Team 23 — Low-Cost Uterine Manipulator for Minimally Invasive Surgery

ME 450 Final Report

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Executive Summary

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Currently, access to laparoscopic ("minimally invasive") surgery in low-resource settings is limited due to expensive, single-use instrumentation. One of these instruments is the uterine manipulator, which positions the uterus for optimal surgeon access and visualization. While this device is commonplace in high resource settings, low resource settings do not have consistent access to this device. This problem is ultimately driven by designs that disregard social, economic, and environmental sustainability in low resource settings. Thus, this project strived to improve access to health care by providing a design for a uterine manipulator that is sustainable for low-resource settings.

To guide design and project outcomes, the team identified the following requirement categories: functionality, safety, patient variation, ease of use, reusability, and compatibility with low-resource settings. Moreover, the team formulated 21 unique engineering specifications relevant to these categories and performed verification testing on 16 of these specifications. The current design passed 11 of the verification tests performed, however redesign does seem feasible to pass the two failed tests. Verification of the remaining specifications has been deemed out of scope of this project; however, the team anticipates that the current design will meet three of the remaining specifications.

The design process for the final design presented here focused heavily on concept generation and iteration throughout the entirety of the project. Extensive research was done to ensure that the team fully understood the unique considerations and constraints associated with medical device design and low-resource settings. Continuously, ideation and feedback was gathered from the project sponsor and primary stakeholders to ensure that the design was tailored to stakeholder needs. The team performed engineering analyses as necessary to derisk and guide design decisions; Notably, analyses were done to ensure patient safety with various device components. Ultimately, the final design was selected based on robustness, adaptability, and sustainability in low resource settings. The final design meets or exceeds the functionality of existing uterine manipulators, while also being low cost and almost entirely reusable.

The final design presented here is not perfect, however. As previously stated, the design failed two verification tests and is only anticipated to meet three of the six unverified specifications. The remaining three specifications were kept in mind during the design process, however the fulfillment of these specifications is still uncertain. Additionally, the current lack of physical testing and validation of the final design leaves questions about the feasibility in a 'real life' setting. Furthermore, usability testing of a prototype revealed that modifications are needed to increase the ergonomics of the device.

While the final design presented here does have some flaws, the team is confident that the design has merit in improving access to health care in low-resource settings.

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Background

Every year, over half a million hysterectomies are performed in the United States alone [1]. A hysterectomy is the medical procedure of removing the uterus (and sometimes the surrounding organs including the cervix, ovaries, fallopian tubes, and more) and is done for a number of reasons such as uterine prolapse, severe pain, endometriosis, and cancer [2]. Evidently, hysterectomies are a common procedure that may be lifesaving.

A laparoscopic hysterectomy (LH) is a minimally invasive surgery (MIS); it is a hysterectomy performed through "ports," small incisions, in the abdomen using a camera and other surgical tools to remove the organs, often through the vaginal canal. Other methods of hysterectomies include traditional laparotomic hysterectomies, laparoscopic assisted vaginal hysterectomies, vaginal, and robotic assisted [2], [3]. However, LHs are considered the least invasive form of hysterectomy, have fewer complications, and shorter patient recovery times compared to other methods [1]. Total laparoscopic hysterectomies (TLHs) are a type of LH in which the entire uterus and cervix are removed; in recent years, TLHs have become more popular at about 44.7% of all performed hysterectomies in some high-resource settings (HRSs) in part due to the laparoscopic benefits as previously mentioned [1]. Throughout this project, the team will maintain a focus on TLHs as directed by the team's sponsor. Another important aspect to note is that in many TLHs, colpotomy (the surgical incision of the vaginal fornix to facilitate the removal of the uterus) is performed, typically via electrocautery instrument [4]. **Figure 1** below shows the anatomy involved in a hysterectomy as well as various other types. In all LHs, there are two ways to remove the uterus and other organs once they have been detached from the rest of the body. The most common is that they are pulled through the vaginal canal; however, in other cases, such as when the uterus is enlarged, the organs may be morcellated (cut into smaller pieces) using a scalpel or electronic morcellator [5]. Morcellation is often slow, tedious, and elevates the risk of the entire procedure, resulting in hesitation from surgeons to proceed with this technique [6].

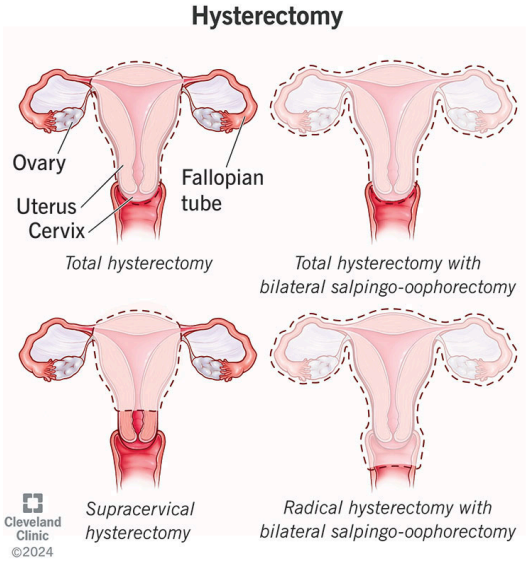


Figure 1. This figure depicts the anatomy involved in hysterectomies. The dashed lines are where incisions are made and the faded areas are the parts that are removed. The cervix is located past the vaginal canal at the bottom of the figures and connects upwards to the uterus. The uterus then leads to the two fallopian tubes which are connected to the ovaries. A total hysterectomy is depicted in the top left; a total hysterectomy with bilateral salpingo-oophorectomy in the top right; a supracervical hysterectomy in the bottom left; and a radical hysterectomy with a bilateral salpingo-oophorectomy in the bottom right [2].

The need for hysterectomies is not limited to HRSs; in low-resource settings (LRSs), there is also a need for these surgeries, but they often lack the equipment necessary to perform them since, as previously mentioned, LHs require more surgical devices [7]. This ultimately stems from the various challenges associated with trying to adapt devices designed for HRSs into LRSs contexts, meaning the devices often are too expensive or cannot be repaired in a LRS. One such device that is often used is a uterine manipulator (UM), which is the focus of this project.

Problem Description

A UM allows for orientation and position of the uterus for optimal access and visibility for the surgeon while performing a hysterectomy or other laparoscopic obstetrical or gynecological procedures such as chromopertubation (occasionally referred to in the literature as chromotubation), a procedure to assess the openness of the fallopian tubes, typically by injecting a colored fluid into the uterus [8]. In operation, the UM is inserted vaginally then past the cervix and into the uterus where it is secured, typically with a balloon or jaws. Once secured, the UM can be manipulated to move the uterus, providing exposure of the operative field, allowing for better visualization. UMs are further beneficial as they reduce the risk of harm to other structures, such as the bladder, that may be in the vicinity of the operation [9]. It has also been found that surgeries that use a UM often have fewer complications and improve patient outcomes [10]. **Figure 2** depicts an existing UM, the RUMI II, that is widely used in operation.

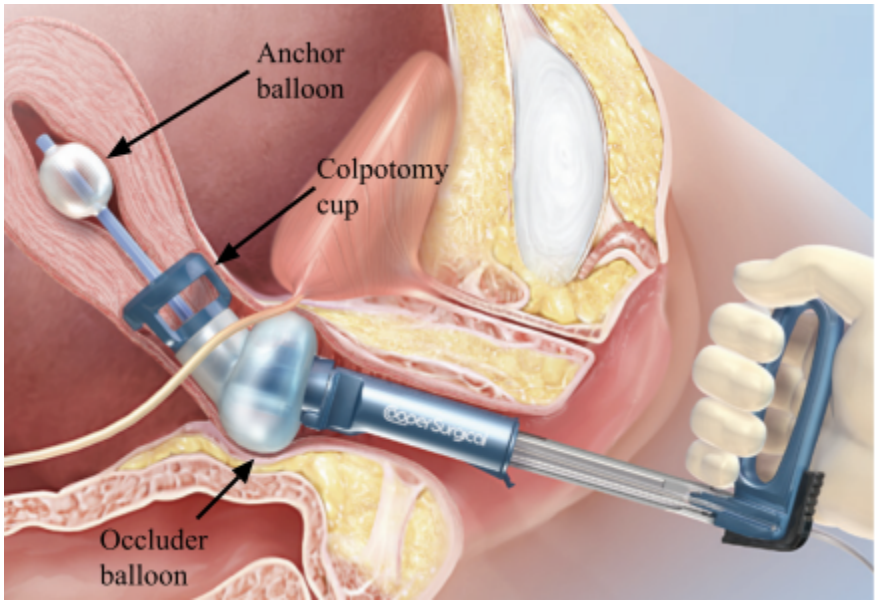


Figure 2: The UM depicted is the RUMI II. It is inserted vaginally to the cervix and into the uterus. The UM is able to manipulate the uterus with the handle, actuating the end tip. The key features of this UM are the anchoring balloon, colpotomy cup, and occluder balloon, all labeled. The anchor balloon is used to assist with uterus manipulation. The colpotomy cup is used to assist with guiding the colpotomy incision. The occluder balloon is used to maintain pneumoperitoneum. Image is from "CooperSurgical RUMI II System Brochure" but labels are added by the team [11].

To fully comprehend the design context of the project the team found it necessary to determine not just how, but also why current UMs do not solve the identified problem. Investigation into this topic led to a clear answer: medical devices, in general, are not designed to be sustainable in LRSs. The motivation behind this is not entirely clear; however, profits are likely a driving factor. HRSs, which represent only 13% of the global health market, consume 76% of all medical devices manufactured [12]. High costs are often cited as a barrier to performing healthcare in low and middle resource settings [13], so much so that over 80% of the current medical devices used in LRSs have been donated by aid organizations or private donors (this is also known as importing devices) [14].

Aside from being unsustainable, this approach ultimately does not solve the problem. Of all of the medical devices that have been donated, only 10-30% of them are operational [14]. This is largely because current medical device designs are not considerate of the differences in low and medium resource settings. Much, if not all, of the currently produced medical devices are intended to be used in a manner where strict standards and expectations dictate things such as the use, lifetime, storage, and maintenance of the devices [14]. Standards can be hard or impossible to achieve in LRSs and often operating environments differ drastically from HRSs. This leads to frequent decommissioning of reusable medical devices [15] and promotes the use of single-use disposable devices. Furthermore, the ones that are reusable are too expensive for LRSs, not fully reusable, are not repairable in LRSs, and/or have poor functionality [16]. Discussion with Dr. Thiyag (the project's sponsor) and Dr. Kwabena Ababio (a stakeholder doctor in Ghana) revealed that once the supply of UMs had been used, hysterectomies and related procedures simply stopped occurring. It is also notable that UMs are not solely used in hysterectomies; however, it was determined by the team's mentor that the team should design a UM that

is able to be used in these surgeries as the UM would thus be usable in ‘related procedures’. Furthermore, when interviewing Dr. Ababio, there was a desire for UMs to assist in TLHs, the removal of the uterus from the body, and chromopertubation [17], [18].

Ultimately, there is no existing UM that is suitable for LRSs that also has the same functionality as ones utilized in HRSs as they are either too expensive, not fully reusable, have limited rotation, and/or have other poor functionality. Additionally, no UM assists in uterus removal. Therefore, the purpose of this project is to develop a low cost and reusable uterine manipulator for LRSs. The project is sponsored by the University of Michigan Global Health Design Initiative (GHDI) with Dr. Dhanu Thiyag. The project is also designed to help doctors in Ghana specifically, namely Dr. Kwabena Ababio. The team’s major objectives include a semi-verified prototype, as well as documentation supporting future progress towards deployment in LRS healthcare facilities. A successful outcome will constitute a working prototype that has intuitive and robust articulation mechanisms, while remaining affordable to doctors and patients in LRSs.

In working with the GHDI, the team has an IP agreement with the GHDI allowing a nonexclusive license with the, right to sublicense, to the University of Michigan to allow for future development while still retaining ownership rights to designs developed during this project. Various companies, such as Thomas Medical and Cooper Surgical, hold patents for existing designs and mechanisms used in UMs, which the team has been mindful about.

Stakeholder Analysis

Stakeholders of this project have been identified through a primary-secondary-terciary method as well as ecosystem mapping. Some stakeholders have been mentioned previously such as Dr. Thiyag, Dr. Ababio, the University of Michigan, and the GHDI. The primary-secondary-terciary method categorizes stakeholders in accordance with their proximity to the identified problem. Primary stakeholders are those whose lives or work are directly impacted by the identified problem and the development of a solution. Secondary stakeholders are those who are still within the problem space, but do not experience the problems themselves and/or are not directly impacted by the implemented solution. Tertiary stakeholders do not experience the problem themselves, however they still have some influence in the success of the solution.

Ecosystem mapping further categorizes stakeholders into six groups: resource providers, supporters and beneficiaries of the status quo, complementary organizations and allies, beneficiaries and customers, opponents and problem makers, and affected or influential bystanders. These groups are not exclusive, and some of the identified stakeholders fit into multiple groups.

The identified stakeholders for this project have been categorized below in **Figure 3**. The three rings in the diagram represent the primary, secondary, or tertiary standing and the assigned color represents the ecosystem grouping of each stakeholder. Stakeholders belonging to more than one group have multiple assigned colors.

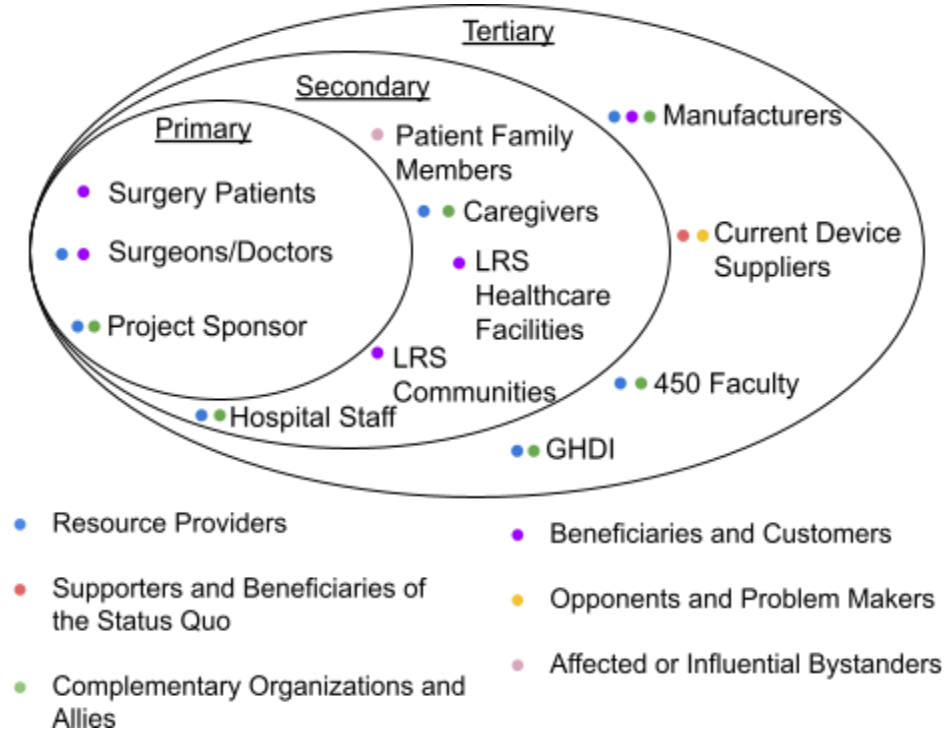


Figure 3: Identified stakeholders organized by primary, secondary, tertiary and ecosystem mapping.

The identified primary stakeholders are surgery patients, surgeons/doctors (Dr. Ababio), and the project sponsor (Dr. Thiyag). Surgery patients and the surgeons/doctors performing the surgeries have been identified as direct beneficiaries of the solution. Surgeons/doctors have also been identified as resource providers as they are the ones who have the skills and knowledge to perform the surgeries and will likely dictate use of the solution in patients. The project sponsor has been identified as a resource provider and an ally due to their knowledge and close connection with the project.

Secondary stakeholders are patient family members, caregivers, LRS healthcare facilities, and hospital staff. Patient family members are affected bystanders. Caregivers encompass nurses and other people who would be caring for surgery patients, and may or may not overlap with some of the other identified stakeholders. Caregivers have been identified as resource providers and allies. LRS healthcare facilities are those who would likely be responsible for obtaining or facilitating the proposed solution and have been identified as customers. LRS communities have been identified as beneficiaries. Hospital staff, like biomedical technicians, would likely need to interact with the proposed solution and have been identified as allies and resource providers.

Tertiary stakeholders are device manufactures, current device suppliers, ME 450 faculty, and the GHDI. The solution manufacturers will play a critical role in determining the feasibility and sustainability of the solution and have been identified as resource providers, beneficiaries, and allies. Current device suppliers, which refers to the companies that are producing the current devices are supporters and beneficiaries of the status quo as well as opponents and problem makers. The ME 450 staff do not experience the

identified problem; however, they will guide decision making during the project and have thus been identified as resource providers and allies. The GHDI has been identified as resource providers and allies.

Some of the identified stakeholders will be positively impacted by this project, while others may be impacted negatively. Surgery patients will have greater access to laparoscopic surgeries, surgeons/doctors will experience less shortages in medical devices and thus can do their job more efficiently, LRS healthcare facilities will have a low cost and sustainable device, and LRS communities will have increased access to healthcare. However, current device suppliers may face economic hardships as introduction of cheaper UMs may reduce their market share and profits. Additionally, communities may experience negative environmental and economic effects due to improper disposal of the device.

Design Process

The design process the team followed is an iterative and cyclical process as seen in **Figure 4**. The process is modeled after the ME 450 design process with the only notable difference being that the team performed "subfunction divergent concept generation." This approach was taken in order to ensure that the team fully explored the solution space and was largely driven by the fact that UMs have many different aspects, which will be covered later. It is notable that this approach was not something that the team had initially planned but instead decided to proceed with once research, benchmarking, and the requirements and specifications had been significantly pursued.

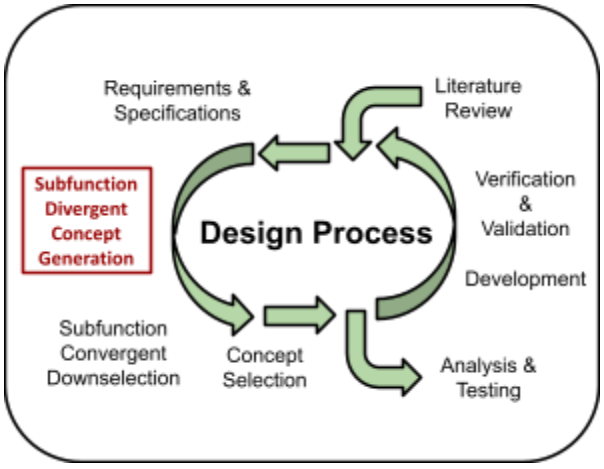


Figure 4. This figure shows the design process that the team followed to complete this project. The overall process is cyclical but one can move to any point from any point in the design process. The team started at "Literature Review" which is why it sticks out of the cycle. The main part of the process that differs from the ME 450 process is the "Subfunction Divergent Concept Generation." Finally the "Analysis & Testing" section branches out as most complete "Development" and "Verification & Validation" is out of the scope of this project.

This process was chosen largely because the entire team is familiar with the process and has significant understanding as it is covered during ME 450. Furthermore, the process is well structured to guide the team in their design while still being simple, fluid, and continuous. Finally, as previously mentioned, at the beginning of the project, the team had not anticipated straying from the ME 450 design process but this model left room to do so. Overall, the design process

being fluid and allowing the team to move between stages freely was extremely beneficial. Throughout the project, the team had to revise all parts of the project based on developments in the design and aspects that were researched.

Knowledge and Data Collection

In order to ensure that the team appropriately understood the problem domain, the team conducted research and compiled on information from medical literature, patents, standards (ASTM, ISO, and the FDA), and interviewed stakeholders. The team was initially directed by Sarah Barbrow, an Assistant Director of the Engineering Library for the University of Michigan, on the databases available. The initial research conducted by the team was to first understand the problem and the medical background, which is heavily detailed in the previous sections. Since UMs are medical devices, it was also obvious to the team from the start of the project that biocompatibility and sterilization would be important. Therefore, to ensure that the device is appropriately sterilized and biocompatible, the team found various standards such as ISO 10993, AAMI TIR17, and ISO 13402. These standards discuss how and what materials qualify to be used for medical equipment and sterilization [19], [20], [21].

The team also conducted research on the capabilities of LRSs, focusing on Ghana. Through this, the most common methods of formal sterilization in LRSs was found to be steam sterilization via a floor-model or tabletop autoclave, used in 93% of the settings reviewed in Forrester et al., “Surgical Instrument Reprocessing in Resource-Constrained Countries.”; the next most commonly used methods were chemical and dry heat sterilization at 38% and 34%, respectively [22]. Additionally, the team initially thought climate conditions might be an important factor and thus conducted research on the climate of Ghana; however, after discussions with Dr. Ababio these were climate conditions were no longer a concern [17].

The next source of information for the team is both Dr. Ababio and Dr. Thiyag. The team conducted interviews with both doctors in order to learn more about the equipment and current solutions in LRSs and understand what the requirements for the project were. Through these interviews, the team learned about how UMs are currently stored, the need for UMs to assist with TLHs, the repair capabilities in LRSs, the sterilization methods in LRSs, and what features of current UMs are liked and disliked [6], [16], [17], [18], [23].

Additionally, the team conducted research on existing UMs to obtain a deeper understanding of the common device functions. One such aspect that was revealed, that hadn’t been previously discovered, was pneumoperitoneum. During a LH, the abdomen may be inflated with gas, typically CO_2, causing pneumoperitoneum, in order to assist with manipulation of the uterus and obtaining visualization of the organs. Some UMs possess the ability to maintain pneumoperitoneum by filling the vaginal canal, typically with a balloon or cup, to prevent the gas from escaping [24].

Furthermore, the team researched average vaginal canal lengths, uterine mass, internal uterine and cervical channel length, and cervix diameters to provide context for the forces that the device must produce and inform key design dimensions. To further build confidence on key dimensions, the team compared their findings to the dimensions of existing UMs and adjusted values accordingly. Furthermore,

the team conducted research on uterus removal in TLHs in consideration of a possible uterus removal mechanism for a UM. Once the uterus has been fully detached from the body, it needs to be removed from the abdomen. In the ideal case, the uterus is able to be pulled through the cervix and out of the vaginal canal. However, the uterus is often too large to be removed in this way. Oftentimes it takes surgeons and nurses considerable time to attempt to maneuver the uterus so that it fits through the cervix otherwise they have to perform morcellation [23].

Overall the team had to conduct research and literature review consistently throughout the entire project. The main challenges the team faced with information gathering was more so a lack of any initial familiarity with the medical field. This led to the team needing to spend more time familiarizing themselves with medical terminology, processes, and regulations. In addition, the team had challenges in finding times to be able to consistently meet with key stakeholders due to them being doctors and one being in Ghana. However, the team did well at gathering information to understand the problem due to a few key strategies including splitting up research and then sharing findings in team meetings and benchmarking to see all the functions UMs had and discerning their purpose.

Benchmarking

Existing UM were compiled and analyzed to determine if there is a UM that already solves the project problem. **Table 1** contains the UMs that the team researched and shows that there is not a UM that solves the team's problem. Additionally, through benchmarking the team was able to analyze the various features of UMs and determine if they performed tasks or held purposes relating to the team's needs. Note, in the rotation column anteversion-retroversion refers to the movement towards the front and back of the body respectively.

Table 1. Benchmarking table consisting of seven different UM. This table compares the UMs based on several categories including rotational range of motion (RoM), price per unit or use, reusability, adjustability, colpotomy assistance, and uterus removal capabilities. This table demonstrates that there are currently no UMs on the market that fulfill all of users' needs.

Uterine Manipulator	**Characteristics**					
	RoM (°)	**Price***	**Reusable**	**Adjustability**	**Colpotomy Assistance**	**Uterus removal**
Gerati Spring Cup	90	$450.00	Yes	One size (diameter) head	No	No
Gerati Clement Ferran	90	$595	Yes		No	No
Cooper Surgical Advincula Delineator	-	$47.25	No	Balloon inflation	Yes	No
Conmed VCare Plus	140	$210.75	No	Multiple cup sizes	Yes	No
Laborie ClearView	210	$257.20	No	Balloon inflation	No	No
Thomas Medical K-UMI	140	$22.43	No	Balloon inflation	Yes	No
RUMI II Cooper Surgical	140	$1,734.95	Yes	Balloon inflation	Yes	No

*Price references price per use for reusable UMs and price per unit for disposable UMs.

The **Gerati Spring Cup** in **Figure 5** is a reusable $450 UM which features 6 detachable tips to accommodate various uterine depths. The tips are detached and reattached via a spring loaded trigger with ratcheting stops that inserts a rod to secure the tip in place. This UM can assist in TLH as well as related procedures previously mentioned. It is made of stainless steel with a shaft length and diameter of 33 cm and 5 mm respectively. This UM can move 90 degrees anterior-posterior [25]. There is no mention of colpotomy or uterus removal assistance. The uterus is directly manipulated by rotating the handle. Note there is limited information on this device.

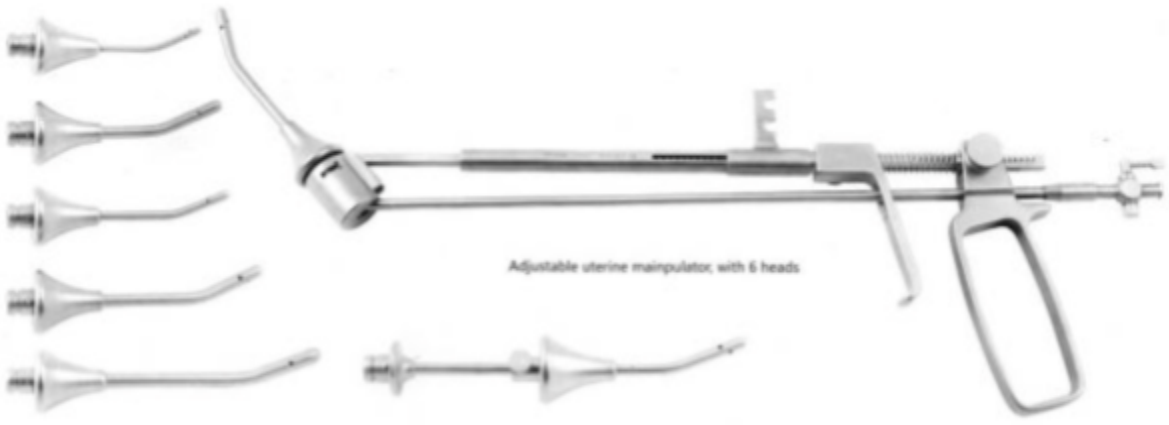


Figure 5: Gerati Spring Cup type UM [25].

The **Gerati Clement Ferran** in **Figure 6** is a reusable $595 UM with 3 different tip attachments, one small and two large cup sizes, a cone silicone seal, silicone ring seals, and handle with ratcheting mechanism. The UMs tips, shaft, and handle ratchet mechanism are made of stainless steel 302 grade. The cups and shaft sheath in blue are made of medical grade plastic, the manufacturer has no further information on the material [26]. The cups do not provide any colpotomy assistance. It appears the stainless steel components are sterilizable via autoclaving, however it is unclear if the plastic can be sterilized as well. This UM can assist in TLH as well as related procedures previously mentioned. Releasing the silver hinge on the black handle and applying downward pressure on the handle will move the tip anteriorally.



Figure 6. Gerati Clement Ferran [26].

The Cooper Surgical Advincula Delineator features an S-curved shaft, ergonomic handle, pneumo occluder balloon and a balloon on the tip for anchoring device in uterus seen in **Figure 7** [27]. It is $47 and completely disposable. As the name infers it provides clear delineation of the vaginal fornices using a Koh Efficient colpotomy cup, which comes with 4 varying cup sizes. Procedures it can achieve include TLH, LSH and LAVH. The uterus is sounded (measured using the shaft without balloon), the tip is inserted to previously sounded depth, the colpotomy cup is slid onto the cervix, and the tip balloon is

inflated. The uterus is manipulated directly with the actual, it does not feature any secondary actuation. Once the uterus is free, the pneumo occluder balloon is inflated and colpotomy incision can be made with the guide of the colpotomy cup. The device does not feature any chromopertubation abilities.



Figure 7: Cooper Surgical Advincula Delineator [27].

The Conmed VCare Plus is a $210 disposable UM and can be seen in **Figure 8.** It features an S-curve shaft, with an intrauterine (tip) balloon, chromopertubation capabilities, a colpotomy cup for incision guidance, and an pneumo occluder cup [28]. The pneumo occluder cup maintains pneumoperitoneum inside the abdominal cavity and can be easily locked in place with a twisting clip.



Figure 8: The Conmed VCare Plus [28].

The Cooper Surgical RUMI II is a $1,734.95 reusable UM and a major benchmark, specifically requested for review by Dr. Thiyag and Dr. Ababio. As seen in **Figure 9**, it features a stainless steel shaft, handle with a button, Koh Efficient colpotomy cups, a pneumo occluder balloon, and an intrauterine balloon. There are 6 different lengths ranging from 6.7mm x 12cm to 5.1mm x 3.75cm and 4 different sizes for the Koh Efficient (colpotomy assistance) cups ranging from 2.5 cm to 4 cm [11]. The RUMI II system is a favorable device due to its intuitive controls, various capabilities, and compatibility with a

wide range of patients. The button on the handle is depressed, it allows the uterine tip to move freely, once the desired angle of the tip is found the button is released and locked into place.

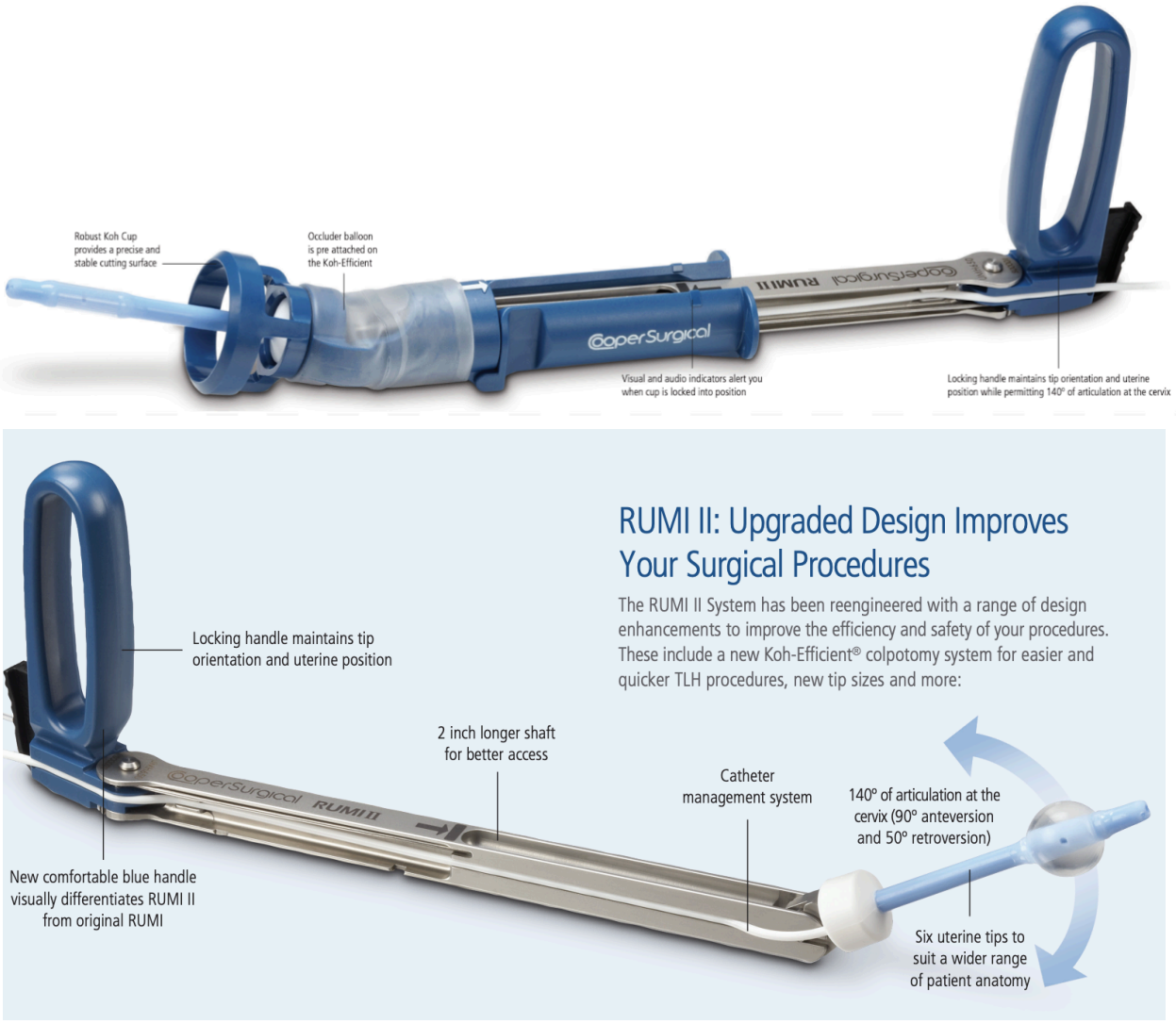


Figure 9: The Cooper Surgical RUMI II [11].

The Laborie ClearView seen in **Figure 10** is a $257 disposable UM that features a RoM capability of 120° anteversion and 90° retroversion, chromopertubation, two tip lengths with a use of a spacer, three colpotomy cup sizes including 3, 3.5, and 4 cm [29]. Additionally it includes an intrauterine balloon and a pneumo occluder balloon for device anchoring and maintaining pneumoperitoneum. Twisting the handle moves the tip posteriorly and anteriorly.

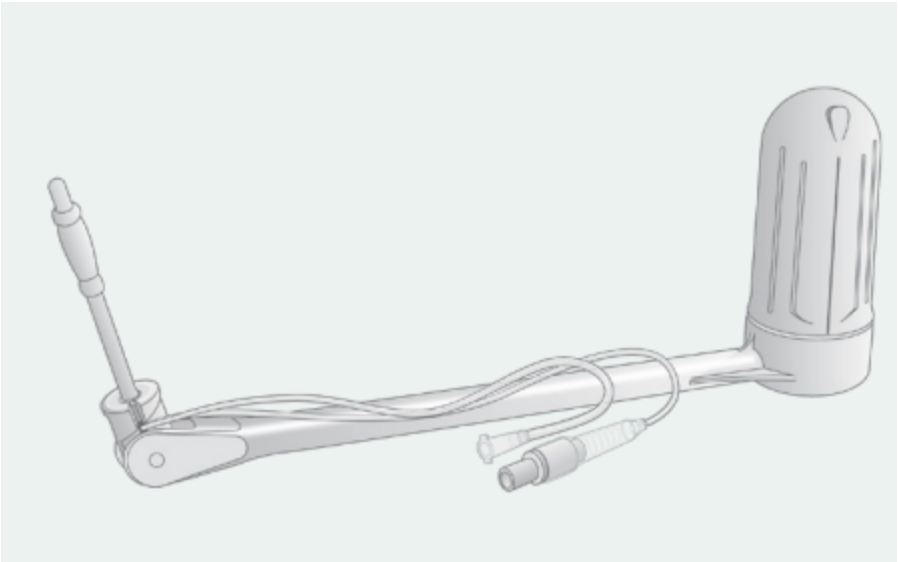


Figure 10. The Laborie ClearView UM [29].

The Thomas Medical K-UMI seen in **Figure 11** features a C-curve shaft, pinch grip that moves the entire device, and an intrauterine balloon. The device costs $22 and is completely disposable [30].

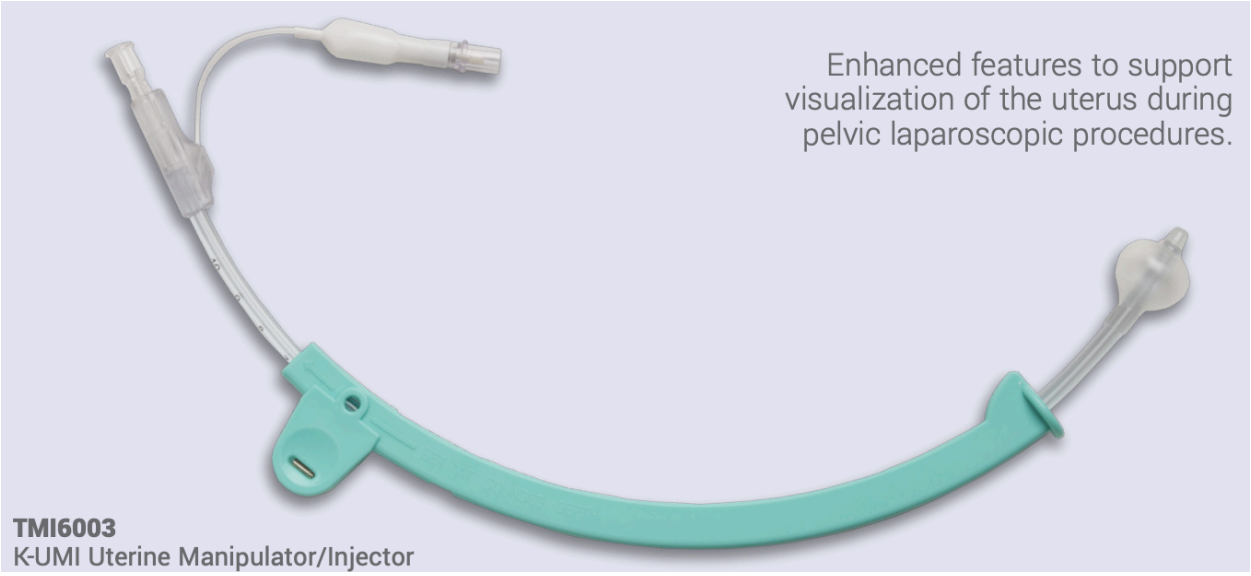


Figure 11. The Thomas Medical K-UMI [30].

