

Team Fundus

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Contents

Project Background.....	3
Physiological Need.....	3
Device Selection	4
User Profile	6
User Needs.....	7
Problem Statement.....	8
Ideation Prompts.....	9
Concept Ideation and Rapid Prototyping	9
Design Process.....	25
Thread 1: Spring Sheath.....	25
Thread 2: Graded stiffness hysteroscope tool with measuring ring.	27
Thread 4: Fluidic Low-Pass Filter	28
Appendix	30
References	33

Project Background

Physiological Need

Uterine polyps are abnormal growths of uterine connective tissue, glands, and blood vessels protruding from the endometrium, the lining of the uterus ^[1]. Polyps range in size, from 5 mm to filling the uterine cavity, and shape, as shown in **Figure 1** ^[1]. They can develop in both reproductive-aged and postmenopausal women, but patients of 40 to 49 years old are at greater risk due to experiencing perimenopause, a period before menopause characterized by estrogen and progesterone fluctuations, hormones critical to endometrial growth regulation ^[1,2]. Polyps are the most common uterine pathological finding and are estimated to develop in 25 percent of women ^[1,3]. While a significant portion of polyps are asymptomatic (about 40 percent), they are a contributing factor to 50 and 35 percent of abnormal uterine bleeding (AUB) and infertility cases, respectively ^[1,4].

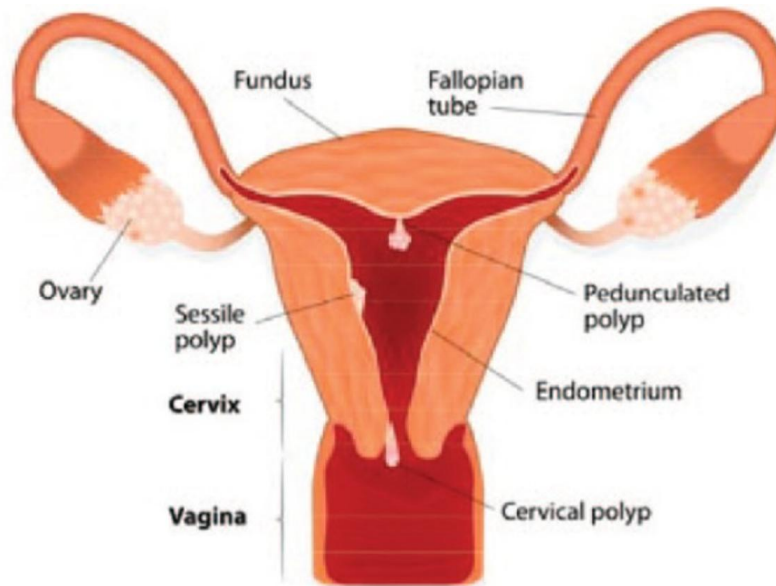


Figure 1. Illustration of the uterus with endometrial polyps ^[1]. The endometrium is accessed through the vagina, the muscular canal that connects the external genitalia (i.e. vulva) to the cervix, the entry point to the uterus. Near the fundus (i.e., the region of the uterus farthest from the cervix), the fallopian tubes connect to the uterus at the tubal ostia, allowing the transportation of oocytes, or unfertilized eggs, from the ovaries to the uterus to facilitate egg fertilization. Polyps can be attached to the uterine wall via a narrow section of tissue (i.e. pedunculated) or a broad base (i.e. sessile) ^[1].

Uterine polyps develop when menses fails to occur in a specific region of the endometrium, for which there are several proposed mechanisms ^[1]. The primary theory suggests that polyp-bearing endometrial regions have high concentrations of estrogen receptors and low concentrations of progesterone receptors, increasing sensitivity to estrogen and decreasing sensitivity to progesterone ^[1]. Estrogen promotes endometrial growth while progesterone promotes maturation; consequently, the endometrium proliferates but does not mature, preventing menses ^[1]. Another potential mechanism is that regions that develop polyps express higher levels of B-cell lymphoma-2 (Bcl-2) marker ^[1]. Bcl-2 marker inhibits apoptosis, a form of cell death; consequently, an increased concentration of Bcl-2 would prevent the cell death associated with menses. Another reason for polyp formation may be an increased concentration of mast cells ^[1]. Mast cells are responsible for inflammatory responses, which induce angiogenesis, or the formation of new blood vessels. Consequently, an increased concentration of mast

cells may produce more vascularized endometrial tissue that can resist shedding, leading to polyp formation ^[1].

