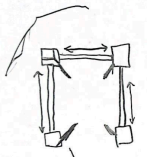
← Arms connected to bed
Can have as many arms as you want, for surgeries

↑ make the poles so can slide/latch to any bed



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LINKAGE 3



slides with blades at junction points, should be high friction slides or use some sort of locking like a luggage handle.

adding wider blades / pads



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GAS 1

Hole in middle for visualization



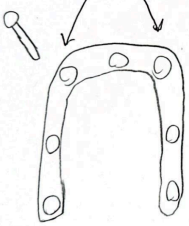
Inflatable retractor

Way to adjust easing?

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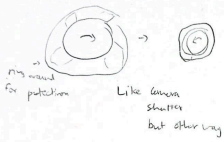
JIG 1

· adding linkage joints here to adjust size



Solid piece of rigid steel, pins go through to hold back skin

Opening 1





Need to avoid sharp ends
Backwards logic

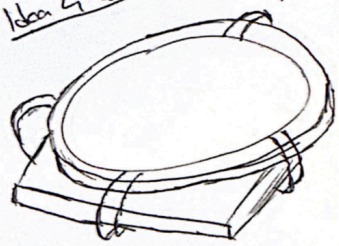


Allows bigger openings, pins on ends of each spoke

I think the word is camera aperture

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2) - Idea 4 & 2



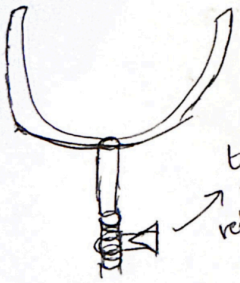
clamps to table for tensioning & mounting

7) - Idea 3



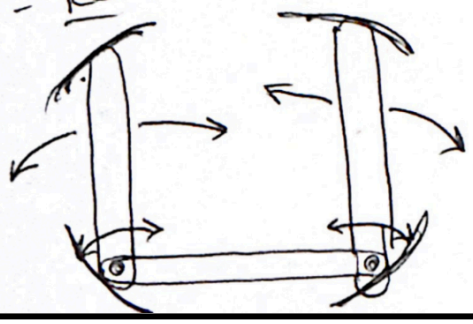
adjustable mount to control reflector width

5) - Idea 9

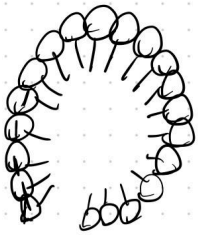


twistable screw to adjust reflector retaining mechanism

9) - Idea 6

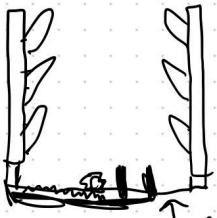


1



essentially a chain with prongs sticking out the bottom, can retain it's shape by locking each chain together

2

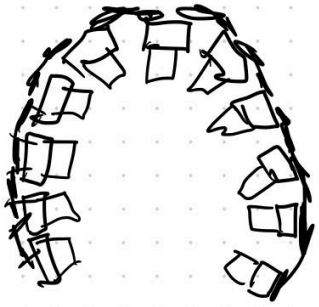


Handle

Squeeze handle to incrementally open, lock w/ ratchet and spring to close when ratchet unlatched

shape

(4)



Bars on friction hinges, only opens/closes w/ excessive force

Strength device for doctors

Enhance Doctors

Give a gym

use solutions from gym equipment

Hire athletes

Shrink to fit in cavity

enlarge patients

Rubber bands → ropes are stronger

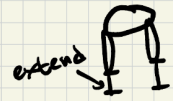


Free standing or table retractor

deeper blades

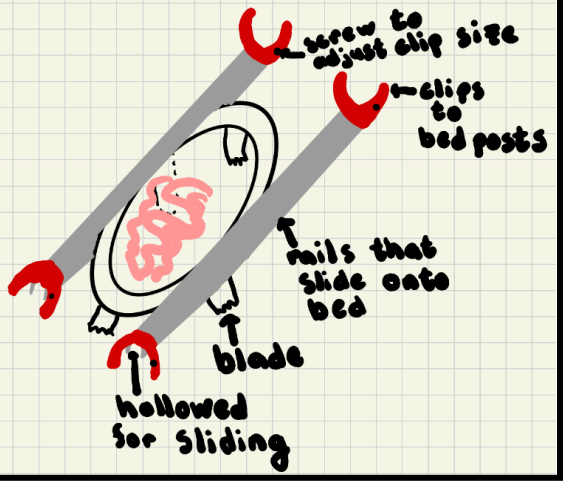
make sterilizing better

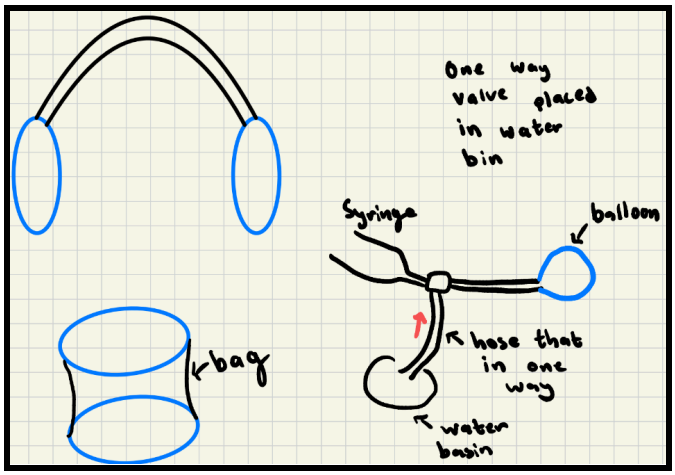
extend



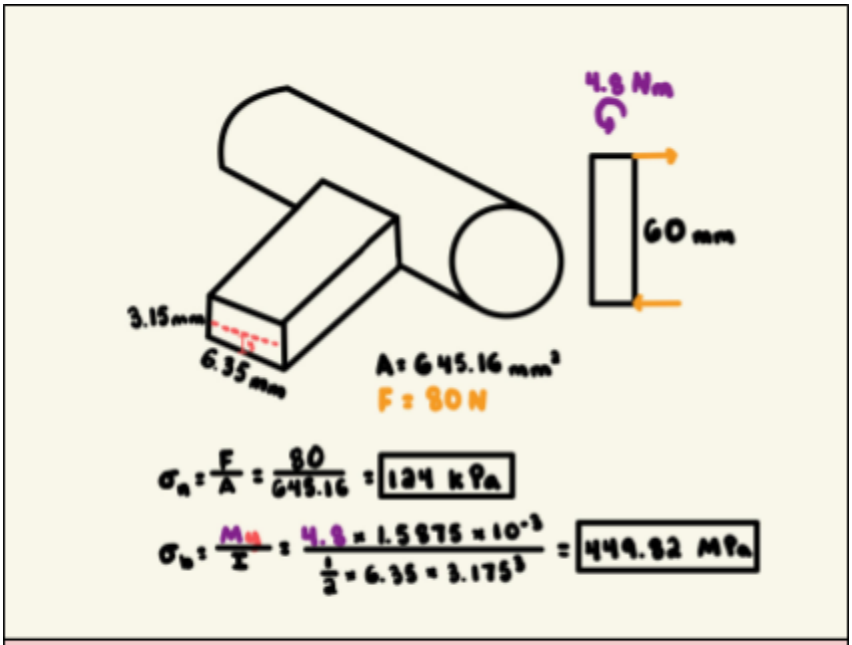


light clips onto existing rectractor

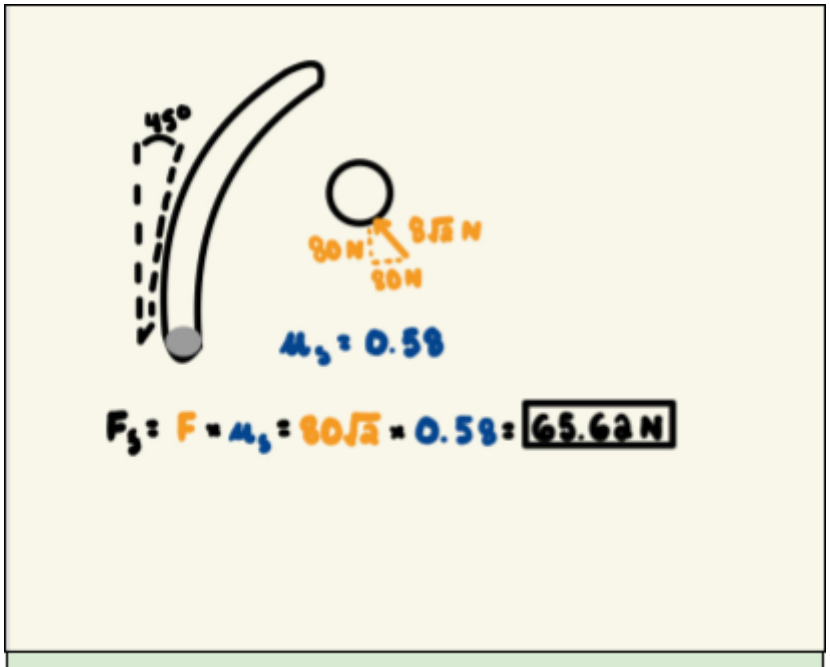



One way valve placed in water bin
Syringe
balloon
bag
hose that in one way
water basin