Benchmarking proved useful for understanding the range of UMs available on the market, along with defining characteristics. Some of these characteristics prelude to the major requirements and specifications. While helpful, the previous table is merely a high-level overview of the devices, no breakdown of sub-functions was done. Large gaps of information were identified but not explored such as device life span for reusable devices, specific mechanisms for control of lateral uterus movement, and maintaining pneumoperitoneum. Initially, a characteristic about "placement/colpotomy time" was included, however, lack of proper definition caused confusion and so was replaced with colpotomy

assistance. Uterus removal assistance is the largest gap seen and has also been mentioned by Dr. Thiyag. She stated no current UM can assist in actual uterus removal, this was further validated by benchmarking.

Apparent tradeoffs are made between price and reusability. The price of a UM drastically increases if it is reusable. A somewhat fair comparison of this can be made with the RUMI II ($1700) (partially reusable) and the Delineator Advincula ($47) (disposable). While the Delineator does not offer the same range of motion or chromopertubation, there is a large enough difference in price to say there is an apparent tradeoff between reusability and price.

Benchmarking has informed design opportunities including overall shape of a UM, RoM capabilities, and high level descriptions of various functionalities. The Gerati Spring Cup UM offered a very simple and intuitive understanding of an UM. Leading to an understanding that UMs will have a shaft of some sort and a handle to move said shaft. The Gerati Clement Ferrand offered insight to additional components found on most UMs including the usage of cups to surround the cervix, silicone stops, and ratcheting mechanism for the handle. This was a helpful early indicator of gaps in knowledge, since it was not clear what some of the additional pieces were used for. A large milestone for design understanding was the exploration of the RUMI II because it would include and explain the usage for colpotomy cups, tip and occluder balloons, and handle rotation for uterus manipulation.

There are numerous UMs on the market, all with the intended function to manipulate the uterus to reveal sensitive surrounding structures. Benchmarking revealed and alluded to numerous additional functions that can aid in main function or increase robustness of the UM. However, it also revealed that UMs vary in what kinds of functions they offer: no two are the same.

Overall, benchmarking exposed gaps in the team's knowledge about the extent of UM capabilities. This lack of knowledge will appear in concept generation, where a unique approach is taken to categorize and semi-benchmark UM sub-functions.

Requirements and Engineering Specifications

Twenty-one requirements were established to meet stakeholders' needs. **Table 2** provides summarized information regarding the level of priority, engineering specification(s), and justification for each requirement. Priority levels were labeled as nice-to-have or need-to-have based on their importance relative to the basic functioning and use of the device. Initial targets were generally guided by Dr. Thiyag, Dr. Ababio, literature review, benchmarking, and engineering standards.

Table 2. Requirements and engineering specifications

Category	Index	Requirement	Priority	Specification	Sources
Functionality	001	Robust Range of Motion	Need to have	The device shall facilitate ≥ 140° smooth uterine antero-posterior (anteversion and retroversion) and lateral movement	[11], [31]
	002	Chromopertubation	Need to have	The device shall include a method to transfer up to 50 ± 2mL dilute methylene blue dye into the uterus for chromopertubation	[32], [33]
	003	Maintenance of pneumoperitoneum	Need to have	The device shall be able to maintain a minimum abdominal cavity pressure of 12 mmHg	[24], [34]
	004	Removal of Uterus	Nice to have	The device shall assist in the removal of the uterus from the body	[5], [16], [35]
Safety	005	Biocompatibility	Need to have	The device shall contain only biocompatible materials as determined by 10993-1. Necessary tests include cytotoxicity (ISO 10993-5), sensitization (ISO 10993-10), irritation (ISO 10993-23), and systemic toxicity (ISO 10993-11), unless the material has been previously established to pass each test through other medical devices.	[19], [36]
	006	Safety	Need to have	The device shall not contain sharp edges as determined by testing under ANSI/UL 1439 with the exception of the parts directly in contact uterine removal subsystem, or cause unintended harm to any structures external to the uterus	[37], [38], [39]
	007	Cleanability	Need to have	The device shall expose or be capable of exposing all surfaces in contact with biomatter to enable cleaning with a brush	[40], [41]
	008	Autoclave/Dry Heat Sterilizability	Need to have	The device shall use materials scoring ≥ 2 in Annexes E and F of AAMI TIR17:2024 for autoclave (steam cleaning) and dry heat OR pass autoclave and dry heat testing as outlined in ISO 13402:2025	[21], [22], [42]

	009	Chemical Sterilizability	Nice to have	The device shall use materials scoring ≥ 2 in Annexes D, G, H, I, J, and K of AAMI TIR17:2024	[20], [22]
Patient Variation	010	Uterine Mass	Need to have	The device shall be able to move uteri with uterine masses ≥ 1000g	[43], [44], [45]
	011	Uterine Length	Need to have	The device shall perform the full range of motion for uterine lengths (measured from beginning of cervix to fundus) from 5±1cm to 11±1cm	[43], [46]
	012	Vaginal Fornix Diameter	Need to have	The device shall be capable of delineating vaginal fornices with diameters ranging between 2.5 - 5 cm undilated	[11], [29], [47], [48]
	013	Cervical Channel Diameter	Nice to have	The device shall be capable of fitting inside a ≤ 2.5 cm diameter for all parts of the device intended to enter past the cervix	[31], [49]
Ease of Use	014	Ease of use	Need to have	The device shall receive an average score of ≥ 75 from at least 5 surgical assistants after a 20 minute exploratory/familiarization period, scoring using the System Usability Scale.	[50], [51]
	015	Device Weight	Nice to have	The device shall weigh ≤ 1000g in total	[4], [18]
	016	Setup and Placement Time	Nice to have	The device shall be able to be fully set up and placed in ≤ 7 minutes	[4], [52]
	017	Operation Force	Nice to have	The device control shall require 2 to successfully actuate the device at maximum expected loading	[53], [54]
Reusability	018	Sodium Hypochlorite (Bleach) Resistance	Need to have	The device shall not allow ≥ 50 mils of 5% sodium hypochlorite solution penetration per year of immersion	[21], [22], [55], [56], [57]
	019	Durability	Need to have	The device shall be composed of various parts, of which at least 90% be able to be reused a minimum of ≥ 300 times and ideally ≥ 1000 times	[58], [59]

	020	Low Cost	Need to have	The device shall cost ≤ $1 per use in material and manufacturing costs	[6], [58]
Compatibility With Low-Resource Settings	021	Repairability	Need to have	The device shall require no more than standard screw drivers to assemble and disassemble	[12], [15]

Functionality— The requirements under this section define the core functionality of the uterine manipulator.

001 Robust range of motion: This requirement addresses the flexibility expected for the UM in the antero-posterior (up and down) and lateral (side to side) planes with the cervix as the center of rotation. The project description at the beginning of the semester requested "robust 360-degree uterine motion." After some analysis, 360° was determined to be unreasonable given the physical constraints and range of motion of the uterus within the abdominal cavity. Thus, benchmarks with dynamic actuation methods were compared in order to understand what a robust range of motion would look like.

Of the four highest-performing benchmarks in this regard, the Conmed VCare Plus, Thomas Medical K-UMI, and Cooper Surgical RUMI II all had a range of motion of 140° [11]. The three lower scorers reached at most 90° range of motion, while the Laborie ClearView Total was able to achieve an impressive 210°. Little evidence was found for the necessity of uterine manipulation outside of 140° bounds in context of the surrounding structures, so it was determined to be a satisfactory range of motion for the project. Based on this, the specification to achieve a range of motion ≥ 140° was established. This decision was further supported in Mettler et al., which also established 140° range of motion as the upper threshold [31].

Earlier iterations of the specification also included requirements for lateral movement capabilities. However, this was determined to be unnecessary since the manipulator can simply be rotated 90° around the shaft axis to access the lateral plane of movement.

"Need to have" priority was given as the ability to move the uterus in a wide range of motion is a central attribute to the functionality of a uterine manipulator. Without this function, there would have been little use for the other features of the device.

002 Chromopertubation: In the process of conducting chromopertubation, there are several factors to consider. The first two are how the dye is delivered into the uterus and where exactly in the uterus the dye should be deposited. Attempting to specify these parameters unnecessarily restricted the concept pool and started to dictate factors of the design itself. In contrast, the volume of dye was considered an appropriate parameter to constrain that would both ensure a useful specification without leading towards a specific solution.

The standard clinical protocol for chromopertubation requires up to 50mL of dye to be delivered to the uterus to check drainage through the fallopian tubes [33]. Thus, delivery of 50mL was set as the design-agnostic specification for the device.

This requirement and specification was added after DR1 in conversation with Dr. Ababio who mentioned assistance with dye deposition as an aspect that he appreciated from current uterine manipulators [17]. As four of the seven benchmarks (VCare, ClearView, K-UMI, and RUMI II) also had this feature, chromopertubation assistance became a “need to have” feature for the final design.

003 Maintenance of pneumoperitoneum: Pneumoperitoneum was noted as an important factor in surgeons' comfort in the procedure. Thus to ensure that the device would be useful to surgeons, and to compete with existing solutions, some form of occlusion in the vaginal canal to maintain abdominal pressure was deemed a necessary feature. Additionally, five of the seven benchmarks include solutions to maintain pneumoperitoneum.

Review of literature regarding optimal pressure inside the abdominal cavity yielded an optimal value of 12 mmHg, which was then set as the target value for the specification.

004 Removal of uterus: The uterine manipulator should be able to remove the uterus from the body after the colpotomy incisions are made. As enlarged uteri are especially difficult to remove as a whole through the vaginal canal, the specification may be considered partially fulfilled if the device substantially reduces the amount of time needed to remove the uterus (for instance, if the device reduces the morcellation time needed from 30 minutes to 15 minutes). Further development of this specification is required to find the most appropriate way to characterize this property.

This feature was specifically requested by both Dr. Thiyag and Dr. Ababio as an opportunity to streamline the workflow and receive more value from one reusable instrument. Additionally, since no uterine manipulators currently on the market are equipped to assist with the removal, it is an excellent opportunity for innovation and a competitive advantage if this device were taken to market. This requirement was labelled "nice to have" as an experimental feature that would provide benefit to the user, but that is not necessary for the basic function and need case of the project.

Safety— The requirements under this section ensure safety and accordance with medical device standards and best practices.

005 Biocompatibility: Research of leading standards for biocompatibility of medical devices was conducted. Under ISO 10993, Biological evaluation of medical devices, uterine manipulators fall under

section 6.4.4.5 as a device in contact with internal tissues other than circulating blood. With a type A limited duration of exposure of ≤ 24h, the relevant biological effects to consider are cytotoxicity, sensitization, irritation, and systemic toxicity. Thus, these standard tests were invoked in the specification.

Biocompatibility is a non-negotiable quality of the device in order to acquire regulatory approval and ensure patient safety, making this a "need to have" requirement. All the benchmarks are necessarily made of materials qualified under the same or similar standards of biocompatibility.

Changes to the specification over time have increased its precision as the team's knowledge of the standards deepened.

006 Safety: This requirement limits a source of risk in order to reduce the potential for unintended injury during use. The device should not cause lacerations, punctures or perforations in any part of the body, including during placement, operation, and withdrawal. To accomplish this, the testing procedure from ANSI/UL 1439 to test sharpness of edges should be implemented to reliably ensure safety in this sense. A singular exception exists for removal of the uterus; the device may cut or dig into the uterine tissue to secure the organ for removal. The forms across all the benchmarks are rounded, showing a consideration for safety as well. This specification underwent several iterations. The reference to UL 1439 was added to increase specificity. This was a "need to have" requirement for the device.

007 Cleanability: Research of leading standards for cleanability of medical devices was conducted. ASTM F3357-19 lists considerations for designing reusable medical devices, which boil down to ensuring that anywhere biomatter may reach is also reachable by a brush [40]. The same sentiment was echoed in conversation with Dr. Awtar, a faculty at the University of Michigan. The disposable benchmarks do not need to be cleanable, but the reusable ones must be. This requirement was labeled a "need to have" in order to ensure that the device would be fully reusable.

008/009 Sterilizability: These requirements specify the testing procedures used to evaluate the compatibility of the device with common sterilization procedures. The most common formal sterilization method found in low-resource settings was steam cleaning via floor-model or tabletop autoclave; the next most commonly used methods were chemical and dry heat sterilization [22]. Due to the variety of reagents grouped into the chemical sterilization methods category, it was determined that autoclave and dry heat compatibility would be prioritized as "need to have" characteristics.

As per the "ISO 13402:2025 Surgical and Dental Hand Instruments — Determination of Resistance against Autoclaving, Corrosion and Thermal Exposure.", the testing procedures for these two sterilization methods are as follows:

Autoclave: "Procedure is performed at 134 °C. After cooling down to room temperature, no corrosion shall be visible during the visual inspection. Direct visual testing shall be done according to EN 13018. Use a magnifying lens (×10) to check for any signs of corrosion on the surface. No changes in the surface or the connections are allowed."

Dry heat: "Place instrument or component in the apparatus and heat to 150 °C ± 5 °C. After reaching this temperature, leave the instrument or component in the closed oven for 30 min ± 1 min. Direct visual testing shall be done according to EN 13018. Use a magnifying lens (×10) to check for any signs of corrosion on the surface. No changes in the surface or the connections are allowed" [21].

Alternatively, sterilizability using either of these processes may be established if a chosen material receives a score ≥ 2 in the respective Annex of AAMI TIR17; Compatibility of materials subject to sterilization [20].

To account for chemical sterilization processes, which are also quite common in low-resource settings, materials in the device should also ideally receive scores of ≥ 2 in Annexes D, G, H, I, J, and K of AAMI TIR17, representing compatibility with ethylene oxide, hydrogen peroxide, nitrogen dioxide, peracetic acid (liquid and vapor), and chlorine dioxide. Due to the lower share of the total chemical sterilization count used that each of these chemicals hold, this specification was labeled a "nice to have." Compatibility with some, but not all, of these chemicals will be considered a partial fulfillment of the specification and is also a satisfactory result.

As bleach is no longer recommended (but still widely used) as a sterilizing or disinfecting agent for medical applications, the specification regarding bleach resistance has been moved into the reusability subset of requirements and has been titled "Resistance to chlorination."

Patient variation— The requirements under this section ensure that the device serves as much of the target population as possible.

010 Uterine mass: There is extensive documentation of minimally-invasive gynecological surgeries being performed on patients with large uteri (over 1000g). In fact, relative to lower uterine weights, surgeons were found to give patients laparoscopic surgery instead of open laparotomy if the patient had a large uterus [45]. Thus, it is imperative that the uterine manipulator is capable of moving uteri ≥ 1000g. No data regarding uterine weight capacity was found for any of the benchmarks, but as many surgeries take place due to exceptional circumstances that could add mass to the uterus, the ability to withstand that elevated mass was a necessary requirement for the device.

011 Uterine length: The device must be able to move uteri with varying lengths (measured from entrance of cervix to the fundus, the very back of the uterus). Based on a 1984 study of various uterine cavity measurements, a range of 5±1cm to 11±1cm will suit the vast majority of patients [46]. Several commercially available UMs like the ClearView and RUMI II operate within a similar range as well, which provided extra backing for this decision. High priority was given to this specification to ensure that the device would be usable for all patients.

012 Vaginal fornix diameter: To guide colpotomy incisions, many uterine manipulators provide a cup/cuff that nestles securely around the cervix and separates the layers of the vaginal fornices. This cup must be closely fitted to the tissues in order to be effective, so it became necessary to include a corresponding requirement. The majority of vaginal fornices fall between 2.5-8.3 cm in diameter [47].

However, the leading benchmarks only provide between 2.5-4 cm in colpotomy cup diameter. Thus, the team selected a range of 2.5 - 5 cm.

The time-based colpotomy assistance from DR2 was determined to be excessively broad in attempting to evaluate the device's ability to guide surgeons to place the colpotomy incisions. Thus, the foundational parameter of fornix diameter was selected to replace this requirement and corresponding engineering specification.

013 Cervical channel diameter: The tip subsystem reaches the uterus by insertion through the cervical channel. A maximum diameter of 1cm was chosen, which is quite generous but still feasible with minimal dilation required. The specification previously allowed up to 2.5cm dilation, but a smaller diameter was preferred to avoid unnecessary post-operative pain. The RUMI II tips range from 0.5-0.6cm; diameters for the other benchmarks were not found.

Priority for this was set as "nice to have" since dilation is technically possible to allow a wider device to pass, but is ultimately undesirable.

Ease of Use— The requirements under this section ensure that the device is intuitive and comfortable to use, preventing fatigue, errors, and unnecessary prolonging of the operation time.

014 Ease of Use: Initially, ease of use was defined by the number of cases needed to reach a plateau in the procedure learning curve. After reflecting on the purpose of including an ease of use requirement, the team decided to move towards a specification that rewarded simple, intuitive controls that would be easily learned and successfully implemented, even without reaching the 75-repetition mastery plateau. Thus, the SUS was selected. A minimum score of B (75%) was selected for the specification to stay competitive since (though not graded on the SUS rubric) the benchmarks have reportedly mixed reviews in terms of ease of use and assembly [31]. "Need to have" priority was assigned to reflect the importance of user experience on the staying power of a design.

015 Device weight: In order to reduce muscle fatigue while operating the UM, the device weight was constrained to weigh no more than 1000g in total. The initial target value was 500g, which was based on the weights of two lightweight benchmark devices [4]. This value was then updated to 1000g/1kg to reflect more robust features and more durable material selections.

016 Setup and placement time: Specified by a device placement time of ≤ 7 minutes, from assembly to proper positioning of the UM so that the uterus can be effectively manipulated. These values were determined through literature review comparing placement for abdominal uterine manipulators and vaginal manipulators. This requirement was deemed nice-to-have because it does not directly affect operation outcomes. However, it was nonetheless an important factor to consider because if the setup time were to be excessively long, it would inhibit adoption of the device over other options.

017 Operation force: In the same vein as device weight, the operation force requirement was designed to maintain a safe level of force input by the user. For sustained repetitive tasks such as controlling a uterine manipulator for the length of a surgical procedure, the force required for movement should be at most

15% of the maximum voluntary contraction (MVC) force that the user is capable of producing [54]. Looking at grip strength data for a Swiss population (taken as a proxy) and taking an overly cautious selection of 70-79-year-old women results in a maximum grip strength of 250N [53]. Thus, at most 37 Newtons of force may be required to actuate the loaded device. For similar reasoning as Setup and placement time (and with the same caveat), the "nice to have" priority was assigned to this requirement.

Reusability— The requirements under this section ensure that the device is capable of withstanding a long life span

018 Sodium hypochlorite (bleach) resistance: Despite no longer being recommended as a sterilizing or disinfecting agent for medical devices, sodium hypochlorite (bleach) is still widely used in healthcare settings and thus critically important to consider [55]. To avoid excessive corrosion, the device shall not allow ≥ 50 mils of 5% sodium hypochlorite solution penetration per year of immersion.

Previous versions of the specification pulled from testing procedures outlined in ISO 13402 to analyze visible corrosion after immersion. The specification was updated to the current iteration for clarity and to avoid relying on the less precise visual test.

019 Longevity: This requirement states the minimal number of uses for the UM is 300 and an ideal number would be 1000. Current manipulators in the market do not explicitly offer a number of uses, this is likely due to the limited reusable devices and because there is not a plethora of studies done on the number of cycles an instrument can be sterilized. The minimum number of uses is based on the expected lifetime of a speculum, a gynecological instrument used for inspecting body orifices. Bridea Medical Group suggests reusable stainless steel specula should survive hundreds of sterilization cycles, where lifetime is highly influenced by user maintenance. The ideal number of uses is based on the average number of procedures done within a year where a UM was utilized in a LRS [18]. This requirement was deemed need-to-have due to the need for an access-sustainable uterine manipulator.

Compatibility with Low-Resource Settings— The requirements in this section aim to address some of the challenges associated with operating in low resource settings.

020 Low-cost: This requirement specifies an ideal per use cost of ≤ $1. The current high costs of UM is the largest barrier LRS have for obtaining these devices [60]. A low cost UM is a need-to-have requirement due to the limited access of funds a LRS has to purchase medical devices. The initial value was $15 per use, which was lowered and defined with only material and manufacturing costs over time.

021 Repairability: Repairability of the UM should not rely on any specialized tooling. All necessary tools for UM repair should be currently available in hospitals or found locally. This is a basic requirement for the successful design of medical devices in LRS. Despite this, for the disposable benchmarks, repairability is a non-issue. The reusable UM benchmarks are not designed for repairability at this time. Based on discussion with Dr. Ababio, screws were cleared to be used in the design.

Concept Generation

Extensive initial concept generation was completed with a total of 211 sub-function concepts generated. Generation methods included brainstorming, sub-system breakdown, morphological chart, SCAMPER, and design heuristic cards. A sub-system morphological chart combination was created early on in concept generation to better understand the extent of sub-functions present in a UM.

Initial concept generation was done individually with each team member creating 20 concepts each. A total of 80 concepts were created with 64 being unique; these consisted of sketches, broad concept ideas, and sub-function descriptions. The team gathered during an in class workshop to analyze and group designs. An example of this is seen in **Figure 12**. Design heuristic cards and SCAMPER were used for further concept generation. As an example, the design heuristic card 16: "Bend" was used to generate the concept in **Figure 13** that explores a bendable tip on the UM. Concepts in this stage were counted (number in parentheses) and grouped together to begin analysis of the solution space, including Grabbing (4), Balloon (4), Vacuum/suction (6), User interface (5), Ratchets (5), Electronics (2), Placement methods (3), Non-physical manipulation (5), Shafts (4), Adjustability (3), Ball, Joint(2), Pierce (3), Magnets (3), String (3), Expanding tip (7), and Around uterus (5).

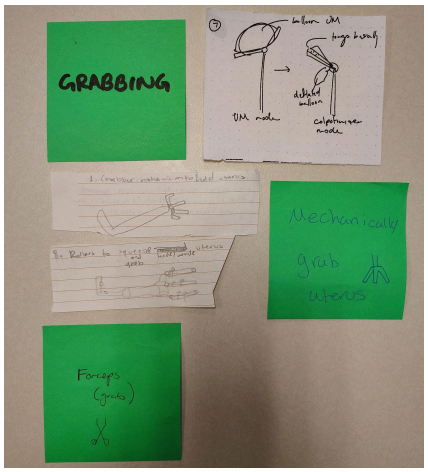


Figure 12: Grabbing category as an example of a group work from in class workshop.

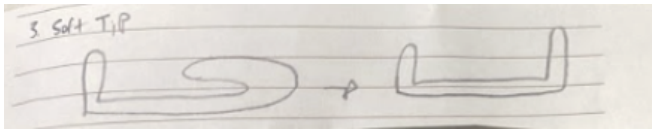
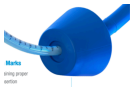
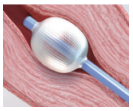
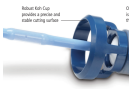
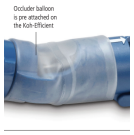
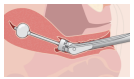
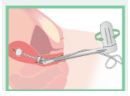


Figure 13: Preliminary concept made using Design Heuristic card 16.

As previously mentioned in the benchmarking section, a sub-system analysis was done after individual concept generation to increase understanding of existing UM sub-functions as seen in **Table 3**. The V-Care Plus, RUMI II, and the Laborie ClearView were analyzed. As sub-functions of each device were defined, descriptions for sub-functions in a morphological chart were developed. The sub-functions include: Uterine Depth/Fit/Adjustability, Main Body, User Interaction, Actuation Method/ Mechanism, Anchor, Colpotomy Assistance, Maintain Pneumoperitoneum, and Uterus Removal. Group brainwriting exercises were done for each category.

Table 3: Sub-system analysis on three existing UMs.

Sub-function—>							
Existing Uterine Manipulators	Uterine Depth/Fit/ Adjustability	Main Body	User Interaction	Actuation Method/ Mechanism	Anchor	Colpotomy Assistance	Maintain Pneumoperitoneum
V-Care Plus	 -graduated shaft -locking mechanism	 - curved	 -direct control from handle to tip	-direct control from handle to tip	 -balloon at tip	 -colpotomy cups sizes S,M,L,XL	 -proximal occluder
RUMI II	-sounded with a separate instrument -appropriate tip length selected 	 -straight rod  -koh efficient casing	 -handle rotation and locking to move tip	-unknown	 -balloon at tip	 -koh cups -4 sizes	 -occluder balloon on koh-efficient
Laborie ClearView Total	 -graduated shaft -spacer	 - straight rod	 - vertical control handle, twisting	-unknown	-balloon at tip	-colpotomy cups, 3 sizes	-occluder balloon

The functionality identified in **Table 3** was further refined and is presented in **Table 4.**

Table 4: Morphological chart based on **Table 3.**

Sub-function	Uterine Depth/Fit/Adjustability	Main Body	User Interaction	Actuation Method/Mechanism	Anchor	Colpotomy Assistance	Maintain Pneumoperitoneum	Uterus Removal
Description	How can the device serve different uterine and cervix	How is the distance from the cervix to vaginal opening spanned?	How can the user control the device?	What are the inner workings of the actuation?	How does the device stay positioned in the uterus?	How can the device assist in colpotomy?	How can the device maintain pressure in the abdominal cavity during colpotomy?	How can the device assist in physically removing the uterus?
Concepts	Found via brainstorming, compiled in **Appendix A**							

"Uterine Depth/Fit/Adjustability" describes how the device accommodates varying uterine, cervix, and vaginal canal depths. Full team brainstorming was conducted and a total of 23 concepts were generated, some include thermal color indicator, different tip lengths, and a pin slide lock. The "Main Body" describes the geometry of the UM that sits between the cervix and vaginal opening. A total of 24 concepts were developed, including worm gear rod, squishy snake, and ribbed. "User Interaction" describes how the user controls the UM motion. The most obvious being a handle, there were a total of 23 concepts generated e.g. trigger and handle bars. "Actuation Method/Mechanism" describes the inner mechanisms that drive tip to uterus movement. The "Anchor" describes how the tip end of the device stays positioned inside the uterus. "Colpotomy Assistance" describes how the device assists in colpotomy. The "Maintaining Pneumoperitoneum" sub-function is defined as how the UM maintains pressure in the abdominal cavity during colpotomy. The "Uterus Removal" sub-function describes how the UM assists in the direct removal of the uterus. For all concepts, full brainstorming results can be found in **Appendix A**.

Concept Selection Process

After concept generation, the team found it necessary to go through an initial concept down selection process to shrink the potential solution space by removing inauspicious concepts. This process was both convergent and divergent, with some concepts being removed from the solution space entirely and some concepts being iterated on. This process ultimately brought the team from the 211 initial sub function concepts to 4 full device concepts and 60 sub function concepts. The overall flow of the concept selection process is shown in **Figure 14** with the steps detailed below.

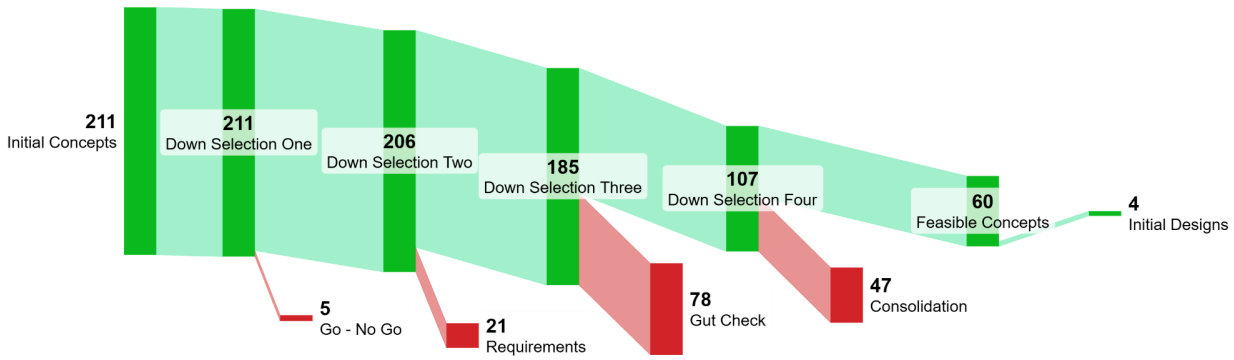


Figure 14: High level overview of the concept selection process. The red bars represent removing concepts from the solution space.

The first down selection method was a 'Go-No Go' screening process. Concepts either passed or failed the question 'Is this concept physically possible?' To answer this question, the team used their best judgement to determine what was and what was not physically possible. If the concept failed this question, it was removed from the potential solution space. This removed five concepts from two of the identified sub functions: 'freezing time' within the maintain pneumoperitoneum subfunction as well as 'nicely asking the uterus to leave', 'teleporting', 'shrinking down tiny people to push', and 'phasing uterus through the body' within the uterus removal subfunction. This brought the total number of subfunction concepts down to 206.

The second method was checking the concepts against some of the project requirements and specifications. For this step, the team identified what they thought were the most restrictive requirements: reusability, sterilizability, and biocompatibility. Reusability is one of the major motivations of the project and greatly determines success in a low-resource environment, and the specifications necessary to meet the sterilizability and biocompatibility are tied to standards set by nationally recognized standard development organizations. Again, the team used their best judgement to determine if a concept could feasibly meet the specifications for the three requirements. If a concept was found to not be able to meet a requirement, it was removed from the potential solution space. This step removed concepts such as tapes, glue, fabrics, and cloths on the basis of not being reusable or sterilizable. Additionally, it removed designs that would cause adverse effects during surgery and thus would not meet the biocompatibility requirement. For example, using needle or fish hook type designs to anchor the uterine manipulator in place, but not in uterus removal. This step is shown in further detail in **Appendix B**. This brought the total number of subfunction concepts down to 185.

After the first two down selection steps, the team decided to take a more aggressive down selection approach. To accomplish this, the team decided to perform a 'Gut Check' for feasibility in low resource settings. The team asked 'given what we know about the barriers in low resource settings, is this concept feasible?' To answer this question, the team considered all of the requirements that were not previously considered as well as the complexity of each concept. If a concept was considerably more complicated than another concept within the same subfunction, or it could not meet the project requirements, it was removed from the potential solution space. For example, active suction cups were removed on the basis

that they are more complicated than passive suction cups and achieve the same outcome within the ‘anchor’ subfunction. Again, all concepts removed during this step are shown in further detail in **Appendix B**. After this step, the total number of subfunction concepts remaining was 107.

Next, the team decided to look at the remaining concepts and consolidate them or iterate on them. Across the different concept generation stages the team had come up with identical or very similar concepts. These concepts were merged into a single concept where appropriate. For iteration, there were some concepts that were too vague or broad to be useful for concept generation, and these concepts were explored further or removed from the potential solution space. Specifics on this process are shown in **Appendix B**. This brought the total number of subfunction concepts to 60.

The team then began to put these concepts together into a cohesive system. This was done with members of the team using their best judgment for what would be the ‘best’ concept for a given subfunction. With this process, the team created four initial device concepts. There were four major semi-developed concepts generated, the ‘Ribbed With Screw Head’, ‘Flex Steel’, ‘One Way Gate’, and ‘S-Curve’.

The first of the initial concepts was titled ‘Ribbed With Screw Head’ and is shown in **Figure 15.** This device features a rigid body with extendable length, an actuation handle, and an expanding end made of metal ribs for anchoring. The pros with this design is that there is a clear anchoring subfunction and adjustable length. The cons are that the depth control of the device is rigid because of the button controls, there are many small parts that may inhibit sterilization, an unclear range of motion, and no pneumoperitoneum, uterus removal, or colpotomy assistance subfunctions.

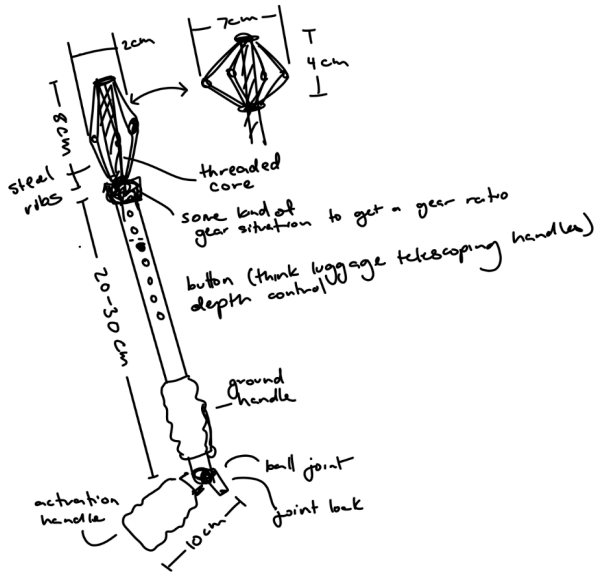


Figure 15: ‘Ribbed with screw head’ design

The second concept created was the ‘Flex Steel’ design, shown in **Figure 16**. This design is similar to the previous design, with a few notable differences. This device has flexible steel ribs at the end, a double walled shaft to control the depth control and the extending end, and a method for maintaining pneumoperitoneum. The pros of this device is that there is an obvious anchor mechanism, and a relatively

simple mechanism for depth control. The cons are that the thin metal sheets at the end of the device could be a high injury risk, small parts make sterilization hard, and there is no colpotomy or uterus removal subfunctionality.

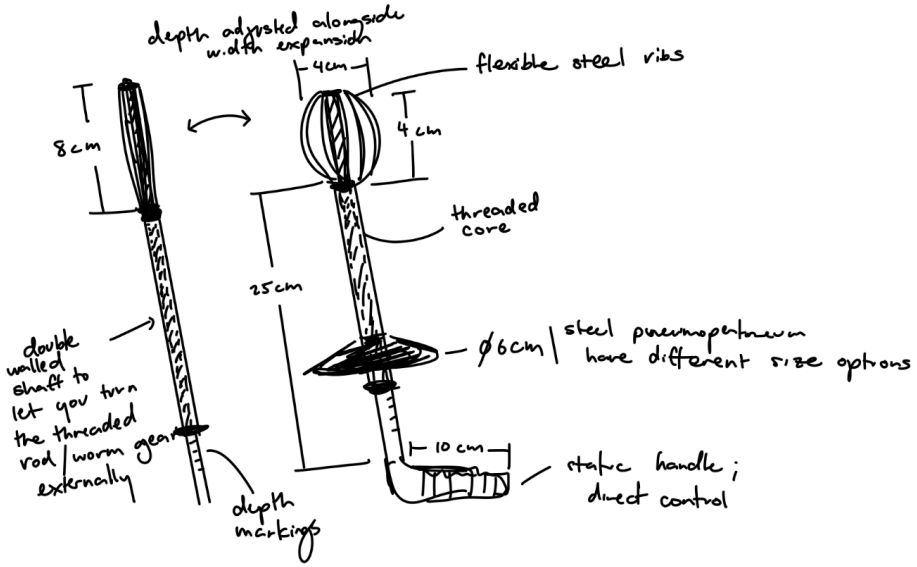


Figure 16: ‘Flex Steel’ design.

The third concept created was the ‘One Way Gate’ concept, shown below in **Figure 17.** This device has a rigid body with an adjustable silicone mesh to meet the pneumoperitoneum subfunction and a flared tip that can manipulate the uterus via a trigger on the handle. The pros of this device is that there is an obvious pneumoperitoneum and anchoring subfunctionality, and there are relatively simple control mechanisms. The cons are that the anchoring mechanism may perforate the uterus and that the pivot point of the device is far from the uterus.

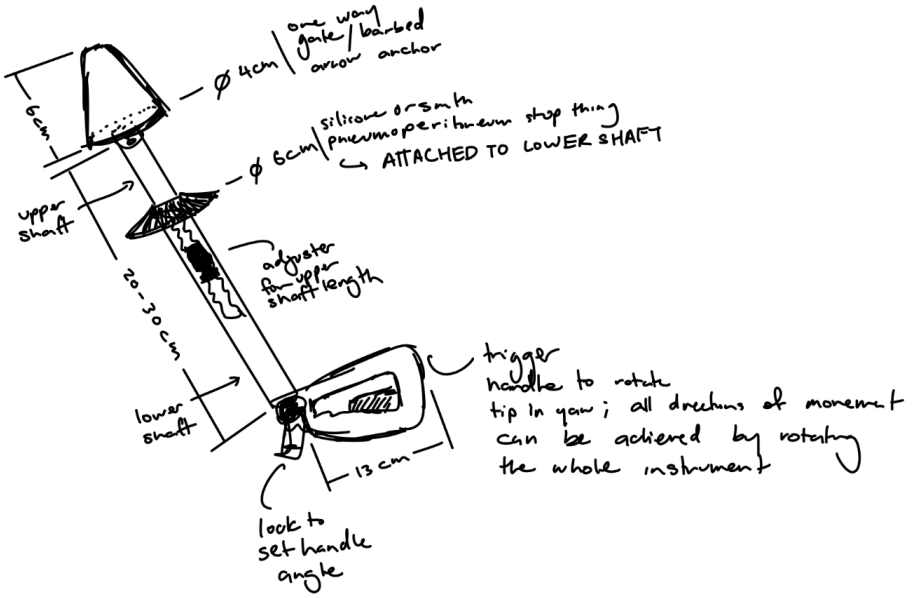


Figure 17: ‘One Way Gate’ design.