As pictured in **Figure 2**, hysteroscopic polypectomy, or polyp removal with a hysteroscope, is widely recognized as the gold standard for treatment because it has higher accuracy than other imaging techniques and allows the definitive sampling and treatment of polyps ^[1,5]. It is estimated that polypectomies account for nearly 50 percent of all hysteroscopic interventions, which is a \$4 billion market ^[6,7]. Another common procedure is dilation and curettage (D&C), which involves using forceps to scrape the sides of the uterus ^[1]. However, it is commonly known as a “blind procedure” because of its large potential for missing polyps ^[1]. There also exist several hormonal medication treatments, such as estrogen suppression to reduce polyp growth, progestins to stimulate progesterone, and GnRH agonists, or synthetic drugs that mimic GnRH to stimulate LH production and, therefore, increase progesterone levels ^[1,5]. However, symptoms generally resurface after stopping medication ^[5]. A more extreme treatment generally reserved for cancerous polyps is a hysterectomy, which involves the complete removal of the uterus ^[8]. Lastly, it is relatively common to closely monitor polyps, especially in asymptomatic and reproductive-aged patients, instead of operating upon discovery ^[5]. While uncommon, it is possible for polyps to spontaneously regress (about 6 percent) ^[9]. Because of the high rate of asymptomatic polyps (44.4 percent in reproductive-aged women and 36.1 percent in postmenopausal women), failure to address these growths is relatively common ^[4]. If left untreated, various complications may ensue, such as heavy menstrual bleeding, infertility, postmenopausal bleeding, abdominal and back pain, and uterine cancer ^[10].

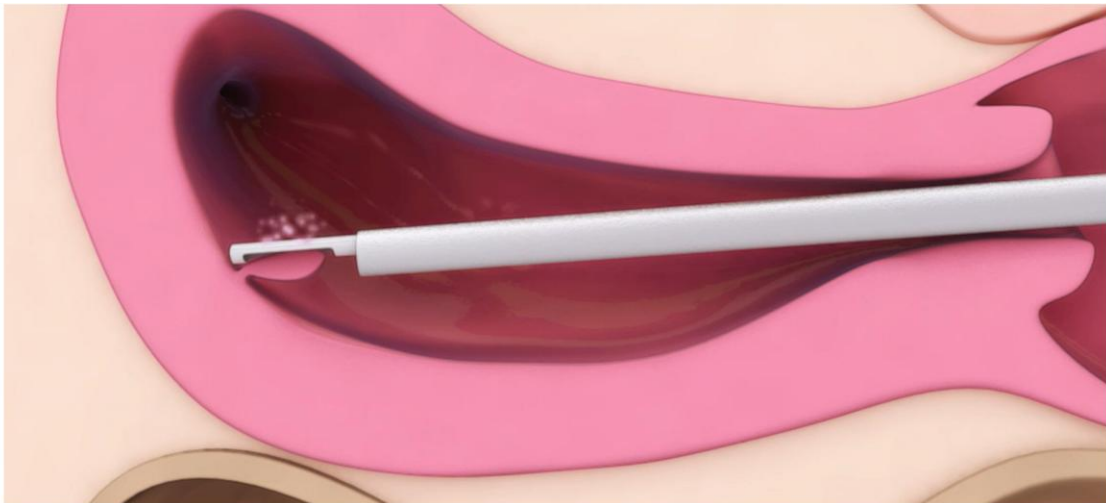


Figure 2. Illustration of a hysteroscopic polypectomy ^[9]. The uterus is expanded using distension fluid, and a hysteroscope is inserted through the cervical canal. Inside the outer sheath is an endoscope to visualize uterine pathology and an operative tool to remove polyps.

Device Selection

As mentioned, hysteroscopic polypectomy is the gold standard for polyp treatment. This procedure uses an operative hysteroscope, a long metal sheath containing channels for a telescope, operative tools, and distension fluid delivery meant for visualization and performing surgical procedures within the uterine cavity through cervical insertion ^[11]. Hysteroscopes can vary in geometry, sheath rigidity, fluid management, and surgical instruments depending on the procedure. For polypectomies in particular, the principal classifications of hysteroscopes used are resectoscopes and hysteroscopic tissue removal systems (TRS) ^[22]. A resectoscope uses an electrical loop to cut polyps into small fragments. It is best for removing large polyps in an operating room with patients under general or local anesthesia. A TRS contains a rotating blade that cuts polyps into fragments that can be suctioned out of the uterus.

While generally used for “see and treat” procedures in office settings, TRSs have higher polypectomy success rates and decreased procedure times ^[22].

State of the Art/Prior Art



Figure 3. Image of the Medtronic® TruClear™ Elite hysteroscope.

The Medtronic® TruClear™, a type of TRS, represents the current state-of-the-art in hysteroscopic efficiency, safety, and functionality. As shown in **Figure 3**, The TruClear™ system integrates mechanical morcellation and suction for simultaneous tissue resection and extraction, eliminating the need for multiple instrument switches. Its rigid hysteroscope (5 to 5.7 mm OD) contains a working channel through which a motor-driven morcellator blade rotates with in a stationary outer tube, shaving polyp tissue while suction removes debris through the same pathway. This continuous resection and extraction design maintains constant visualization, shortens operation time, and reduces fluid absorption risk compared to manual curettage or electrosurgical systems. The TruClear™ uses rod-lens optics, a series of aligned glass rods and lenses that transmit light and images with minimal distortion, providing superior resolution and brightness relative to flexible fiber optics and enabling clear imaging during fluid flow and tissue ^[12,13].

The system uses continuous flow, with separate inflow and outflow channels that circulate distension fluid to flush blood and debris from the. Pressure-controlled pumps maintain consistent distension and prevent spikes that could damage uterine tissue. ^[12,14,15].