Appendix C: Analysis Calculations



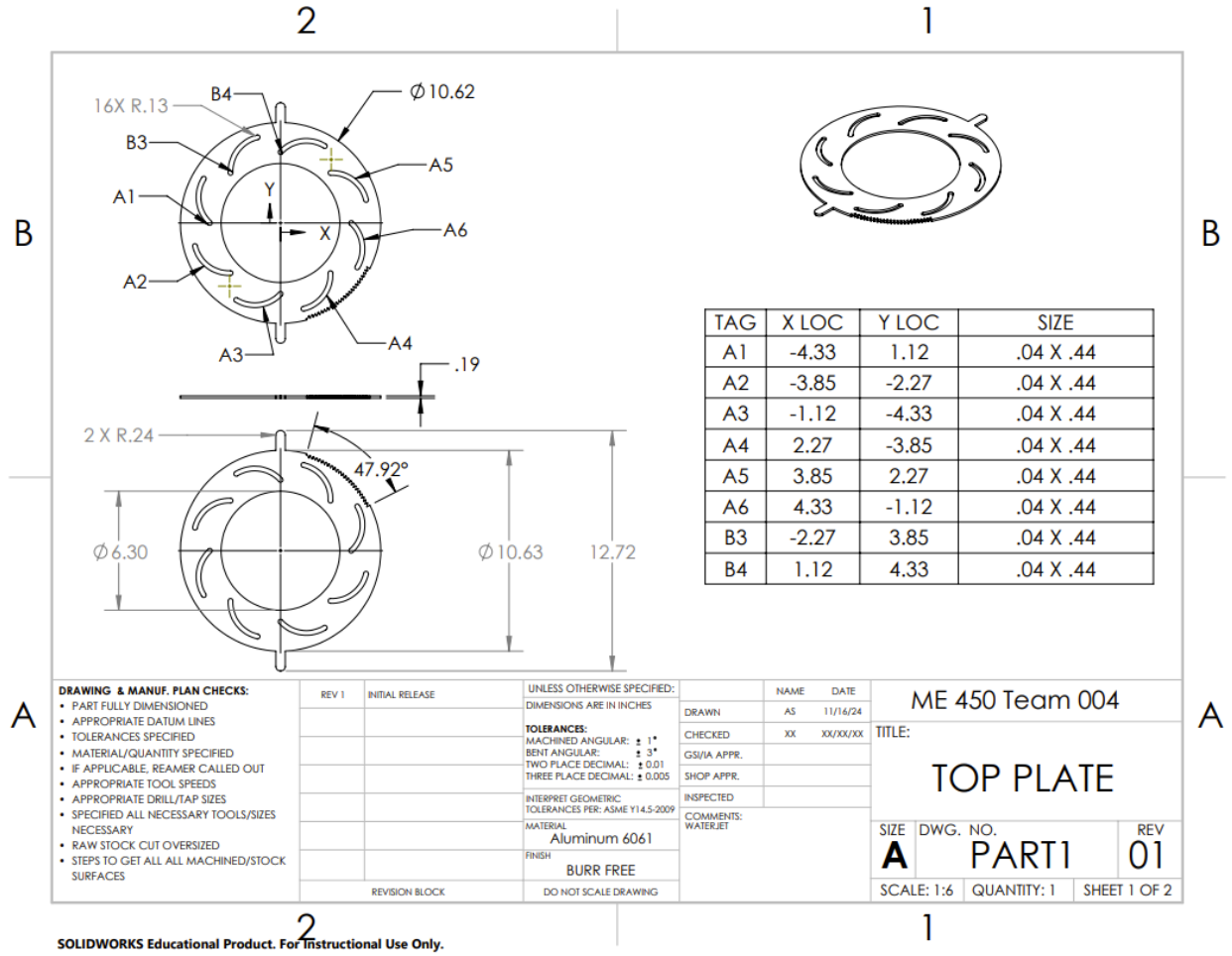
Max Stress = 449.82 MPa



Max Frictional Force = 65.62 N

Appendix D: Engineering Drawings for Build Design

Top Plate



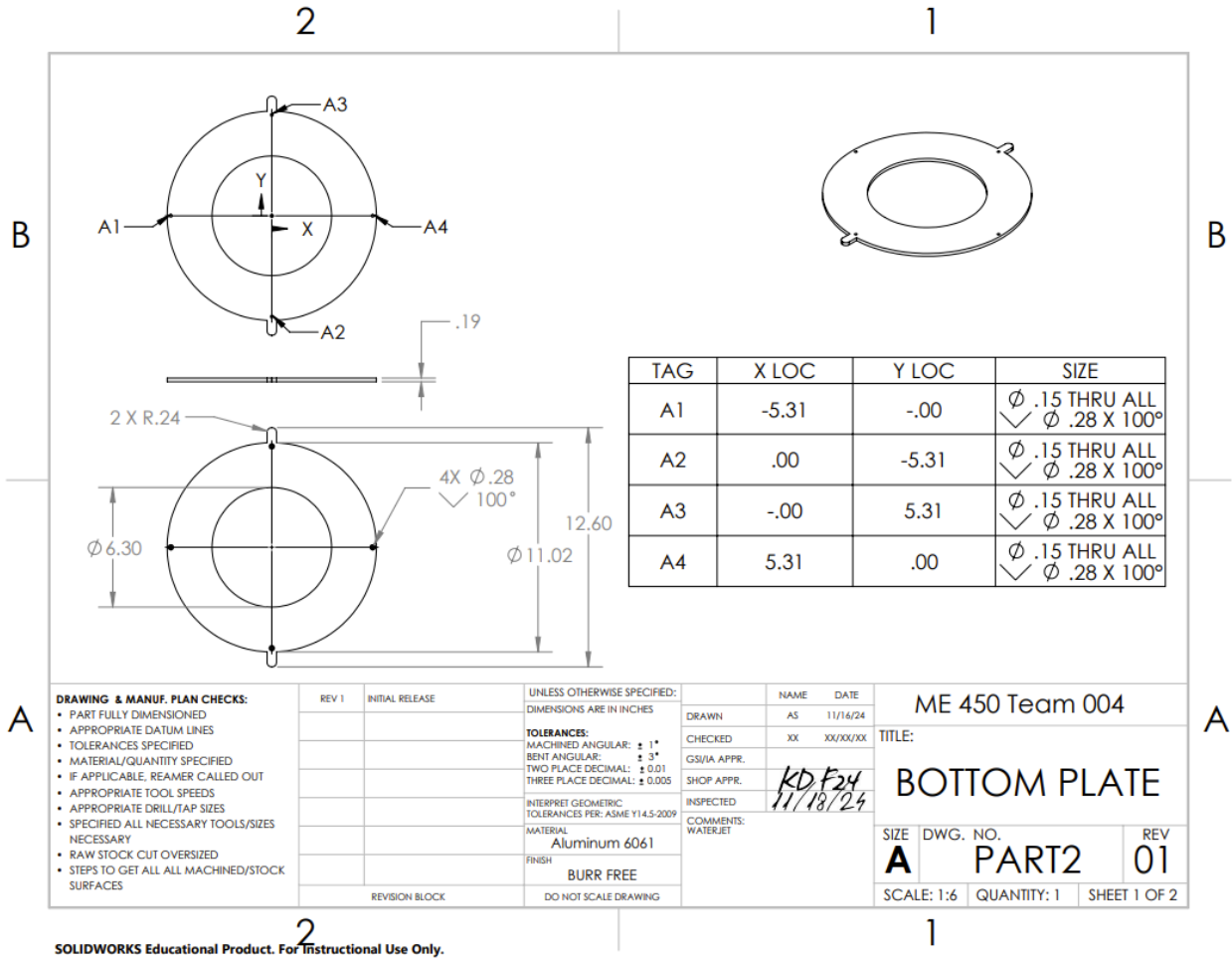
TAG	X LOC	Y LOC	SIZE
A1	-4.33	1.12	.04 X .44
A2	-3.85	-2.27	.04 X .44
A3	-1.12	-4.33	.04 X .44
A4	2.27	-3.85	.04 X .44
A5	3.85	2.27	.04 X .44
A6	4.33	-1.12	.04 X .44
B3	-2.27	3.85	.04 X .44
B4	1.12	4.33	.04 X .44

MANUFACTURING PLAN

RAW MATERIAL STOCK: 12" x 24" x 3/16" Aluminum

STEP	PROCESS DESCRIPTION	MACHINE	FIXTURE	TOOL(S)	SPEED (RPM)
1	Waterjet Part	Waterjet			
2	Deburr Part			File, deburring tools	