The fourth and final initial concept is the 'S-Curve' design, shown in **Figure 18.** This device has a semi-flexible, curved main body that rotates via a ratcheting mechanism. It also features a manual suction system to anchor onto and grab the uterus. The pros with this design is that it has a large range of motion, works well with the natural shape of the body, and has clear anchoring and control mechanisms. The cons are that there is no colpotomy or pneumoperitoneum subfunctionality, there is a manual pump that needs to be used during surgery, and the nested tube design within the main body could lead to sterilization issues.

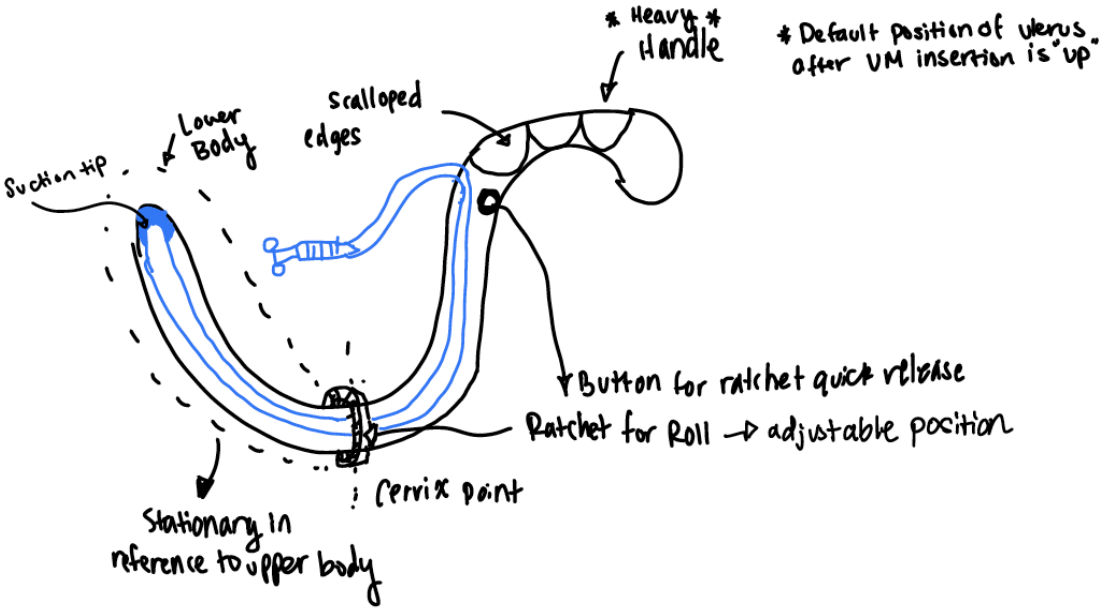


Figure 18: S-Curve design.

To weigh the pros and cons of each device concept, the team created a scoring matrix. This matrix includes the concerns associated with the different concepts and weighs them based on how likely the concern was to hinder device functionality. Device safety, sterilization, and colpotomy and uterus removal assistance all had a weight of three based on the priorities of the sponsor and device users as well as the utmost need for a surgical device to not cause adverse effects on the patients. A high score on this matrix means that the device will perform poorly based on the identified concerns, whereas a low score means that the device is anticipated to perform well. The scoring matrix is shown below in **Figure 19.**

Concerns = Cons

Rank is based on hindrance to device main functionality (uterus manipulation)

1 = No
2 = Maybe
3 = Yes

Concepts & Concerns	Device safety (3)	Maintaining Pneumoperitoneum (2)	Sterilization (3)	Colpotomy/ uterus removal assistance (3)	Maintenance (2)	Range of motion (2)	Depth control (1)	Total
S-Curve								10
Ribbed w/ Screw Head								13
One Way Gate								5
Flex Steel								8

Rank awarded = Bad Rank not awarded = Good

Figure 19. Initial device concept scoring matrix. A low score indicates that the device is anticipated to perform well.

This scoring matrix revealed that the 'One Way Gate' device, which can be seen previously in **Figure 17**, was the best design. The team performed some iteration on the design to arrive at the 'Alpha Design' illustrated in **Figure 20**. The tip of UM consists of a 6 cm tall cone with a 4 cm base diameter. The cone features a flat top. The main purpose of this tip design is to ensure the UM does not leave the uterus, essentially an anchor. The tip and the connecting joint would be controlled (actuated) by a button on the handle that would be able to lock. The shaft of the UM is a telescoping arm, the motion is controlled by a serrated sliding mechanism. It is important to note that key details for important components including chromopertubation are missing and not all aspects were fully defined, such as the actuation joint in green.

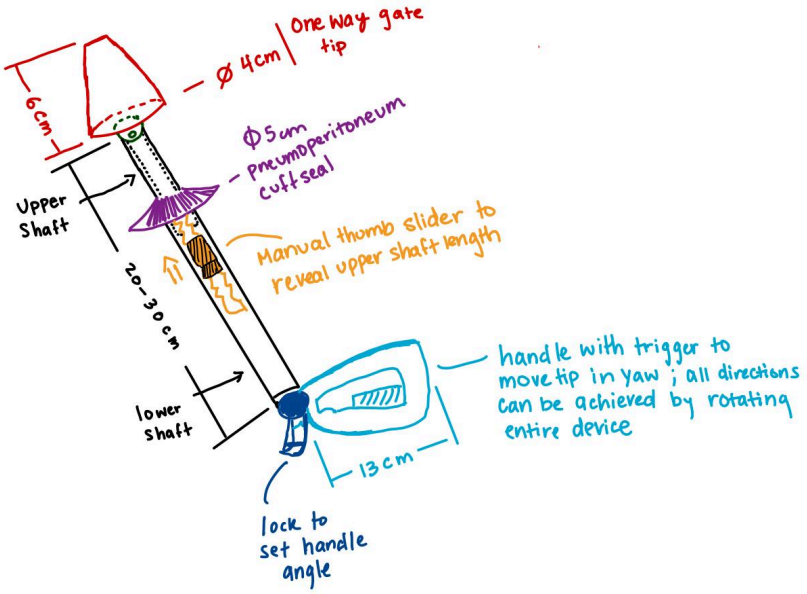
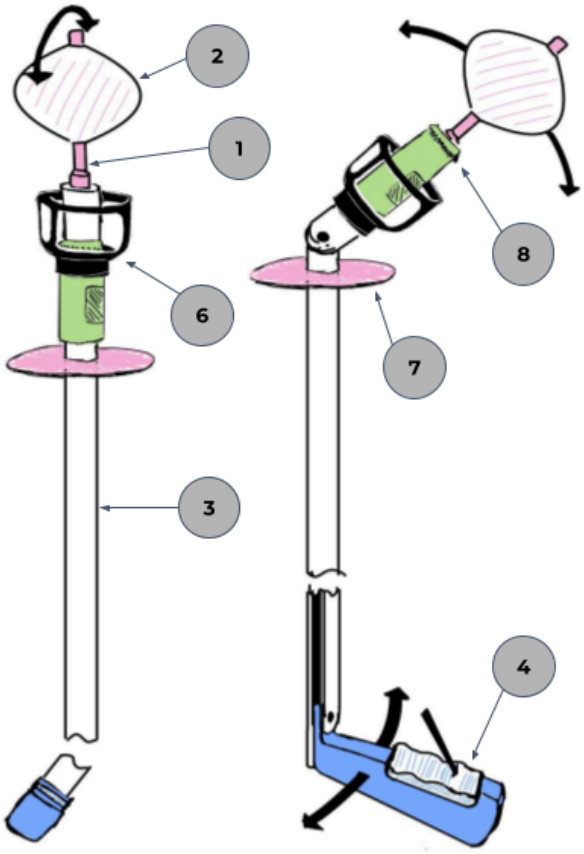


Figure 20. One Way Gate, "Alpha Design" with color coded function breakdown.

Final Concept

The final concept is shown in **Figure 21**. The design features a tip that transfers rotational motion from the device joint into movement of the uterus. It also attaches to tubing in order to inflate the balloon or conduct chromopertubation interchangeably (**Figure 22**). The balloon inflates inside the uterus once the device is positioned to anchor the device internally. The colpotomy cup (callout 6) ensures the device remains inserted into the uterus at an appropriate depth by fitting snugly around the vaginal fornices (see **Figure 23**). Both the tip and colpotomy cup are offered in several different sizes, allowing for adaptability for patients' varying anatomical proportions.



Function	Design
1) Uterine depth control/fit/adjustability	Several length options (5 - 6.5 - 8 - 9.5 - 11cm)
2) Anchor/tip style	Balloon
3) Main Body	Straight (~20cm)
4) User Control (controls in the brainstorming)	Handle + trigger for locking
5) Actuation mechanism	Rotation-linkage
6) Colpotomy assistance (GUIDING INCISION)	Several cup diameters (2.5 - 3.25 - 5cm)
7) Maintain pneumoperitoneum	Rigid silicone disk (need dimensions)
8) Uterus removal	Ring of "teeth" (inside cervix)
9) Chromopertubation	Silicone tube feeding to tip

Figure 21. Final concept sketch and subsystem overview.

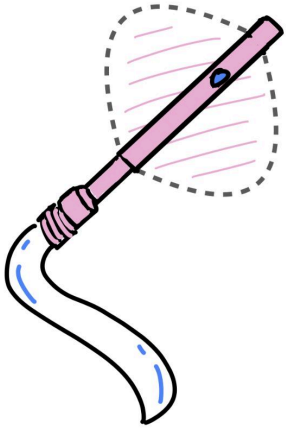


Figure 22. Manipulator tip subsystem with balloon inflation/chromopertubation dye port (blue), balloon placement, and silicone tubing.

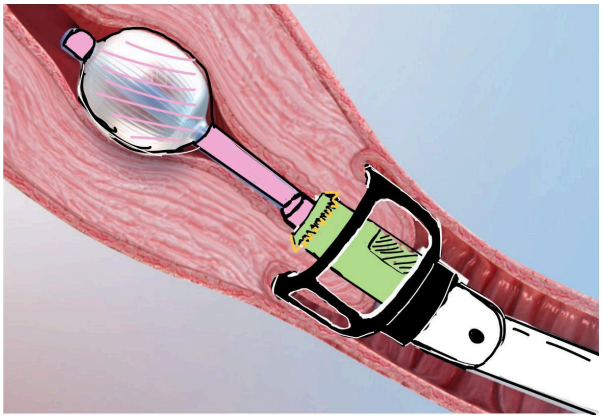


Figure 23. Placement of the tip, balloon, and colpotomy cup relative to the vaginal fornices and uterus.

The main shaft of the device running through the vaginal canal is a straight rectangular shell, which houses the internal mechanism and is largely held still during operation. On this main shaft about 2cm from the tip-end joint is the flexible occluder disk to maintain pneumoperitoneum. The disk wraps around the shaft and holds itself closed using dovetail joints, as seen in **Figure 24**.

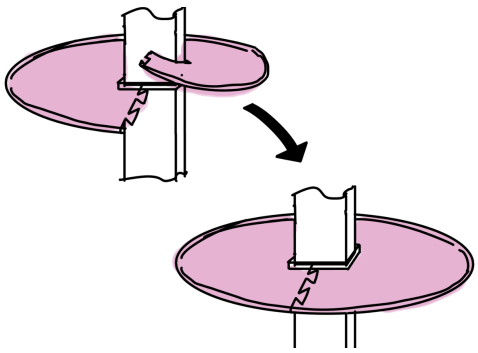


Figure 24. Attachment of occluder disk to the main body shaft.

The user moves the handle left and right which translate to an upwards and downwards motion on the tip end, respectively. The handle itself features a trigger that can be squeezed to unlock the device and enable actuation, preventing unintentional movement of the uterus during operation.

Finally, the uterus removal mechanism shown in green grabs onto uterine tissue and "sandwiches" it between the teeth and the colpotomy cup in order to facilitate removal of the uterus. A low-fidelity prototype of the concept was developed, shown below in **Figure 25**.



Figure 25. Prototype of the uterus removal mechanism concept open (left) and deployed (right).

Engineering Analysis & Iteration.

During the design process, the team had many questions relating to how specific parts of the concept should be designed. To find answers to some of these questions, the team found it necessary to formulate and perform various engineering analyses. These engineering analyses drew on the knowledge from previous courses such as solid mechanics, dynamics, and fluid dynamics to answer the proposed questions. The findings from these analyses could then be used to inform design decisions and iterate on the overall design.

The design questions and analysis descriptions can be found in **Table 5** for all sub-functions including: Main body, Uterine depth control and adjustability, Uterus removal, Maintaining pneumoperitoneum, Chromopertubation, Tip actuation, User interaction, Tip anchor, Colpotomy Assistance and General/Subsystem Interfaces. The team recognizes the range of necessary engineering analysis, however, due to time constraints and number of sub-functions not all could be completed. The different status of the analyses in the table are "Future Work", "Completed & Implemented", or "Out of Scope". "Future Work" are the analyses the team would have wanted to complete if time permitted to increase the reliability of design decisions. "Completed & Implemented" analyses directly correlate to final design decisions. "Out of Scope" is in reference to the uterus removal sub-function that was developed and abandoned, more discussion can be found in later sections of the report including the Verification Plans and Discussion sections.

The analyses selected and performed include a thread engagement calculation for all threaded parts, minimum occluder disk diameter, geometric CAD analysis to assist in linkage selection, required forces to actuate the selected linkage and end effector, FMEA for handle development, minimum balloon volume for anchor size selection, a general safety inspection and a full audit of material selection for sterilization requirements in the post prototype device. The discussion of each analysis can be found below in **Table 5**.

Table 5. Overview of design questions for the final design.

Subsystem	Question	Analysis Method	Status
Main Body	What shaft wall thickness is needed for a 1kg load without bending or experiencing fatigue over repeated actuation?	FEA Stress and fatigue analysis	Future Work
Uterine depth/ control/adjustability	What length of thread engagement is needed to ensure the tip components stay securely attached to the main shaft?	Thread engagement calculation evaluation	Completed
	What tip diameter is required to withstand repeated actuation loads for uteri weights ≤ 1 kg?	Stress and fatigue analysis	Future Work
Uterus removal	How can the removal apparatus stow away when removal of the uterus is not required?	CAD Assembly	Out of Scope
	How can nested mechanisms slide w/o interference?	CAD Assembly	Out of Scope
	How will the 'uterus removal' sleeve be controlled and manipulated from outside the body?	CAD Assembly	Out of Scope
Maintaining Pneumoperitoneum	What is the necessary occluder disk diameter in order to maintain pneumoperitoneum?	Minimum occluder disk diameter	Completed & Implemented
Chromopertubation	How can tubing for dye delivery be routed without interfering with internal mechanisms?	CAD Assembly	Future Work
Tip Actuation	How does the mechanism achieve the required range of motion?	Geometric CAD modeling	Completed & Implemented
	What is the required user input force to actuate the tip with maximum loading of 1 kg?	Manual force analysis	Completed & Implemented
User Interaction - Handle	How can we ensure reliability of the handle and locking mechanisms?	FMEA	Completed & Implemented

	How to ensure the trigger for tip actuation does not interfere with user input?	CAD Assembly	Completed & Implemented
	What is the input force required to use the locking mechanism?	Manual force analysis	Future Work
Tip Anchor	How can tubing for balloon inflation be routed without interfering with internal mechanisms?	CAD Assembly	Future Work
	What syringe volume is needed to sufficiently fill the balloon?	Empirical test with silicone balloons	Completed & Future Work
Colpotomy Assistance	What cup design and wall thickness is required to minimize weight and maximize life expectancy?	FEA stress and fatigue analysis	Future Work
General/Subsystem Interfaces	Is the device safe for the users?	Safety inspection	Completed & Implemented
	What are appropriate materials for sterilization requirements?	Audit of sterilization methods. Reference verification.	Completed

Main Body - The rectangular design of the shaft stemmed from the need to house the linkage system used to actuate the tip, compatibility with handle design, and being able to hold the occluder disk. Since the main body is a housing case and there were no requirements relating to shape, no analysis was completed for general design. A circular shape was considered but maximizing space for the internal components was ultimately deemed more important. However, the wall thickness and material needed to withstand cyclical loading of a 1 kg uterus in addition to the weight of the rest of the device is a valid design question. By initially overestimating the necessary thickness for the prototype, issues with shaft failure were avoided. Manual calculations for stress and fatigue could be done but this process is tedious. Instead, a finite element analysis (FEA) for stress and fatigue evaluation is recommended for further development of the main body design. The analysis would aid in identifying points of stress throughout the shaft specifically at connection or high load bearing points. By identifying these points, material and thus weight could be redistributed or reduced for optimal user experience and manufacturing. Additionally, it could prove helpful in determining if the rectangular design is best for withstanding cyclical loading.

Uterine depth control + adjustability - Thread engagement calculation. This question relates to the thread engagement necessary for the threaded components to have a secure connection to the main body shaft. These components include the colpotomy cup and tip shaft. The main shaft has a diameter of 2.5 cm and is externally threaded, for a steel to steel connection the required thread engagement should be 1.5x the nominal diameter of the female connector. During design evaluation, it was found the thread engagement for the colpotomy cup to the external main body shaft was insufficient with a thread engagement of 1.5 cm. While rudimentary, this analysis was essential to determine if failure would occur and if the tip would break rather than the threads stripping. The tip could be replaced but thread

destruction could render the shaft useless and directly fail the reusability requirement. This application of analysis is widely used for bolts and studs so its usefulness in this sense should be further researched.

The tip diameter necessary to withstand cyclical loading of uteri ≤ 1 kg is a valid design question the team would have explored if time permitted. The current tip diameter was chosen based on the RUMI II benchmark and based on discussion with both Dr. Thiyag and Dr. Ababio, tip failure has not occurred. While sufficient for the time constraint, a manual stress and fatigue analysis would enhance the reliability of chosen tip diameter. A manual analysis is acceptable due to the simple geometry and non-complex nature of loading. The tip could be modeled as a cantilever beam with a circular cross-section and distributed load to represent the attachment to the main body shaft and uterus weight.

Uterus removal - Since this sub-function was removed from the scope of the project, it is not possible to perform an analysis. However, if it were in scope, initial analyses would consist of clearance checks performed with CAD creation followed by various force analyses. This approach is superior to creating the mechanism physically as it would reduce time spent on iteration.

While this sub-function was ultimately removed, understanding the reasoning behind this decision provides valuable insight for future work aimed at improving user experience during TLHs. The primary reason for its removal stemmed from a gap in the team's understanding of the underlying problem associated with uterus removal.

Initially, the team believed the issue was the lack of UMs designed to assist directly with the removal of the uterus during a TLH. Based on this assumption, research focused on current removal methods, including the use of forceps, manual extraction, and morcellation, which involves cutting the uterus into smaller pieces. Concept development was centered on integrating these existing techniques into a new UM design.

However, after presenting a proposed design to Dr. Thiyag, the team learned that the problem was more complex. The core issue is not only the absence of a tool to assist with removal, but also the lack of solutions for managing enlarged uteri. Specific challenges include difficulty grasping the uterus with fingers or forceps and safely extracting it through the vaginal canal. These difficulties can prolong surgery time and increase associated risks [23]. Although morcellation can help address these challenges, it introduces additional risks, such as the potential spread of undetected cancerous tissue within the abdomen. For this reason, its use is often limited [61].

With this new understanding, the team revisited concept generation. However, due to time constraints late in the design process, incorporating a revised sub-function was not feasible. As a result, the decision was made to discontinue further development in this area.

Maintaining pneumoperitoneum - Determine minimum occluder disk diameter to maintain the required pressure in the abdomen. A simple back of the envelope calculation was performed to determine minimum diameter as seen below in **Equation (1).** Where D_{disk} is the chosen disk diameter in the final design, $D_{opening,max}$ is the largest expected vaginal fornix diameter, and SM is the seal margin used for

any extra overlap needed for positioning error. The initial chosen disk diameter was 2.5 cm, max found diameter was 5 cm, and seal margin is 2 cm [11], [47], [48]. Based on this analysis, the initial design failed and the occluder disk diameter was changed to an acceptable 6.5 cm for the final design. The method was chosen based on its simplicity and robustness. By considering the max vaginal fornix diameter and including a seal margin, the disk would be appropriate for essentially all patients. The main limitation for this analysis is the case of an extremely small vaginal fornix diameter. The success of the occluder disk is then based on material flexibility, thus material selection.

$$D_{disk} \geq D_{opening,max} + SM \quad \textbf{(1)}$$

Chromopertubation - How the tubing for chromopertubation is integrated into the main shaft is a reasonable design question but not a vital aspect of the device. Its lack of criticality resulted in the categorization of "Future Work". Currently, the tubing sits outside of the main shaft up until the main shaft on the tip end, meaning it has no support and is dangling. This is an issue because it could interfere with device insertion by creating resistance between the tube and vaginal walls. The future analysis will utilize CAD and consist of clearance and tolerance checks to ensure the tubing remains out of the way of the linkage movement, while still accessible for intended use and cleaning. The infancy of this design requirement justifies the reliance on the chosen analysis method.

Tip Actuation - The design question posed to complete the range of motion requirement has proven to be a difficult and trying process. The best approach was determined to be the creation of a CAD model that would be able to translate a rotating motion (in one plane) to a pitching (up and down) motion in the plane perpendicular. The chosen method proved best to sufficiently model this motion and convey its effectiveness to complete the requirement with ease. The selected motion was based on feedback from Dr. Ababio who appreciated the similar motion seen in the RUMI II. There were two distinct versions of the actuation mechanism, with several iterations of the second design. Design (1) was a linkage with pins directly connected to each other in the handle disk and the end effector disk. Design (2) is a scotch yoke mechanism that had gone through three iterations to combat issues with a weak end slot which would eventually lead to a fourth and final design.

Design (1) consisted of a linkage with pins directly connected to each other in the handle disk and the end effector disk. An initial proof of concept was developed using cardboard and dowels to show how the rotational to vertical motion would work seen in **Figure 26**; the mechanism was then modeled in CAD seen in **Figure 27**.

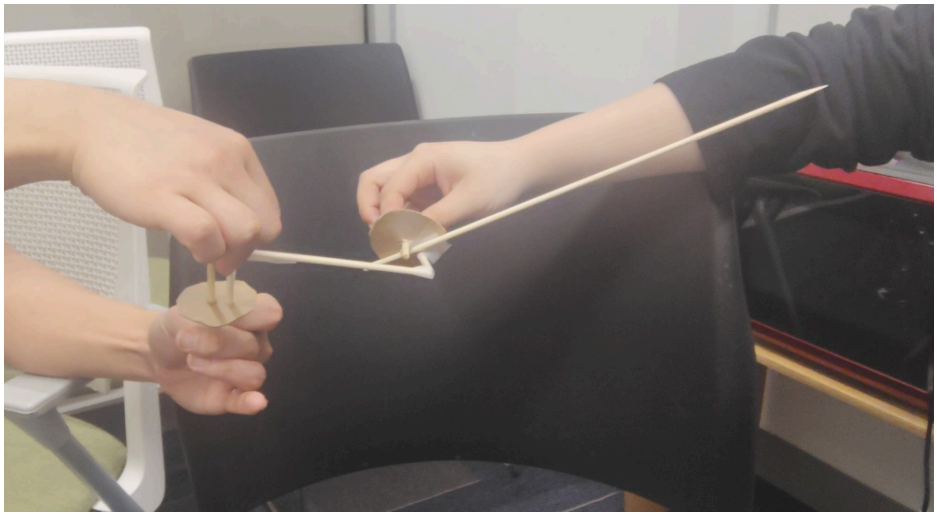


Figure 26. Proof of concept model of Design (1), demonstrating required motion using cardboard and dowels.

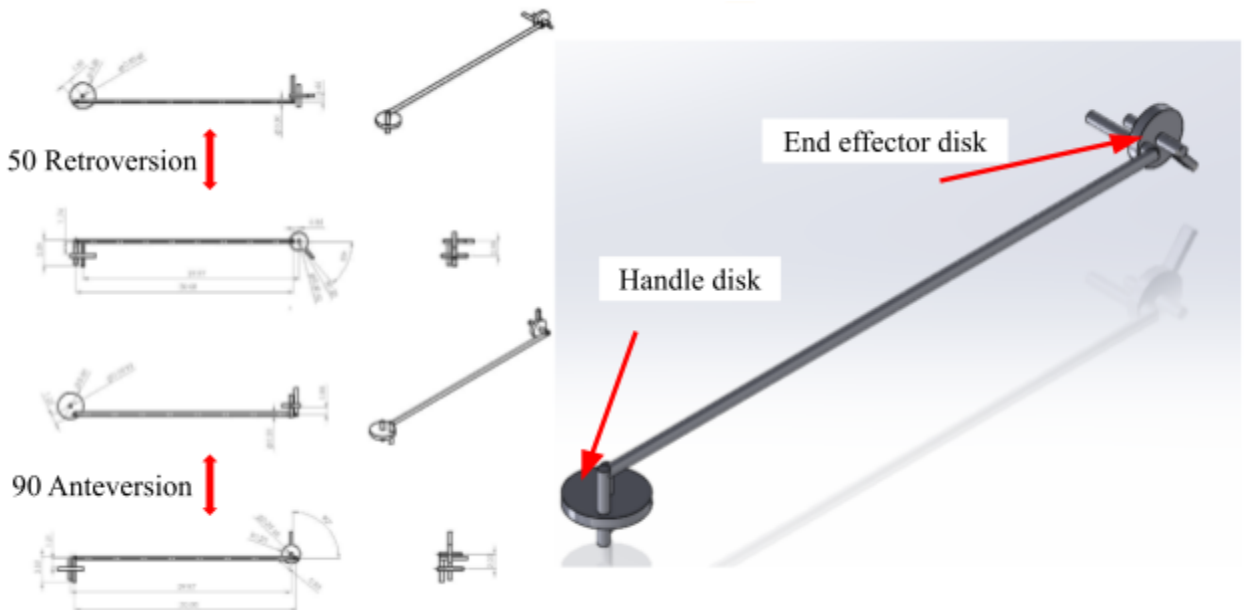


Figure 27. CAD of Design (1) actuation mechanism. The drawings on the left show the mechanism in full retroversion (top left) and full anteversion (bottom left). The image on the right is the CAD model of the mechanism. The bottom left disk is the handle disk and the top right is the end effector disk. All dimensions are in centimeters or degrees.

The actuation mechanism utilized a linkage with pin slots in the handle disk and the end effector disk to translate horizontal rotational movement to vertical rotational movement. The design reached the required 140° of rotation, 90° anteversion (pitch up) and 50° retroversion (pitch down). The main concern with this version of the mechanism was the motion sensitivity when the handle disk was rotated. The translation was not one-to-one and a little movement from the handle disk would cause the end effector disk to

quickly pitch up or down. Rotating the disk a quarter of its diameter would complete the entire 140° of motion. This would likely cause issues when it came to the need for performing precise movements. The minimal amount of movement available with the handle disk also posed concerns about the forces that would be required to operate the device. Additionally, the anteversion and retroversion translations were not equal, meaning the translation rate for retroversion was higher than for anteversion. With all of these concerns, the team decided to focus on improving the actuation mechanism design and continuing to analyze its ease of use.

Design (2) was based on a scotch yoke mechanism. This mechanism translates rotation to linear movement by using pins and slots. An in depth discussion on the mechanics of this design can be seen under Final Design Description. There were multiple iterations on this mechanism to produce the intended actuation performance, and images of these iterations are shown in **Figure 28**.

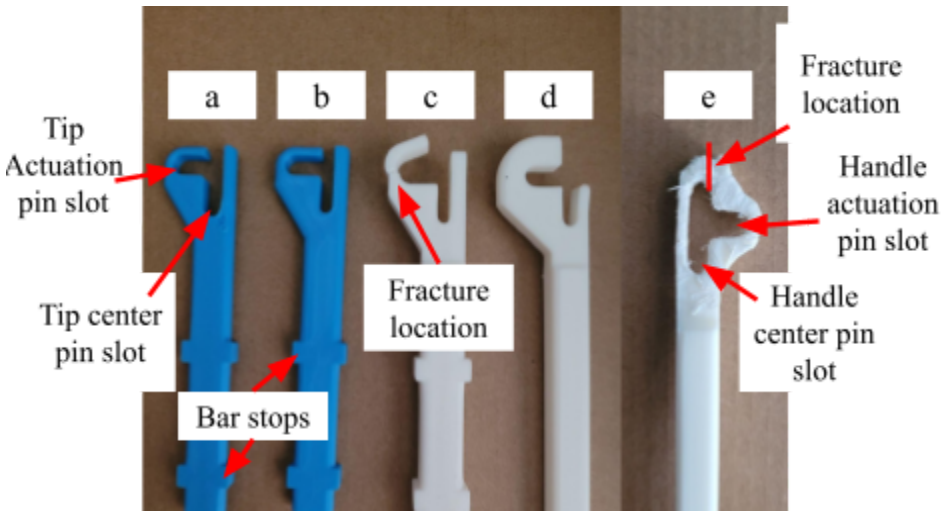


Figure 28. The various iterations of the scotch yoke bar. (a)(b)(c)(d) are the variations of the tip end of the bar, (e) is the first failure location of the handle end.

The first version of the tip half of the design, shown in **Figure 28(a)**, was composed of two slots with pins of the same size. However, when the two pins were the same size it caused the mechanism to lock when it reached ~120° of input rotation. This was because the actuation pin partially entered the center pin slot and did not have enough contact area in the actuation pin slot to produce rotation, as shown in **Figure 29**.

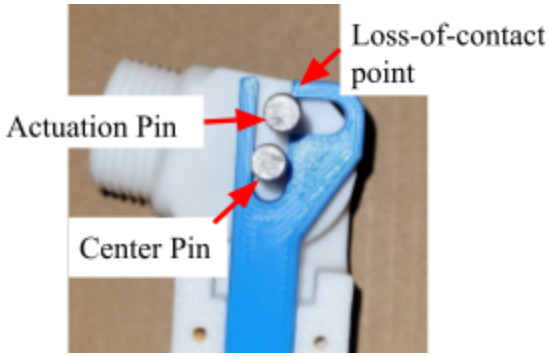


Figure 29. Demonstration of loss-of-contact failure with first scotch yoke mechanism.

This was remedied by the design shown in **Figure 28(b)**, which had a smaller center pin. A smaller center pin was chosen for three reasons: CAD revealed that a small actuation pin would likely not have enough contact area to reach 140° of rotation, and there were concerns with device alignment and forces. If a small pin was located at the edge of the actuation and center slot and the tip was pushed or pulled in the axis of the mainbody shaft, there was a chance that the small pin would enter the center pin slot and cause the device to lock up. It was also discovered that this phenomenon could occur if the two pins were the same size as well due to deflections in the material, and is demonstrated in **Figure 30**.

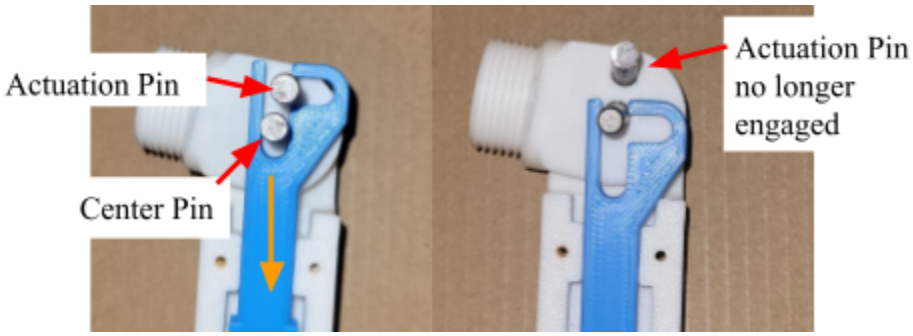


Figure 30. Demonstration of misalignment failure.

When a smaller pin was located in the center slot it would be constrained and had no chance of causing the device to become misaligned. Furthermore, force analysis revealed that the majority of the forces associated with actuation would be acting on the actuation pin. Choosing a smaller sized actuation pin would increase the likelihood of this being a failure point. Because of these factors, it was determined that the center pin size would be reduced. The size of the center pin was chosen by using CAD to approximate what size pin would allow for the appropriate contact area of the actuation pin to produce rotation.

While the iteration shown in **Figure 28(b)** fixed the alignment issue, it also brought to light a failure point in the design. After ~200 actuation cycles under low load, the design experienced fracture at the location shown in **Figure 28(c)**. This failure occurred perpendicular to the part's layer lines, which signaled to the team that this was not just shear failure due to printing orientation and was likely a real failure point for the final design. To remedy this, this point was reinforced as shown in **Figure 28(d)**. Additionally, the non-actuation half of the center pin slot was shortened due to the mechanism colliding with other components and the bar stops were removed. The stops were removed because it was discovered that it was more reliable to constrain the actuation pin through slots in the main body shaft instead of relying on the scotch yoke bar.

Iteration on the handle end was due to fracture failure in the center slot after ~200 cycles, as shown in **Figure 28(e)**. This failure occurred parallel to the layer lines of the print, which signaled that this failure may be due to the orientation of the part while printing. This location was slightly reinforced and the print orientation was changed. Consequently, this part did not experience failure for the remainder of the project.

Another essential tip actuation design question is correlated to the ease of use requirement for device operation force $\leq 37 \pm 12$N. This analysis is meant to assist in evaluating the off axis pin placement for the

Scotch Yoke Linkage. The FBD for the end effector is seen in **Figure 31** and found the required yoke input force was found to be 22N. Based on this result, the current off-axis pin placement meets the required operation force, if user input force is considered equal to the yoke force.

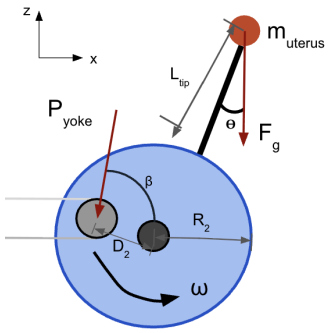


Figure 31. End effector FBD.

User Interaction - Assess threats to the reliability of the handle and locking mechanism. The initial steps to failure mode and effects analysis (FMEA) were selected to ensure a thorough understanding of potential risks and failure modes at the main point of user interaction. **Table 6** below summarizes the considerations made.

Table 6. Initial FMEA matrix for main user interaction points (handle and trigger subsystem)

Process Function	Potential Failure Mode	Potential Effect(s) of Failure	S	Potential Cause(s)/ Mechanism(s) of Failure
Handle actuation	Handle does not move	Unable to move tip OR tip is uncontrollable	7	Jammed linkage, excessively dense packaging inside the shaft
	Handle moves, but manipulator tip does not	Unable to move tip	9	Broken linkage (cam-link joints, any joints, the parts themselves)
Pressing lock button/ trigger	Trigger is pressed but linkage does not unlock	Manipulator is stuck in one position	9	Lock spring failure, lock pin disconnected from spring
	Trigger is not activated but linkage is unlocked	Unable to move tip	9	Lock spring failure, disconnected lock pin, material failure at locking grooves

Only the first few steps in the typical FMEA process were considered, as the later analyses (current process controls, likelihood of detection before the end user, actions taken, etc.) are best applied later in the development process. Overall, this process provided several key points of failure to consider, especially as the locking mechanism is further developed. This analysis method was chosen due to the novelty of the design and the need to identify a range of failure points, the effects, and the severity of each. It adequately provided guidance for the design, more specifically mitigating the potential failure modes. Based on this analysis a precaution taken to ensure the locking mechanism does not fail was simplifying the design as much as possible. This can be seen in the effort to avoid mouldarity within the handle design. Slots, pins, and spring stops were designed to be extruded from the handle base. Also, by

implementing pins in the design to stabilize springs there would be reduction in the spring locking failure. There are a few limitations to the FMEA approach because it is a preliminary design analysis. Another FMEA analysis should be conducted to evaluate the handle design to increase reliability.

Another design question that deserved analysis was to ensure the trigger did not interfere with user interaction. This was a problem brought up by Dr. Thiyag that she had experienced when using the RUMI II manipulator. Since that design features a trigger on the back end of the handle, there was consistent accidental depression of the trigger. To design around this the team would perform a CAD assembly analysis to optimize the ease and space for trigger depression. This was sufficiently implemented, however this design would limit the general usability of the handle. The handle size was increased and was ultimately bulky beyond comfort. The time constraints did not allow for proper redesign of the handle, however, the initial analysis did prove helpful in designing against accidental depression of the trigger.

A future recommended analysis would be to determine the input force required to depress the trigger and use the locking feature. A basic manual force analysis would be sufficient due to the basic geometry of the mechanism. It would provide insight to the ease of depression and ultimately help optimize user experience.

Tip Anchor - Since the selected method for anchoring the device in the body was an inflatable balloon, it is an obvious next step to include an analysis that could determine how much liquid is necessary. The most sufficient way was determined to be a back of the envelope equation that would account for all parts of the device that would need to be filled with liquid. This equation can be seen in **Equation (2)**. V_{Fluid} represents the volume of the syringe, V_{Tubing} is the volume of the tubing used for Chromopertubation and balloon inflation (not simultaneously), $V_{Uterus\ Cavity}$ is the approximate volume of the balloon. The final volume was estimated to be 300 mL. However, this value is larger than expected, most likely due to the assumption that the volume of the uterus cavity itself is the balloon volume. Further evaluation revealed a wrong value was most likely used for the volume of a uterine cavity. The correct total V_{Fluid} value should be in the range of 40-60 ml. Based on this analysis, a 50 ml syringe was implemented.

$$V_{Fluid} = V_{Tubing} + V_{Device} + V_{Uterus\ Cavity} \quad \textbf{(2)}$$

Colpotomy Assistance - The colpotomy cup design was based on the RUMI II benchmark, including the range of sizes for different cervixes. While the general design is suitable, an analysis on cup wall thickness would be a valid and important next step in increasing the practicality of the design. Specifically, optimizing wall thickness, to reduce weight and material usage could enhance user comfort and lower production costs. The team recommends an FEA stress and fatigue analysis to observe sub-function performance over approximately 300 use cycles. This method is an effective approach because it enables dynamic evaluation of structural performance under realistic loading conditions without the need of extensive prototyping. This would provide insight to stress concentrations and fatigue life at varying wall thicknesses. Overall, it would inform how to balance structural integrity with design and manufacturability.