Flexible hysteroscopes may also be used for endoscopy and intrauterine procedures. These models can span the cavity space more completely; however, they are difficult to use for polypectomy procedures as sufficient force cannot be translated through the flexible sheath. ^[22].

Despite advantages, the TruClear™ system remains costly and less accessible. It requires single use morcellator blades and sheaths, producing high recurring costs compared to reusable systems. It also depends on proprietary Medtronic components (the drive console, motor unit, foot pedal, and tubing sets) which are incompatible with other manufacturers devices and add to setup and maintenance costs. Most critically, the rigid sheaths blunt distal end can generate high localized contact pressure against the uterine wall during insertion or manipulation near the fundus, increasing the risk of perforation, hemorrhage, or cervical laceration ^[13,14]. This risk is compounded by limited fluid-flow control and turbulent distension ^[16]. Visual and tactile cues are the only safeguards against perforation, yet visualization can be obscured by tissue debris, and tactile resistance is often insufficiently transmitted to the physician’s hand.

User Profile

To identify user needs related to this issue, the following user profile was developed:

Primary Users: Gynecologists and Obstetrician-Gynecologist (OB/GYN) Surgeons

These users actively handle hysteroscopes during operative procedures, giving them direct control over the device. Furthermore, if a complication occurs (i.e., uterine perforation), the surgeon will be handling the device in that event ^[17]. Despite complications being more likely when using rigid hysteroscopes, surgeons often prefer to use them anyway due to their better visualization and higher efficacy compared to flexible designs ^[18]. Risk also increases when operating on patients with abnormal uterine anatomy, such as cervical stenosis, uterine malposition, or abnormal uterine tilt ^[17,19,20]. Consequently, physicians require a design that facilitates procedural success without compromising patient safety. Physicians can provide unique insight into the performance of the hysteroscopes they have used, such as how well they provide visibility, how much tactile feedback they receive, and what design characteristics may be causing procedural complications.

Secondary Users: Hysteroscopy Patients

These users are at the greatest risk should device complications occur but have little to no control over the outcome of the procedure. Polyps most commonly affect women aged 35 and above, with a higher incidence for postmenopausal patients and those with abnormal uterine bleeding or infertility ^[1,8]. Depending on the level of anesthesia used and whether complications occurred, patients may provide feedback on how the procedure feels and what post-procedure recovery was like ^[21]. Consequently, patient testimonies are key to understanding the safety of the device and the experience of the procedure.

Tertiary Users: Other Healthcare Staff, Family Members

Nurses or medical assistants may be asked to prepare the device by inserting the telescope into the sheath. Furthermore, they may have more responsibilities in procedures employing manual distension fluid management. However, they have little direct control or risk associated with the hysteroscope's use ^[22,23].

A patient's loved ones are often relied upon to provide care and support during the recovery period for patients after successful and damaging procedures. Consequently, they may be affected by the patient's experience with hysteroscopy. While there aren't statistics for the percentage of patients cared for by their family members, hysteroscopy patient information sheets suggest that family members accompany patients to and from the hospital to monitor post-procedure recovery ^[24].

User Needs

Identifier	User Needs	Objectives
UN1	The hysteroscope should be easy to operate without making the OB/GYN uncomfortable.	Does not hinder hysteroscopy procedures due to straining the physician's muscles, joints, or bones during use
		Lightweight
UN2	The hysteroscope sheath can access the uterus without causing injuries or pain on entry.	Can enter the cervix without causing cervical injury or requiring significant cervical dilation
UN3	The hysteroscope can easily access all parts of the uterus.	Has sufficient working length
UN4	The hysteroscope can be used in a "see-and-treat" approach.	Able to switch between diagnostic and operative modes without significantly increasing the procedure duration
UN5	The sheath facilitates distension fluid control to provide optimal visualization during hysteroscopy procedures.	Distension fluid puts enough pressure on the uterine wall to optimize visualization
		Distension fluid doesn't cause complications due to fluid absorption
UN6	Hysteroscopy procedures will not cause significant complications for the patient.	Will not perforate the myometrium
		Provides feedback to the surgeon to prevent myometrial perforation
UN7	The hysteroscope can be used multiple times without sterilization issues.	Sheath should be safely reusable and compatible with standard clinical and hospital sterilization methods.
UN8	The sheath should not cause significant pain to the patient due to perforation.	Sheath should conform to uterine tissue upon contact
UN9	The sheath should be aligned with the cervical canal during a procedure.	Sheath maintains coaxiality with the cervical canal
UN10	The hysteroscope sheath is compatible with all common hysteroscopy tools.	Sheath contains an appropriately sized independent channel for standard operative tools
		Sheath contains an appropriately sized independent channel for a standard endoscope
		Sheath should be able to withstand curving in the uterus and cervix without buckling or applying excessive stress to channels within
		Sheath does not impede the endoscope's field of view
		Sheath should prevent pulsing of distension fluid to improve visibility.

Table 1. User needs and corresponding objectives. User needs were developed through interviews, research, and device use workflow to capture user preferences at every point of the device lifecycle. As previously described, the market lacks a device that properly integrates both the current functionality of a rigid hysteroscope with the conformity of a flexible design, increasing the likelihood of myometrial perforation. Consequently, UN6, UN8, and UN10 are of particular importance.