Bottom Plate

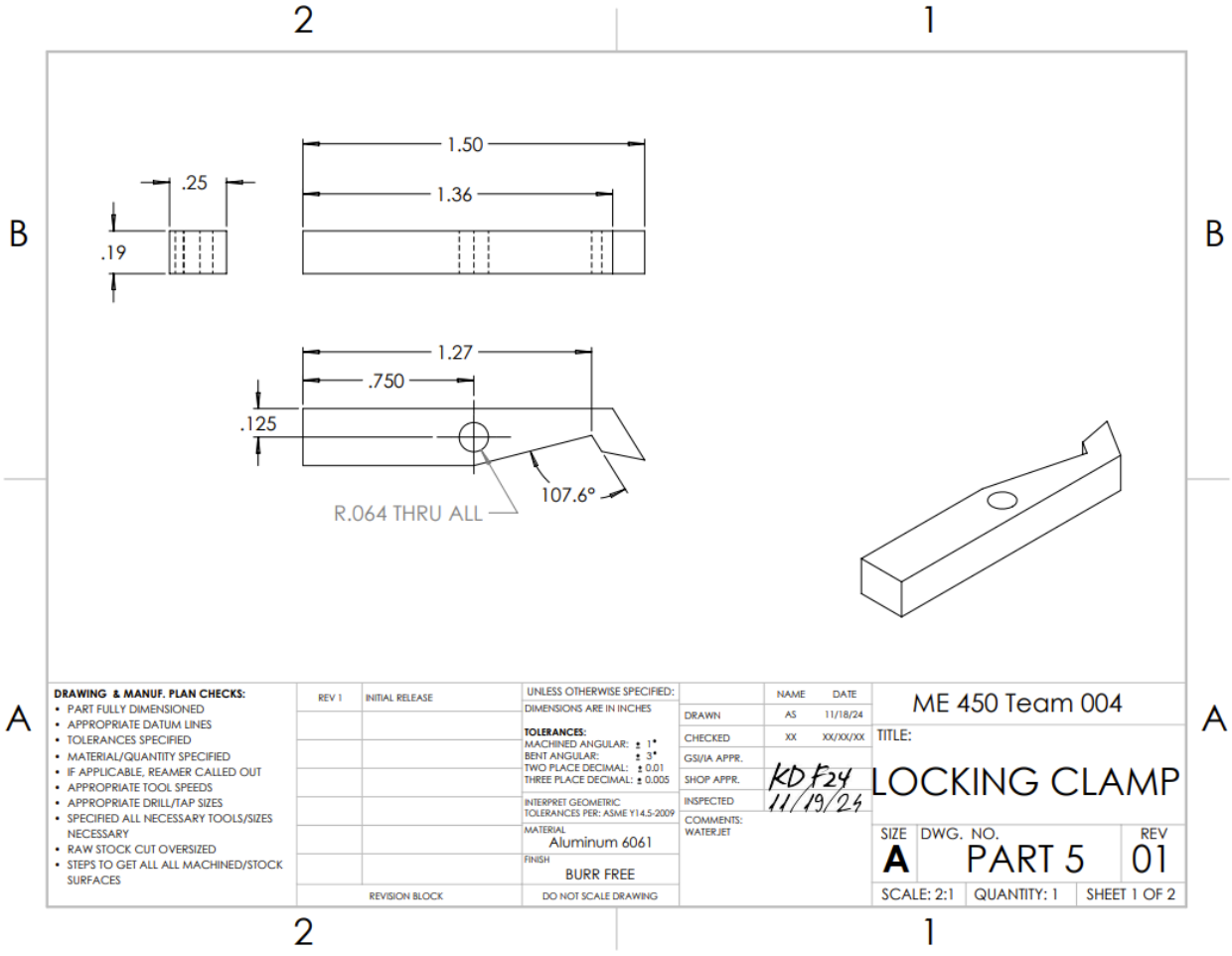


MANUFACTURING PLAN

RAW MATERIAL STOCK: 12" x 24" x 3/16" Aluminum

STEP	PROCESS DESCRIPTION	MACHINE	FIXTURE	TOOL(S)	SPEED (RPM)
1	Waterjet Part	Waterjet			
2	If desired, holes can be countersunk using a mill	Mill	Vise		

Ratcheting Locking Clamp

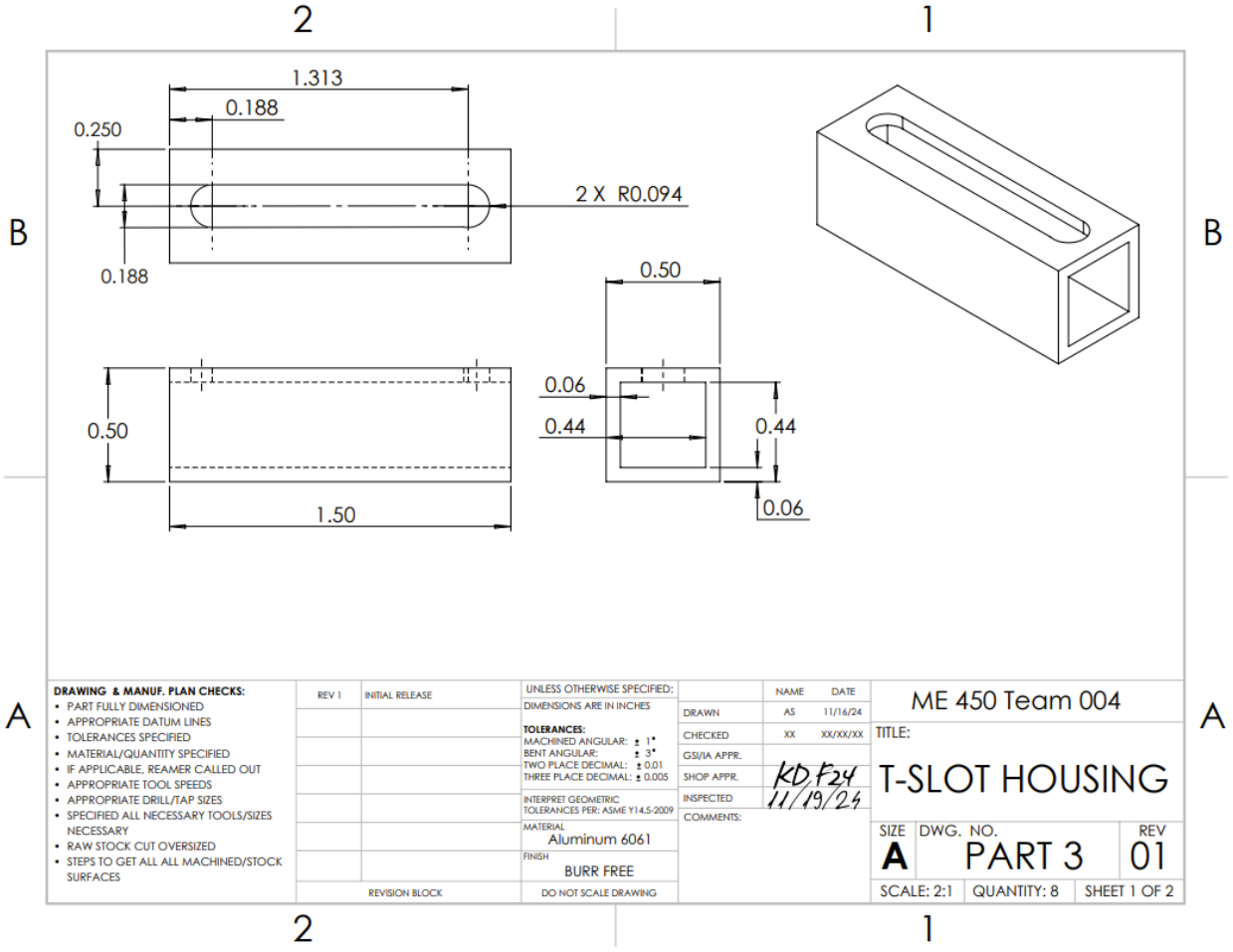


MANUFACTURING PLAN

RAW MATERIAL STOCK: 12" x 12" x 3/16" Aluminum

STEP	PROCESS DESCRIPTION	MACHINE	FIXTURE	TOOL(S)	SPEED (RPM)
1	Waterjet Part	Waterjet			
2	Deburr Part			File, deburring tools	