Although this is the best approach, it still contains limitations. The accuracy of the results are based on model assumptions such as boundary conditions and loading setup. If the model is oversimplified, like

assuming idealized contact conditions, it may not be able to capture the complexities experienced in an actual TLH. As a result, FEA is suitable for providing an analytically backed range of wall thicknesses but experimental validation should always be done to ensure reliability and safety.

General/Subsystem Interfaces - An analysis was completed to respond to the concern with sterilization requirements of the device. While implementation of this analysis is notably out of scope for this project, as a medical device, the team felt it was pertinent to complete. The following discussion is standard practice for material selection in FDA Class II medical devices. Initial downselection of materials was conducted based on the materials listed in material compatibility tables for various sterilization techniques in AAMI TIR17:2024 Annexes. Compatibility with autoclave and dry heat sterilization methods were initially prioritized from this list to narrow down the options—materials that scored 2 or higher based on support for the material through a combination of history, literature, and empirical evidence/reasoning moved onto the next round of selection. Then, resistance to corrosion in sodium hypochlorite solution was taken into account, receiving passing "R" for nonmetals, "G" for metals that enabled ≤ 20 mils of bleach penetration/year, or an unsatisfactory "U" for > 50 mils of chemical penetration/year of immersion [57]. The tables consider constant immersion in a 20% sodium hypochlorite solution, whereas bleach "sterilization" is typically completed in minutes, using a 5% solution, increasing confidence in this analysis.

Table 7. Materials in consideration for use in the device

Family	Material	AUTO [20]	DRY HEAT [20]	BLEACH [20]	Notes
Elastomers	Silicone	2	2-3	R	
	Pebax MED (TPE)	A [62]	-	-	Unable to find evidence for resistance against several chemicals sterilization methods and bleach
Stainless Steels	304	3	3	U	Less corrosion resistant than 316L
	316	3	3	U	Less corrosion resistant than low-carbon variety
	316L	3	3	U	Better welding performance than 316, more corrosion resistant
	440B	3	3	U	Martensitic; holds an edge — not necessary
	440C	3	3	U	
	630 (17-4)	3	3	U	Good for mirror finishing — not necessary
Aluminum	6061-T6	3	2	G	Lightweight

Despite its weakness to bleach, it became immediately evident that stainless steel was the leading choice for metals, as supported by the material's dominance in surgical tooling. Silicone as a broad category was deemed appropriate for use, with different shore hardnesses selected for different parts of the device. Aluminum was added as an option to help lightweight the device.

Design Descriptions

Final Design Description

The final design performs many of the critical functions of existing uterine manipulators while also being appropriate for low resource settings. The design meets sterilization and biocompatibility standards by being made of stainless steel and medical grade silicone, and careful considerations regarding patient safety were taken during the design process. It has a wide range of motion for manipulation, and interchangeable components make the device to be suitable for a wide range of patient anatomies. The CAD of the final design can be seen in **Figure 32** and the detailed layout of the overall design can be seen in **Figure 33**. This design consists of three main subsections: the handle, the mainbody, and the tip.

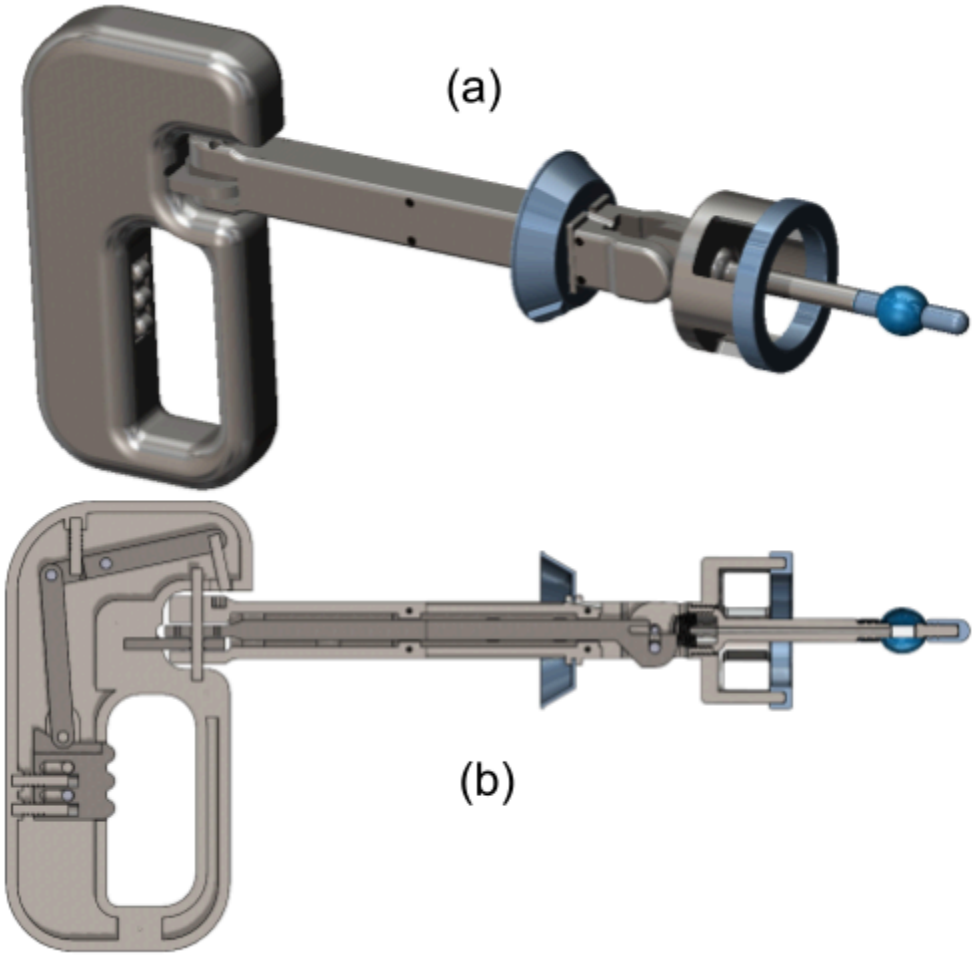


Figure 32. Isometric CAD of the final design (a) and cut away (b).

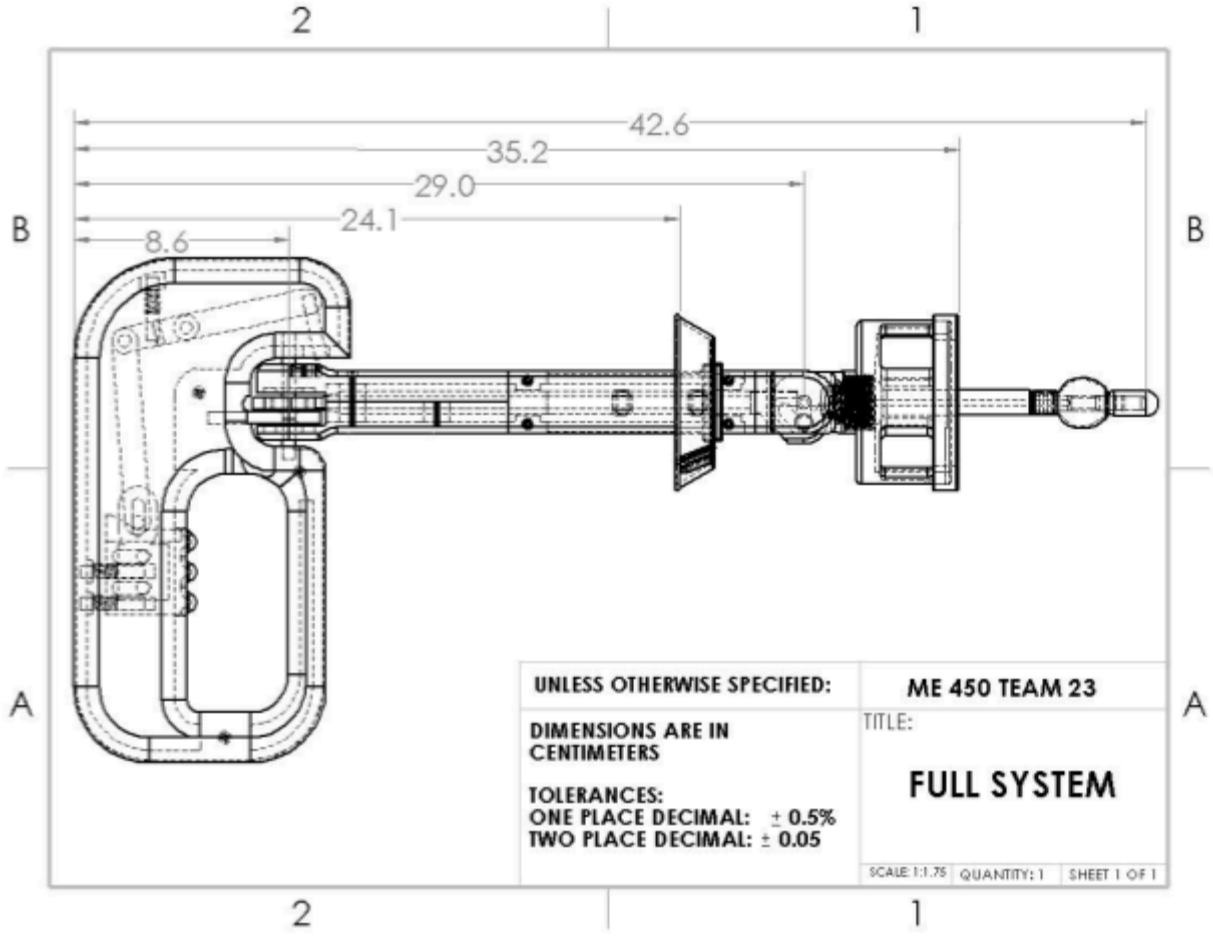


Figure 33. Full final design drawing (b).

The handle is the subsystem that users interact with to create movement of the patient's uterus. Lateral movement of the handle creates vertical movement of the tip of the device. The device has a range of 70° anterior and 70° posterior movement, for a total of 140°. Inside the handle are the positional locking mechanism components. The locking mechanism is intended to reduce fatigue during use by holding the uterus at discrete positions without needing to hold the handle. The current design locks the tip at 0°, 35°, and 70° in both anterior and posterior movement. The CAD and layout drawing can be seen in **Figure 34** and **Figure 35**. All components of this sub system are made of 316 or 316L stainless steel.



Figure 34. CAD of handle subsystem.

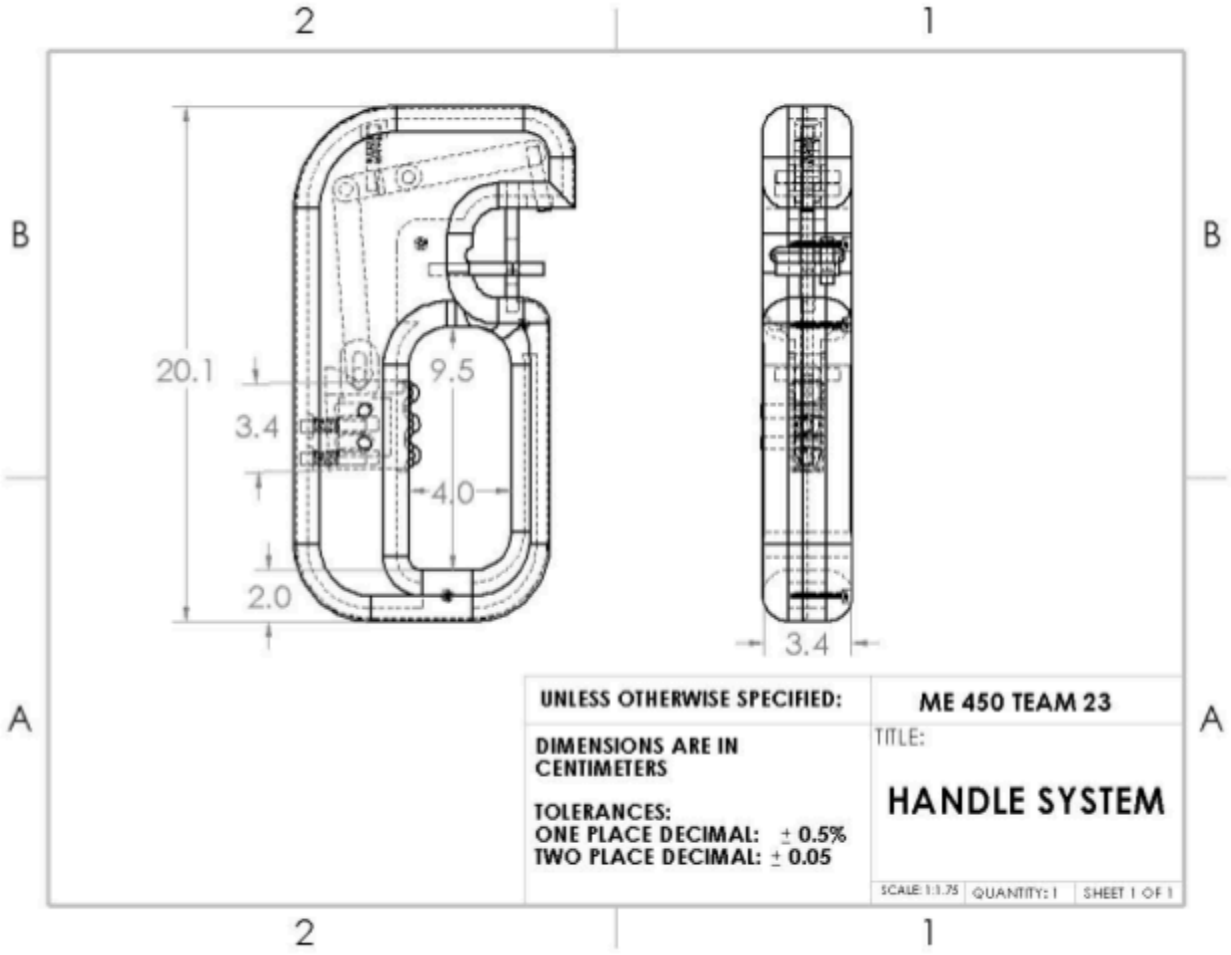


Figure 35. Engineering drawing of the handle subsystem.

The main body subsection consists of the main body shaft, pneumoperitoneum occluder disk, and actuation bar that translates user input into tip movement. The main body shaft is composed of four individual sections that connect via screws. All of the components can be disassembled with a screwdriver for easy cleaning and sterilization. All components except for the occluder disk are made of 316 or 316L stainless steel, while the occluder disk is made of silicone. More details of this subsection can be seen in **Figure 36** and **Figure 37.**

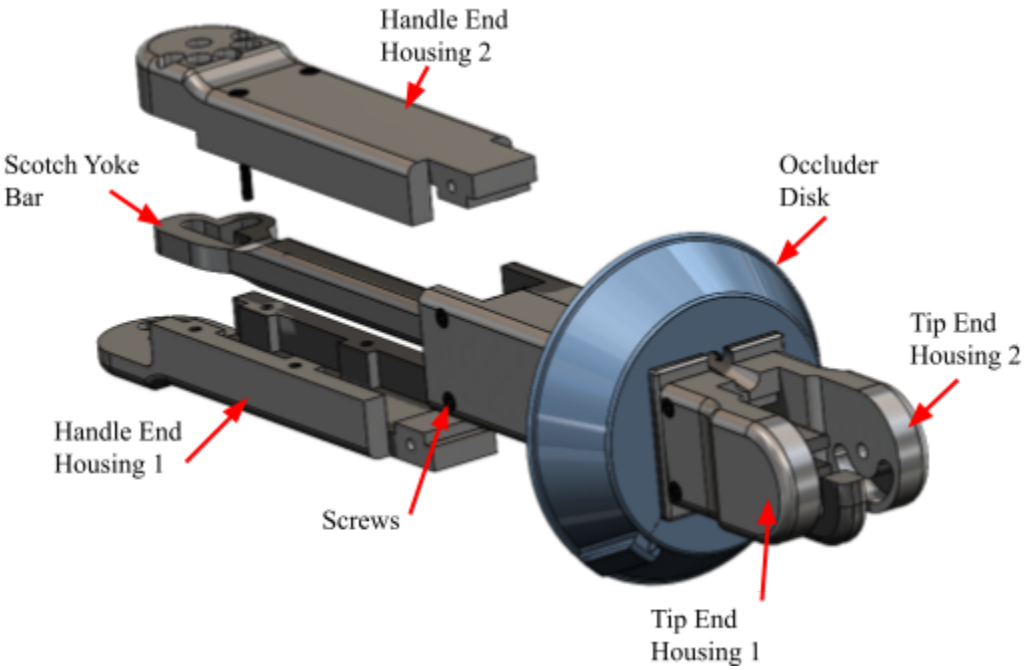


Figure 36. CAD of the main body subsystem.

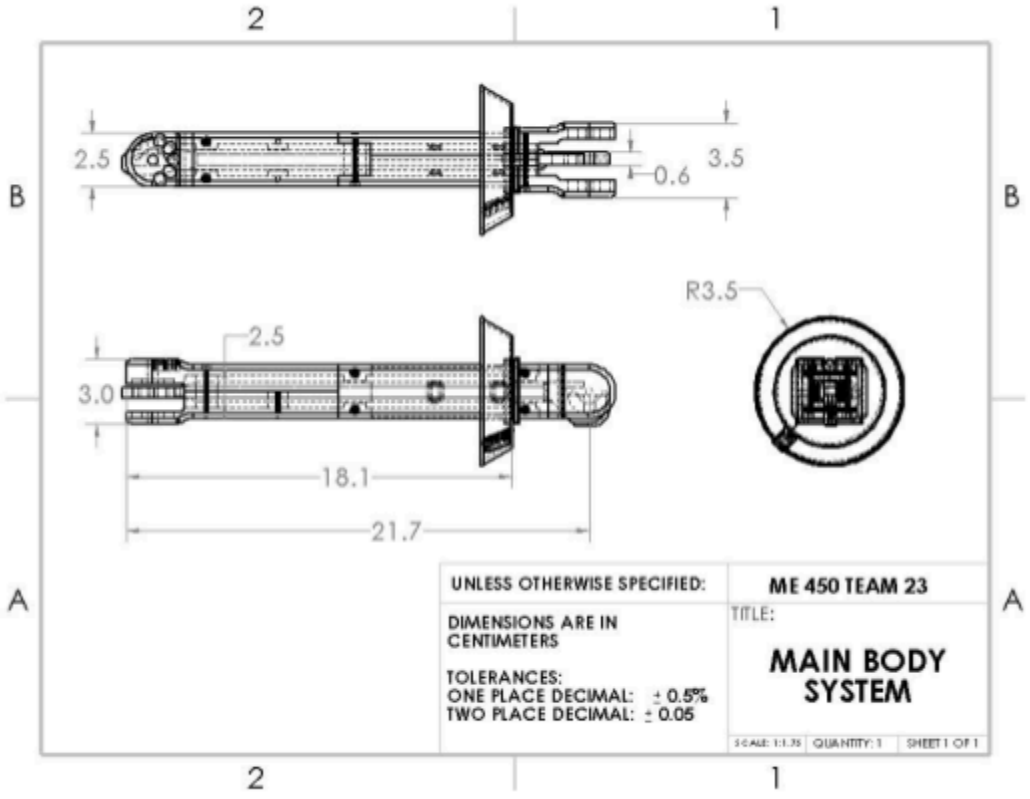


Figure 37. Engineering drawing of the main body subsystem.

The tip connects to the main body shafts and its main function is to be the interaction point between the device and the uterus. This subsection rotates vertically with horizontal rotation of the handle at a 1:1 ratio. It features a colpotomy cup to guide incisions during surgery and, if electrocauterizer devices are used during surgery, the silicone electrocauterizer guard should be installed to prevent injury. The anchoring mechanism relies on two silicone caps to seal the finger of a sterile medical glove around the shaft of the tip. Tubing is connected to the base of the tip, allowing the medical glove to be filled with saline or air. All components except for the balloon caps are made of 316 or 316L stainless steel. The schematics for this system can be seen in **Figure 38.**

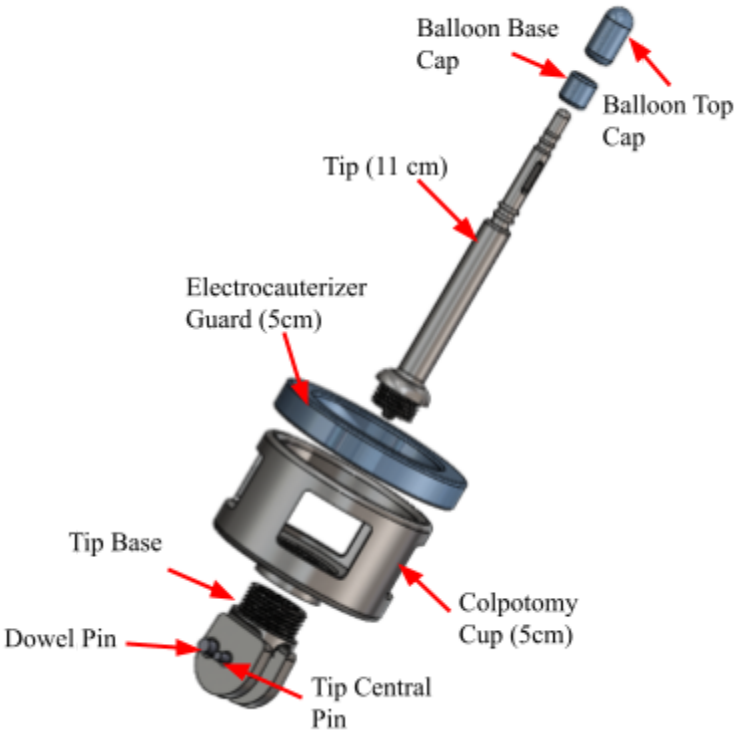


Figure 38. CAD of the tip subsystem.

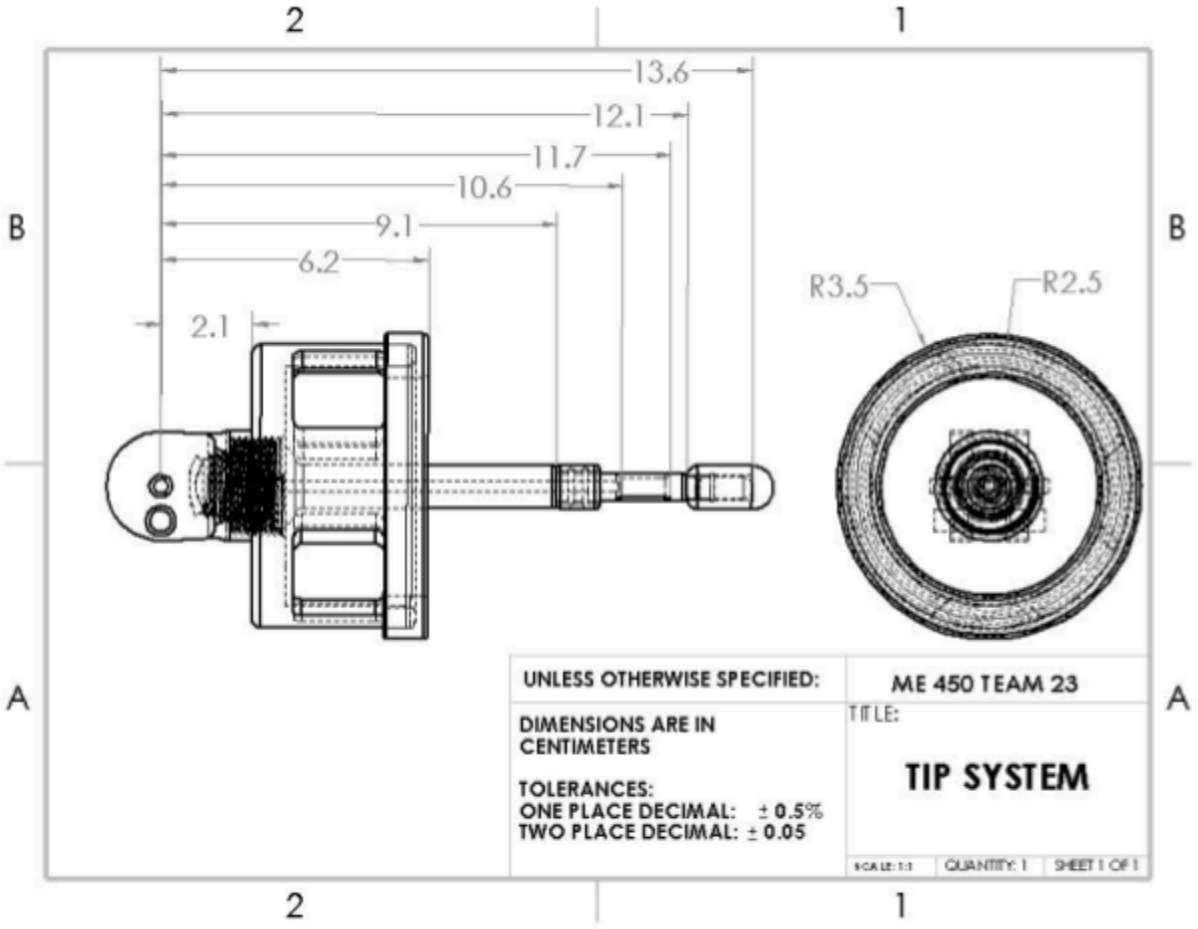


Figure 39. Engineering drawing of the tip subsystem.

The manufacturing plans of the final design depend on if the device would be mass produced. Assuming that the device would not be extremely mass produced, most of the parts would be machined from stocks of material. This is because creating molds and tooling for the multitude of parts would be very costly and likely not worth the price considering the device is intended to be cheap for LRSs. Further development in the future on tooling costs would have to be done. However, the silicone parts would require molds to be formed. Parts such as springs and screws would be sourced as directly as possible from suppliers to reduce cost.

The device operation procedure can be found in **Appendix C**.

Build Design

The overall shape and function of the build design is similar to the final design, however there are a few notable changes. Firstly, nearly all components of the build were 3D printed. The parts intended to be made of metal on the final design were printed with PLA, and the silicone components were printed with TPU. To have improved performance of the device, some critical mechanism components were not 3D printed. These components were fasteners, pins, springs, and medical adapters. Many of these

components required no modifications, however a few of the pins had to be cut to length with the rod shears in the undergraduate machine shop.

Secondly, multiple small design changes were necessary to overcome some of the challenges associated with using a relatively inaccurate fabrication method. This included things such as tubing connections and adapters. On the build design, these features were prefabricated parts and design changes were necessary to properly implement them. These features were critical during the prototyping and verification process, and 3D printing did not prove to be a sufficient medium for creating these features. In the final design, these features would be built into the design and thus there is no need for these prefabricated components. The build design also does not feature bushing at any of the joints, this is because securing the correct size bushings would not be possible without custom manufacturing and the device had acceptable performance without them. Additionally, the locking mechanism was manufactured but never assembled in the physical prototype. This was because of tolerancing issues due to 3D printing, and it was deemed not critical to spend too much time redesigning this mechanism because it did not directly relate to any of the specifications within the scope of the semester.

The third difference between the final and the build is the team needed to supply some common medical supplies in order to perform verification testing. This included IV tubing, syringes, and medical gloves. In the final design, these materials would be supplied and installed by the healthcare facility on device use.

The build design CAD can be seen below in **Figure 40(a)(c)(d)**, with the physical build shown in **Figure 40(b)**.

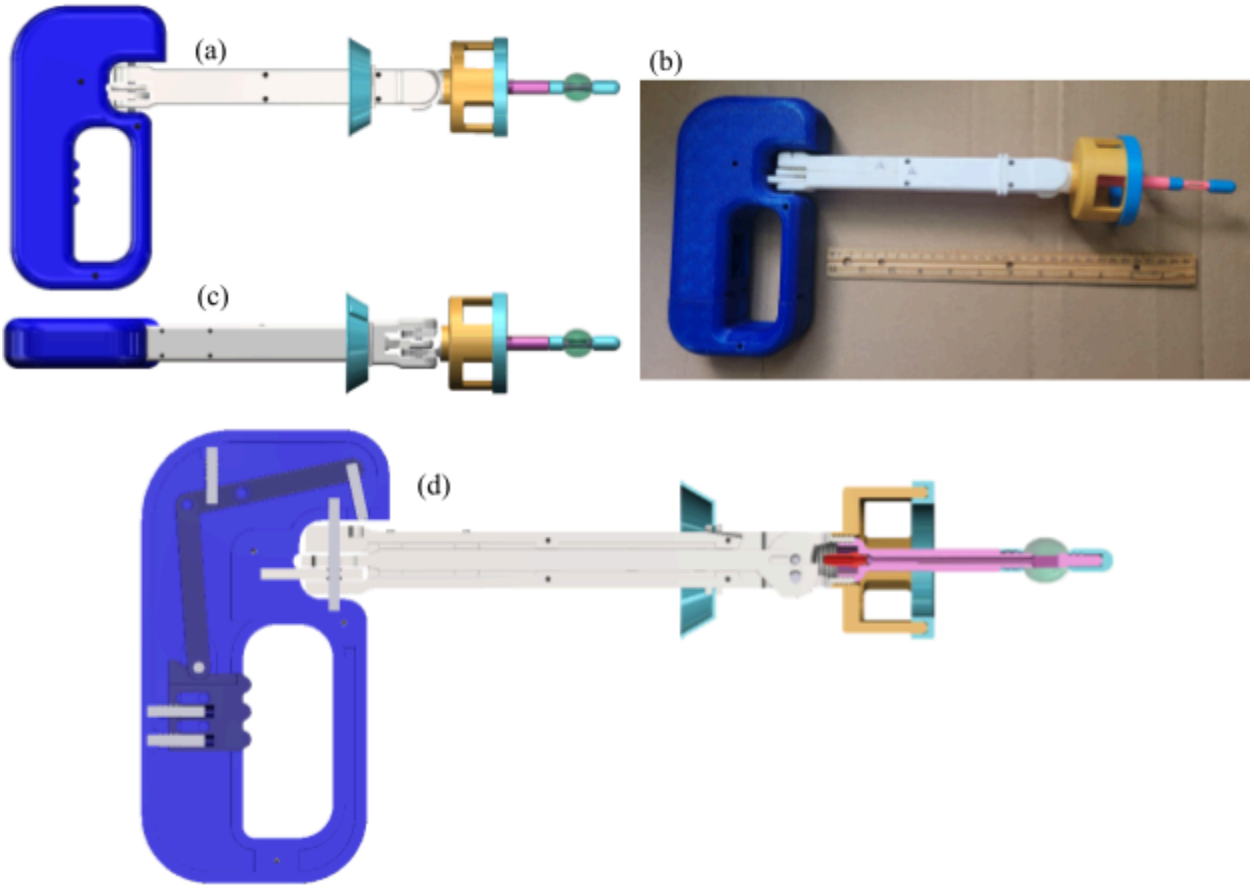


Figure 40. CAD (a) and physical build design (b).

The build design has different colored components to aid in explanation of device functions during design reports and the design expo. Reproduction of the build does not need the variation in the colors to have the same functionality.

All of the design changes between the final design and the build design can be seen in **Figure 41**. (a) shows the tube connection located at the bottom of the tip. This modification was done because of concerns with getting a 3D printed connection to be air tight. The threads of the connector were wrapped with teflon tape during testing to further improve the seal. On the final design this connector is built in. (b) shows the design change that was done with the various fasteners on the device. Instead of tapping plastic, holes were made to be normal fit and cutouts for nuts were made. On the final design, the holes will be threaded instead. (c) Shows the interior of the handle created during the semester. It is missing the locking mechanism because of tolerancing issues. In the final build, there would be pins, springs, and linkages inside the handle.

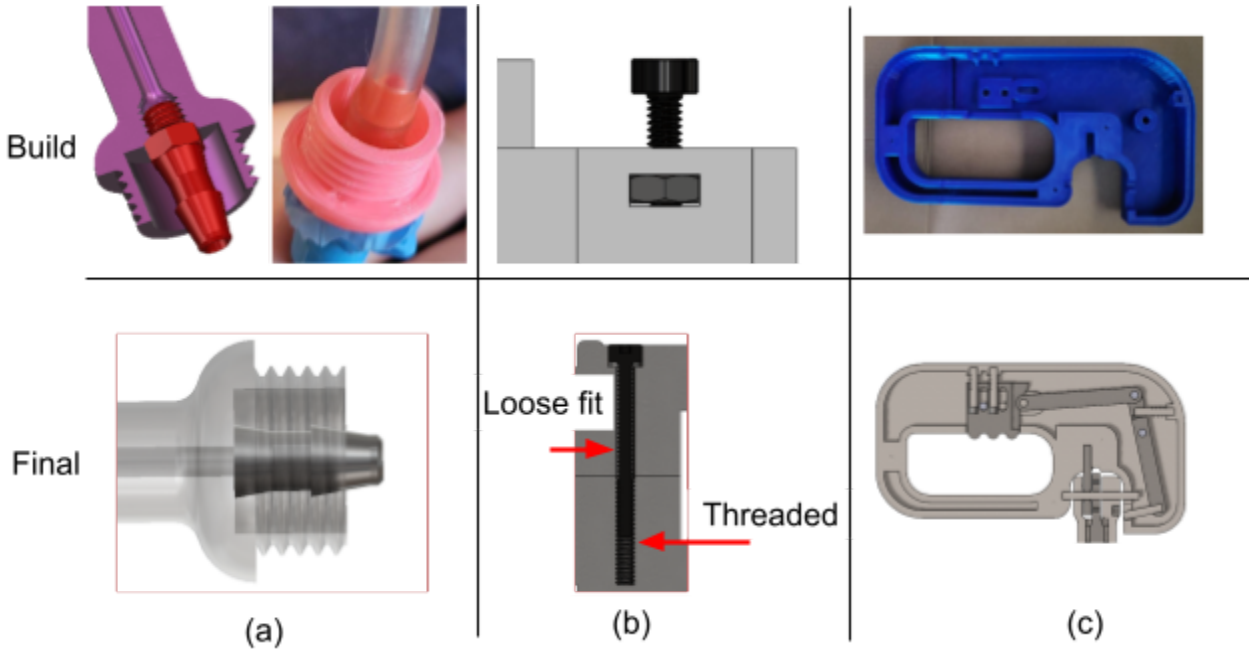


Figure 41. Callouts of the build design changes.

A physically built prototype was deemed appropriate for this project for a number of reasons. The design changes were made so that the build would better mimic the behavior of the final design. Material composition was deemed as not critical for device function and most of its effects can be estimated theoretically (i.e., material costs can be estimated via CAD and biocompatibility can be confirmed with literature review). The prototype has the same overall functionality as the final design despite these differences, and functionality was deemed to be the most important factor of this project.

Additionally, having a 1:1 scale model to work with turned out to be crucial for design iteration and verification of the final design. Having a correct scale model of the device made it much easier to visualize the size constraints associated with the device and brought many issues to light that were not identifiable with CAD alone. Significant iteration was performed on various parts of the design after components were printed and assembled. For example, the scotch yoke mechanism underwent four iterations during the 3D printing process, and the issues associated with each iteration of the scotch yoke were issues that were not noted in the CAD. Having a physical device also enabled the team to perform formative usability testing. This testing revealed multiple ergonomic issues associated with the device that would not have been considered if a physical device was not present at this testing.

Verification testing of 8 specifications were also performed using the physical build. While some of these tests may have been possible with CAD (i.e range of motion), it was deemed more impactful to have physical verification of the device instead of theoretical alone. Some of the verification tests were not possible due with CAD alone, however. For example, setup time of the device would have been challenging to estimate solely with a computer model.

In total, the build design contains 528 grams of PLA and 14 grams of TPU without supports. TPU and multiple colors of PLA were purchased by the team, with the rest of the components gathered from the

x50 assembly room and the biomechanical engineering assembly room. The full bill of materials and manufacturing plan can be found in **Appendix D** and **E**.

Description of Verification and Validation Approach

Verification Testing

Verification procedures are necessary to ensure a functional device in accordance with the 21 identified specifications. Due to the nature of the device, it was determined that many specifications would be best verified using clinical simulation models. Thus, the team contacted both the University of Michigan Medical School Clinical Simulation Center and the University of Michigan School of Nursing Clinical Learning Center to request access to relevant uterus/cervix models. Following failure to receive a favorable response from either organization, the team decided to pursue verification by assembling simple models themselves.

The most important characteristics for the simulation models are accurate simulation of the physical tissue behavior (texture, elasticity, and pliability) and the structural dimensions (uterine length, cervical channel width, and fornix diameter). Through review of existing low-cost "DIY" simulation models, several models for different aspects of the device were selected and adapted for the team's capacity. Soft rubber stress toys were used to simulate tissues for the uterus manipulation, removal, and colpotomy, subsystem tests; this mirrors the texture of silicone molding materials used [63].

To create the model seen in **Figure 42** a cylindrical hollow rubber stress toy was stretched, filled, and shaped into an enlarged uterus with paper. The cervical entrance was created by folding the rubber end over itself. For reference, dimensions of a normal uterus are 5 cm fundus, 8 cm main body (fundus to cervical entrance), and a width of 6 cm, image for clarity can be found in **Appendix F** [64]. The average patient receiving a TLH does not have the dimensions of a normal uterus, they have an enlarged uterus. Procuring exact dimensions of an enlarged uterus weighing 1 kg was difficult due to the usual chosen metric for these cases, uterine weight and weeks of pregnancy. However, the general definition of an enlarged uterus has a fundus larger than 10 cm [65]. Based on this, the dimensions chosen were 11 cm fundus, 16 cm fundus to cervical entrance, and a width of 4 cm.