Problem Statement

OB/GYNs performing polypectomies need a less traumatic hysteroscopic sheath that does not compromise visualization to reduce the risk of uterine wall perforation and subsequent discomfort.

Design Inputs

The critical design inputs address the following three objectives under UN6, UN8, and UN10, respectively: the sheath will not perforate the myometrium, the sheath should conform to uterine tissue upon contact with the uterine wall, and the sheath should prevent pulsing of distension fluid to improve visibility. Constraints for these objectives were determined via engineering analyses “Force Required for Myometrial Perforation” and “Spring Constant for Distal Sheath Conformity”, as well as guidelines for distension fluid pressure management ^[25]. For the first analysis, the maximum force that a sheath can apply to the fundus of the uterus without causing perforation was determined to be approximately 78 N, given the diameter of the sheath and all channels in the sheath. Decreasing the sheath diameter or increasing the size of the channels would decrease this force, and vice versa.

In the second analysis, the proximal and distal segments of the sheath were assumed to be joined by 3 ideal springs. The spring constant required for the springs to be fully compressed upon the sheath applying the minimum force required for myometrial perforation (as informed by the first analysis) was determined to be about 260 N/m. Under the assumptions, the springs would act opposite the force of the uterus on the sheath when the sheath contacts the uterus. Furthermore, the distal sheath segment would retract into the proximal sheath segment until the perforation force is achieved, allowing conformation to the uterine wall through axial compression. This reduces the contact force experienced by the uterine wall, reducing the likelihood of myometrial perforation.

For the third objective, it was determined through literature review that the general maximum intrauterine pressure during a hysteroscopy is 100 mmHg, whereas the recommended pressure during a procedure is 70 mmHg ^[25]. To prevent impaired visualization due to turbulent flow arising from changes in pressure, the pressure should settle from 100 mmHg to 70 mmHg in under 2 seconds ^[16].

One key essential design input addresses the ability of the sheath to access the uterus via insertion through the cervix. It was determined that the diameter of the tip of the sheath should be between 2.7 mm and 10 mm based on the typical lower bound diameter of sheaths on the market and standard cervical dilator sizes ^[26,27]. Other essential constraints relate to device sterilization, compatibility with operative tools and optical elements, and ease of use by physicians.

Concept Ideation and Evaluation

Ideation Prompts

The following ideation prompts (IPs) were created to identify specific modes to help guide the solution process.

1. The distal portion of the sheath conforms upon contact with the uterine wall.
2. The sheath delivers feedback to the physician upon contact or prior to contact with the uterine wall.
3. The hysteroscope sheath is specialized for polypectomy.
4. The sheath better manages distension fluid flow.
5. The interaction of the sheath with the cervix relays to the surgeon how much farther the sheath can be advanced.

All IPs were written to address one or multiple user needs associated with the critical design inputs (i.e., UN6, UN8, and UN10). IP1 was written to address the objectives under UN6 and UN8 to not perforate the myometrium and to conform upon contact with the uterine wall. IP2 and IP5 directly address the objective under UN6 to use feedback to prevent perforation. IP3 and IP4 were written to address the requirements for compatibility with operative tools and distension fluid, respectively, under UN10.

Five concepts were generated for each prompt and evaluated using benefit-effort matrices to determine the most promising ideas, which were then evaluated using a Pugh matrix with the following criteria: cost, size, likelihood of perforation, sanitation, precision, and visualization. Cost refers to the production costs depending on material and design complexity. Size refers to the weight and outer diameter of the sheath. Likelihood of perforation refers to whether the design will increase or decrease the rate of occurrence of myometrial perforation during procedures. Sanitation refers to how easily the design can be sanitized. Precision refers to how easily the device can be operated on a small scale. Visualization refers to whether the design will augment or impede visualization of the uterine cavity.

Concept Ideation and Rapid Prototyping

	Criteria	Cost	Size	Likelihood of Perforation	Sanitation	Precision	Visualization			
Ideation Prompt	Weight	0.02421	0.0658	0.4863	0.0658	0.1789	0.1789	Total	Individual Rank	Overall Rank
1	Concept 1	0	0	1	0	1	1	0.8441	1	2
	Concept 2	-1	0	1	0	1	1	0.81989	2	4
	Concept 3	-1	-1	1	-1	0	-1	0.15159	3	11
2	Concept 4	0	0	1	1	1	1	0.9099	1	1
	Concept 5	0	0	1	-1	1	1	0.7783	2	6
3	Concept 1	0	0	1	0	0	0	0.4863	2	8
	Concept 4	-1	0	1	0	1	0	0.64099	1	7
4	Concept 1	0	0	1	0	1	1	0.8441	1	2
	Concept 2	-1	0	1	0	0	0	0.46209	2	10
5	Concept 1	0	0	1	0	0	0	0.4863	2	8
	Concept 5	-1	0	1	0	1	1	0.81989	1	4

Table 2. Pugh Matrix used to evaluate Ideation Prompt concepts. Concepts were ranked -1,0, or 1 in categories cost, size, perforation likelihood, sanitation, precision, and visualization. Categories were weighed based on importance. The highest ranked concepts were chosen for the rapid prototyping phase.