T-Bar Housing

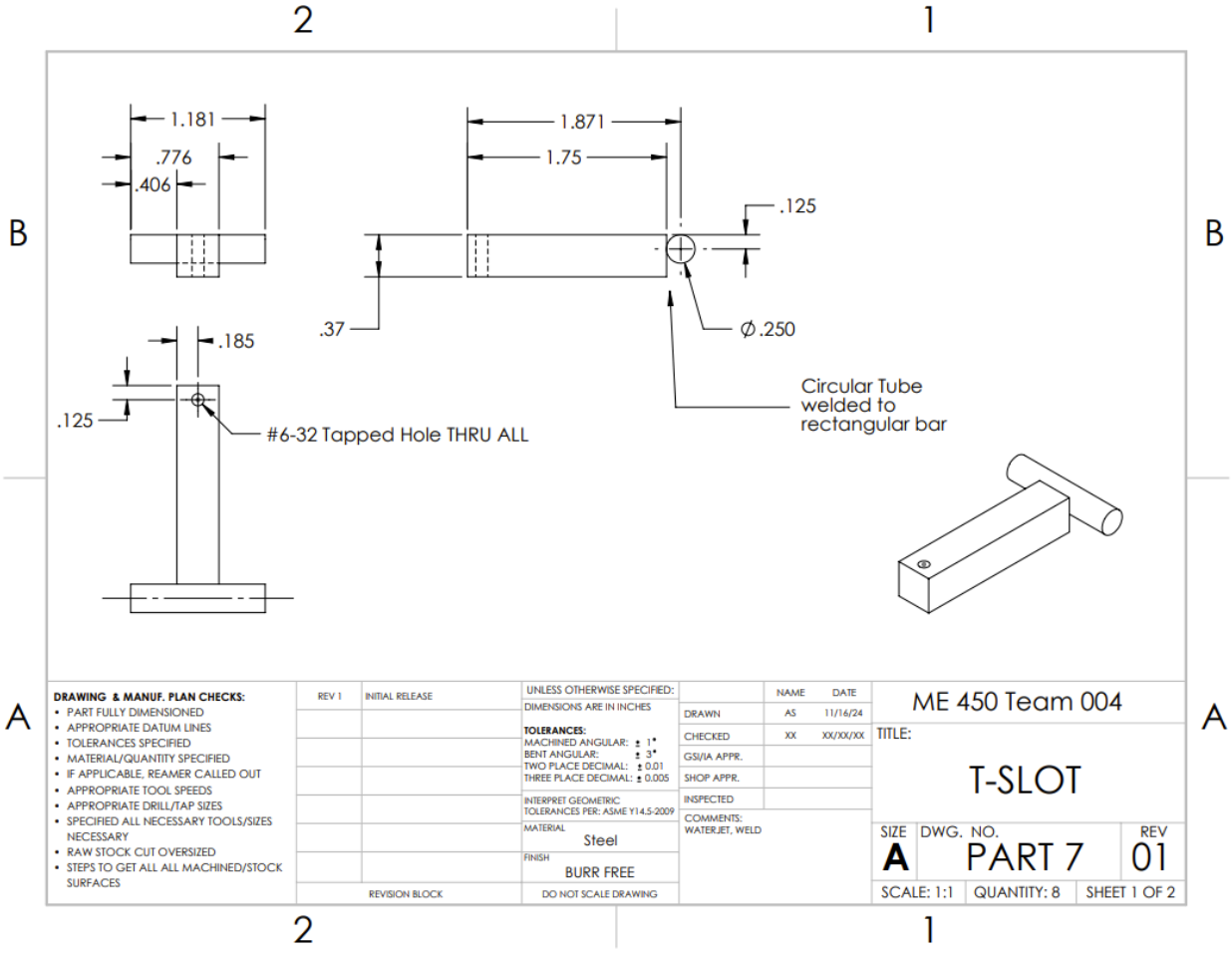


MANUFACTURING PLAN

RAW MATERIAL STOCK: Aluminum

STEP	PROCESS DESCRIPTION	MACHINE	FIXTURE	TOOL(S)	SPEED (RPM)
1	Cut stock to over 1/8" final length and deburr	Band saw	Vise, Jaw Stop	Deburring tools, file	300 ft/min
2	Mill both ends of the part, just enough to provide a fully machined surface	Mill	Vise, Jaw Stop	3/4" two flute endmill	500
3	Measure the part with a calliper and bring to the certain dimension, taking pauses at 0.050" or less passes	Mill	Vise, Jaw Stop	3/4" two flute endmill	500
4	Find Datum	Mill	Vise, Jaw Stop	1/2" collet, edgefinder. 1 3/8" parallels	1000
5	Remove cutter and collet and install drill chuck	Mill	Vise, Jaw Stop	Drill chuck, 1 3/8" parallels	
6	Use the plunge method to rough cut the slot. Bring each side to width using conventional milling	Mill	Vise, Jaw Stop	Drill chuk. 1 1/2" parallels. 3/16" endmill	1400
7	Remove part from vice and deburr			Deburring tools	

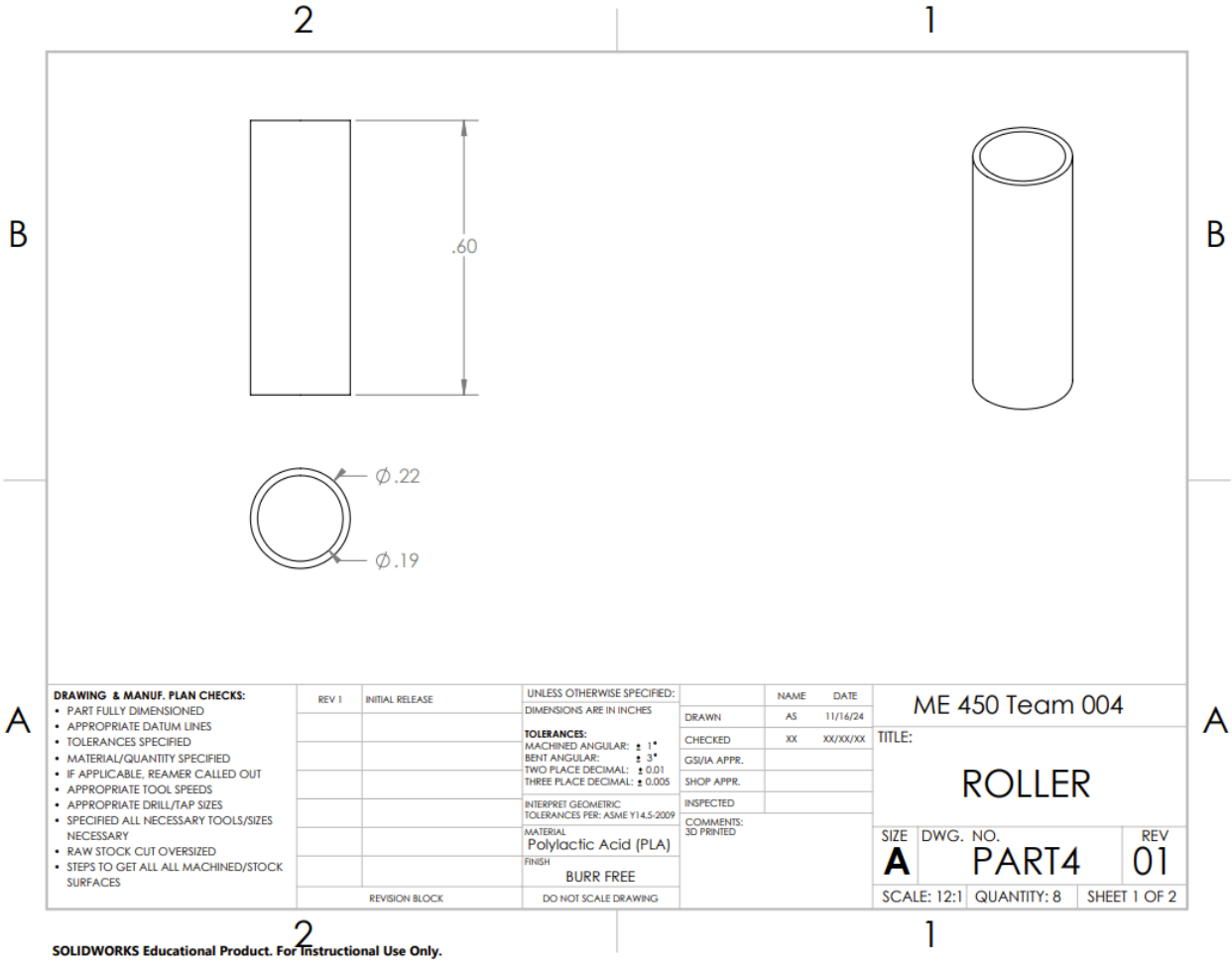
T-Bar


2
1
B
A
1.181
.776
.406
1.871
1.75
.125
.37
Ø.250
.185
.125
#6-32 Tapped Hole THRU ALL
Circular Tube welded to rectangular bar
DRAWING & MANUF. PLAN CHECKS:
• PART FULLY DIMENSIONED
• APPROPRIATE DATUM LINES
• TOLERANCES SPECIFIED
• MATERIAL/QUANTITY SPECIFIED
• IF APPLICABLE, REAMER CALLED OUT
• APPROPRIATE TOOL SPEEDS
• APPROPRIATE DRILL/TAP SIZES
• SPECIFIED ALL NECESSARY TOOLS/SIZES NECESSARY
• RAW STOCK CUT OVERSIZED
• STEPS TO GET ALL ALL MACHINED/STOCK SURFACES
REV 1
INITIAL RELEASE
REVISION BLOCK
UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN INCHES
TOLERANCES:
MACHINED ANGULAR: ± 1°
BENT ANGULAR: ± 3°
TWO PLACE DECIMAL: ± 0.01
THREE PLACE DECIMAL: ± 0.005
INTERPRET GEOMETRIC TOLERANCES PER: ASME Y14.5-2009
MATERIAL
Steel
FINISH
BURR FREE
DO NOT SCALE DRAWING
NAME
DATE
DRAWN
AS
11/16/24
CHECKED
XX
XX/XX/XX
GSI/IA APPR.
SHOP APPR.
INSPECTED
COMMENTS:
WATERJET, WELD
ME 450 Team 004
TITLE:
T-SLOT
SIZE
A
DWG. NO.
PART 7
REV
01
SCALE: 1:1
QUANTITY: 8
SHEET 1 OF 2