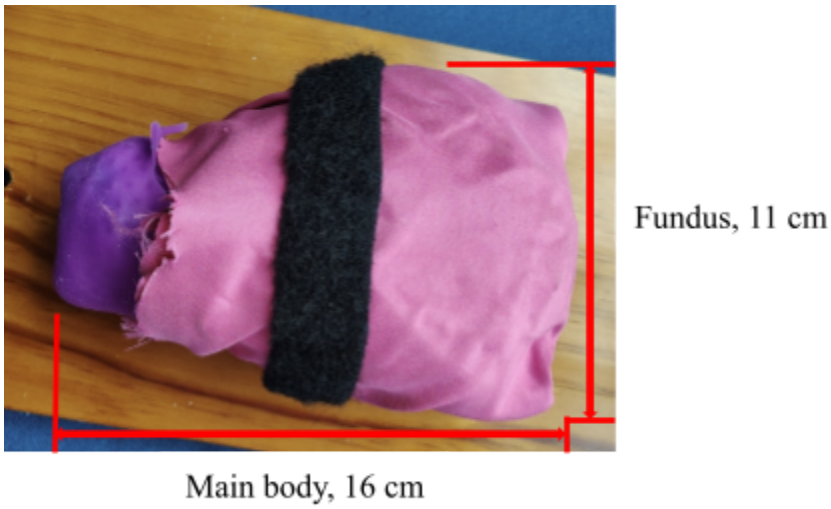


Figure 42. The simulated enlarged uterus with a fundus length of 11 cm, 16 cm main body (fundus to cervical entrance), and a width of 6 cm.

To simulate the vaginal canal a pringles can was shortened to a length of 9 cm. A 2.5 cm strip was cut from a rubber stress toy and stretched over one entrance to represent the vaginal fornix flap that sits around the cervix. The uterus was then inserted into the can and attached with velcro. The fully assembled uterus can be seen in **Figure 43**, attached with a rubber band and secured to a Costco ham leg stand. The intention of this setup was to provide support to the uterus thus UM the same way a patient on a table would be.



Figure 43. Simulated uterus used for verification testing.

Verification Test Plans

A brief overview of the verification testing procedures are shown in **Table 8** below, followed by an explanation for each selected test. Priority level was determined based on risk level of the specification as well as relevance to the functionality of the device within the scope of ME450. Material selection-related specifications are relatively low-risk since the anticipated materials are well-documented in surgical settings and a "works-like" prototype can be built without selecting the precise materials, resulting in a low priority rating.

Table 8. Overview of verification testing plans and priority level

Spec #	Priority	Verification Method	Proxy Test (if applicable)	Status
001	High	Measure actuation angle extrema	N/A	Passed
002	Low	Deliver 50±5mL dilute methylene blue dye from the external end of the chromopertubation tube to the tip of the device	Replace dilute methylene blue solution with tap water	Passed
003	Low	Clinical trial with the device shaft and occluder disk to test if pneumoperitoneum stays at 12mmHg or higher	Test using simulated model and water pressure	Failed
004	Low	Clinical trial to remove an enlarged uterus through the vagina using the device	Use the manipulator to pull the enlarged simulated uterus through a 1" diameter PVC pipe	Plan Developed
005	Low	Materials that have substantial literature and documentation in their favor may be used; more novel materials should be tested for cytotoxicity, systemic toxicity, irritation, and skin sensitization according to ISO 10993-5, -10, -11, and -23	3+ instances of literature, supplier documentation, etc. supporting the material for medical device use	Passed
006	Medium	Test edges with UL 1439, then simulate manipulation on a clinical model and inspect the simulation uterus for pinches, tears, or weak spots	Simulate manipulation only	Passed
007	Medium	Coat all surfaces potentially exposed to biomatter in dye, then use a cleaning brush to remove and visually inspect for any unreachable spots	N/A	Confident it would pass
008	Low	Apply the autoclave and dry heat methods, then visually check for corrosion or deformation	Literature search/AAMI TIR17 backing	Passed
009	Low	Apply the various chemical sterilization methods, then visually check for corrosion or deformation	Literature search/AAMI TIR17 backing	Passed
010	Medium	Attach a 1kg mass to the tip of the uterine manipulator and follow testing procedure	Scale mass to 100 g for prototype material PLA	Confident it would

		for range of motion (001) to ensure that it still works		pass
011	Low	Create simulation uteri of the maximal and minimal depth values and ensure that the testing procedure for range of motion is successfully executed	N/A	Confident it would pass
012	Low	Measure the internal diameter of the colpotomy cups	N/A	Passed
013	High	Measure the diameters of parts that pass the trans-cervical portion of the UM	N/A; may scale the pipe diameter according to prototype scale	Passed
014	Medium	Have assistant surgeons briefly familiarize themselves with the device controls, then have them simulate TLH and score the device using the SUS	Recruit nearby non-surgeon participants to participate	Plan Developed
015	Low	Weigh the device using a digital scale	Simulate the device mass with CAD	Failed
016	Medium	Start with the parts disassembled as they would be for sterilization, and measure the time it takes to fully assemble and place the device in the anatomical model	N/A	In Progress
017	Medium	Use a spring scale or strain gauge to measure the force required to complete the actuation interaction with a 1kg mass attached to the manipulator end	N/A	Plan Developed
018	Low	Cyclically submerge device in 5% bleach solution, then calculate the chemical penetration	Review literature to ensure corrosion resistance	Passed
019	Medium	Set up a testing apparatus to actuate the controls and device 10,000+ times	Calculate cyclical loading/fatigue effects for the selected materials	Plan Developed
020	Medium	Conduct a cost audit using GRANTA Edupack	N/A	Passed
021	Medium	Using no more than a screwdriver, successfully disassemble the device into each individual piece, and successfully reassemble.	N/A	Passed

More detailed explanations and justifications of the test and proxy selections are listed below:

001 Robust range of motion: In order to verify a minimum of 140° actuation range of motion of the device, the center of rotation of the assembled uterine manipulator prototype will be placed at the center of a protractor. The device will then be actuated from end to end of the range, which will be recorded to determine the full range of motion of the manipulator. This test provides the baseline for several other verification tests that address specific loading cases. No proxy tests are required. This test is valid but is subject to human error.

As arguably the most basic function of the device, it is critical that this specification is met. Despite proven range of motion in the initial CAD model, factors such as shaft packaging and mechanism friction (and loading, such as in the tests for specifications 009 and 010) may affect the quality of actuation. Combined with a low setup and time cost for the test, high priority was placed on verifying this specification.

002 Chromopertubation: To verify this specification, 50 ± 5mL of the diluted methylene blue dye used for chromopertubation should be injected into the device tubing and successfully exit at the dye port on the actuating end of the device. To test the most extreme bend in the tubing, the manipulator should be placed at the maximum rotation position (≥ 90°) during the procedure to ensure that the tubing does not kink excessively, restricting dye flow. For testing in ME450, the methylene blue solution will be replaced with tap water since visibility will not be an issue during the test, and the viscosity is similar. Due to low risk of failure and simplicity of the subsystem, this test was placed low in priority for verification. While similar viscosity, the fluid behavior may be different in an actual clinical setting.

003 Maintenance of pneumoperitoneum: In the ideal case, maintenance of pneumoperitoneum would be tested via clinical trial to properly represent operation conditions and how pressure is introduced and lost in the abdominal cavity during surgery. However, a more realistic test within the bounds of ME450 tests the ability of the device to maintain a pressure using a simple simulator model. A toy made of elastomeric material with a similar diameter to the baseline vaginal canal may be used as a simulator. From there, the device is inserted and the system is held upright. Water should then be injected into the toy using a syringe. Once the system starts leaking water, take note of the volume of water added. The water volume may then be used to calculate the pressure applied to the occluder, which directly corresponds to the air pressure that the occluder can maintain under operating conditions. The test priority is rated low due to similarities of the design with other common structures to maintain pressure, as well as the low complexity of the subsystem.

004 Removal of uterus: As previously stated, the status of this requirement is defined as out of scope for the project scope. Since this decision was made late into the project, a discussion on the possible verification plan has been explored and is as follows.

Clinical trials for TLH with enlarged uteri would ideally be implemented to ensure efficacy of the system. This would allow the team to properly assess the removal mechanism's ability to improve speed and ease of uterus removal in cases where the detached uterus cannot be simply pulled out through the vaginal canal. Within the time and resource constraints of ME450, fulfillment of the uterus removal specification would be verified if a typically-sized simulation uterus can be removed through the vaginal canal using only the UM. For larger simulation uteri, the device should at minimum substantially reduce the volume of uterine tissue removed before it is possible to try and remove the uterus.

Given the incomplete state of this specification, refinement of this verification test is anticipated. Due to the status change, a low priority level was assigned to this test.

005 Biocompatibility: Materials that have substantial literature and documentation in their favor regarding biocompatibility should already have been prioritized in the material selection process.

Nonetheless (but especially if more novel materials are eventually selected), all materials should be tested for cytotoxicity, systemic toxicity, irritation, and skin sensitization according to ISO 10993-5, 10, 11, and 23, which is the leading standard and testing procedure for biocompatibility.

Within the scope of ME450, given the goal to produce a functional manipulator but not necessarily an operation room-ready one, an appropriate level of satisfaction with material selection can be achieved simply through substantial (3+ instances) proof of biocompatibility through literature review and existing devices. This approach of verifying materials based on existing documentation mirrors that of the material evaluations for various sterilization procedures in AAMI TIR17:2024, making it an appropriate proxy to the physical testing experiments. Additionally, since materials can generally be swapped without substantially modifying the base design, the verification priority was determined as a low risk of hindering the team's progress towards a working design.

006 Safety: For the "final" device, the UL 1439 testing procedure for sharpness of edges should be implemented to minimize cutting risk. Then, simulations using the device on realistic/animal tissue should be conducted to inspect for any missed edges or points. In particular, the uterus removal mechanism has potential to cause unintended damage outside of its intended deployment method. For ME450, the simulation will likely be conducted on less realistic tissue material. However, this loss in fidelity is considered acceptable since material selection and manufacturing methods play a large role in the potential for sharpness. Thus, only the manipulation test will be conducted. This test earns a medium priority level.

007 Cleanability: To verify cleanability, the device should be disassembled to its cleaning state. Every exposed surface should then be coated with a visible dye or removable paint. A cleaning brush should then be used to remove the dye from every surface, with remaining patches of color indicating a failure point for cleanability. Given the necessity of cleaning as a step in the reprocessing pipeline balanced against the intentionally cleanable design, this test earned a medium priority designation.

008/009 Autoclave, dry heat, and chemical sterilizability: Verification of the sterilizability of materials is largely built into the specifications themselves since the majority of materials considered were pre-approved in the AAMI TIR17:2024 indices. However, testing of the materials as outlined in ISO 13402:2025 Annexes G and H should be performed regardless. As a proxy within ME450, samples of the materials can be heat-tested in a conventional oven and "autoclaved" by boiling in a pot of water or pressure cooker, pending availability of suitable appliances that do not come into contact with food. For both of these tests, ISO 13402 should be consulted for appropriate testing temperatures. Otherwise, verification for the purposes of ME450 can be established using existing documentation. For similar reasons as the biocompatibility specification, verification of material selection for various sterilizability methods was decided to be low.

010/011 Uterine mass and length: The verification plan for this specification is largely based on the range of motion (001) test. The original range of motion test should be repeated with an evenly distributed 1kg mass attached to the manipulator, repeated for each tip length option. Due to the potential for different Young's moduli between the prototype's printed PLA filament and the final tip material, the mass attached to the tip for testing in ME450 differs substantially. The test would be completed using the

100 g tip mass previously seen in **Figure 42**. Between the necessity to ensure that the manipulator is capable of moving the full range of uterine masses and lengths and the difficulty in doing so at an incomplete material stage, this test receives a medium priority level.

012 Vaginal fornix diameter: Compatibility with a range of vaginal fornix widths can be verified simply by measuring the inner diameter of the assembled colpotomy cup using calipers. With low risk and system complexity, this test was assigned low priority.

013 Cervical channel diameter: The trans-cervical parts of the manipulator should be measured to verify they are ≤ 2 cm. No proxy test is necessary. As there have been concerns and challenges packing the device tip to be narrow enough, this verification test was assigned high priority.

014 Ease of use: For verification, operators should briefly familiarize themselves with the device controls, then simulate TLH using the manipulator and score the device using the System Usability Scale. As a proxy test this semester, each team member will recruit an outsider to the project to simulate TLH and score the device. Usability is a significant factor considered in the prototype, but since many aspects of use are anticipated to change (notably friction in the joints) and an in-depth instruction manual is not an intended deliverable for the team, priority is medium at the time.

015 Device weight: The final verification test for this requirement is to weigh the complete device using a digital scale to ensure it stays at or below the maximum weight of 500g. However, since the team deliverable for the semester is a 3D-printed prototype in entirely different materials than the official design, the proxy test will be to model the weight by assigning the selected materials to each part in the CAD model. As another largely material-dependent specification, priority is low.

016 Setup and placement time: To verify that this specification has been met, an assembly test is conducted starting with the parts fully disassembled as they would be after sterilization. Then, the time it takes to assemble and place the device in the anatomical model should be measured and compared to the ≤ 7 minute time specified. In the ideal testing scenario, this procedure would be conducted by end users in the operation room. This test is still valuable with the prototype, conducted by recruited participants, to identify pain points in assembly of the device, although understanding the impact of material selection and varying tolerances between the prototype and final design lends some flexibility in this measurement. The slightly less critical and lower-risk nature of this specification lends itself to a medium priority verification test.

017 Operation force: Verification of this specification is linked to the verification of suitability for uterine mass. To test the maximum loading scenario, a 1kg mass should be attached to the actuated manipulator tip, and a spring scale should be used to measure the force required to actuate the device. No proxy will be needed. With similar rationale to the priority assignments for 013 and 015, medium priority is given for this verification test to honor the impact that ME450-important subsystems (actuation mechanism, handle/interaction method) have on the operation force, while also acknowledging that a precise measurement remains difficult. Depending on the spring scale results as well as time constraints, digital simulation of the actuation input force may be implemented.

018 Sodium hypochlorite (bleach) resistance: The device should be repeatedly submerged in 5% sodium hypochlorite solution at 25°C for 30 minutes for 300 cycles to simulate the cleaning process. The device should be thoroughly rinsed with water after each cycle. The concentration of metals and polymers leached into the solution after each cycle should be recorded and likewise the solution penetration into the device should also be noted. As a proxy in ME450, synthesis of published data can be conducted to simulate the testing process. Testing priority for bleach resistance was low, for the same reasons as the other material-dependent specifications.

019 Longevity: The device should be mechanically tested to actuate to full range limits 10,000 times to account for several actuation movements per operation. This poses obvious challenges in time and setup capabilities in the scope of ME450, so a more manageable test would be to calculate cyclical loading/fatigue effects for the selected materials, which would provide an acceptably accurate estimation of the device's material limits for longevity. Due to the reusability requirement central to the motivation for the project, verifying this specification is a medium priority task, higher than other material-dependent parameters.

020 Low-cost: A cost audit using GRANTA Edupack and price/mass data collected from online/literature review and the CAD model will be conducted to verify the low-cost specification. This test is achievable within the scope of ME450. Medium priority is given as a relatively low-risk core tenet of the project motivation.

021 Repairability: In order to verify repairability in a low-resource setting, users will be asked to fully disassemble the device into the individual pieces and reassemble into the functioning instrument using only a screwdriver and a pair of pliers. This ensures that all parts can be accessed and replaced individually, ensuring that the entire device does not become defunct due to failure of one component. This test is medium priority, corresponding to the level of confidence that the team has in the potential for success of this parameter.

Interrelated verification tests: Verification tests should be performed together to maximize efficiency based on the setup needs and co-dependency between different specifications. **Table 9** below shows how the verification tests are grouped.

Table 9. Clustered verification tests based on specification codependency and test method

Range of operation w/ simulation model	**Usability testing**	**Literature review**	**Independent tests**
001 Robust range of motion 006 Safety 010 Uterine mass 011 Uterine length 017 Operation force	002 Chromopertubation 007 Cleanability 014 Ease of use 016 Setup and placement time 021 Repairability	005 Biocompatibility 008 Autoclave/dry heat sterilizability 009 Chemical sterilizability 018 Sodium hypochlorite (bleach) resistance	003 Maintenance of pneumoperitoneum 004 Uterus removal 012 Vaginal fornix diameter 013 Cervical channel diameter 015 Device weight 019 Durability 020 Low cost

Verification Test Results — V&V traceability log in **Appendix F**

Range of operation

001 Range of motion: The prototype tip was moved to the most ante- and retroverted positions and the angle was measured relative to the shaft of the device. In **Figure 43**, a protractor is overlaid digitally for clarity, showing that an angle of 140° was achieved. Three iterations of the actuation mechanism were designed before this specification was satisfied. **Figure 43** provides a clear demonstration of this test, verifying the completion.

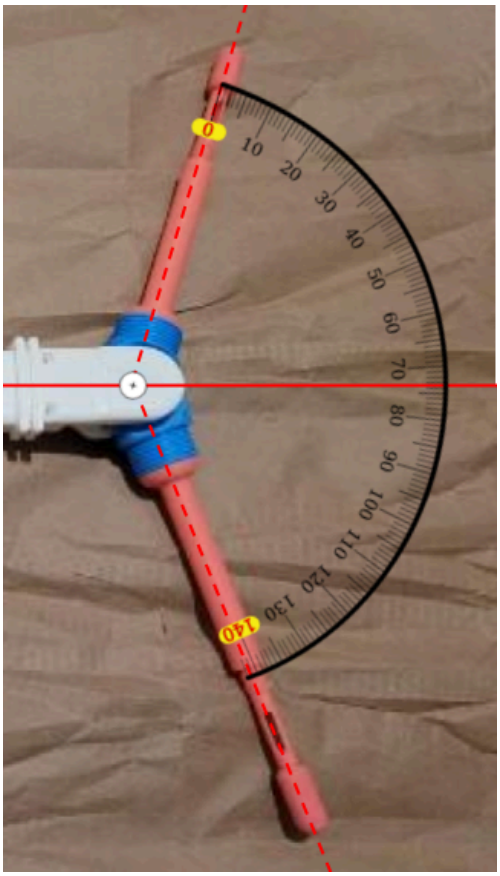


Figure 43. Range of motion verification test setup.

006 Safety: Within the scope of the course, the manipulation tests yielded no damage to any of the rubber simulated tissues in the uterus model. Additionally, no pinching risks were observed on the user end throughout usability testing and informal interactions with the prototype in development and at Expo. Since every exposed edge of the device has been filleted and with the joints rounded, there is high confidence that the design will continue to fulfill the safety specification with proper manufacturing and material finish.

010 Uterine mass: The simulated uterus seen in **Figure 44** weighs approximately 100 g and was used to verify the UMs ability to actuate the full range of motion. Unfortunately, there are no images that directly follow the testing procedure seen in 001. However, there is evidence that proves the device can actuate

the scaled uterus weight a large range seen in **Figure 44** and **Figure 45**. The scaled uterus was attached and manipulated. While the team can personally verify the UMs ability to actuate the full range, without the proper test seen in 001, the requirement remains unverified and in progress.

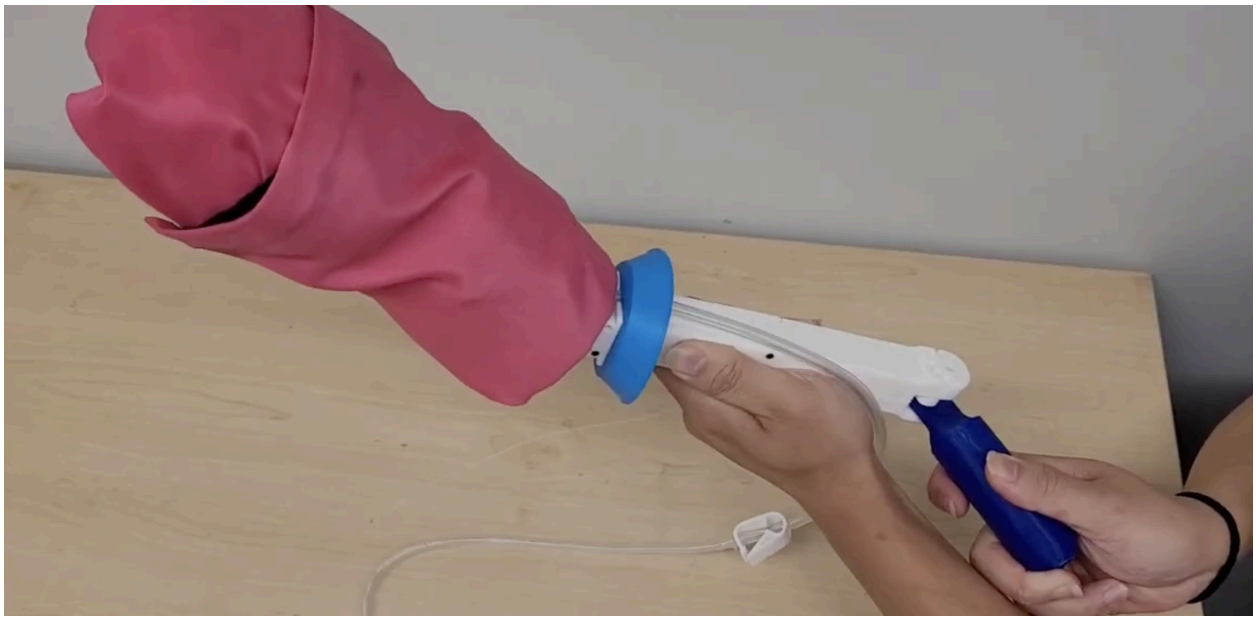


Figure 44. Scaled 100 g uterus actuated in retroversion by what is assumed to be the full 70°.

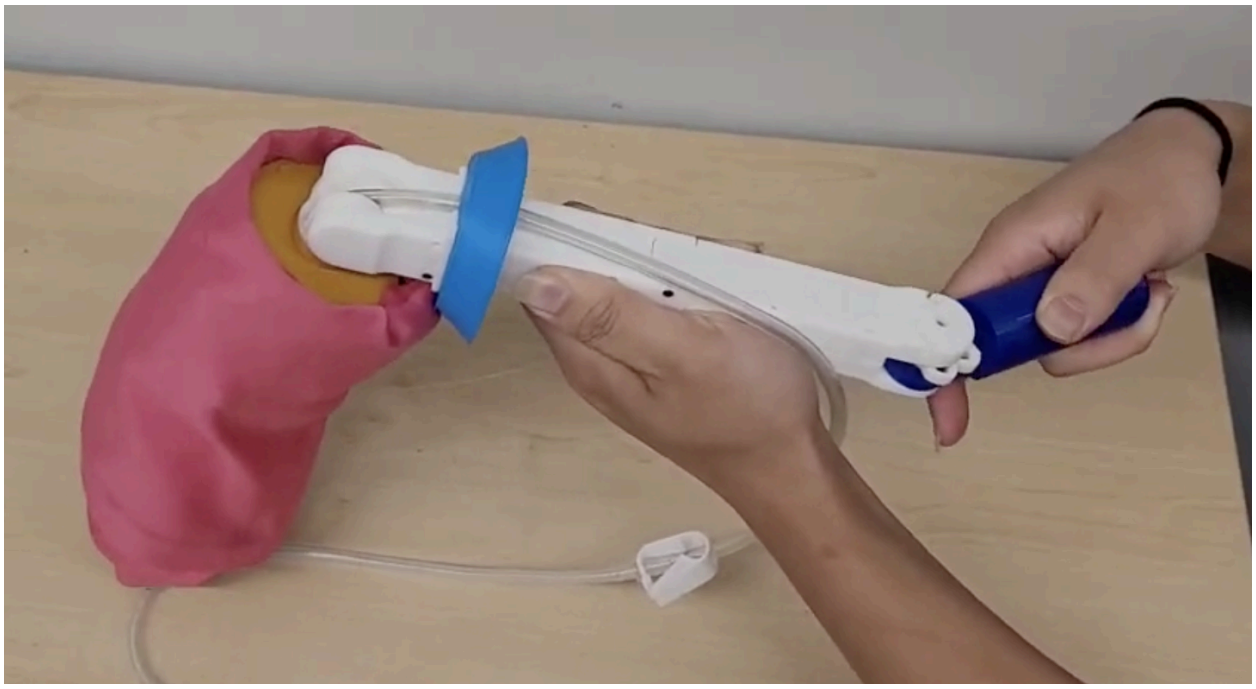


Figure 45. Scaled 100 g uterus actuated in anteversion to the full extent of motion.

011 Uterine length: Not completed, however, the team is confident this requirement could be verified if the testing procedure was completed since a range of tip lengths from 5±1cm to 11±1cm were developed.

017 Operation force: Not completed.

Usability testing

002 Chromopertubation: As described in the testing procedure, a 50 ml syringe was used to fill the tubing, device volume in the UM tip cavity, and anchor balloon verifying its ability to reach the tip end of the device. The demonstration can be seen in **Figure 46**.



Figure 46. Demonstration of liquid reaching the tip end of the device.

007 Cleanability: The full cleanability test was not conducted. However, the device was designed such that the intended disassembly of parts for cleaning and sterilization exposes every surface that may be exposed to biomatter during operation. All lumens, such as in the tubing and the tip subsystems, are designed to be reachable using standard lumen brushes. The only cleaning challenge in the prototype are the small pockets where the nuts are set to hold the main body shaft together. However, this feature exists due to material constraints of the prototype; no part of the final design contains any similar crevices that are not directly reachable. The device is thus reliably believed to be cleanable.

014 Ease of use: Not completed.

016 Setup and placement time: A summative usability test was conducted to verify the setup and placement time of ≤ 7 minutes. In depth instructions and raw data for this test can be found in **Appendix E**. Utilizing the provided material on usability testing, an instructional guide for device assembly was developed [66]. The instructional guide (test procedure) consisted of four steps to assemble the base components and nine steps to assemble the various attachments. Construction of the base included the tip base, half A and B of the outer shaft and screw installment. The various attachments include the colpotomy cup, tip shaft, anchor balloon, both balloon collars, tubing and occluder disk.

The results of the testing can be seen in **Figure 47**. Note the variety of users who completed the test include a master user who is familiar with the project, an inexperienced user with zero knowledge of the project or field, and an experienced user who regularly assembles medical tools in a professional setting.

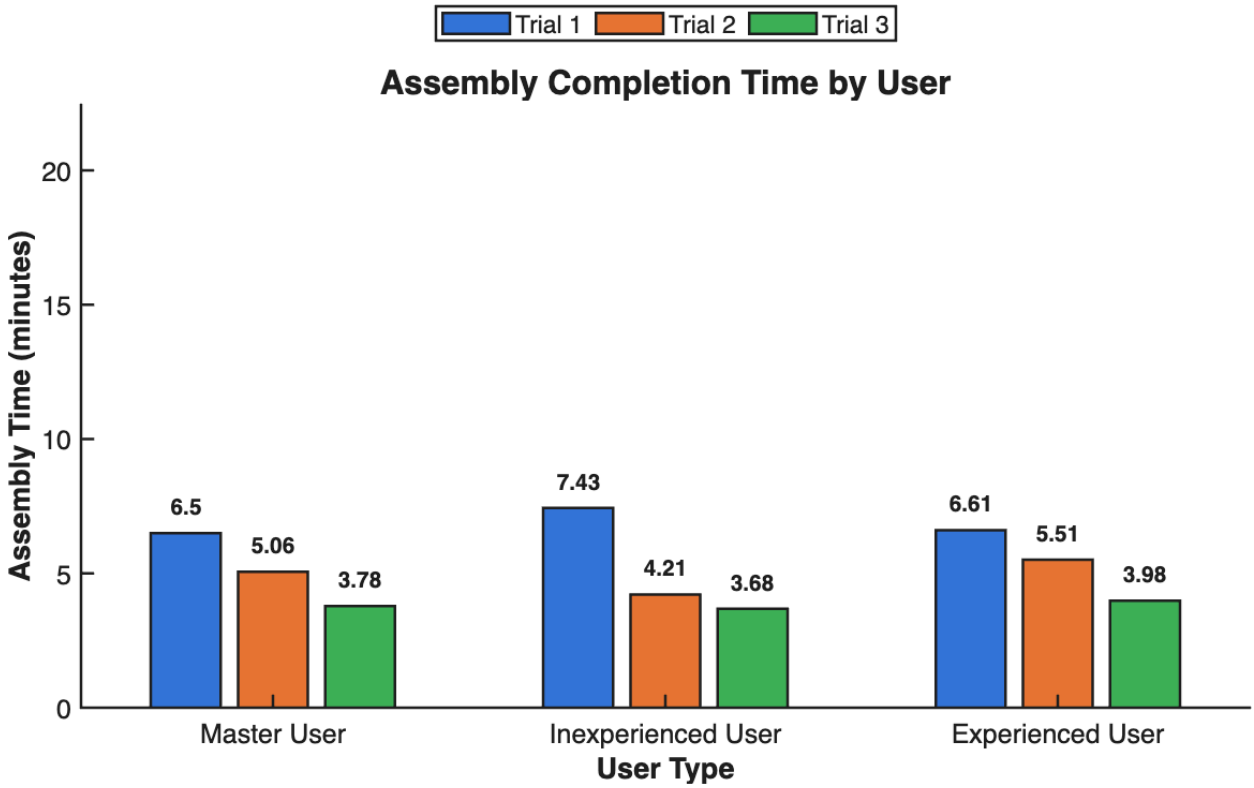


Figure 47. Results from summative usability test for assembly time.

The results verify users from various backgrounds can complete the assembly of the device in ≤ 7 minutes, however, placement time was not considered and so this requirement is still in the verification process.

021 Repairability: As noted in the instructional guide, the only tool utilized in the assembly of the device was an allen key, a non-specialized tool. Therefore, the requirement is verified and no further testing is necessary.

Literature review

005 Biocompatibility: Biocompatibility of all three materials used in the device were verified by examples of existing FDA-approved medical devices that fall into the same or higher risk category based on exposure type and time from ISO 10993. Devices were found using the Devices@FDA database and internet search, and are listed below in **Table 10**.

Table 10. Existing medical devices used to verify biocompatibility of selected materials

Material	**Example 1**	**Example 2**	**Example 3**
Silicone	Cook Medical- Black silicone filiform double pigtail ureteral stent	Biotronik- Solia S pacing lead	Medline- Silicone wound drains with trocars
SS 316L	Ethicon Incorporated- Stainless steel	iCast™ Covered Stent System	Karl Storz- CLERMONT

	suture		Uterine Manipulator
Al 6061-T6	EXELINT Aluminum Hub Blunt Needles	Brasseler- Posterior Temporary Impression Tray	gSource- Gunnar Hey Roller Forceps 7 1/2″ with aluminum rollers

008/009/018 Autoclave/dry heat sterilization, chemical sterilization, and sodium hypochlorite resistance: Literature review and synthesis was conducted in accordance with the verification plans, wherein prospective materials were narrowed down using sterilization compatibility and corrosion resistance data, ensuring these critical criteria would be met [20], [57]. The final material selections of medical-grade silicone, 316L stainless steel, and 6061-T6 aluminum were all confirmed to be compatible with autoclave, dry heat, bleach, and various chemical sterilization processes, shown in **Table 11**below.

As with the analysis, the numbers denote the number of ways that each material has been assessed for compatibility with a given sterilization process, from 0-4. The methods for verification include peer-reviewed literature (P), a 10+ year history of use with established compatibility (H), degradation pathway analysis (D), and white paper literature (W). For bleach corrosion resistance, 20% sodium hypochlorite solution was assumed, although 5% concentration is standard in healthcare settings.

Table 11 Sterilization compatibility and bleach corrosion resistance for final selected materials.

	Sterilization Processes							**Other**
Material	**Auto-clave**	**Dry Heat**	**Ethylene Oxide**	**Chlorine Dioxide**	**Peracetic Acid (liquid)**	**Hydrogen Peroxide**	**Nitrogen Dioxide**	**Bleach**
Silicone	2 (H)	2-3 (W)	3 (D, W)	4 (P, H, D)	3 (H, W)	4 (P, H, W)	3 (H, W)	R
SS 316L	3 (H)	3 (W, D)	3 (H)	4 (P, H, W)	3 (H, W)	4 (H, D, W)	3 (H, W)	U*
Al 6061-T6	3 (H, D)	2 (W)	3 (D)	2-3 (P, W)	3 (H, W)	4 (P, H, W)	2 (H)	G

*Further investigation yielded a high sensitivity of stainless steels to chlorination, but was generally accepted when concentration, temperature, and exposure time were limited, and if the solution was rinsed off immediately after exposure.

Confidence in the sterilizability of these materials stems from the standardization of material compatibility through AAMI TIR17 and the history of these materials being used in surgical devices. For bleach, the materials selected are reliably verified despite the unsatisfactory rating for SS316L because the table ratings are based on a sodium hypochlorite concentration four times higher than the standard concentration used in hospitals, and with long-term continuous exposure rather than short periods of time where the device is rinsed off afterwards.

Independent tests

003 Maintenance of pneumoperitoneum: An image of the verification testing setup is shown below in **Figure 48**. The purple elastomeric toy is attached to the syringe using a small hose clamp, and the prototype has its tip subsystem removed as it is not relevant to the test. This test ultimately failed because the team failed to consider that the main shaft body is open and fluid can thus escape through that route.

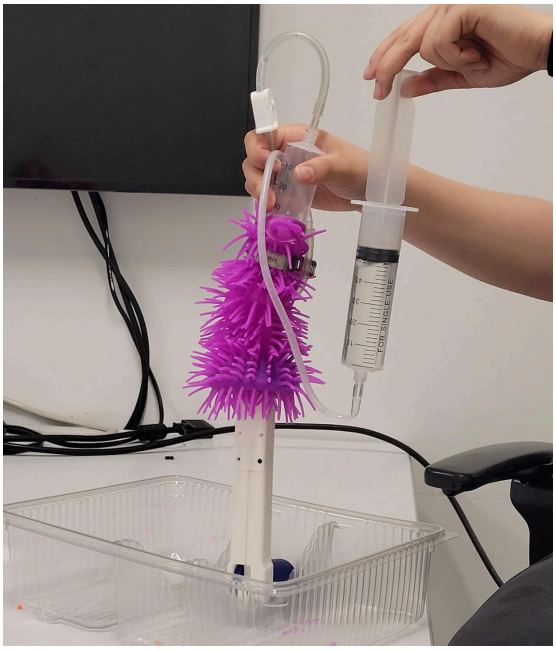


Figure 48. Testing setup for maintenance of pneumoperitoneum

004 Uterus removal: Not completed and deemed out of scope.

012 Vaginal fornix diameter: Colpotomy cups with diameters 2.5 and 5 cm were printed to verify the requirement of designing for various vaginal fornix diameters. See **Figure 49** for evidence. This method was deemed the only valid approach to verify this requirement.

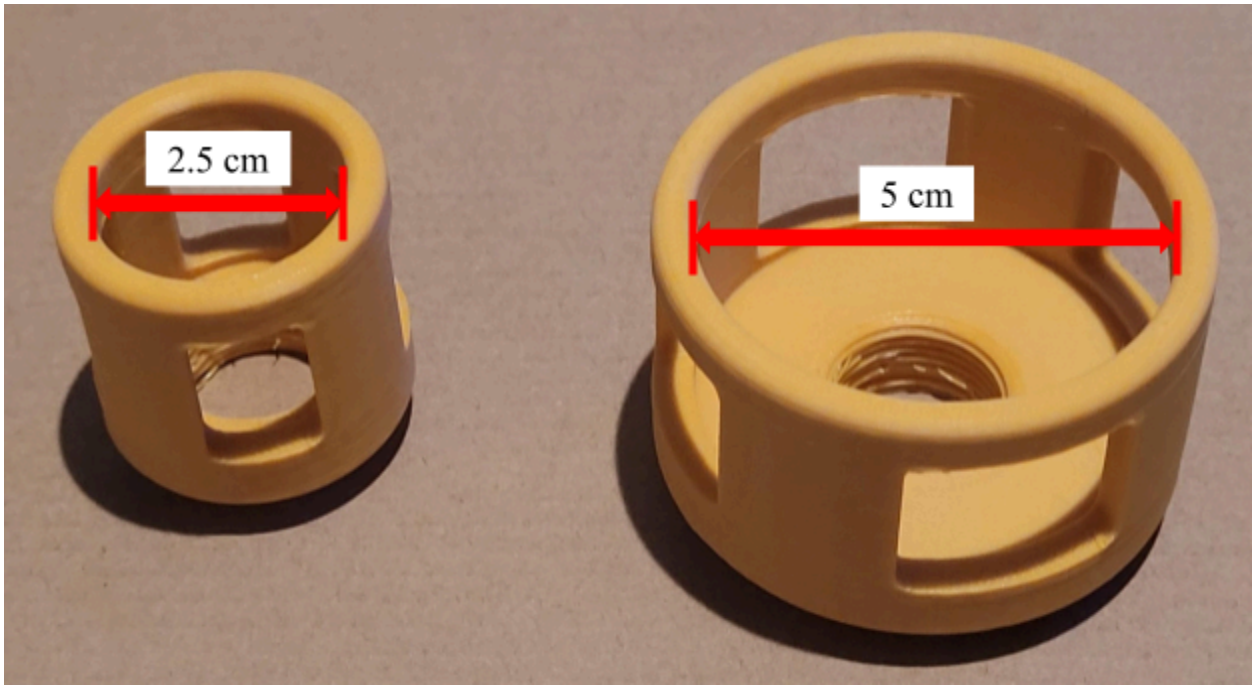


Figure 49. 3D printed 2.5 and 5 cm colpotomy cups.