Ideation Prompt 1

The concepts developed for ideation prompt 1 involved adding a component to the distal portion of the sheath or altering its material to enhance its conformity and address the following critical design input: the sheath cannot apply a force of greater than or equal to 78.035 N to the uterine wall. One idea (i.e., spring sheath (concept 1), as seen in **Figure 5**) involved having two separate sheath segments (i.e., proximal and distal) connected via one or multiple springs. Consequently, the spring(s) would compress upon contact with the uterine wall, decreasing the stress experienced by the uterine wall, ultimately decreasing the likelihood of myometrial perforation. A similar concept (i.e., flexible tip sheath (concept

2)) involved constructing the distal sheath segment with a more flexible material than the proximal sheath, allowing the distal sheath itself to compress upon contact. Another approach (i.e., inflatable cover sheath (concept 3)) was to place a button-actuated inflatable cover over the distal end of the sheath. The cover would inflate slightly in front of the tip of the sheath. Furthermore, it would be more flexible than the sheath and increase the contact surface area upon hitting the uterine wall, decreasing the pressure experienced by the myometrium and, therefore, the likelihood of perforation. As shown in **Figure 4**, these three concepts were found to be the most impactful and attainable.

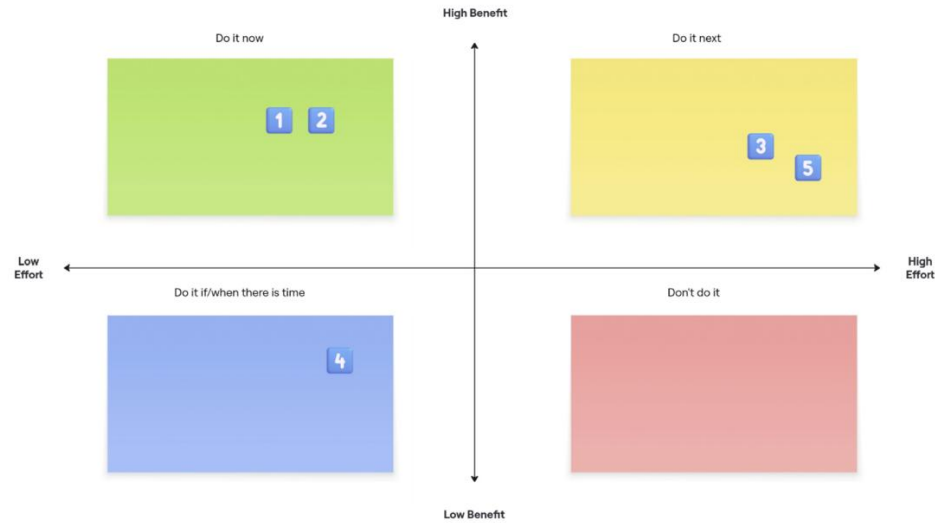


Figure 4. Benefit-effort matrix for concepts addressing ideation prompt 1. (1) The spring sheath, (2) the flexible tip sheath, (3) the inflatable cover sheath, (4) a sheath with a rounded tip, and (5) a sheath with compressible support arms that are released from the outer surface of the distal sheath upon button actuation.

It was determined that an inflatable cover may significantly impede visualization and increase the effective outer diameter of the sheath. Furthermore, the flexible material and pneumatic components required for the flexible tip and inflatable cover concepts, respectively, would have significant negative impacts on manufacturing costs. Consequently, the spring sheath was determined to be the best concept for ideation prompt 1, and a low-fidelity model was developed to determine its viability.

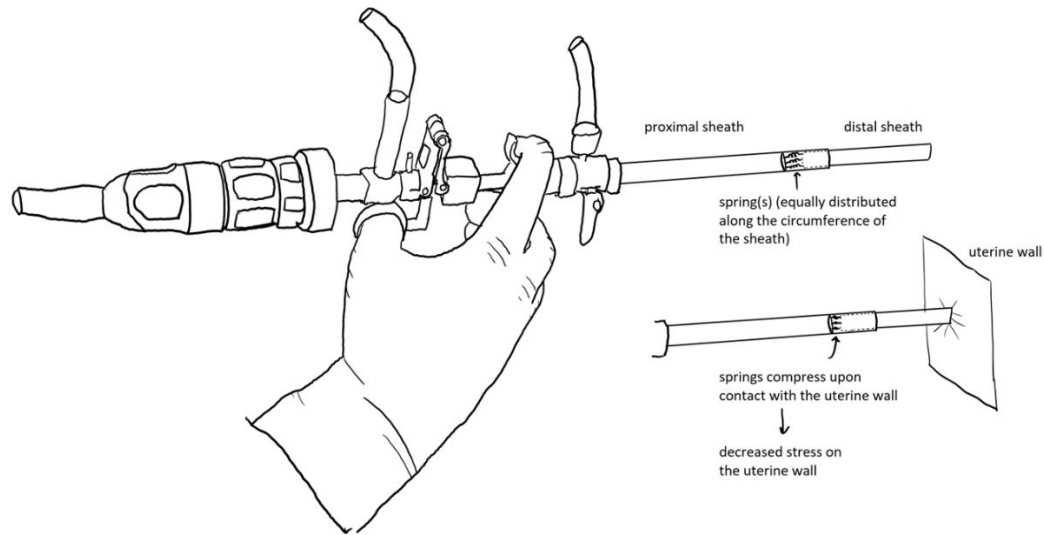


Figure 5. Sketch of the spring sheath ideation concept. The incorporation of springs into the sheath allows the distal segment to retract into proximal segment upon contact with the uterine wall. Consequently, a larger force can be applied to the sheath before the force experienced by the myometrium causes perforation.