MANUFACTURING PLAN
RAW MATERIAL STOCK: Steel

STEP	PROCESS DESCRIPTION	MACHINE	FIXTURE	TOOL(S)	SPEED (RPM)
1	Waterjet the outline of the rectangular part	Waterjet			
2	Mount rectangular part in mill	Mill	Vise, Jaw Stop		
3	Find Datum	Mill	Vise, Jaw Stop	1/2" collet, edgefinder, 1 3/8" parallels	1000
4	Center drill and drill the hole	Mill	Vise, Jaw Stop	Drill chuck, 0.75" parallels, #3 center drill, #36 drill bit	1200, 1200
5	Tap the hole	Mill	Vise, Jaw Stop	Drill chuck, 0.75" parallels, #6-32 tap, tap wrench, dead center	
6	Remove part from vice and deburr			Deburring tools	
9	Cut round stock to length oversized by 1/8"	Horiz. Bandsaw			
8	Place round part in lathe and face one end	Lathe		1" Collet, Colletstop, Turning and Facing tool	750
9	Switch part around and face other end Lathe			1" Collet, Colletstop, Turning and Facing tool	750
10	Measure part and bring to length Lathe			1" Collet, Colletstop, Turning and Facing tool	750
11	Remove part from vice and deburr			Deburring tools	
	Hand off to the shelf for welding				

Roller

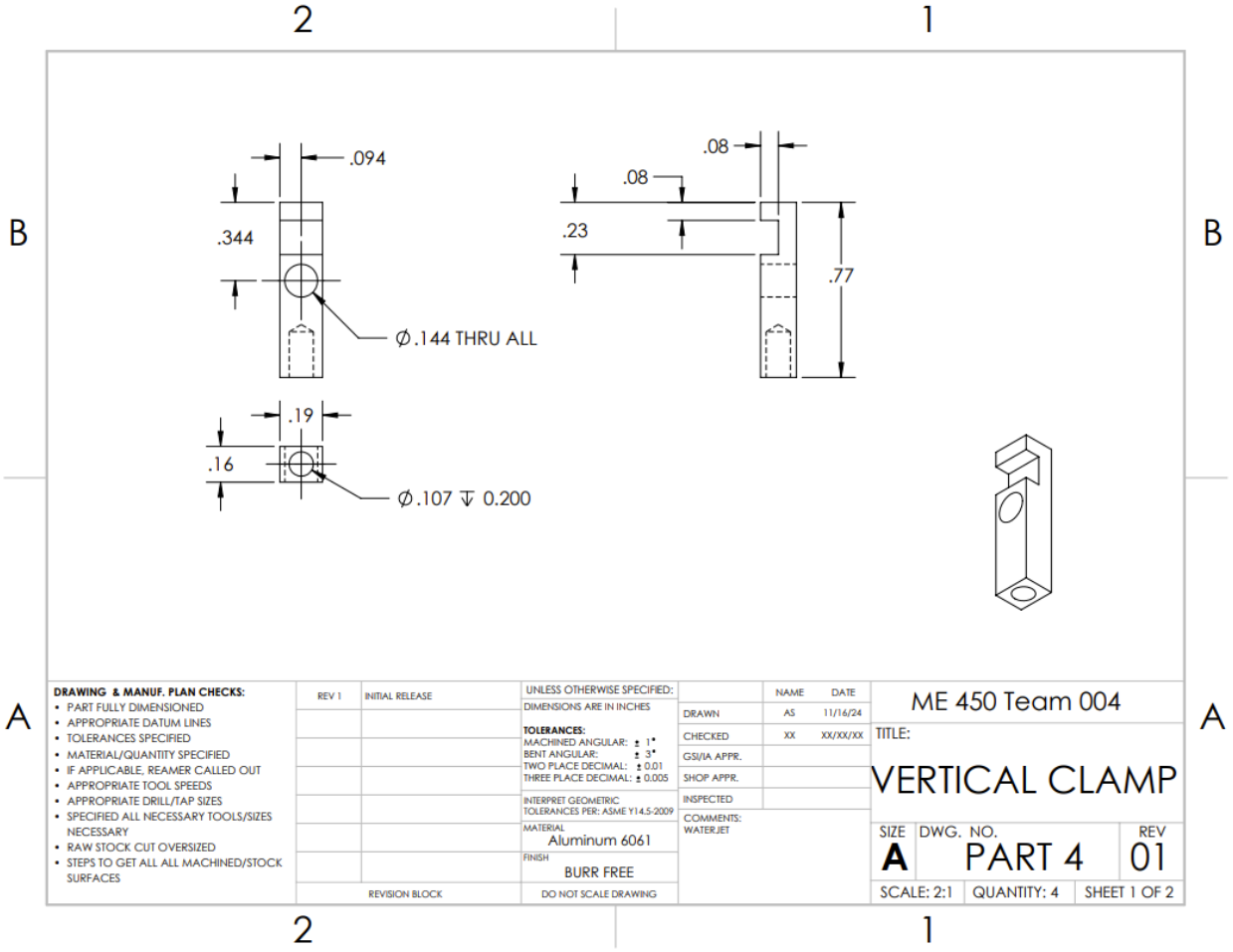


MANUFACTURING PLAN

RAW MATERIAL STOCK: PLA

STEP	PROCESS DESCRIPTION	MACHINE	FIXTURE	TOOL(S)	SPEED (RPM)
1	3D Print Part	3D Printer			
2	Deburr Part			File	