013 Cervical channel diameter: Similarly to 012, the diameters of the parts past the trans-cervical portion of the UM were designed and measured to be ≤ 2 cm. The largest dimension past said point is tip shaft diameter which is 1 cm. **Figure 50** verifies the requirement. Note the balloon does not need to abide by this requirement since it is uninflated upon entry, and to be a reliable anchor it must be larger than the cervical entrance.

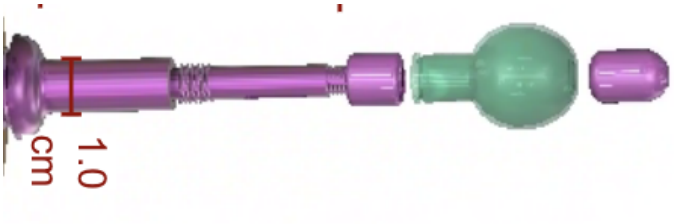


Figure 50. Image of the parts that pass the cervix.

015 Device weight: A weight analysis of the device was performed using SOLIDWORKS mass analysis features and summing the weights in a graph using MATLAB.

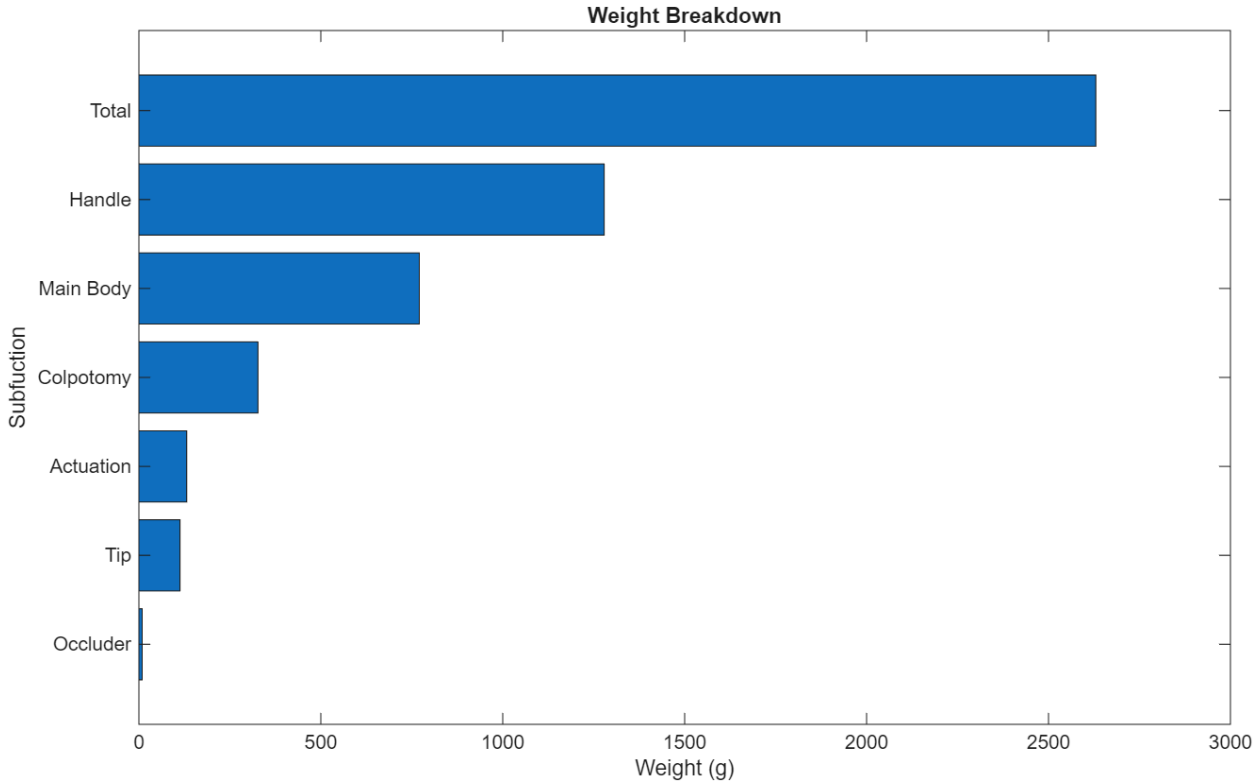


Figure 51. Weight breakdown of the device with total weight and weight for subfunctions. The total weight of the device is 2630g based on using the largest colpotomy cup and tip length.

019 Durability: Not completed.

020 Low cost: A GRANTA Edupack cost audit was conducted and off the shelf parts (i.e. springs and screws) were sourced from McMaster-Carr. The cost breakdown was condensed in a graph using MATLAB and can be seen in **Figure 52**.

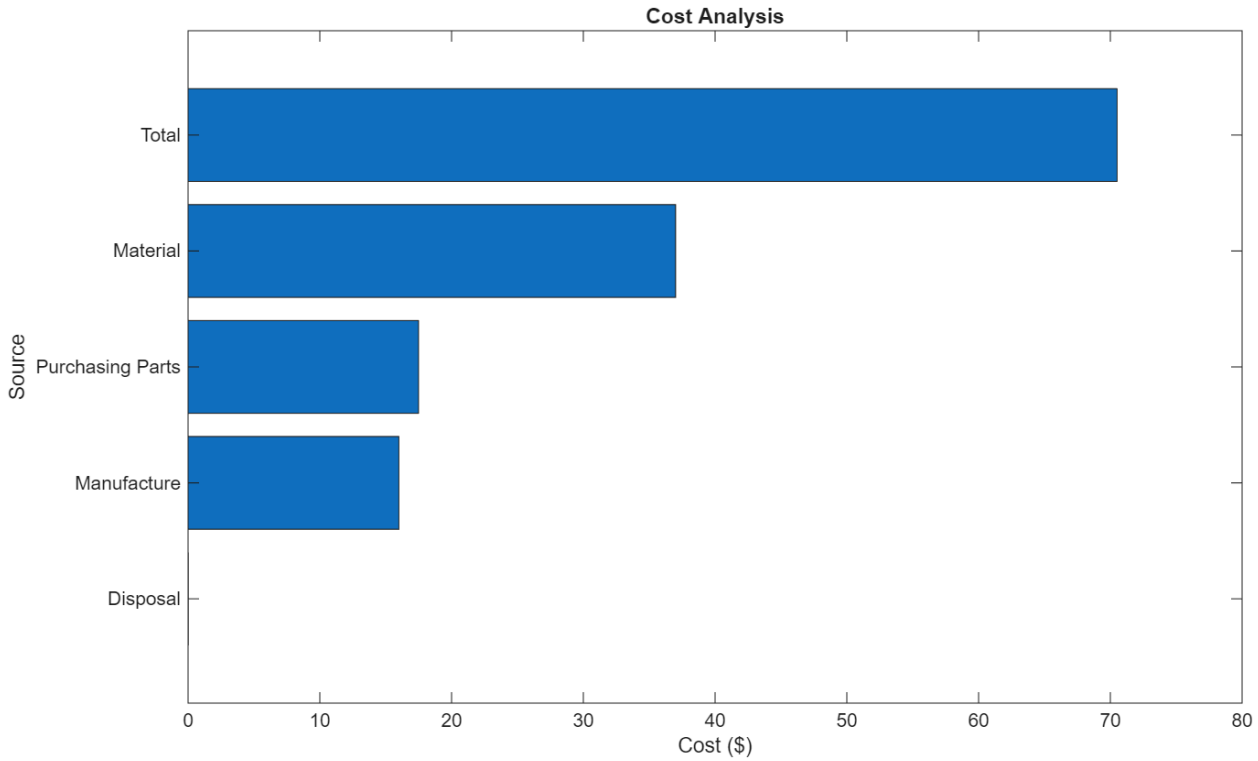


Figure 52. Cost analysis of the device using Granta EduPack. The total cost to produce one device is estimated to be $71.49.

Validation Approach

In order to test efficacy and reliability in real surgical environments, clinical trials represent the most rigorous pathway for validating Class II medical devices such as the UM. By evaluating device performance during TLHs, quantitative data on procedure time and complication rates can be obtained. Feedback from surgeons can help assess whether the design actually improves workflow in comparison to existing UMs. Additionally, performance on variable patient anatomy can offer a comprehensive measure of clinical effectiveness. While essential to proceed toward widespread adoption, clinical trials are resource intensive and require significant regulatory approval, time, and funding.

Summative usability testing with five surgeon assistants provides a focused lens on the device's ease of use and ergonomic design. By observing how trained users interact with the UM in simulated or controlled environments, the team can continue to identify challenges in assembly, handling, and operation. The primary limitation of this usability testing is the relatively small sample size, which may not fully capture the diversity of user experience levels or surgical preferences. Additionally, simulated environments cannot perfectly replicate the pressures or constraints experienced during an actual TLH.

Post-manufacture quality assurance focuses on ensuring that the UM meets safety and performance standards set, specifically edge smoothness and material finish. Inspection methods such as visual checks, surface roughness measurements, and material integrity testing can confirm that the device will not cause unintended damage to uterine tissue. A limitation is that it does not evaluate device performance in

functional or clinical contexts. Instead focusing on physical and material properties. As a result, it must be used in conjunction with other validation approaches to provide a complete assessment of the device.

Feasibility and performance demonstration

Overall feasibility of the design was able to be shown through verification of the physical prototype and theoretical analyses. While there were some trade offs to choosing to create a prototype mainly made of PLA, as opposed to metal, the overall functionality of the prototype does mimic the intended behavior of the final design. This was an appropriate decision for the course, as the quality of the PLA print was enough to demonstrate the form factor and functionality of the device. Overall, the team was able to reach a meaningful solution and level of verification. However, the team should have ideally completed verifying the device within the scope of the course.

The design passed 11 of the verification tests that the team was able to perform during the project. These tests include both physical testing and literature review. While it cannot be for certain because of the slight design changes associated with the prototype, the team is confident that these verifications prove that the device meets these specifications.

Despite the successes of the design, there are still uncertainties and improvements to be had. For starters, the current design is confirmed to fail two verification tests: device weight and maintenance of pneumoperitoneum. The team has identified some recommendations to move towards passing these tests.

For device weight, there are two approaches that can be taken: reduction of material and different material choices. In many parts of the design, there are sections that are made of solid metal. While this does provide strength to the overall design, there are likely places where some material can be removed without risking device failure. The most likely places where this would be applicable would be in the main body shaft pieces, the handle, and the colpotomy cup as shown in **Figure 53.**

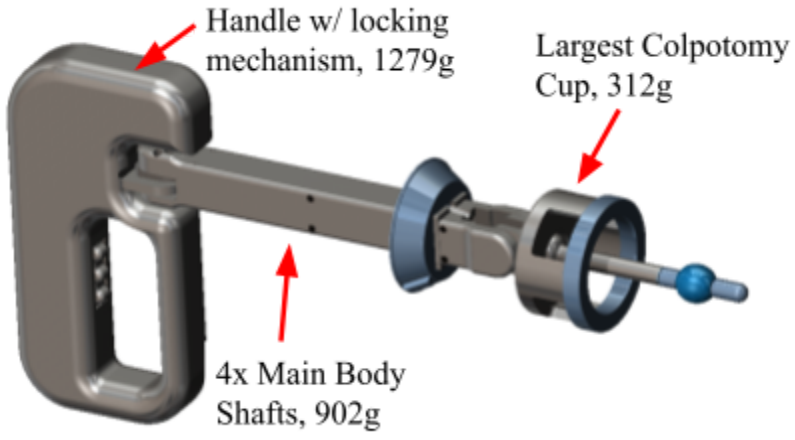


Figure 53. Most likely locations for weight reduction.

The other option for weight reduction would be to use different build materials. A large portion of the device is made of metal with a high density. While metal is required in many places due to biocompatibility and sterilization concerns, the handle is not one such location. Because this portion of

the device is not intended to come in direct contact with a patient's tissue, it has slightly less strict sterilization standards. The team has identified that, in theory, it would be possible to make the handle out of a biocompatible and sterilizable plastic; however, the team has not done thorough enough research to confidently recommend a specific material for this purpose.

Regardless of the approach, the team recommends that a majority of the weight reduction efforts be directed towards the handle. **Figure 51** previously shows the breakdown of device weight where it can be seen that a majority of the weight of the device is located in the handle.

For passing the maintenance of pneumoperitoneum specification, the team recommends the implementation of gaskets. This includes a gasket inside of the main body shaft, wrapped around the scotch yoke bar, to seal the inside of the shaft and gaskets running along the edges of the tip-half body shaft pieces, in a manner similar to that shown in **Figure 54.** Ideally, these gaskets should be attached to existing parts of the device to minimize the number of loose parts that could be lost. These two gaskets, along with the occluder disk, should create an air tight seal between the vaginal canal and the device.



Figure 54. Gasket (red) implementation example to meet maintenance of pneumoperitoneum specification.

In addition to the failed verification tests, there are also some specifications that the team was not able to verify and is not confident that the design will pass if testing is performed. This includes the durability, ease of use, and uterus removal. The team is worried about durability requirements because no test or proxy test was performed, and there were some fatigue failures that occurred during the prototyping of the design. Ease of use is concerning to the team because this testing is highly subjective and the implications of this testing determines if people are able to and/or like using the device. User testing revealed that the current device does have some ergonomic issues that should be addressed. Uterus removal within the current design is entirely undeveloped and unfortunately was not a focus of this project; more information on this topic will be provided in the discussion section.

One improvement that the team recommends is to improve or remove the screw connections within the device. Most notably, this would be the screws securing the main body shaft components together. During assembly testing, this step was identified as a major bottleneck and was verbally noted as quite tedious for

all participants. **Figure 55** presents the breakdown from this assembly testing, where it is clear that the screws took significantly longer than the other steps in the assembly process.

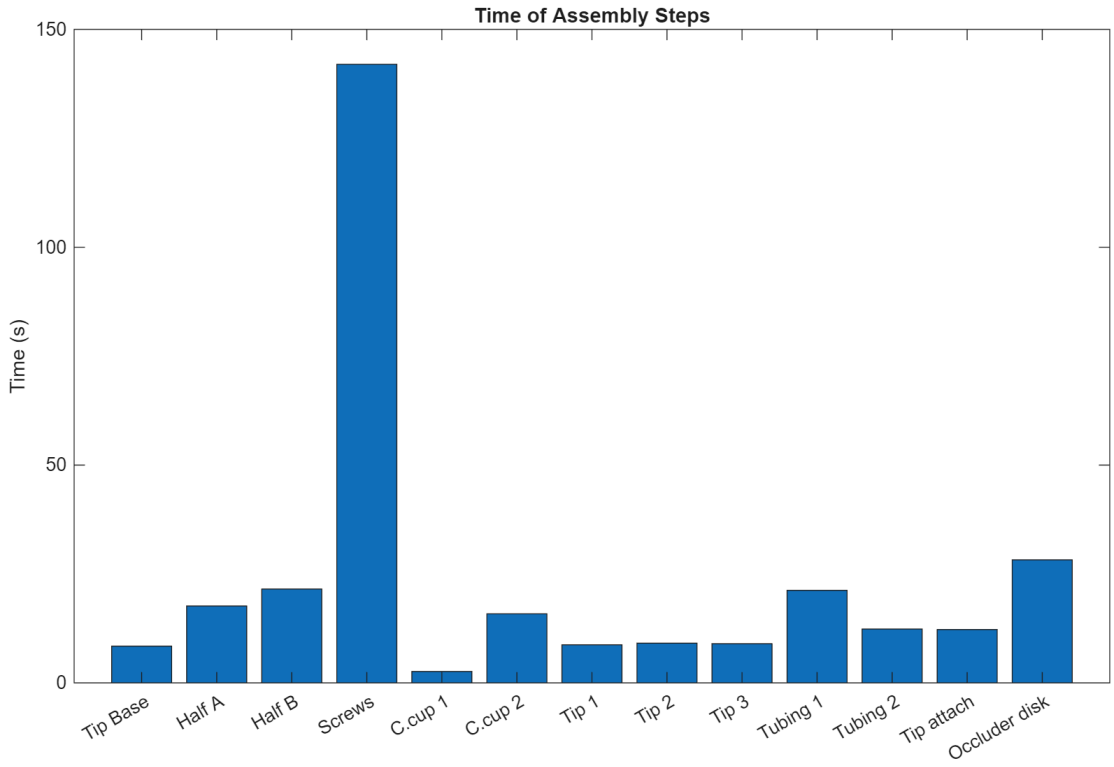


Figure 55. Average times from assembly testing.

The team recommends switching these connections, and possibly other connections on the device, to some kind of snap connector, or significantly reducing the length that needs to be screwed in at connection points.

Discussion and Recommendations

The largest underexplored facet of the design was the uterus removal subsystem that was ultimately dropped from the build model. It became clear to the team that our foundation of knowledge about the uterus removal process was lacking, which led to bottlenecks in the ideation phase for the subsystem. This was especially true during the second attempt at ideating for uterus removal when the team struggled to come up with ideas to facilitate removal of enlarged uteri in particular. It was at this stage in early April that the subsystem was retired from the scope of the ME450 project.

The most obvious weaknesses at the moment are the weight and inability to maintain pneumoperitoneum. The device currently weighs in at over 250% of the specified maximum, with most of the weight coming from the handle and main body subsystems. Currently, the weight verification test currently has the handle casing set as stainless steel, so updating that to aluminum will substantially reduce the mass of the current heaviest subsystem. Lightweighting by introducing cutouts along the yoke link and a structural redesign of the handle to reduce bulk will further lower the weight, making this fairly low-hanging fruit

for future work. To fix the pneumoperitoneum subsystem, gaskets should be implemented into the main shaft design as discussed in the feasibility section.

Other potential areas for future improvement include the attachment design for the occluder; the cutout that wraps around the main shaft should have about 1mm more ease built into every side to avoid stretching and warping the occluder while in use. The closure should be more robust and extend the entire radius of the occluder and wrap around the bottom to keep it secure as well.

A major strength is the actuation mechanism; even without bearings and with PLA material tolerances, the actuation was remarkably smooth and easy to control using the handle. A risk we encountered was establishing the locking mechanism. We wanted the device to be able to lock at small intervals, but with the material constraint of PLA it was decided to choose only five discrete locking positions instead.

Reflection

Societal Context and Reflection— Our design prioritizes reusability and costing, which will enable higher adoption rates of laparoscopic procedures in low-resource settings, improves the welfare of patients through faster and less painful recovery periods. With our commitment to serviceability without specialized tools, we avoid the pitfall of the many medical devices that get decommissioned in low resource settings because they are not serviceable or depend on disposables that are not available, thus reducing the social and economic burden on users. On the other hand, this model of development is much more difficult for medical device companies to make money from devices that rarely need to be replaced vs. devices that are partly or totally disposable generate revenue at a much higher rate.

To analyze the societal context of our design, we started by mapping our stakeholders and considering their needs through stakeholder engagement and review of literature regarding the background. Because our project is so rooted in societal issues, a few of our specifications (low cost, repairability, etc) are specifically geared towards maximizing the societal benefit of the design, and our cost analysis incorporates that as well.

Team and Sponsor Reflection— All of the members have experience navigating the intersection of their personal identities. Combined with a prioritization of communication across the board and a successful history of teamwork between various subsets of the team, this formed a strong foundation to work from. Stylistic differences were largely accommodated by how the focus of tasks were set; for instance, breaking tasks down to extremely granular details for one member, or keeping a broader overview on the to-do list for another. Throughout the semester, collaboration was emphasized at every decision point and particularly for concept generation and subsequent iterations. Nonetheless, each member led an aspect of the project for which they acted as the team “expert”.

The power dynamics between the team, project sponsor, and stakeholders are important considerations in this project. The project sponsor, Dr. Thiyag, holds a unique position within the context of ME 450 because of their past affiliations with the University of Michigan College of Engineering. This creates a dynamic of not only the project sponsor, but also an engineering mentor for the team. Her varied experiences as an engineer and OB/GYN, and as someone with experience working with healthcare

systems in low-resource settings were instrumental in fine-tuning our understanding of the context that we were designing for. However, with her busy schedule, it was difficult to find enough time to meet with her and really connect to ensure that she and the team were fully on the same page. Stylistically and knowledge-wise, it was often a challenge for the team to formulate questions that conveyed exactly what they were hoping to learn, and there was often a disconnect between what Dr. Thiyag knew through experience and what the team had learned from research. The largest effect of this was the loss of our uterus removal subsystem, which was abandoned within the scope of the semester due to a misunderstanding of the fundamental need case driving the subsystem.

Ethics— The team had various social and ethical aspects to consider throughout the project, much of which has previously been discussed. To reiterate, firstly, in the context of UMs, all of the disposable devices found during benchmarking were made almost entirely of plastic. This poses environmental sustainability issues in both their production and disposal, which is exacerbated by the fact that many LRSs do not have the infrastructure to dispose of these devices properly [67]. Secondly, the acquisition of disposable devices poses issues. On a per use basis, disposable devices tend to be more expensive than reusable ones. This approach ultimately worsens financial barriers for low and middle resource settings. Additionally, some low resource settings do not have the infrastructure in place to physically receive devices from device manufacture [68]. This barrier may be overcome feasibly if the retrieval of the devices is infrequent, such as with reusable devices, however frequent restocks of supplies is impossible in some of these settings thus further promoting the need for frequency delivered donations. When UMs cannot be obtained and reusable ones are out of commissions, gynecological care is often limited [16]. Given this and all of the above, it became even more clear that the goal of this project should be to improve access to healthcare by creating a device that is economically, socially, and environmentally sustainable in LRSs. The team believes that of the three, prioritizing social sustainability will lead to the greatest benefits to stakeholders and also believes that this is the mindset of the project sponsor as well.

While the team expects that this approach will maximize the positive social impact of the project, this may require some sacrifice in the design of the device. Prioritizing social sustainability will require adapting to the systems and methods that are currently in place in many LRSs. This will directly alter the way in which the device is implemented and maintained in a health care environment. Manufacturing and disposal of the device will need to conform to the systems that are typically in flow resource settings, which may impact material selection and manufacturing location.

Manufacturing, use, and disposal choices that prioritize social impact could result in undesired environmental effects through the consumption of finite resources or pollution. For example, choosing a local manufacturer would likely increase access to the device, but the local manufacturer may not be as environmentally conscious as a foreign manufacturer. In cases like this, the team will need to take steps to research the direct and indirect effects of all design choices, and weigh them against the anticipated benefits. When choices like this have to be made, it will be particularly important to explore the long term effects of these choices and adapt the solution as necessary to minimize the long term negative impacts.

Prioritizing social impact may lead to some ethical dilemmas for the team. Like in the previous example, the team may have to choose to use a local manufacturer in the name of accessibility even if they are aware that the manufacturer is not environmentally sustainable. A choice like this would be hard for the

team to make, however, the best way to approach this dilemma would be to think objectively about the situation: the benefit of providing healthcare may outweigh the current negative environmental impacts, but steps should be taken to minimize the long term effects. Additionally, choices will likely need to be made around the standards that the device is going to conform to, and these choices may result in a design that does not conform to every standard set for high resource environments. Again, these decisions will need to be made with the mindset of providing the greatest social impact in the given context. This mindset likely aligns with the professional ethics that the team is expected to uphold while working on behalf of the University of Michigan. Future employers, however, will likely have different ethics on these topics due to differing legal and economic priorities. If ethical dilemmas arise that cannot be solved using the utilitarianist approach, the team has been made aware of a few other ethical decision making tools that could help guide the decision making process. For example, developing an empathy map to gain better understanding of stakeholder impact or performing an universality test for a given choice.

Conclusion

Despite more favorable patient outcomes than open-abdomen surgery, access to laparoscopic surgery in low-resource settings is limited due to expensive, single-use instrumentation. One critical instrument used for laparoscopic hysterectomies and similar procedures is the uterine manipulator, used to position the uterus for optimal surgeon access and visualization.

The goal of this project was to design a uterine manipulator with robust insertion, articulation, and uterus removal mechanisms. Safety, sterilization, and suitability for use in low-resource settings were prioritized. Over the course of the semester, the team was able to deliver a uterine manipulator design with 140° range of motion, full cleanability and sterilizability, and independence from specialized tooling to perform repairs. Thus, despite notable opportunities remaining to improve the occluder and user interface aspects of the device, the solution has very high prospective value for use in low-resource settings.

Acknowledgements

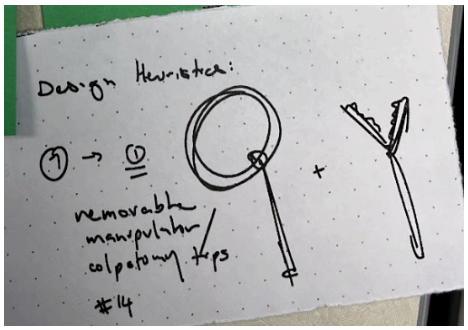
Thanks to Dr. Kathleen Sienko, Dr. Dhanalakshmi Thiyagarajan, Dr. Kwabena Ababio, Don Wirkner, Kemal Duran, Dr. Shorya Awtar, and Sarah Barbrow for their guidance.

Appendices

Appendix A: Full Concept Generation List

Depth Control, Fit, & Adjustability (23)

- Pin slide lock
- Outside hard stop
    - Outside of the body
    - Cups/caps?
- Slider with teeth (e.g. box cutter)
- Color indicator
    - Thermal

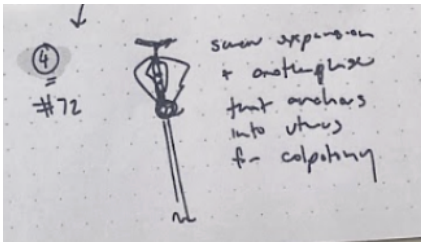
    - pH
- Screws
    - Set screws
    - Worm
- Material shrinks
    - Folding/origami inspired material
    - Chinese finger traps
    - Hydraulic, pneumatic (pressure driven length control)
    - Telescoping
- Alarm when tip is x mm away from uterine wall
    - Ultrasonic sensor
- Extend uterus instead of changing the UM
    - Cage
- Different tip lengths
    - Interchangeable tips with different lengths OR adjust length of a standard
- Tape
- Clamp
    - Chip clip to start
- Placement methods
    - Abdominal Placement Method
    - External placement method, nothing in body
    - Vaginal placement method
- 

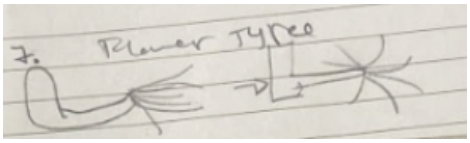
- Multiple cup sizes, device interchangeable
- Elastic cup that can grab onto cervix

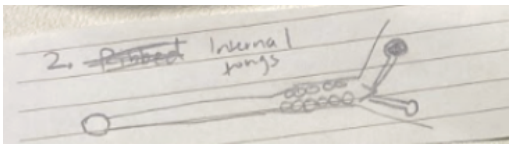
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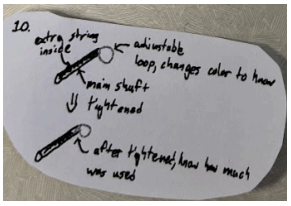
- Flower (Expanding)
    - Exploding petals
    - Screw cage 

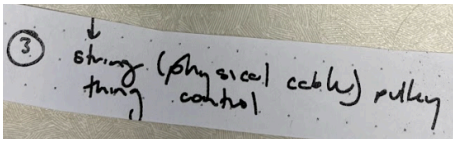


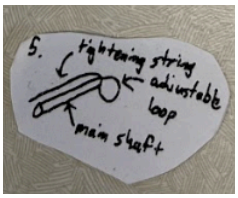
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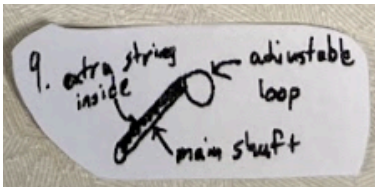
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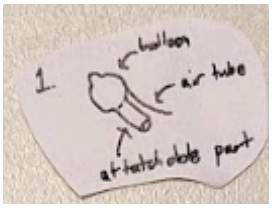
- String
  - Thread (thread the uterus)
  - Attach string to uterus and capture the UM
    - 

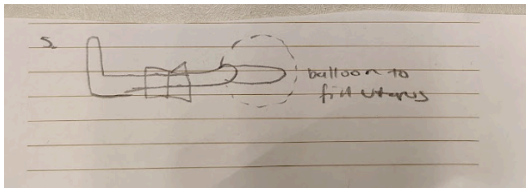
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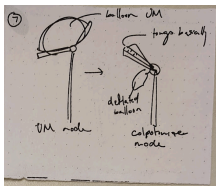
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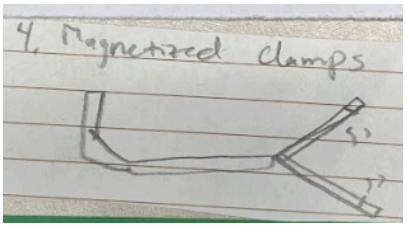
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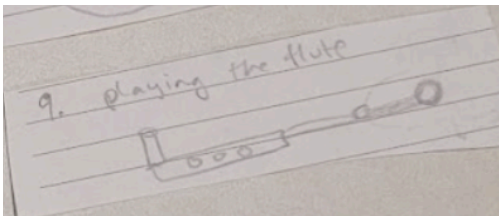
- Balloons
  - Diva cup
  - Expanding ball toy
  - armor plate thing expanding into orb
  - balloon that adheres to the uterine wall

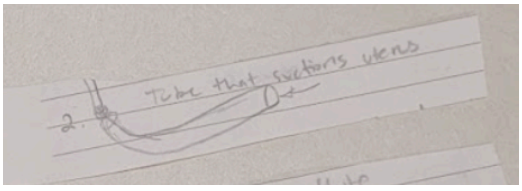
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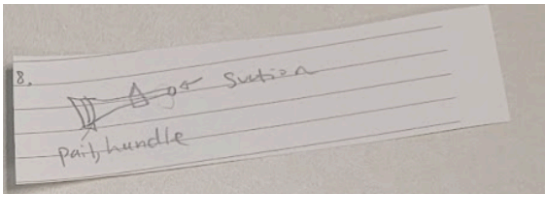
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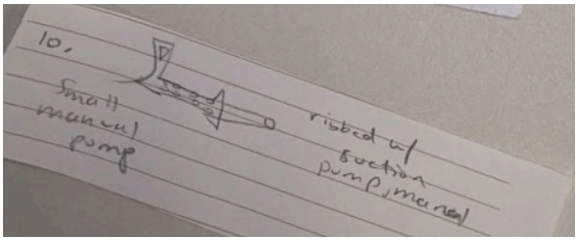
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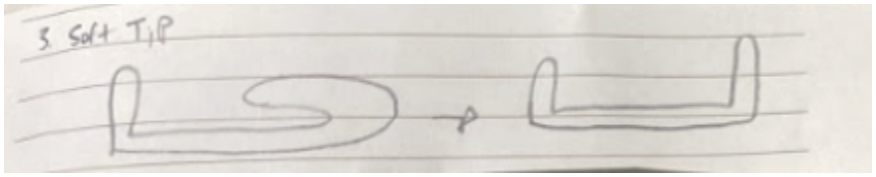
- Weight
- Magnets
  - 

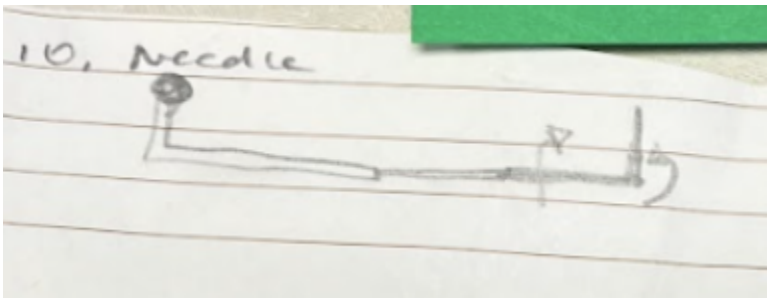
  - Magnets inside/outside
- Glue to uterus
- Flat plate
- Small balls cased in device with micro needles
- Suction
  - Tissue suction
  - Active/passive suction cups
    - 

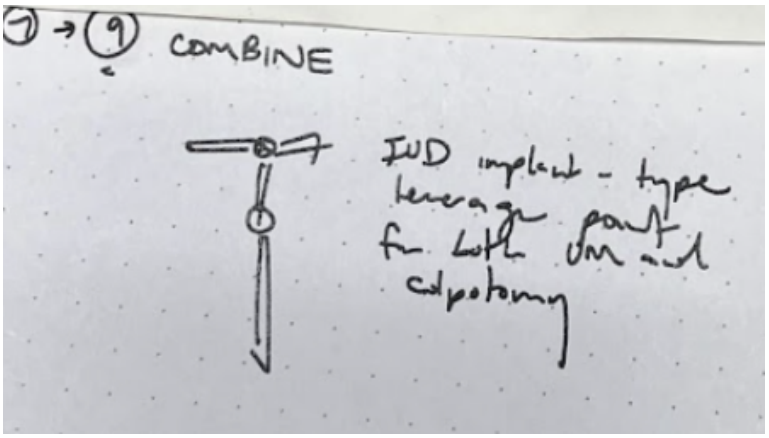
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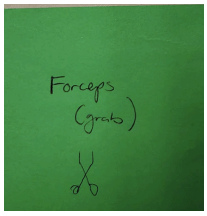
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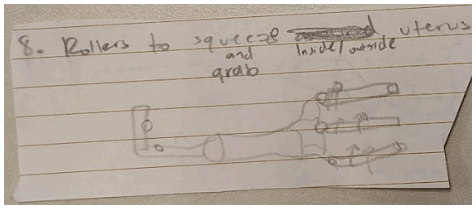
- Squeeze cervix opening
  - Around colpotomy cup
  - Tourniquet
- L-brackets
  - IUD core
- Unidirection piercing/implant
- One way gate
- Pierce
  - 

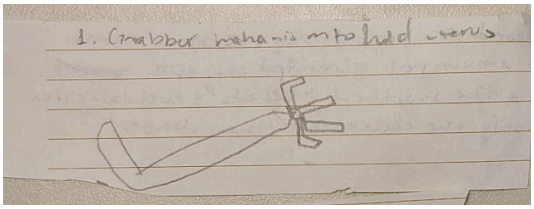
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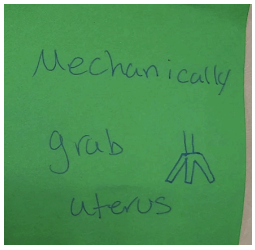
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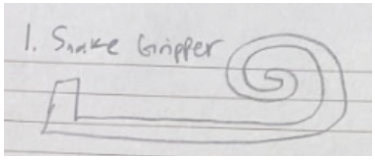
- harpoon/fish hook to grab uterus
- grabbers:

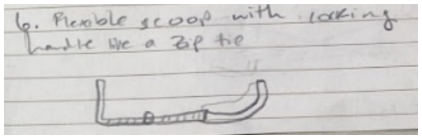


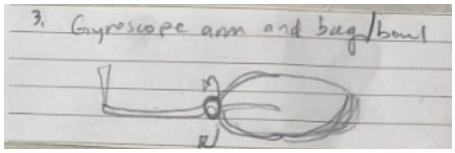






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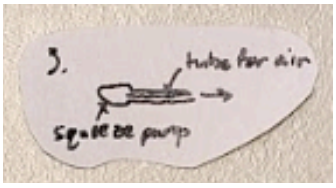
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Main Body (24)

- Squishy
  - Snake
  - Fluid-filled
- Knife
- S-curve
  - various curvatures
  - c-shape
- Rod
  - worm gear
  - metal shaft
  - flat rod
  - flexible ribbon thing
  - slap bracelet
  - hollow

- Materials
    - plastic
    - steel
    - sterilizable
    - not super poky
    - liquid-solid
    - malleable
- includes depth sounding
    - gradation marks
    - telescope
    - scissor lift
    - ultrasound
    - built in stopper
- thickness (dilation)
    - thin then thick
- ribbed body

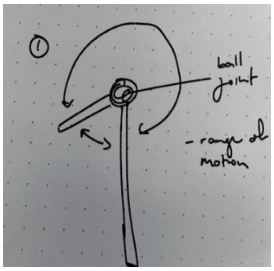
Controls (User Interaction) (23)

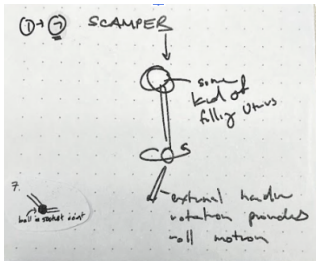
- Direct (nothing)
- Handle
    - Latch
    - Handlebars
    - Shape forming material
    - moldable handle
- Remote control
    - Magnet repulsion
    - Sensors
        - Thermal
        - Finger input
    - Joystick/WASD
- Trigger
    - Squeeze interaction
        - Pump
        - 

- Wind/air
    - Pneumatic/hydraulic (bike brakes)
- Steering Wheel
    - Rack + pinion
- Knobs/dials
    - Progressive

    - Twist
        - Nested cylinders
    - Doorknobs
- Pulling strings (tension)
    - Marionette
- Button
    - Toggle (push -> holds)
- Single action (push -> does action)
- Slider
- Crank
    - Counter weight (like crane)
    - Ratchet
- instruction manual

Control Mechanism (Actuation Method/Mechanics) (36)

- Hydro + pneumatic
    - Lil tubes
- Motors
    - Sterling engine
- Electronic controls
    - robotic actuator
- Gyroscope
- Ball joint
    - 