The spring sheath was constructed using a hollow metal rod (6 mm outer diameter) attached along the outer surface of its proximal end to the distal end of a spring. The proximal end of the spring was embedded in foam and inserted into a hollow plastic tube acting as the proximal sheath, which was then inserted into a block of wood acting as the sheath handle (as shown in **Figure 6**). Furthermore, a different hollow metal rod of the same size inserted into the block of wood was used as the control sheath. As shown in **Figure 7**, a track was built for testing the force required to perforate a piece of paper, in which a force gauge was used to push the sheath handle toward a piece of paper until perforation occurred. Three samples for both sheaths were obtained to demonstrate how the integration of a spring into the sheath can increase the force required to cause myometrial perforation.

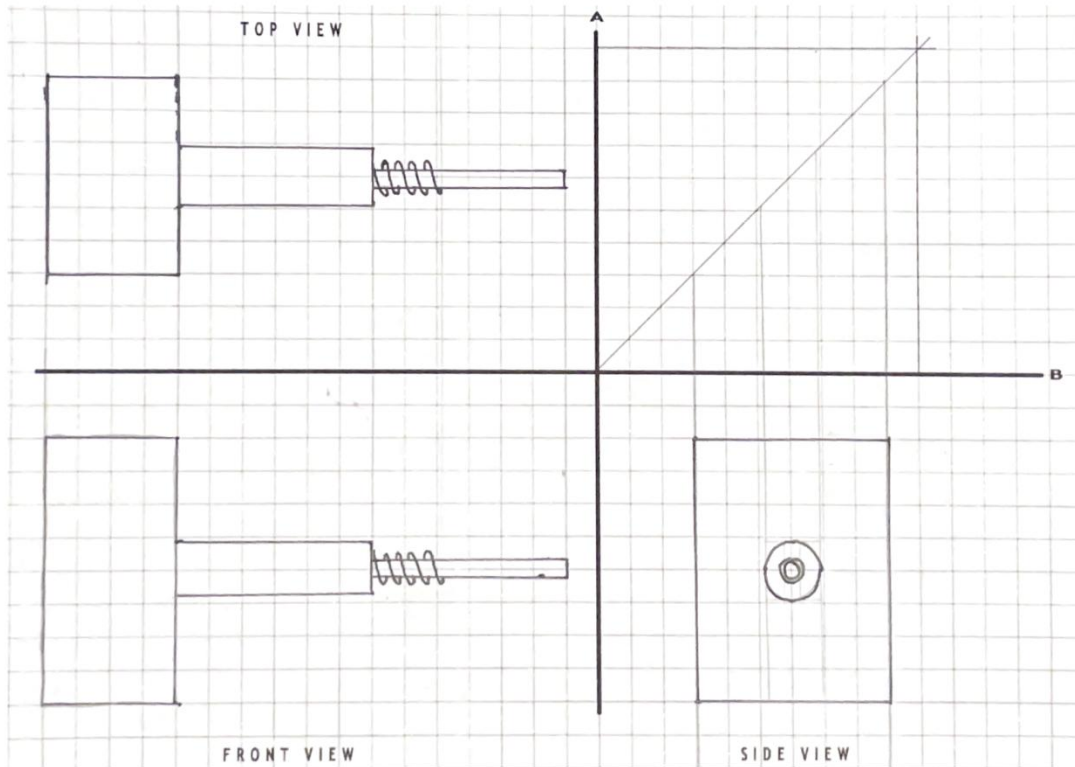


Figure 6. Orthographic sketch of low-fidelity spring sheath model.



Figure 7. Rapid prototyping spring sheath perforation force testing. The top features the spring sheath prior to applying a force to a sheet of paper. The bottom shows the control sheath applying a force to a piece of paper. The force gauge readings were recorded until the paper samples were perforated, and the maximum forces were identified and compared. The mean and standard deviation of the perforation forces for the spring sheath and control sheath were 17.93 ± 1.07 N and 21.73 ± 0.71 N, respectively.

Unexpectedly, the spring group had a lower average perforation force than the control. This may be because the sheath in the spring group was not positioned perfectly normal to the piece of paper during testing due to its flimsy nature. Consequently, the sheath in the spring group was also applying a shear stress to the paper. Because the ultimate shear stress of paper is much lower than the ultimate normal stress, the spring group may have perforated the paper at lower forces than in the control group. Therefore, it was determined that the next generation of this design must not be flimsy, possibly by locating the spring within the sheath instead of on the exterior.