Vertical Clamp

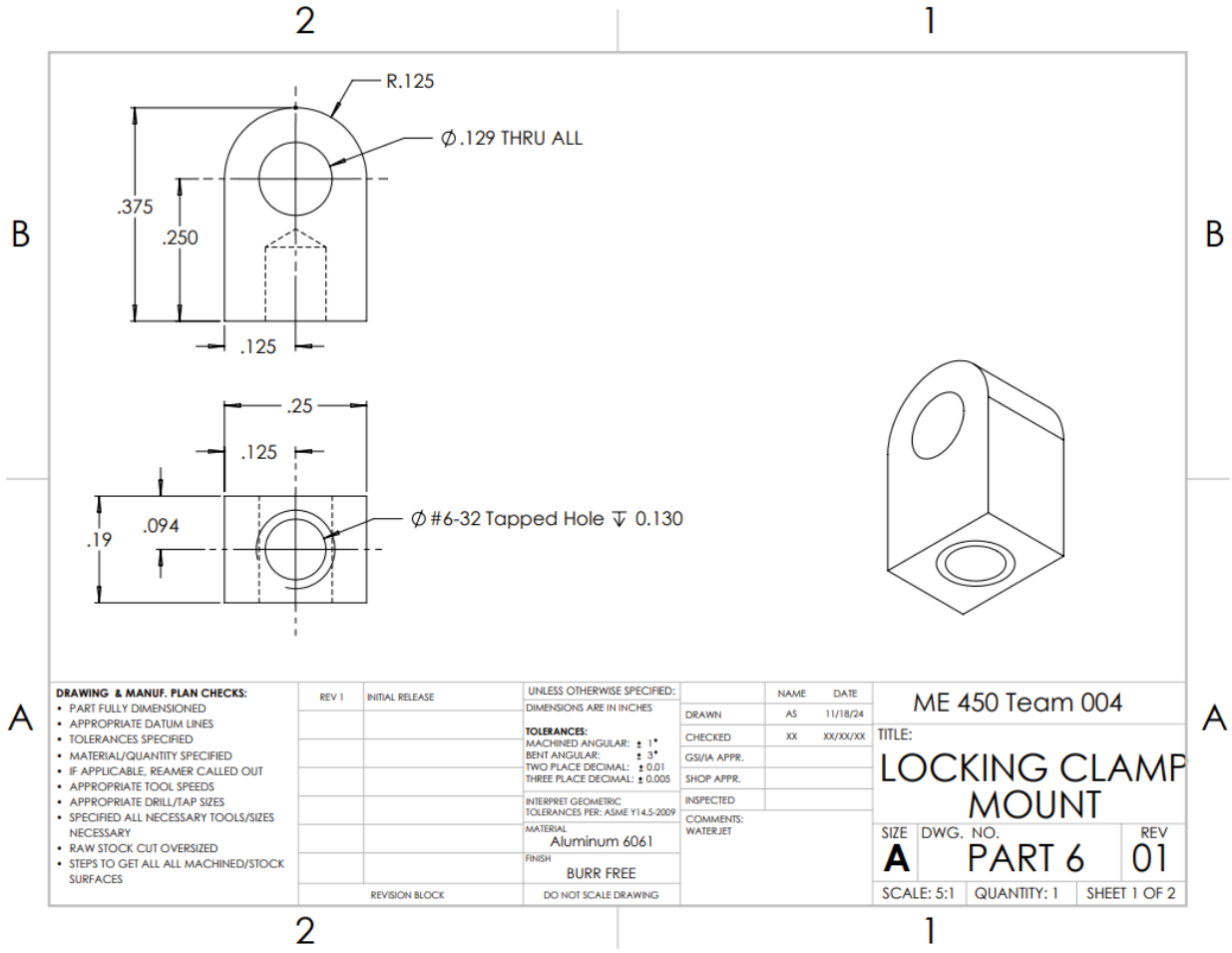


MANUFACTURING PLAN

RAW MATERIAL STOCK: 3/16" Aluminum Rectangular Stock

STEP	PROCESS DESCRIPTION	MACHINE	FIXTURE	TOOL(S)	SPEED (RPM)
1	Waterjet the outline of the part	Waterjet			
2	Find Datum	Mill	Vise, Jaw Stop	1/2" collet, edgefinder. 1 3/8" parallels	1000
3	Remove cutter and collet and install drill chuck	Mill	Vise, Jaw Stop	Drill chuck, 1 3/8" parallels	
4	Center drill and drill through hole	Mill	Vise, Jaw Stop	#3 center drill, drill chuck, 1 3/8" parallels, #27 drill	1200
5	Remove the part and turn it so that the bottom side is facing up	Mill	Vise, Jaw Stop		
6	Drill the bottom hole	Mill	Vise, Jaw Stop	#1 center drill, drill chuck, 1 3/8" parallels, #36 drill	1600
9	Tap the bottom hole	Mill	Vise, Jaw Stop	Drill chuck, 6-32 tap, tap wrench, dead center	
8	Remove part from vice and deburr			Deburring tools	

Locking Clamp Mount



MANUFACTURING PLAN

RAW MATERIAL STOCK: 12" x 12" x 3/16" Aluminum

STEP	PROCESS DESCRIPTION	MACHINE	FIXTURE	TOOL(S)	SPEED (RPM)
1	Waterjet part outline and side hole	Waterjet			
2	Mount in mill with the bottom side up	Mill	Vise, Jaw Stop	1 3/8" parallels	
3	Find Datum	Mill	Vise, Jaw Stop	1/2" collet, edgefinder, 1 3/8" parallels	1000
4	Center drill and drill hole	Mill	Vise, Jaw Stop	Drill chuck, 0.75" parallels, #3 center drill, #36 drill bit	1200, 1200
5	Tap the hole	Mill	Vise, Jaw Stop	Drill chuck, 0.75" parallel, #6-32 tap, tap wrench, dead center	
6	Deburr Part			File, deburring tools	

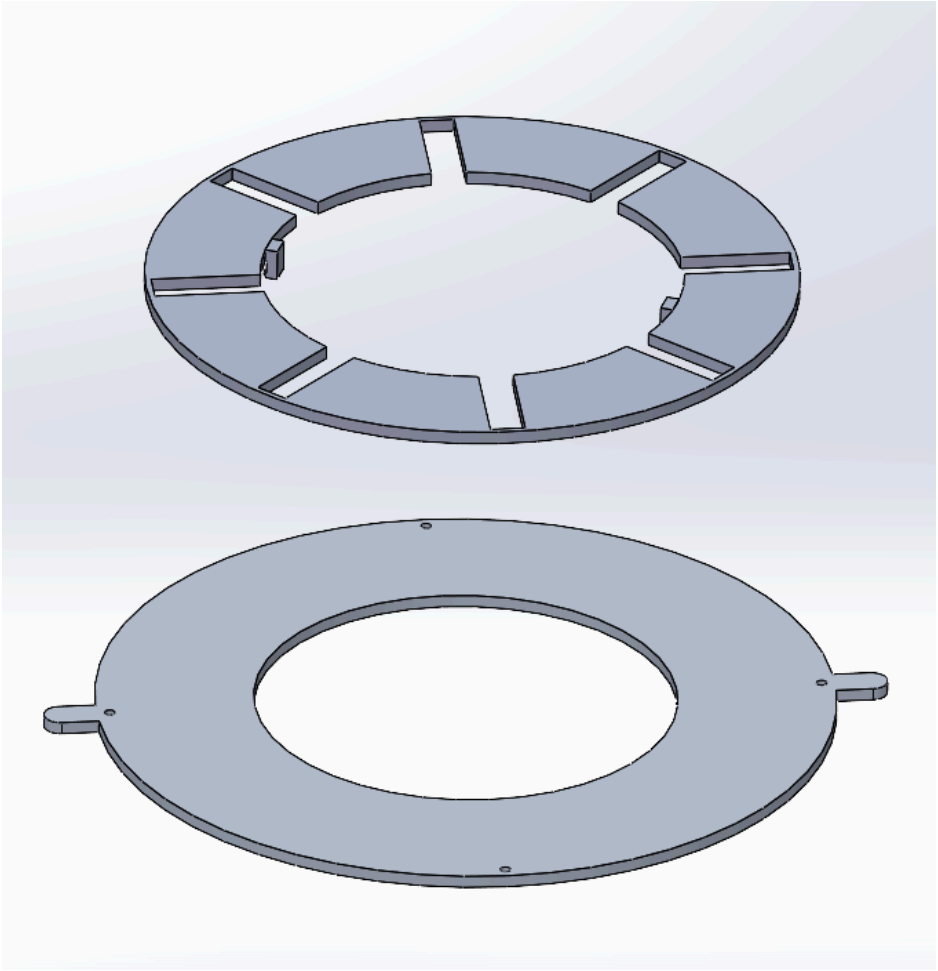
Appendix E: Bill of Materials for Build Design

Part Name	Manufacturer	Quantity	MFG Process	Material	Stock Type	Cost ($)	Notes
Top Plate	Team 004	1	Waterjet	6061 Aluminum	Flat Stock - 12” x 12” x 3/16”	38.63	-
Bottom Plate	Team 004	1	Waterjet	6061 Aluminum	Flat Stock - 12” x 12” x 3/16”	38.62	-
T-Bar Base	Team 004	8	Waterjet & Mill	304 Stainless Steel	Regular stock - 1.75” x ⅜” x ⅜”	10.48	-
T-Bar Circular End	Team 004	8	Bandsaw & Lathe	304 Stainless Steel	Round stock - ¼” radius	8.68	-
T-Bar Shoulder Bolts	McMaster-Carr - 97345A115	8	-	316 Stainless Steel	-	84.92	-
T-Bar Housing	Team 004	32	Waterjet & Mill	6061 Aluminum	Square Tube Stock - ½” x ½” x 12”	5.25	-
Roller	Team 004	8	3D Printing	PLA	PLA Roll	-	3D printed with team member’s personal printer
Turntable	Amazon	1	-	Polypropylene	-	22.25	-

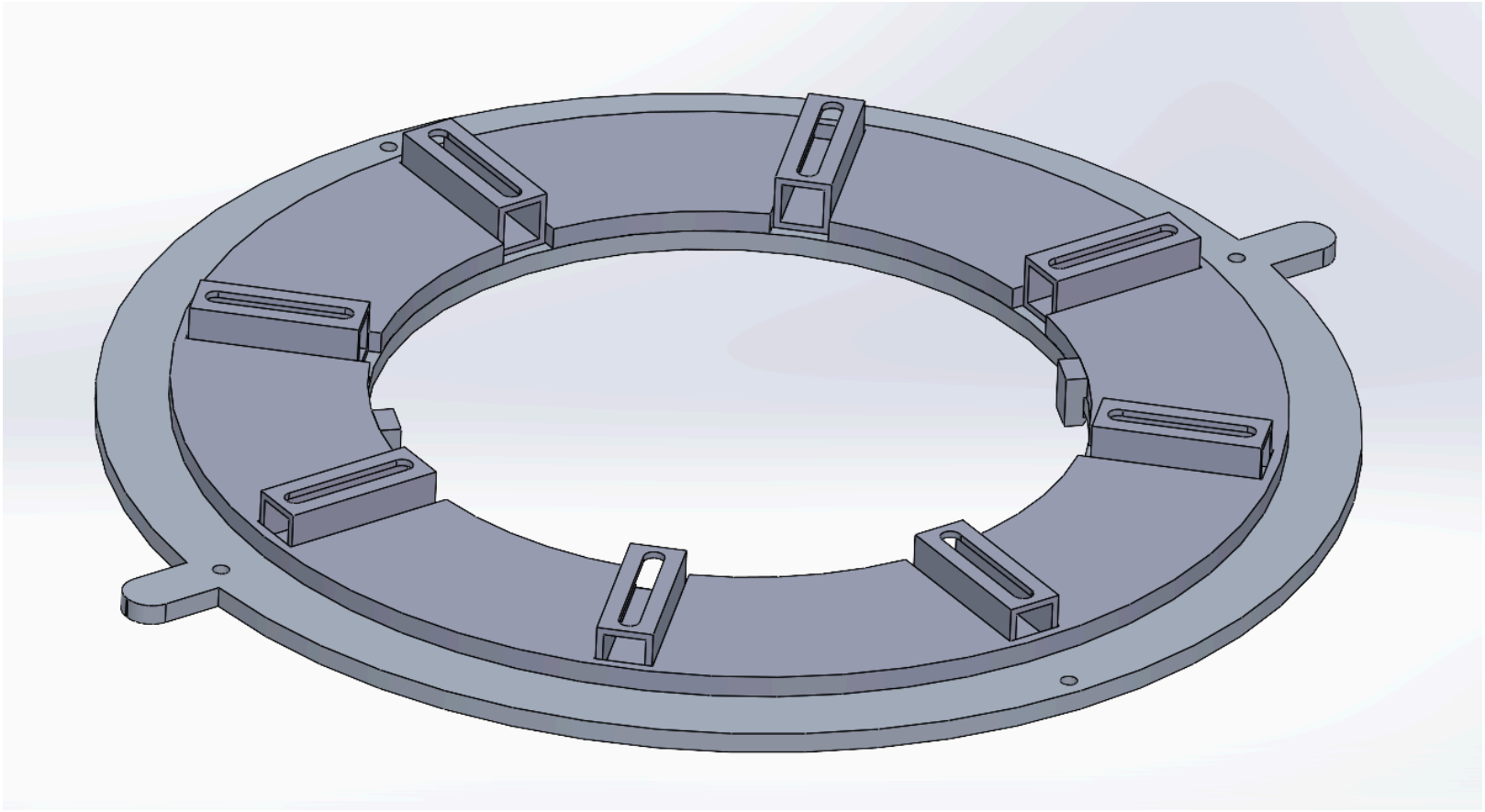
Clamping Bracket	Team 004	4	Waterjet & Mill	6061 Aluminum	Rectangular Stock - 2” x 1/2” x 3/16”	5.63	-
Mounting Bolts	McMaster-Carr - 91781A145	18	-	18-8 Stainless Steel	-	0.86	-
Ratchet Clamp Mount	Team 004	1	Waterjet & Mill	6061 Aluminum	Rectangular Stock - ⅜” x ¼” x 3/16”	4	-
Ratchet Locking Clamp	Team 004	1	Bandsaw	6061 Aluminum	Rectangular Stock - 2” x ¼” x 3/16”	4	-
TOTAL COST						223.32	-