- Piezoelectrics
- Rollers
    - Flywheel
    - Potential to kinetic energy
- Spring
- Piston
    - Actuator
- Gravity
    - Move Patient around, let gravity move uterus
- Magnets
- Vibrations
    - Sound
    - Jiggle
- Gears

    - Worm
    - Bevel
    - Rack + pinion
    - Chain + sprocket
    - Cam + follower
- Bearings
    - Roller
    - Bearings
- Pulley
- Swivel
- Linkages
    - 4 bar
    - Many bar
    - Pull/push one end to rotate opposite end
- Direct control (stick)
    - Seesaw
    - Inverted seesaw
- Sunflower (light following)
- Squeeze/deform material
- ratchets
    - to open/close jaws/branches
    - to change angle of manipulator
- side wheel with locking pins
- Electrical Stimulation
- Dissolve the Uterus

Colpotomy Assistance (22)

- Depth Gauge
- Draw/Mark
    - Marker
    - Tattoo
- Sonar
- Liquid Mold
    - Slime
    - Fluid shape around during
- Physical Cervix Covers
    - Fabric/cloth
    - Tape
    - Cups
        - One vs. multisized
    - Glue
        - Adhesives
    - Guide Slots
    - Ring

    - Guide spacers for incisions
- Sensor
    - Ultra sound
- Laser
    - target/scope
- Air pressure
- Tissue Expander
    - Telescope
    - Clamps
    - Mechanical Mechanisms
    - Springs
    - In then spread
- Adjustable loop stick like a dog leash thingy

Maintain Pneumoperitoneum (14)

- External
    - Separate incision add pressure
- Balloon
- Clamp
    - Ziptie
    - Tourniquet
- Hydraulic
    - ΔP using water
- Cup
    - Diva
- Glue shut to device
- Air lock
    - Gates/phases
- Cork
    - Cone
- Pressurize room
- Freeze time
- Flexible material seal
    - Plastic
    - Fabric
    - Liquid to solid mold

Uterus Removal (34)

- Magnets
    - Colpotomy - device that embeds a magnet into uterus and uses that to pull the uterus out
    - Attraction/repulsion
- Grab from inside
    - Balloon

    - Mechanical
- String
    - Cut uterus into string
    - Spiralize
    - Tie around
- Pliers
    - Locking forceps situation
- Twisting
    - Thread/tap w/screw
- FIsh hook
    - Stabber
    - Barbed arrow
- Outside gripper
    - Snake around
- Let it fall out
- Ask uterus to leave nicely
- Aide removal
    - Speculum
    - Cervix spreader
- Slide
- Take out through abdomen
- Teleport out
- Scoop
    - Hand
    - Ice cream-esque
- Phase through body
- Suction/vacuum
    - Funnel
    - leeches
- Pop out w/ high pressure
    - Fill w/something
        - Orbeez
        - Air
        - tadpoles
- Dissolve
    - Shrink people to push it out
    - Melt
    - Change state (phase change)
    - Full dissolve
- Grab from inside
    - Balloon
    - Mechanical
- External
    - Snake gripper around uterus

Appendix B: Full Concept Down-Selection

Red Highlight - Removed via to 'Go-No go'

Blue Highlight - Removed via reusability requirement

Green Highlight - Removed via biocompatibility and sterilization requirements

Maroon Highlight - Removed via gut check

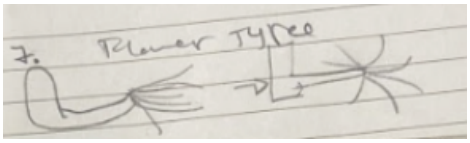
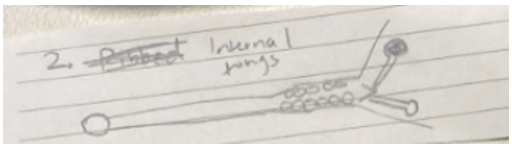
~~**Strikethrough**~~ **-** Iterated upon, combined, or removed

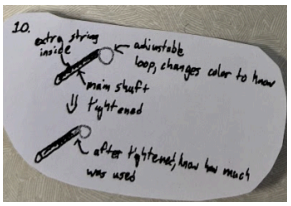
Depth Control, Fit, & Adjustability (23)

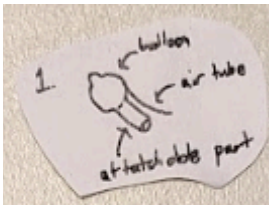
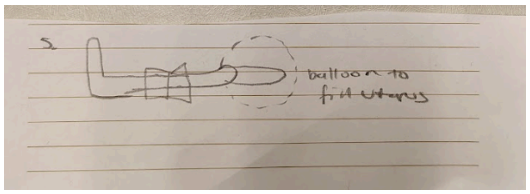
- Pin slide lock
- ~~Outside hard stop~~
    - ~~Outside of the body~~
    - ~~Cups/caps?~~
- Slider with teeth (e.g. box cutter)
- Color indicator
    - Thermal
    - pH
- Screws
    - Set screws
    - Worm
- ~~Material shrinks~~
    - Folding/origami inspired material
    - Chinese finger traps
    - Hydraulic, pneumatic (pressure driven length control)
    - ~~Telescoping~~
- Alarm when tip is x mm away from uterine wall
    - Ultrasonic sensor
- ~~Extend uterus instead of changing the UM~~
    - ~~Cage~~
- Different tip lengths
    - Interchangeable tips with different lengths OR adjust length of a standard
- Tape
- Clamp
    - Chip clip to start
- ~~Placement methods~~
    - Abdominal Placement Method
    - External placement method, nothing in body
    - ~~Vaginal placement method~~
- Multiple cup sizes, device interchangeable
- Elastic cup that can grab onto cervix

Anchor (35)

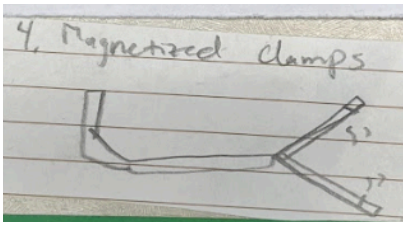
- Flower (Expanding)
    - Exploding petals

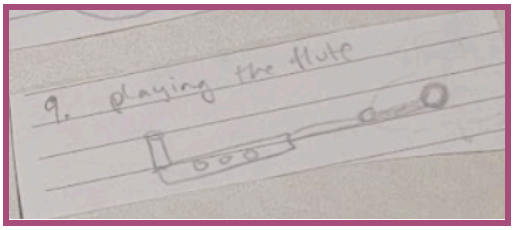
- Screw cage  
- 
- 

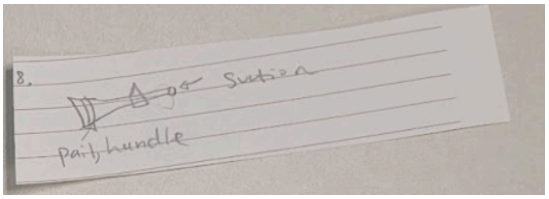
- String
  - Thread (thread the uterus)
  - Attach string to uterus and capture the UM
  - 

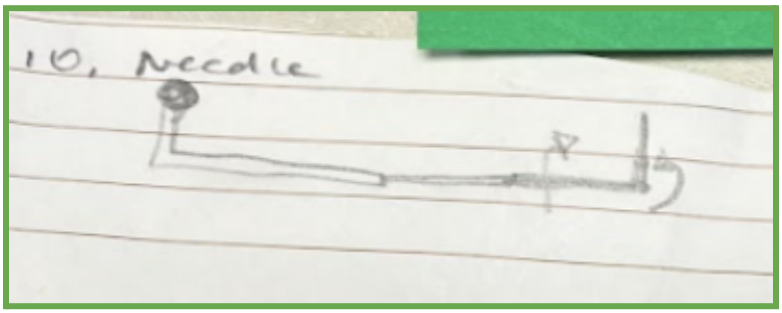
- Balloons
  - Diva cup
  - Expanding ball toy
  - armor plate thing expanding into orb
  - ~~balloon that adheres to the uterine wall~~
  - 
  - 

- ~~Weight~~
- Magnets

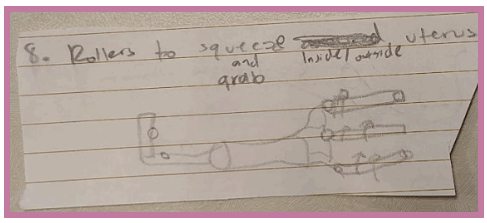
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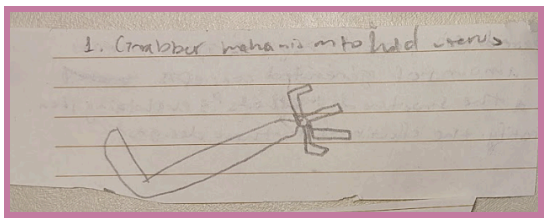
  - Magnets inside/outside
- Glue to uterus
- Flat plate
- Small balls cased in device with micro needles
- Suction
  - Tissue suction
  - Active/passive suction cups
    - 

    - 

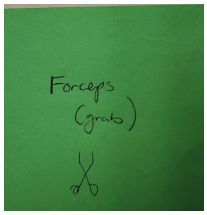
- Squeeze cervix opening
  - Around colpotomy cup
  - ~~Tourniquet~~
- L-brackets
  - IUD core
- ~~Unidirection piercing/implant~~
- ~~Adjustable loop stick like a dog leash thingy~~
- One way gate
- Pierce
-
  - 

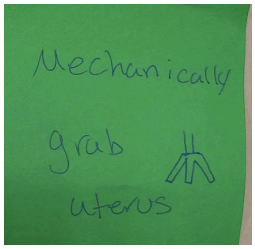
  - harpoon/fish hook to grab uterus

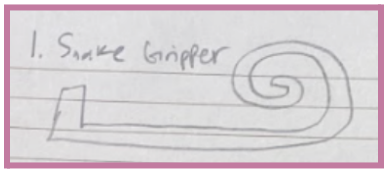


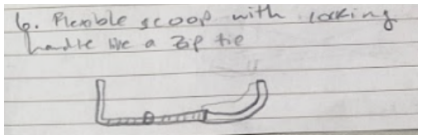


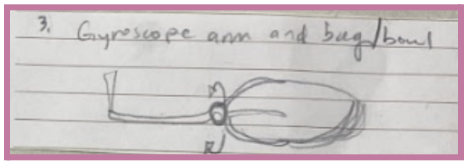
- grabbers:





- 

- 

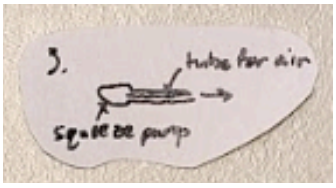
- 

Main Body (24)

- Squishy
  - Snake
  - Fluid-filled
- Knife
- S-curve
  - various curvatures
  - c-shape
- Rod
  - ~~worm gear~~
  - metal shaft
  - flat rod
  - flexible ribbon thing
  - slap bracelet
  - hollow

- Materials
    - ~~plastic~~
    - steel
    - ~~sterilizable~~
    - ~~not super poky~~
    - liquid-solid
    - malleable
- includes depth sounding
    - gradation marks
    - telescope
    - scissor lift
    - ultrasound
    - built in stopper
- thickness (dilation)
    - thin then thick
- ribbed body

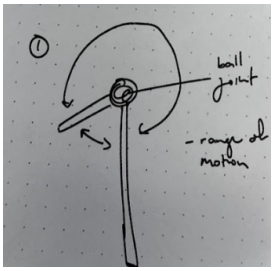
Controls (User Interaction) (23)

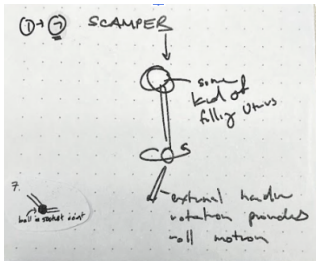
- ~~Direct (nothing)~~
- Handle
    - Latch
    - Handlebars
    - Shape forming material
    - moldable handle
- Remote control
    - Magnet repulsion
    - Sensors
        - Thermal
        - Finger input
    - Joystick/WASD
- Trigger
    - Squeeze interaction
        - Pump
        - 

- Wind/air
    - Pneumatic/hydraulic (bike brakes)
- Steering Wheel
    - Rack + pinion
- Knobs/dials
    - Progressive

    - Twist
        - Nested cylinders
    - Doorknobs
- Pulling strings (tension)
    - Marionette
- Button
    - Toggle (push -> holds)
- Single action (push -> does action)
- Slider
- Crank
    - Counter weight (like crane)
    - Ratchet
- instruction manual

Control Mechanism (Actuation Method/Mechanics) (36)

- Hydro + pneumatic
    - Lil tubes
- Motors
    - Sterling engine
- Electronic controls
    - robotic actuator
- Gyroscope
- Ball joint
    - 



- Piezoelectrics
- ~~Rollers~~
    - ~~Flywheel~~
    - Potential to kinetic energy
- Spring
- Piston
    - Actuator
- Gravity
    - Move Patient around, let gravity move uterus
- ~~Magnets~~
- Vibrations
    - Sound
    - Jiggle
- Gears

    - Worm
    - Bevel
    - Rack + pinion
    - Chain + sprocket
    - Cam + follower
- ~~Bearings~~
    - ~~Roller~~
    - ~~Bearings~~
- ~~Pulley~~
- Swivel
- Linkages
    - 4 bar
    - Many bar
    - Pull/push one end to rotate opposite end
- ~~Direct control (stick)~~
    - Seesaw
    - Inverted seesaw
- Sunflower (light following)
- Squeeze/deform material
- ratchets
    - to open/close jaws/branches
    - to change angle of manipulator
- side wheel with locking pins
- Electrical Stimulation
- Dissolve the Uterus

Colpotomy Assistance (22)

- ~~Depth Gauge~~
- Draw/Mark
    - Marker
    - Tattoo
- Sonar
- Liquid Mold
    - Slime
    - Fluid shape around during
- Physical Cervix Covers
    - Fabric/cloth
    - Tape
    - Cups
        - One vs. multisized
    - Glue
        - Adhesives
    - Guide Slots
    - Ring

    - Guide spacers for incisions
- Sensor
    - Ultra sound
- Laser
    - target/scope
- Air pressure
- Tissue Expander
    - Telescope
    - Clamps
    - ~~Mechanical Mechanisms~~
    - Springs
    - ~~In then spread~~

Maintain Pneumoperitoneum (14)

- External
    - Separate incision add pressure
- Balloon
- Clamp
    - Ziptie
    - Tourniquet
- Hydraulic
    - ΔP using water
- Cup
    - Diva
- Glue shut to device
- Air lock
    - Gates/phases
- Cork
    - Cone
- Pressurize room
- Freeze time
- Flexible material seal
    - Plastic
    - silicone
    - Fabric
    - Liquid to solid mold

Uterus Removal (34)

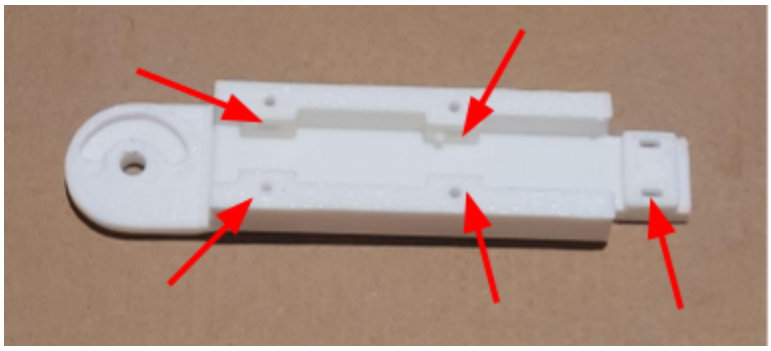
- Magnets
    - Colpotomy - device that embeds a magnet into uterus and uses that to pull the uterus out
    - Attraction/repulsion
- Grab from inside
    - Balloon

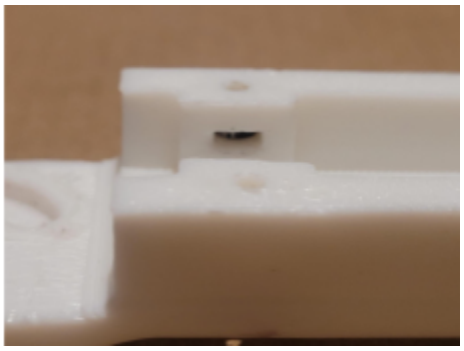
    - Mechanical
- String
    - Cut uterus into string
    - Spiralize
    - Tie around
- Pliers
    - Locking forceps situation
- Twisting
    - Thread/tap w/screw
- FIsh hook
    - Stabber
    - Barbed arrow
- Outside gripper
    - Snake around
- Let it fall out
- Ask uterus to leave nicely
- Aide removal
    - Speculum
    - Cervix spreader
- Slide
- Take out through abdomen
- Teleport out
- Scoop
    - ~~Hand~~
    - Ice cream-esque
- Phase through body
- Suction/vacuum
    - Funnel
    - leeches
- Pop out w/ high pressure
    - Fill w/something
        - Orbeez
        - Air
        - tadpoles
- Dissolve
    - Shrink people to push it out
    - Melt
    - Change state (phase change)
    - Full dissolve
- Grab from inside
    - Balloon
    - Mechanical
- External
    - Snake gripper around uterus

Appendix C: Build Design Manufacturing/Fabrication Plan

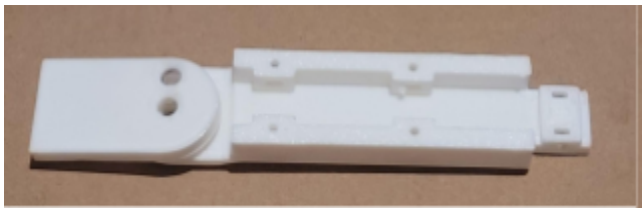
3D print all components and cut the locking pin, handle pins, handle central pin, and handle actuation pin to length with rod shears and deburr the edges.

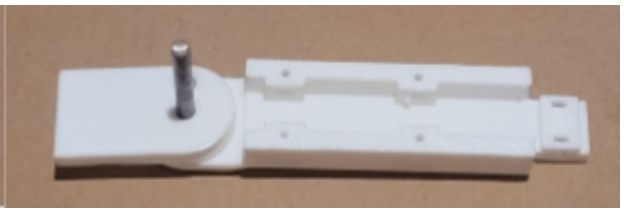
1) Locate handle end housing 1 and install five nuts into the nut cutouts. Ensure that housing 1 is selected



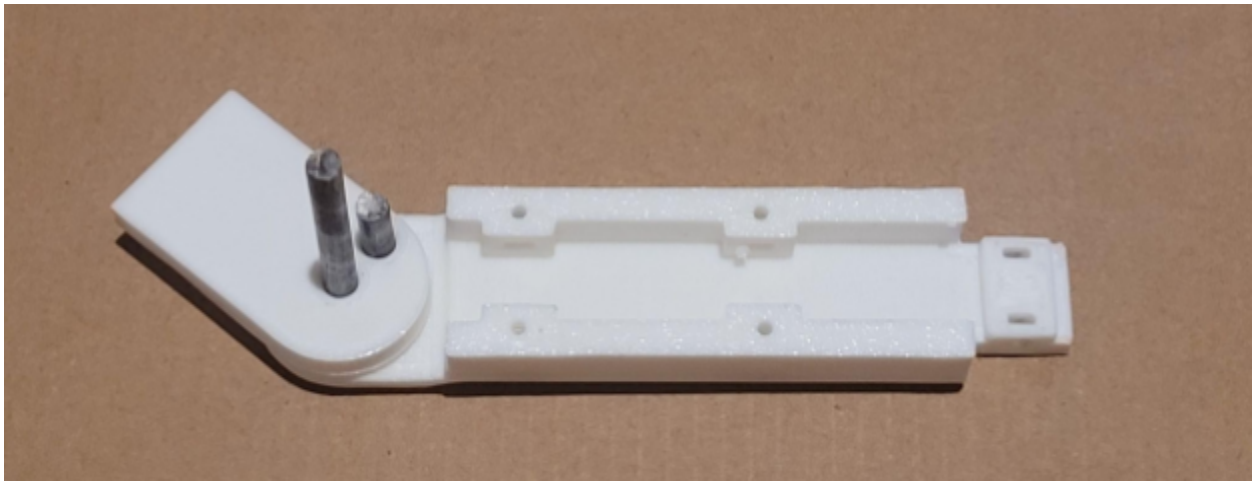


2) Place the Interface key and insert the handle central pin

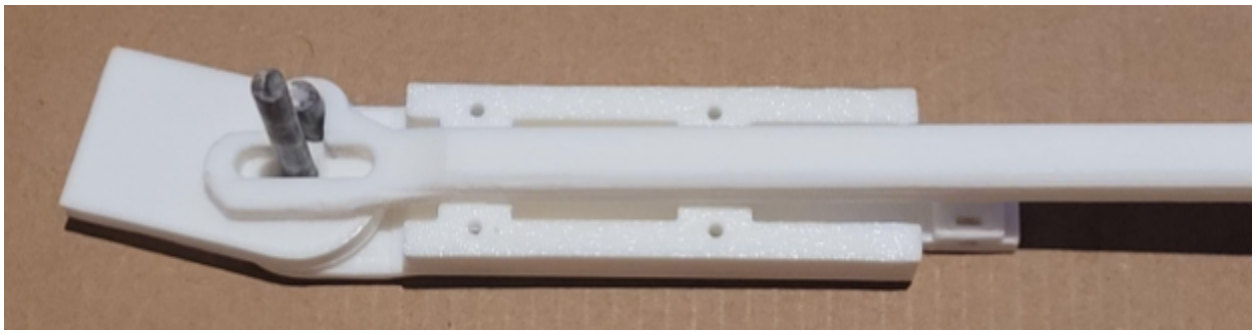




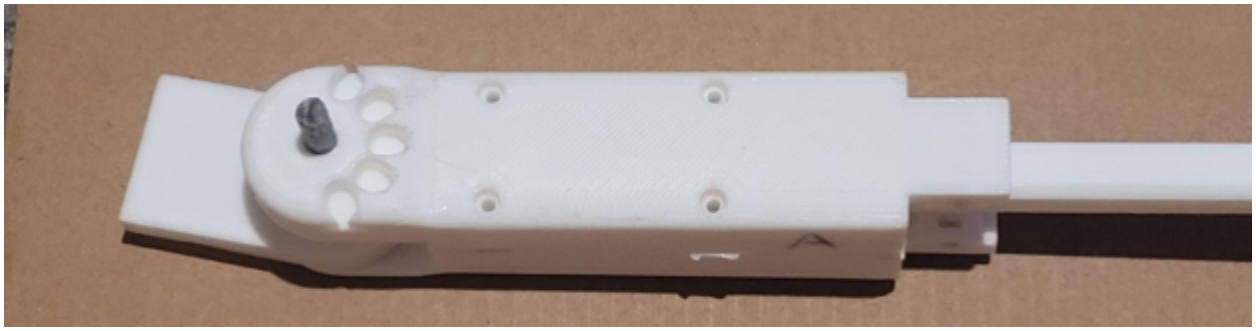
3) Insert the handle actuation pin



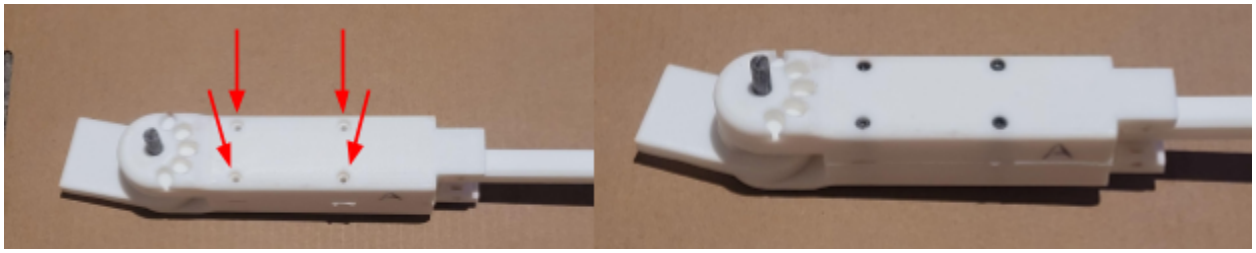
4) Place the tip end of the scotch yoke bar over the central pin and actuation pin, ensuring that the actuation pin is inside of the slot on the bar



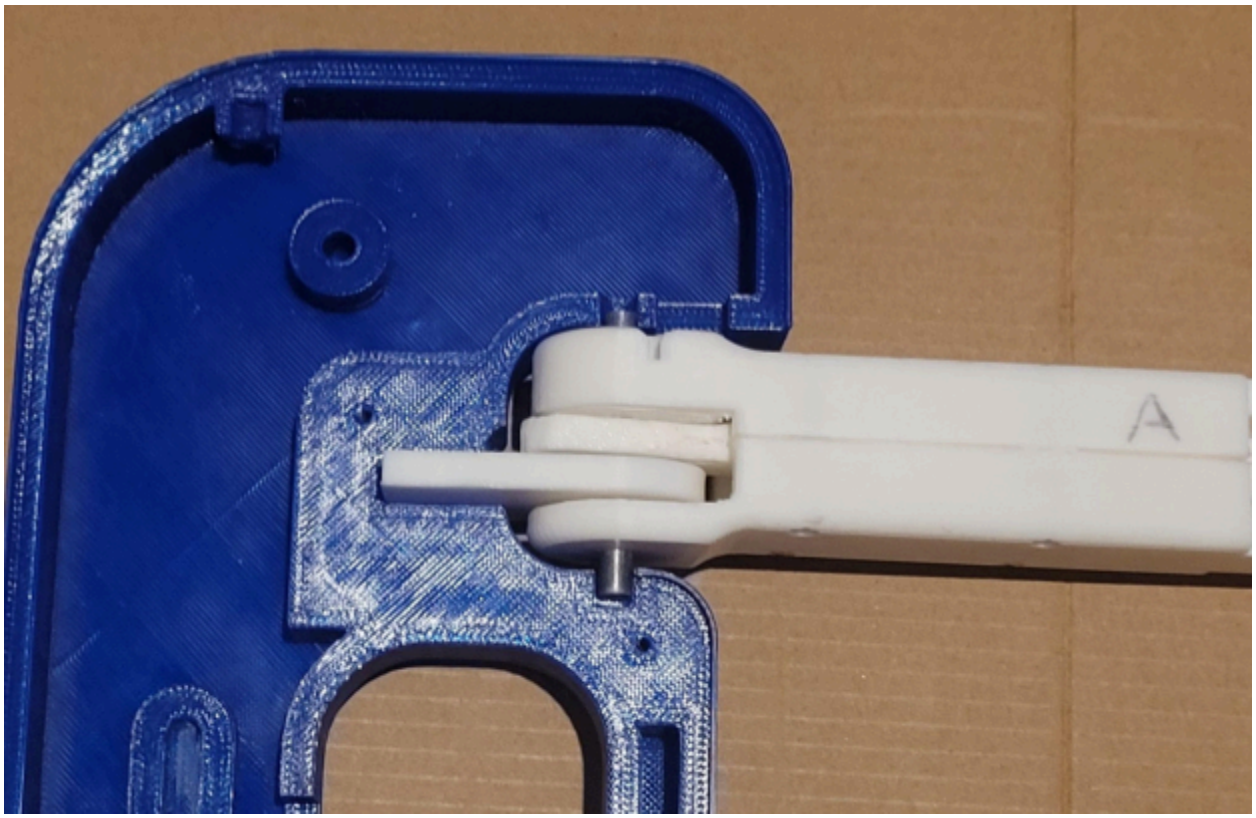
5) Place handle end housing 2 over the assembled pieces in the orientation shown



6) Insert screws into the indicated holes and screw them in until the screw heads sit flush or slightly below the outside of housing 2



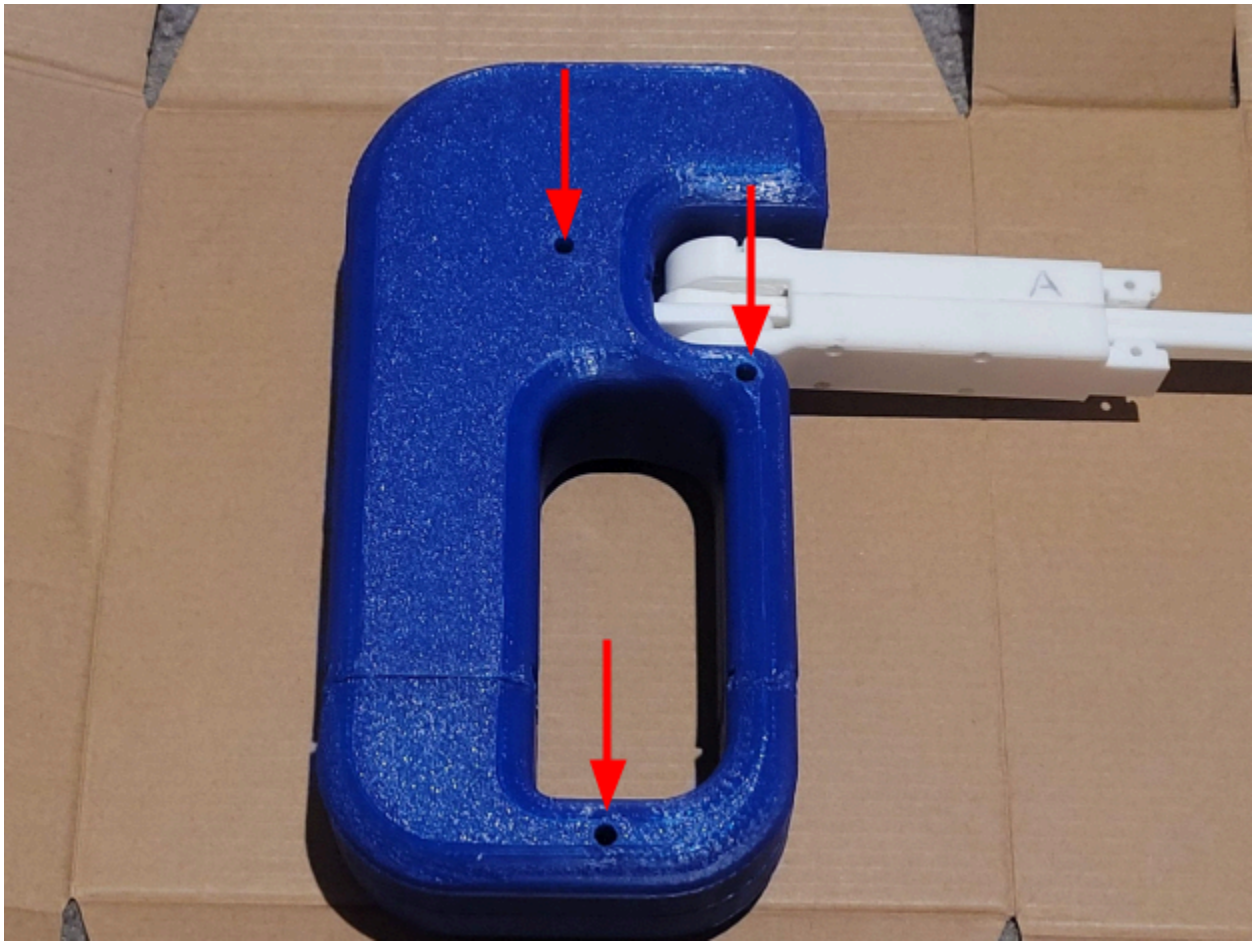
7) Place the interface key into the slot on one half of the handle shell



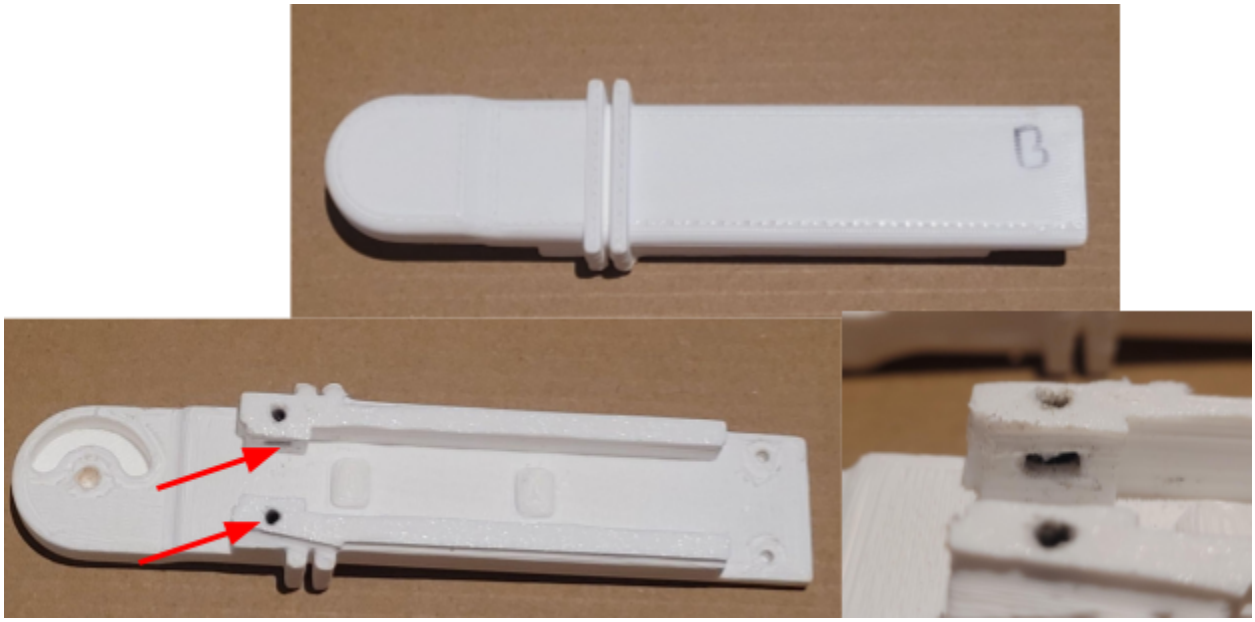
8) Place the other half of the handle shell on the assembled components



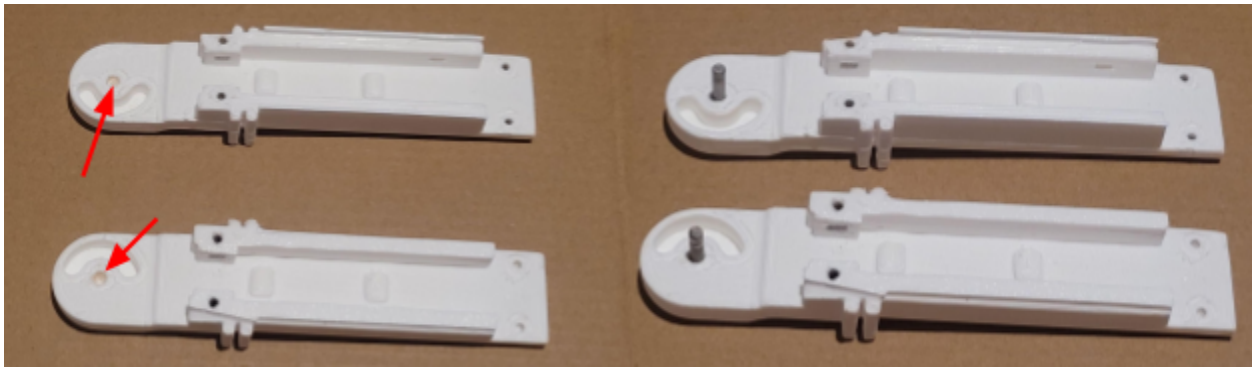
9) Insert screws into the indicated holes on the handle. These screws may be tough to turn, they are tapping into the plastic.