Ideation prompt 2

Ideation prompt 2 states that “the sheath should deliver feedback to the physician upon contact with the uterine wall”, to address the design input, “provides feedback to the surgeon to prevent myometrial perforation”. Current hysteroscope systems offer visual feedback (through the camera feed) and tactile (via distal resistance transmitted through the handle). However, visual cues may be obstructed by distension fluid or tissue debris, while tactile feedback is subtle because the uterine wall is composed of soft endometrial and myometrial tissue. Consequently, the physicians may not perceive sufficient resistance before perforation occurs.

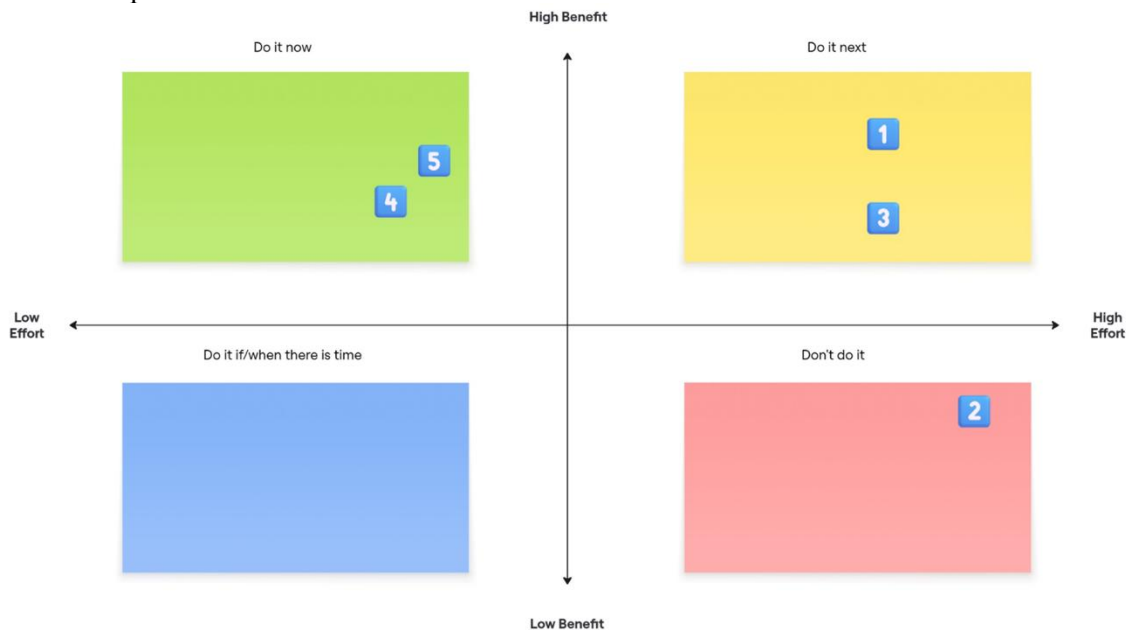


Figure 8. Benefit-effort matrix for concepts addressing ideation prompt 2. (1) A pressure sensing tip with visual feedback from a warning light, (2) A handle that transmits haptic feedback through increased vibration with increased applied pressure, and (3) Acoustic feedback through tone changes upon increased applied pressure. (4) A force limiting compliant tip containing an internal spring at the distal end of the sheath, and (5) A force limiting compliant tip containing a distal tip composed of a graded-stiffness material.

To enhance feedback during insertion and manipulation of the hysteroscope, five design concepts were generated under Ideation Prompt 2

- 1) Pressure-sensing tip with visual feedback (LED warning light)
- 2) Haptic feedback handle transmitting vibration proportional to applied pressure.
- 3) Acoustic feedback system producing pitch changes under increased pressure.
- 4) Force-limiting compliant tip with internal spring at the distal sheath end.
- 5) Force-limiting compliant tip with graded stiffness polymer at the distal end.

Concepts (1)-(3) were identified as high-impact but high-effort ideas due to the integration of electronic systems requiring embedded sensors, signal processing, and sterilizable circuitry, which are features beyond the current prototyping capabilities. Additional evaluation criteria revealed potential usability concerns; the visual or auditory alerts could be confused with other OR equipment, and the haptic vibration feedback may interfere with precise instrument control.

Concepts (4) and (5), in contrast, are mechanically based solutions that limited applied force without relying on electronics. Both designs aimed to conform to intrauterine anatomy upon contact, providing intuitive and tactile feedback through distal compression.

A benefit-effort matrix (**Figure 8**) was used to evaluate each concept based on clinical impact and ease of manufacturing. Concept (5), the graded stiffness distal tip, was determined to offer the highest benefit to effort ratio and was therefore selected for rapid prototyping.