Appendix F: Assembly Instructions

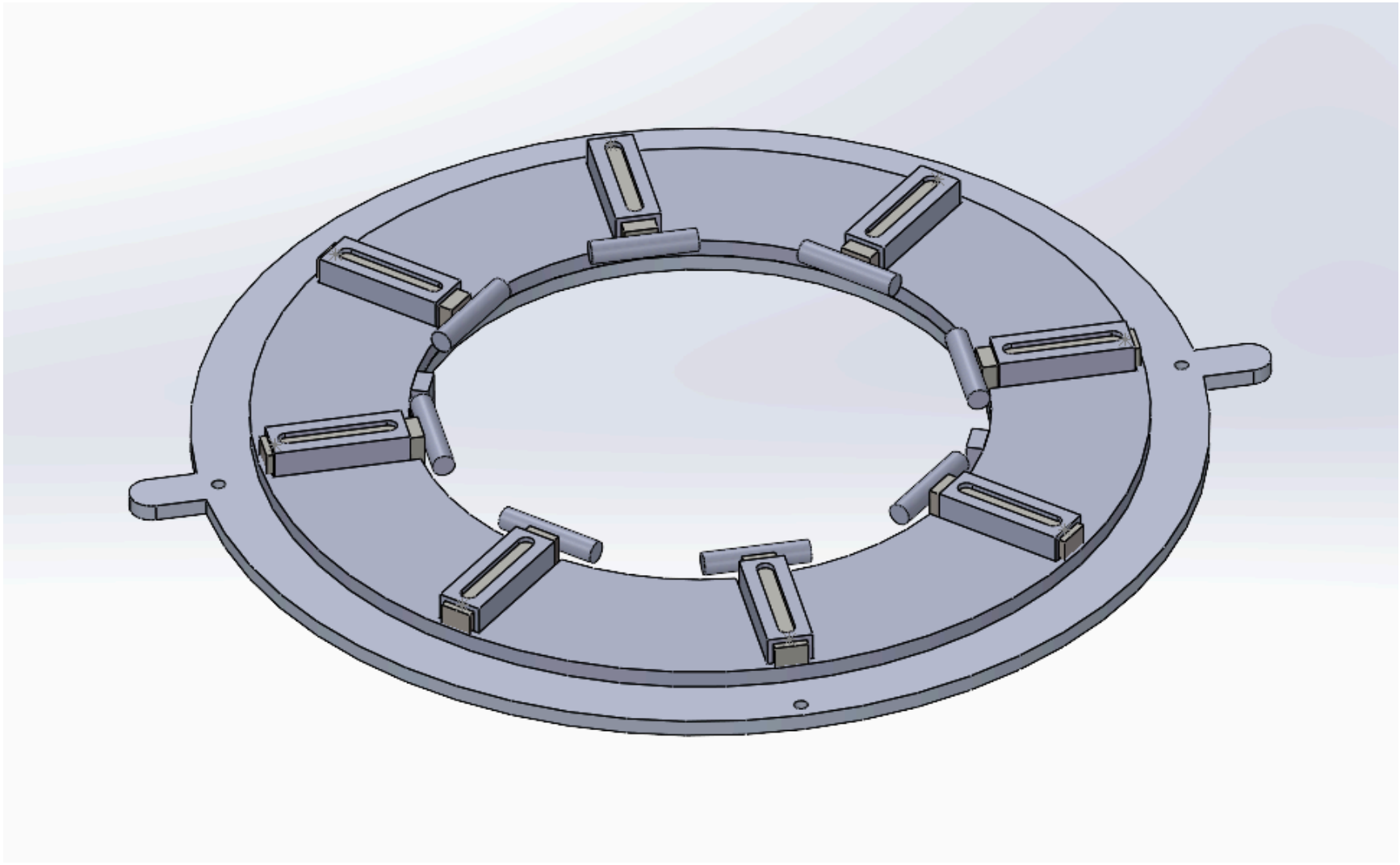
Step 1. Affix 3D printed guide to bottom plate, lining up any one of the slots to be in line with the handles on the bottom plate



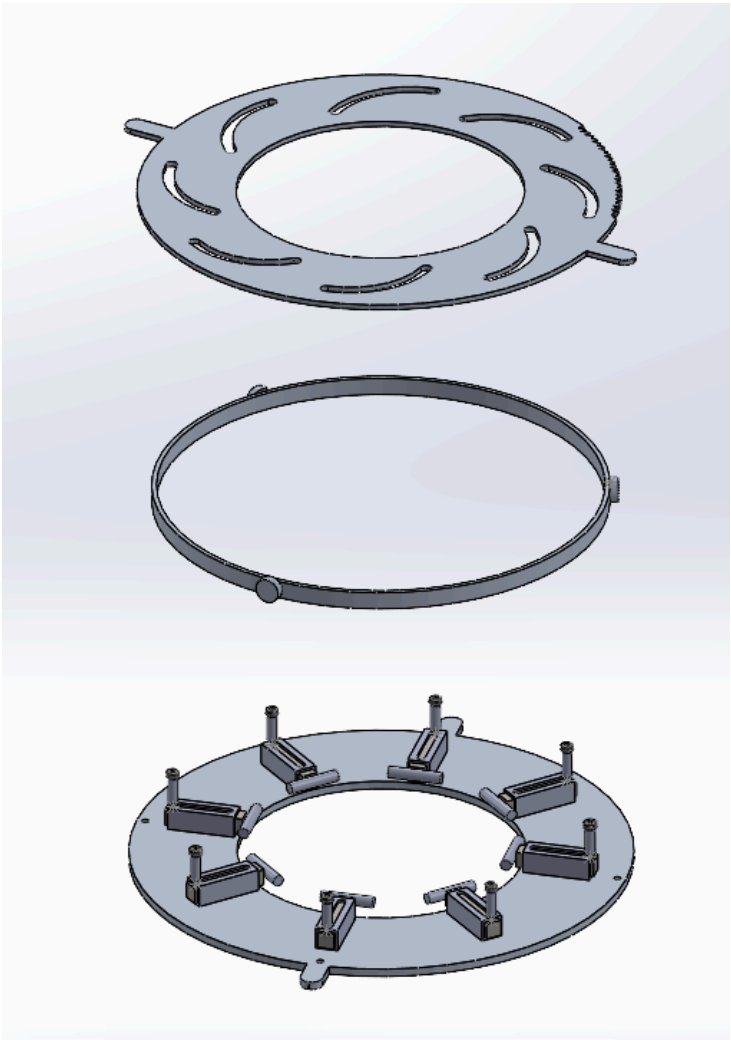
Step 2: Epoxy into place square tubing where it’s designated on the bottom plate using the guide