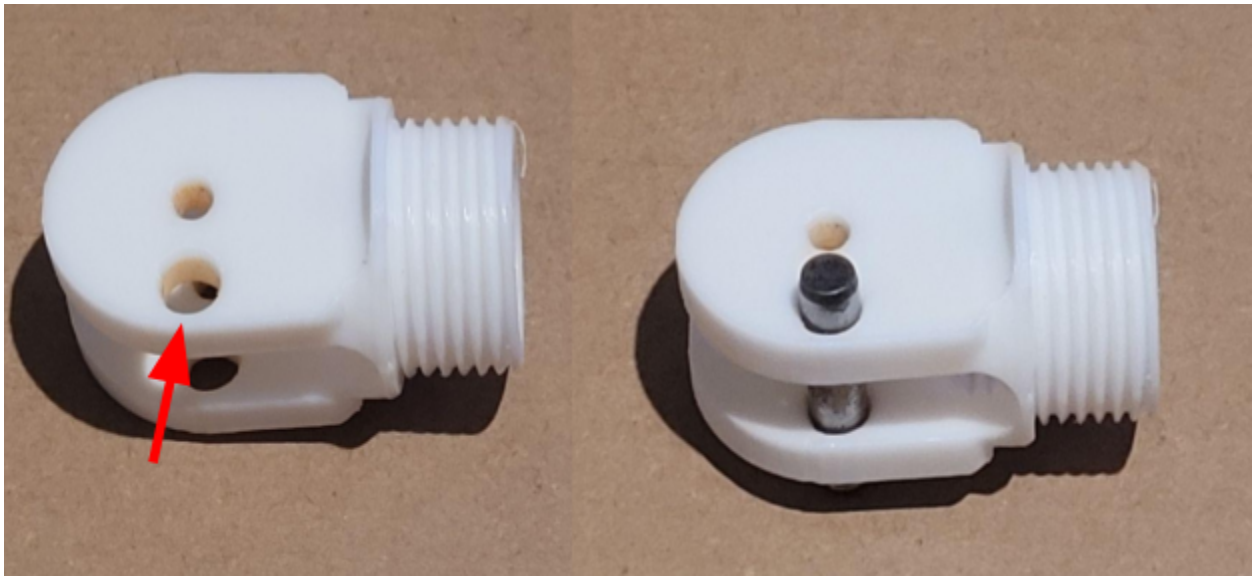
10) Locate tip end housing 2 (the one without through holes) and insert 2 nuts into the nut cutouts



11) Locate the two tip end housings and press fit the tip central pins into the pin holes



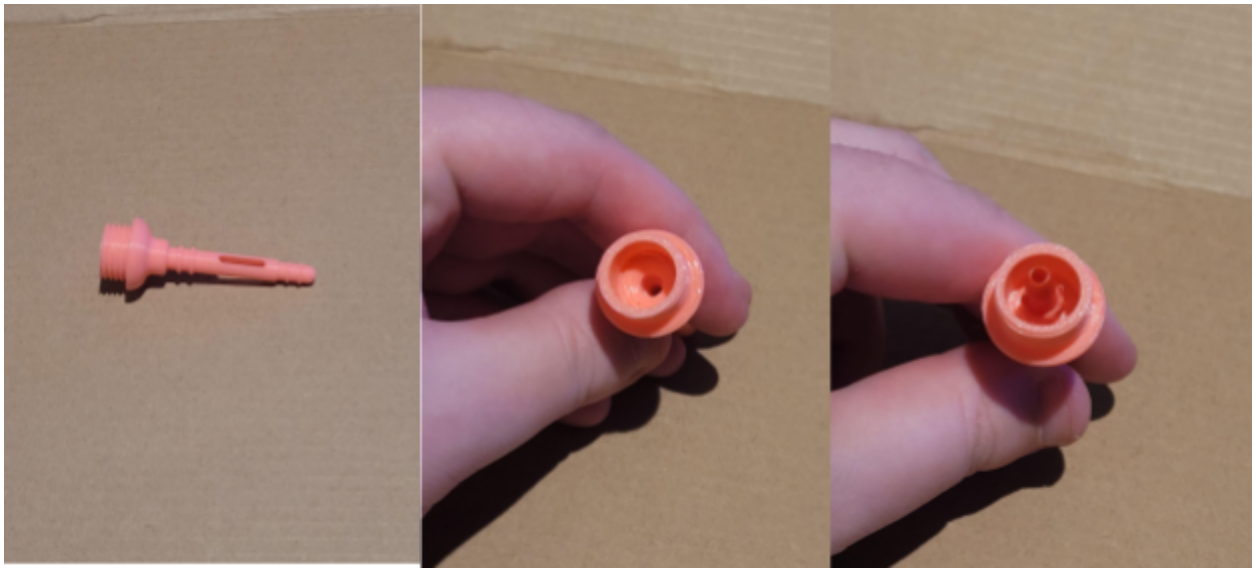
12) Locate the Tip base and insert a dowel pin into the actuation hole



13) Locate the threaded, barbed tubing connector and wrap the threads with teflon tape



14) Locate the tip and install the tubing connector into the threaded hole in the bottom. Repeat this step for each tip length.



15) Place the tip end onto the linkage bar. Do this by placing the extruded pin onto the horizontal linkage slot as seen in Figure 1. Note, there is an incorrect placement seen in Figure 2.

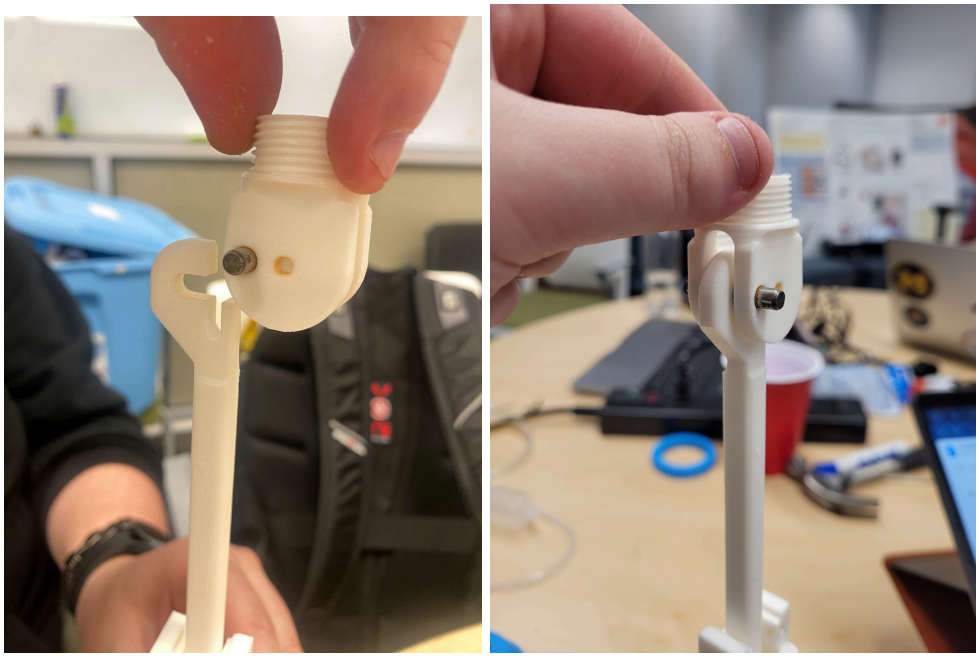


Figure 1. Correct orientation of the tip end.



Figure 2. Incorrect orientation of the tip end.

16) Place tip end housing 2 onto the linkage bar and tip end in the manner shown. Do this by aligning the pin with the center hole and pushing through as seen in Figure 3.

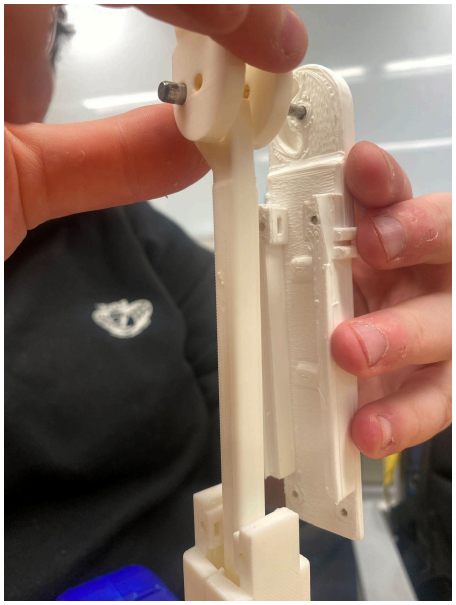
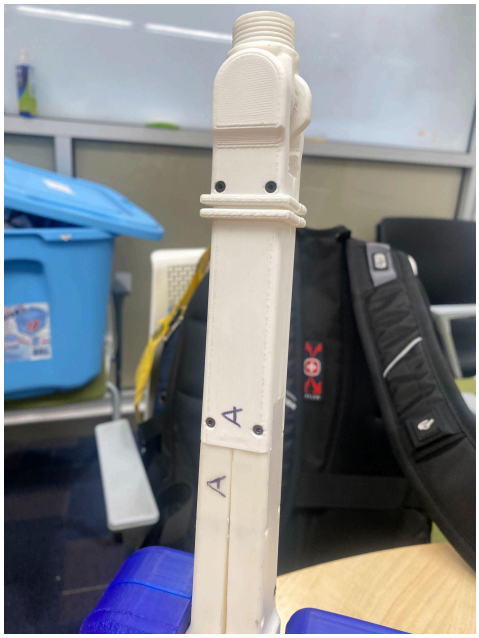


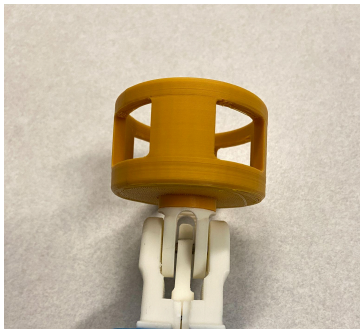
Figure 3. Half A aligned with the tip end and linkage.

17) Align tip end housing 1 with the linkage, tip end, and tip end housing 2. Place tip end housing 1 and apply pressure on both sides till there is an audible click.

18) Insert four screws with an allen key into housing 1.
    a) Make sure the heads of the screw are flush with or slightly below the casing



19) Screw the colpotomy cup onto the non-handle side of the uterine manipulator



20) Loosely place the anchor balloon on the tip.



21) Locate and slip the cylindrical collar over the tip and balloon until roughly ½ an inch of balloon sits above the tip end. With ½ an inch of balloon above, hold the balloon in place at the tip and push the collar down till it snaps into place. You should hear or feel two clicks, the first might be faint.



22) Tightly pull the balloon down and push the rounded tip end until it clicks in place. You should hear or feel one click, it may be faint.



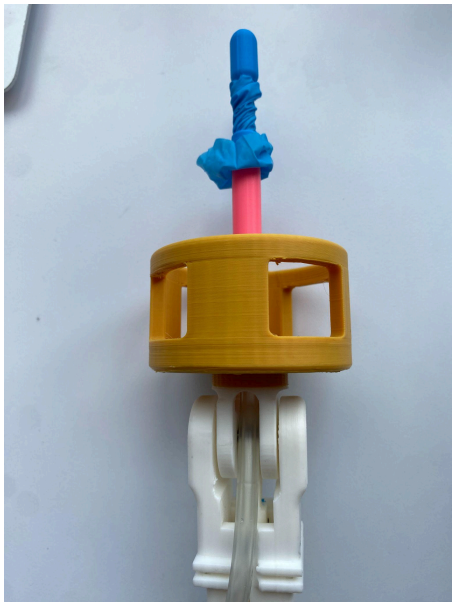
23) Run the clear tubing through the gap in the between the main body and colpotomy cup, it should stick out the middle of the main body and cup.
    a) Ensure the tubing is aligned with the cutout on the shaft.



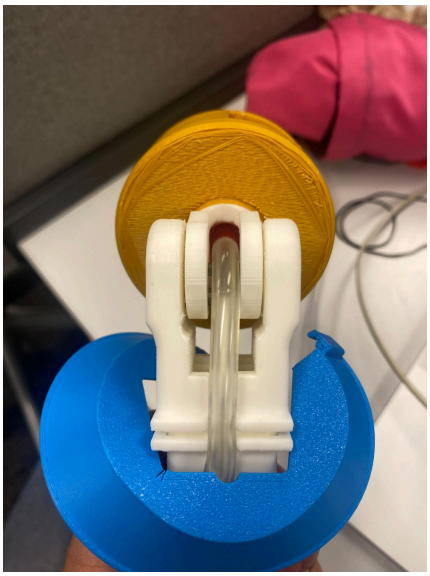

24) Connect the clear tubing to the tube connector on the bottom of the tip



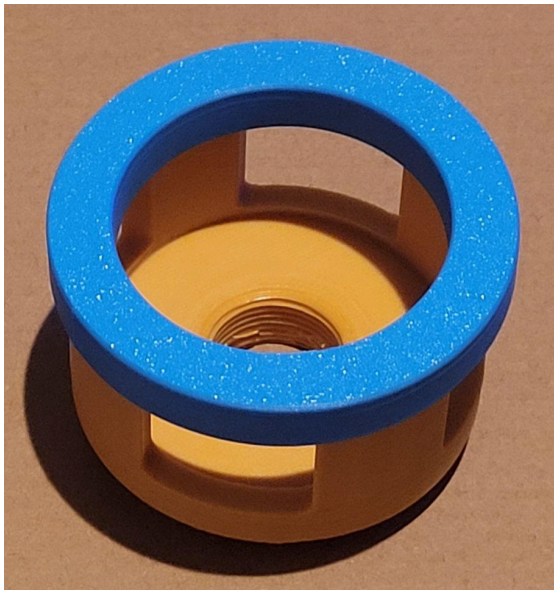
25) Screw the tip into the main body through the middle of the cup




26) Wrap the flexible disk around the shaft and place it in the raised collar.
    a) Ensure the cutout for the tubing is aligned with the hole cutout on the shaft.
    b) The disk may not hold itself closed, just ensure that the disk is snug in the raised collar and the two edges are touching as best as possible.

27) If the electrocauterizer guard is needed, install it on the rim of the colpotomy cup, ensuring that it is sitting flush with the rim of the colpotomy cup



Appendix D: Build Design Bill of Materials

Qty	Part Name	Build Source	Build Supplier	Supplier Part Number	Build Material	Notes
1	Tip (5cm)	3D Printed	N/A	N/A	PLA	
1	Tip (7cm)	3D Printed	N/A	N/A	PLA	
1	Tip (11cm)	3D Printed	N/A	N/A	PLA	
1	Medical Glove	BME Assembly room	N/A	N/A	Latex	
1	Balloon base cap	3D Printed	N/A	N/A	PLA	
1	Balloon top cap	3D Printed	N/A	N/A	PLA	
1	Colpotomy cup (2.5cm)	3D Printed	N/A	N/A	PLA	
1	Colpotomy cup (3.75cm)	3D Printed	N/A	N/A	PLA	
1	Colpotomy cup (5cm)	3D Printed	N/A	N/A	PLA	
1	Electrocauterizer Guard (2.5cm)	3D Printed	N/A	N/A	TPU	
1	Electrocauterizer Guard (3.75cm)	3D Printed	N/A	N/A	TPU	
1	Electrocauterizer Guard (5cm)	3D Printed	N/A	N/A	TPU	
1	Tip base	3D Printed	N/A	N/A	PLA	
1	Female threaded Luer lock adapter	BME Assembly room	Qosina	65261	PP	
1	Threaded Tube Adapter	BME Assembly room	Qosina	11775	PP	

1	Tubing	BME Assembly room	Qosina	T7801	TPE	
1	50cc syringe	Amazon	N/A	C143sy	PP	
1	Tubing clamp	BME Assembly room	Qosina	13606	PP	
1	Handle end housing 1	3D Printed	N/A	N/A	PLA	
1	Handle end housing 2	3D Printed	N/A	N/A	PLA	
1	Tip end housing 1	3D Printed	N/A	N/A	PLA	
1	Tip end housing 2	3D Printed	N/A	N/A	PLA	
1	Occluder disk	3D Printed	N/A	N/A	TPU	
1	Scotch Yoke Bar	3D Printed	N/A	N/A	PLA	
9	Screws	x50 Assembly Room	N/A	N/A	304	M2, 20mm
6	Housing nut (prototype build only)	x50 Assembly Room			304	Hex
3	Springs	x50 Assembly Room	N/A	N/A	304	5/8"
9	Dowel Pin	x50 Assembly Room	N/A	N/A	304	3/16 diam, 1 inch length
2	Tip Central Pin	x50 Assembly Room	N/A	N/A	304	1/8" diam, 1/2" length
3	Handle Pins	x50 Assembly Room	N/A	N/A	304	3/16 diam, 1 cm length
1	Trigger	3D Printed	N/A	N/A	PLA	
1	Left handle casing	3D Printed	N/A	N/A	PLA	
1	Right handle casing	3D Printed	N/A	N/A	PLA	
1	Vertical Link	3D Printed	N/A	N/A	PLA	
1	Horizontal Link	3D Printed	N/A	N/A	PLA	
1	Locking Pin	x50 Assembly Room	N/A	N/A	Aluminium	3/16 diam, 2 cm
1	Interface Key	3D Printed	N/A	N/A	PLA	
1	Handle Central Pin	x50 Assembly Room	N/A	N/A	Aluminium	3/16 diam, 5 cm
1	Handle Actuation Pin	x50 Assembly Room	N/A	N/A	Aluminium	3/16 diam, 1.8 cm length

Appendix E: Final Design BoM

Qty	Part Name	Material	Finish	Supplier	Supplier Part Number
1	Tip (5cm)	SS316L	Satin	Manufacturer	-
1	Tip (7cm)	SS316L	Satin	Manufacturer	-
1	Tip (11cm)	SS316L	Satin	Manufacturer	-
1	Medical Glove	Nitrile	-	Manufacturer	-
1	Balloon base cap	SS316L	Satin	Manufacturer	-
1	Balloon top cap	SS316L	Satin	Manufacturer	-
1	Colpotomy cup (2.5cm)	SS316L	Satin	Manufacturer	-
1	Colpotomy cup (3.75cm)	SS316L	Satin	Manufacturer	-
1	Colpotomy cup (5cm)	SS316L	Satin	Manufacturer	-
1	Colpotomy cup cover (2.5cm)	Shore 20A silicone	-	Manufacturer	-
1	Colpotomy cup cover (3.75cm)	Shore 20A silicone	-	Manufacturer	-
1	Colpotomy cup cover (5cm)	Shore 20A silicone	-	Manufacturer	-
1	Tip base	SS316L	Satin	Manufacturer	-
1	Tubing	TPE	-	Qosina	T7801
1	50cc syringe	PP	-	Manufacturer	C143sy
1	Tubing clamp	PP	-	Qosina	13606
1	Handle end housing 1	SS316L	Satin	Manufacturer	-
1	Handle end housing 2	SS316L	Satin	Manufacturer	-
1	Tip end housing 1	SS316L	Satin	Manufacturer	-
1	Tip end housing 2	SS316L	Satin	Manufacturer	-
1	Occluder disk	Shore 60A silicone	-	Manufacturer	-
1	Scotch Yoke Bar	SS316L	Satin	Manufacturer	-
9	M2 20mm Phillips Head Screws	SSA4(316)	-	Accu-Components	SIP-M2-20-A2
3	3/16” diam x 5/8" length Springs	SS302	-	McMaster-Carr	9435K39
12	3/16” diam, 1” length, precision ground dowel pin	SS316L	Satin	Manufacturer	-
1	Trigger	Al 6061	Satin	Manufacturer	-
1	Left handle casing	Al 6061	Satin	Manufacturer	-

1	Right handle casing	Al 6061	Satin	Manufacturer	-
1	Vertical Link	SS316L	Satin	Manufacturer	-
1	Horizontal Link	SS316L	Satin	Manufacturer	-
1	3/16” diam. Locking Pin	SS316L	Satin	Manufacturer	-
1	Interface Key	SS316L	Satin	Manufacturer	-

Appendix F: Verification and Validation

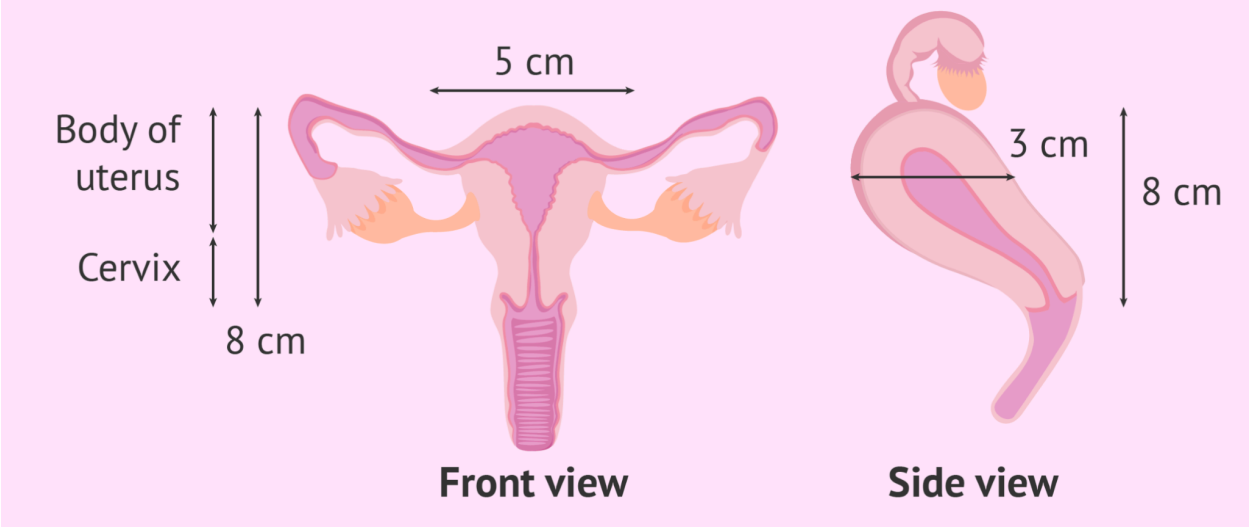


Figure 56. Image of average normal uterus size [64].

This model was used as the main point of reference during the creation of the uterine model used for verification testing.

Summative Usability Testing Procedure

Raw Data

								Time (sec)		
Step	Step Number	Pilot Master (Lisa)			Subject 1 (Unrelated to Project)			Subject 2 (Has experience assemb. medical devices		
Tip End	1	13	8	5	12	5	5	18	5	5
Half A	2	41	20	10	14	4	25	23	11	11
Half B	3	65	10	32	26	6	13	23	6	13
Screws	4	126	146	63	172	150	100	158	222	141
	1		2	1	1	3	3	4	6	1
Colpotomy cup a	2		15	27	26	9	11	17	13	9
	3		10	12	9	9	12	7	7	4
	4		13	10	14	7	5	13	7	4
Tip assembly	5		15	6	11	4	7	10	13	6
	6		8	18	72	8	7	38	9	10
Tubing assembly	7		10	6	30	21	8	7	10	7
Tip assembly	8		20	12	10	5	12	16	10	13
Occluder disk as	9		27	25	49	22	13	63	12	15
Sum		390	304	227	446	253	221	397	331	239

Instructional Guide for Assembling the Uterine Manipulator (note that figure numbers are separate from the rest of the report)

1. Place the tip end onto the linkage bar. Do this by placing the extruded pin onto the horizontal linkage slot as seen in Figure 1. Note, there is an incorrect placement seen in Figure 2.

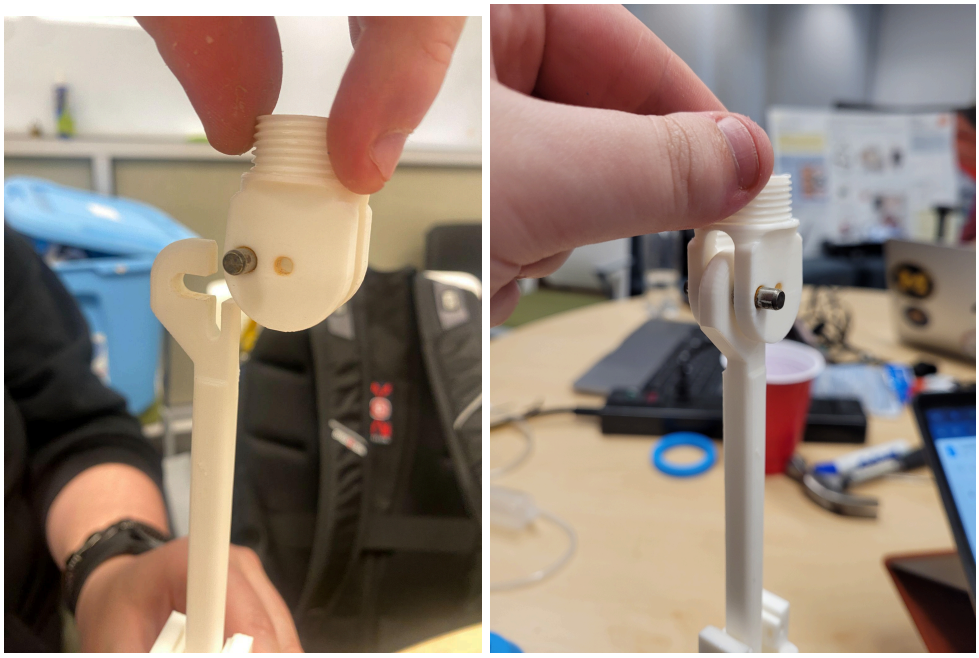


Figure 1. Correct orientation of the tip end.



Figure 2. Incorrect orientation of the tip end.

2. Place half A onto the linkage bar and tip end on the side marked half A. Do this by aligning the pin with the center hole and pushing through as seen in Figure 3.

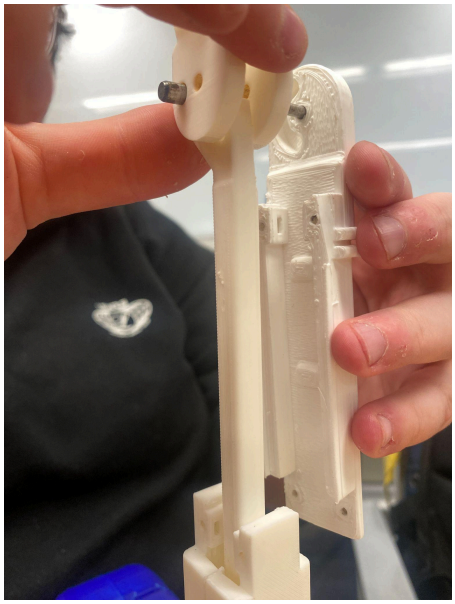


Figure 3. Half A aligned with the tip end and linkage.

3. Align half B with the linkage, tip end, and half A. Place half B and apply pressure on both sides till there is an audible click.

4. Insert four screws with an allen key into half A of the main shaft casing.
    a. Make sure the heads of the screw are flush with or slightly below the casing

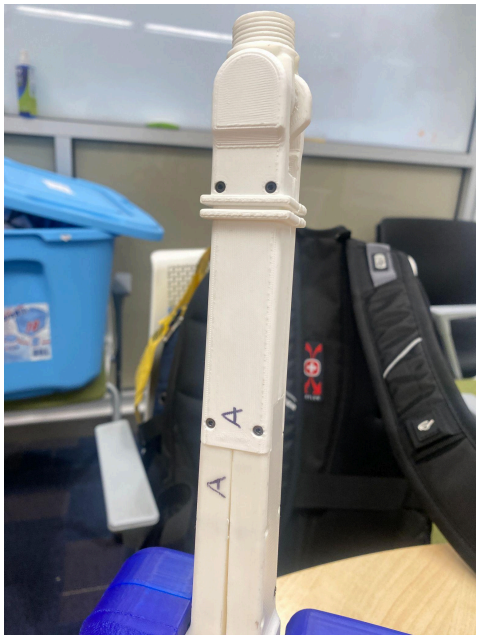
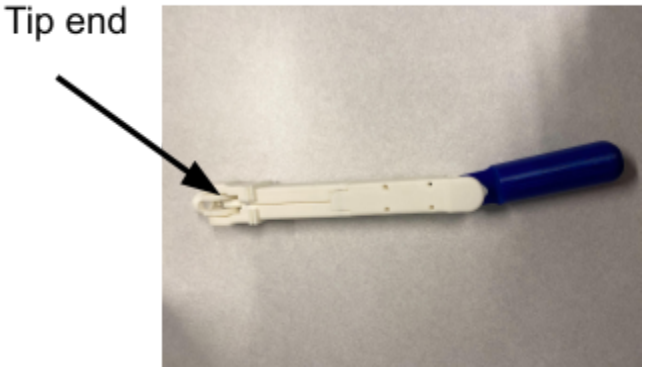
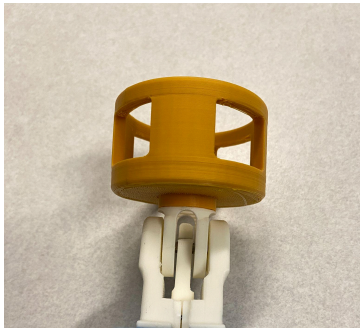


Figure 4. Half A installed with screws.

1. PAUSE



2. Screw the colpotomy cup onto the non-handle side of the uterine manipulator



3. Loosely place the anchor balloon on the tip.



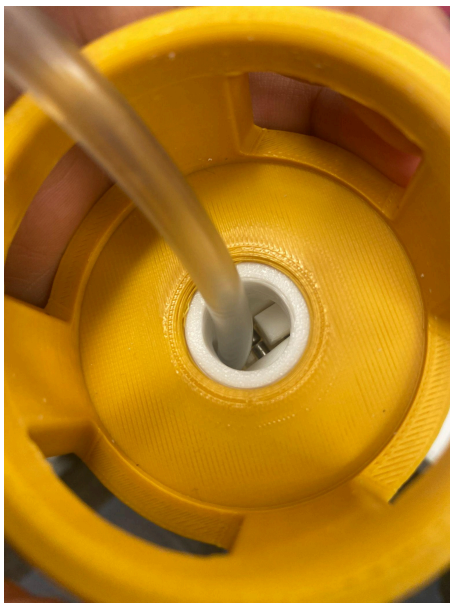
4. Locate and slip the cylindrical collar over the tip and balloon until roughly ½ an inch of balloon sits above the tip end. With ½ an inch of balloon above, hold the balloon in place at the tip and push the collar down till it snaps into place. You should hear or feel two clicks, the first might be faint.



5. Tightly pull the balloon down and push the rounded tip end until it clicks in place. You should hear or feel one click, it may be faint.



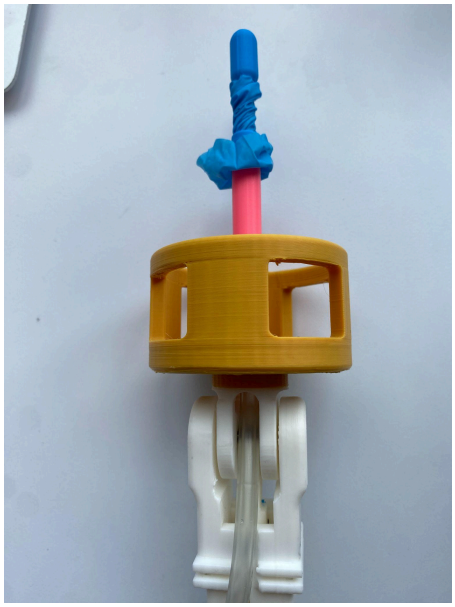
6. Run the clear tubing through the gap in the mainbody, it should stick out the middle of the main body and cup.
    a. Ensure the tubing is aligned with the cutout on the shaft.

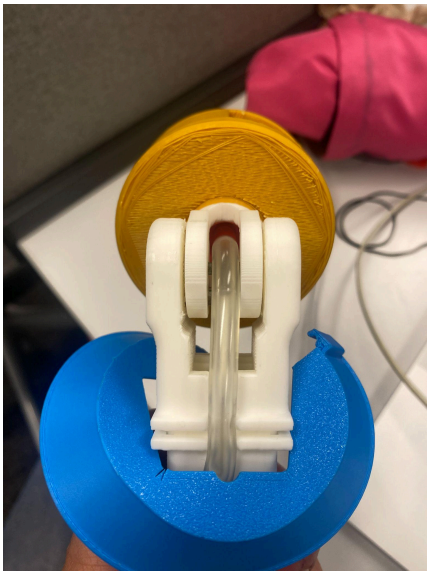
7. Connect the clear tubing to the connector on the bottom of the tip



8. Screw the tip into the main body through the middle of the cup




9. Wrap the flexible disk around the shaft and place it in the raised collar.
    a. Ensure the cutout for the tubing is aligned with the hole cutout on the shaft.
    b. The disk may not hold itself closed, just ensure that the disk is snug in the raised collar and the two edges are touching as best as possible.

Appendix F: Verification Traceability Log

Spec ID	Priority	Owner	Verification					
			Date	Summary	Assumptions	Limitations	Evidence	Result
001	High	A	4/7	- Able to move the required range of motion - 70° both directions	(1) model can simulate real life conditions (2) the prototype range is representative of the actual design range	Limitation: Subject to human error since a protractor is used Solution: Use photogrammetry.	Data collected and recorded from a protractor measuring the range of motion	Pass
002	Low	A	4/7	- Fluid volume only limited by syringe volume - Easy to deposit liquid	(1) dilute dye viscosity equivalent to water	Limitation: The fluid behavior may be different in an actual clinical setting. Solution: N/A.	Used a 50 ml syringe was to fill the tubing, device volume in the UM tip cavity, and anchor balloon verifying its ability to reach the tip end of the device	Pass
003	Low	L	4/7	- Leak through shaft body - Unable to proceed with verification test	(1) prototype material sealing capability is the same as the actual design (2) simulator elasticity is the same as actual tissue	Limitation 1: May be unable to put the anatomical model under the target pressure Solution 1: Develop another testing rig to simulate human body vaginal canal and abdomen	Test data from multiple trials showing that the device can maintain the target pressure for the duration of the estimated surgery length	Fail
004	Low	All	-	-	-	-	-	Incomplete

005	Low	L	4/1	- Referenced existing medical devices using FDA summaries of effectiveness - Difficult to find evidence of aluminum (expected)	Assumed reliable raw material supplier	Limitation: No physical testing can be completed with UM. Solution: Could use smaller samples of material.	Comparing selected materials with materials used in existing FDA-approved medical devices that fall into the same or higher risk category based on exposure type and time from ISO 10993.	Pass
006	Med	L	4/7	- Rounded and filleted edges and corners - Corroborated by usability testing, no pinch points on user end	Assumed simulator accurately represents tissue properties	Limitation: Reliance on visual inspection may not provide accurate results. Solution: Utilize surface roughness tools	Empirical testing of manipulation tests yielded no damage on model or users, consisting of several different individuals with varying familiarity of the device (from none to designers).	Pass
007	Med	L	-	-	Only one simulated consistency of biomatter	Limitation: Test does not account for different biomatter consistency (dried, sticky, etc) Solution: Assume that varying the force applied (rather than access to surfaces) can account for differences in consistency	The device was designed with the ability to be fully assembled and disassembled with only an allenkey (currently) and therefore all parts can be reached.	Confident it would pass

008	Low	L	4/1		(1) may not have real autoclave and dry heat machines (2) properly cleaned device prior to sterilization	Limitation 1: May not be able to use "real" autoclave and dry heat machines Solution 1: Can test the materials in a pressure cooker with water (simulating autoclave) and a convection oven (simulates dry heat)		Pass
009	Low	L	4/1	- Strong backing for selected materials in all the methods - Conducted for general material categories ("aluminum " instead of "aluminum 6061-T6")	Limited-to-no access to chemical sterilization chemicals and tooling	Limitation 1: Little access to the proper materials + lab setup for testing Solution 1: Select materials from the AAMI TIR17 annex tables that have been pre-tested, then conduct literature review to identify possible risk of caveats or special cases that would undermine the sterilizability	Photos showing no corrosion on surface after testing	Pass
010	Med	V	-	-	Attach a 1kg mass to the tip of the uterine manipulator and follow testing procedure for range of motion (001) to ensure that it still works	Limitation: Material used in prototype is not the same as actual UM. Solution: Scale simulated uterus weight.	Device tests with scaled uterus model demonstrate full functionality	Confident it would pass
011	Low	A	-	-	Create simulation uteri of the maximal and minimal depth	Limitation: Does not account for sizes in between extrema.	Device was designed with multiple tips covering a range	Confident it would pass

					values and ensure that the testing procedure for range of motion is successfully executed	Solution: Further testing with varying sizes.	of 5 to 11 ± 1 cm in length	
012	Low	A	4/7	- Able to fit fornices 2.5cm to 5cm	-	Limitation: Does not take into account tissue flexibility or fornix shape Solution: Colpotomy cup designed with extra space at the base to accommodate more tissue if needed	Device was designed with multiple colpotomy cups covering a range of 2.5 to 5 cm diameters	Pass
013	High	V	4/7	- Every part passing through the cervix was 1cm or smaller	CAD reliant	Limitation: Clearance for actual device may alter the diameter Solution: Include a margin of error.	Device was designed that the largest part past the cervix is 1 cm	Pass
014	Med	V	-	-	Have assistant surgeons briefly familiarize themselves with the device controls, then have them simulate TLH and score the device using the SUS	Limitation: User experience may skew results Solution: Make an effort to identify users with similar experience	-	Incomplete
015	Low	M	-	- Device is more than 250% higher than the target weight - Test took place prior to the inclusion of aluminum as a work	Weigh the device using a digital scale	Limitation: Can not actually be completed due to different materials being used for the prototype. Solution: Estimate based on CAD analysis. Note: Handle	Weight was modeled in SOLIDWORKS using final material selection and summed to be over 2.6 kg	Fail

				material		casing in the analysis is set to stainless steel; switching to the selected aluminum would reduce the subsystem weight by about 1/2, resulting in a total mass closer to 2kg		
016	Med	V		-	Device is always disassembled to the intended degree for cleaning	Limitation: A poor instructional guide could lead to skewed results. Solution: Perform formative tests to revise guide.	Summative usability testing conducted with a random selection of students and all could assemble the device in ≤ 7 minutes. Placement times and trials with medical professionals needs to be performed	In Progress
017	Med	V	-	-	Manually actuating the device could result in some people applying an excess amount of force, resulting in a higher force reading than is actually necessary	Limitation: Human error could result in a higher force reading Solution & uncertainty: Can write it into the testing procedure to gently apply force, increasing until movement is achieved. However, getting a higher force reading introduces some redundancy that can accommodate for fatigue as well and other factors,	Data from force meter	In Progress

						so it isn't necessarily a harmful result		
018	Low	L	4/1	- Aluminum and silicone passed successfully - Stainless steel was inconclusive from the corrosion resistance tables, which required further research	Data only available for 20% concentration and sustained immersion	Limitation: Data only available for 20% concentration and sustained immersion Solution: Improves reliability of passing result	Passing scores for aluminum and silicone; white paper documents and books discussing use of stainless steel with bleach makes it usable with caveats on the process	Pass
019	Med	L	-	-	Assumptions of good material quality and no manufacturing defects	Limitation: Not a perfect simulation of the system Solution: Introduce a safety factor on the yield strength of materials	-	Incomplete
020	Med	M	4/6	- Cost remained below $1/use on 300 uses	GRANTA Edu Pack analysis.	Limitation: Oversimplifying assumptions for manufacturing could skew results. Solution: Perform additional review for manufacturing processes.	Granta EduPack analysis conducted and other parts sourced from McMaster-Carr	Pass
021	Med	V	4/24	A singular allen key proved sufficient.	Using no more than a screwdriver, successfully disassemble the device into each individual piece, and successfully reassemble.	N/A	Device currently designed to only required an allen key for assembly	Pass

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