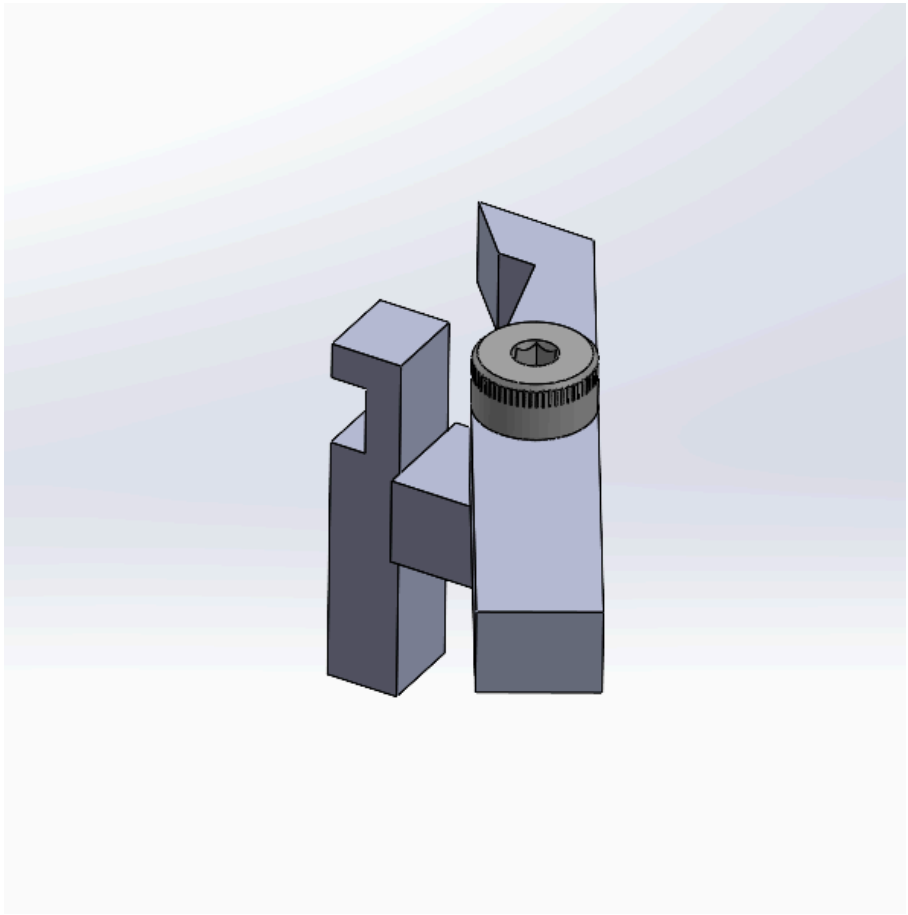
Step 3. Put T slots into square tubing with screw hole pointed up

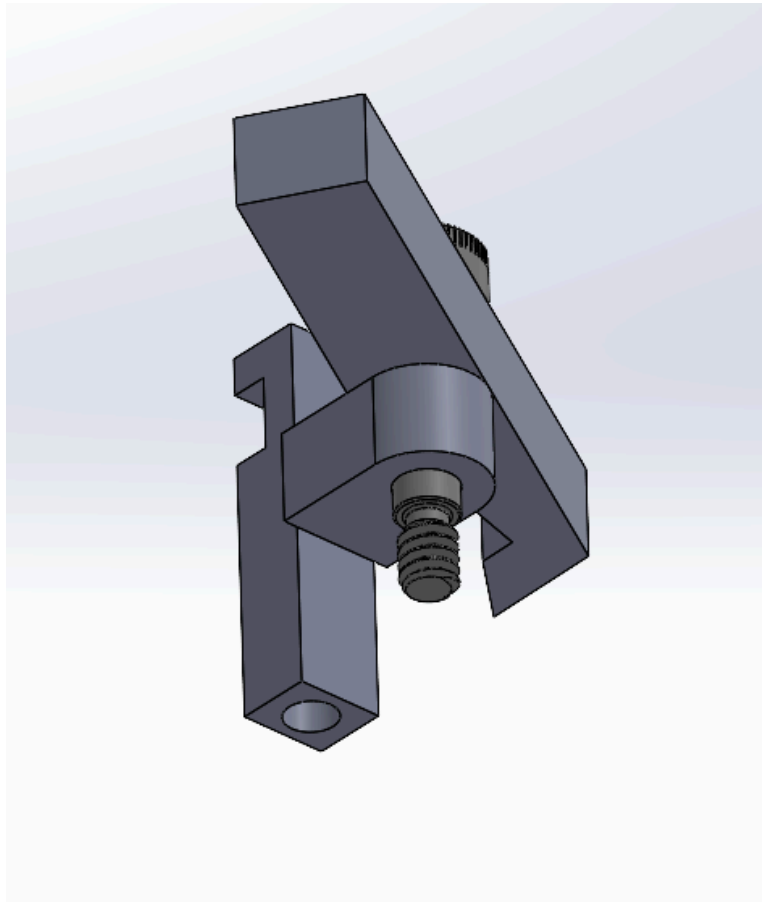


Step 4. Remove the 3D printed guide, even if you have to rip it apart. Put the shoulder bolt and rollers onto T slots through the top plate slots that correspond to each T slot. Make sure that the top plate is in the correct position so that locking can be placed correctly later.

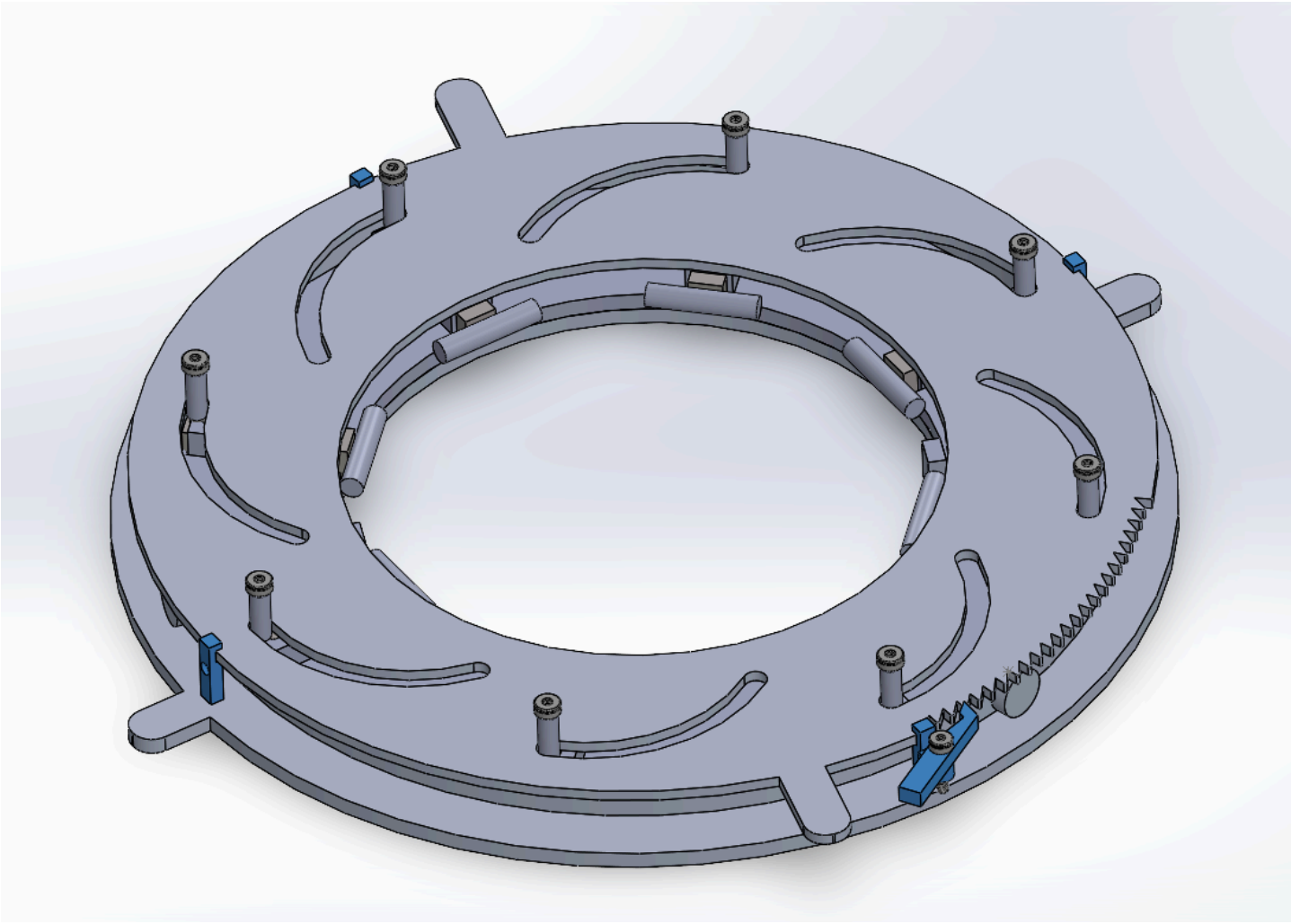


Step 5. Assemble the locking mechanism onto the vertical clamp with a hole on the side, making sure the hole for the axis of the locking is parallel to the screw hole on the vertical clamp (axis for locking is going into the ground).





Step 6. Screw in the vertical clamps, with the locking vertical clamp in the correct position to lock the assembly.



Step 7. Wrap a rubber band around the locking mechanism to tension it for the build.