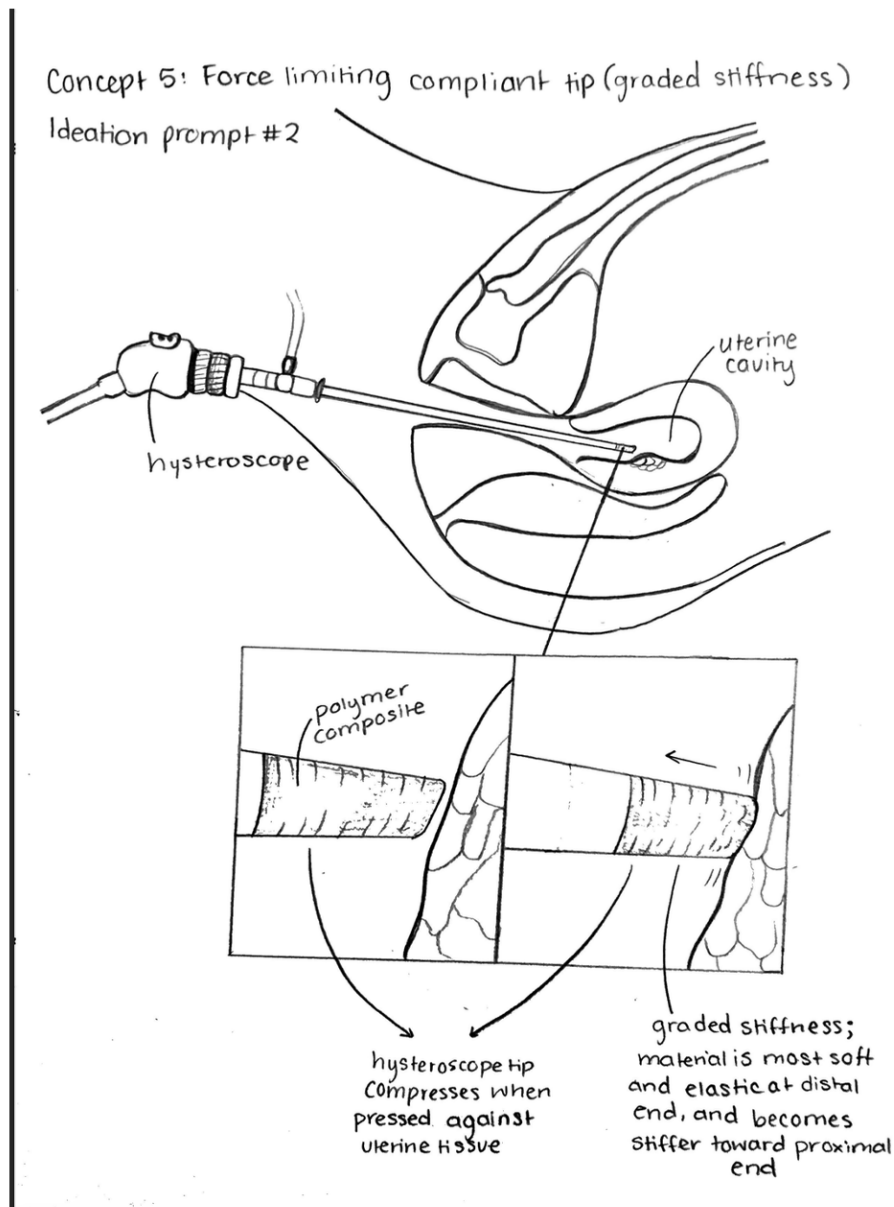


Figure 9. Concept sketch 5: A force limiting compliant tip containing a distal tip composed of a graded-stiffness material.

Concept 5 is a mechanical design that avoids reliance on electronics, is compatible with existing sheath geometries, provides tactile feedback to the physician, and allows for tissue conformity upon impact. The concept sketch shown in **Figure 9** demonstrates a physician operating the graded stiffness sheath. The proximal and middle portions of the sheath remain rigid and metal, however, the distal tip is a polymer composite material that elastically deforms upon contact with the uterine wall, evading the risk of an endometrial and myometrial perforation.



Figure 10. Rapid prototype of force limiting compliant tip containing a distal tip composed of a graded-stiffness material.

A rapid prototype of concept 5 was fabricated as shown in **Figure 10**. The outer hysteroscope sheath was modeled using a 9mm diameter hollow steel tube, while a separate insert tool was created from a thin metal rod with a soft foam distal tip to represent the graded polymer region. The assembly simulated an atraumatic insertable tip that deforms elastically upon tissue contact. To evaluate the design, the prototype was positioned against a silicone slab representing the uterine wall, and a 10N force was applied and measured using a force sensor. The same test was repeated using only the rigid metal sheath. The rigid sheath demonstrated no measurable compression, whereas the compliant prototype compressed by 12 mm under the same applied force. This result confirmed that the graded stiffness design effectively absorbs contact force, reducing localized stress and thereby reducing the risk of myometrial perforation compared to a rigid device.

Ideation Prompt 3

Ideation Prompt 3 addresses the design input of having a hysteroscope that can swap between operative and diagnostic modes; therefore, the concept sketches created a sheath that had a resection tool built in and differences in the manipulated or functionality of the resection tool. Concept (1) featured a built-in resection tool that had continuity in the motion of the retraction of the resection tool by changing the mechanism for pulling the resection tool back so that the operator and the resection tool move in the same direction which would create a more intuitive design. Concept (4) is a built-in resection electrode that is dynamically sized based on the polyp size, improving polypectomy efficiency. This idea contains an electrode loop that can be resized through a mechanical action on the sheath like a notched slider. Concept (5) is a built-in resection tool that is extended out of the sheath, designed to swap between operative and diagnostic modes more efficiently by having the resection tool nested inside the sheath until needed. As shown in **Figure 11**, these three concepts were the highest benefit and lowest effort.

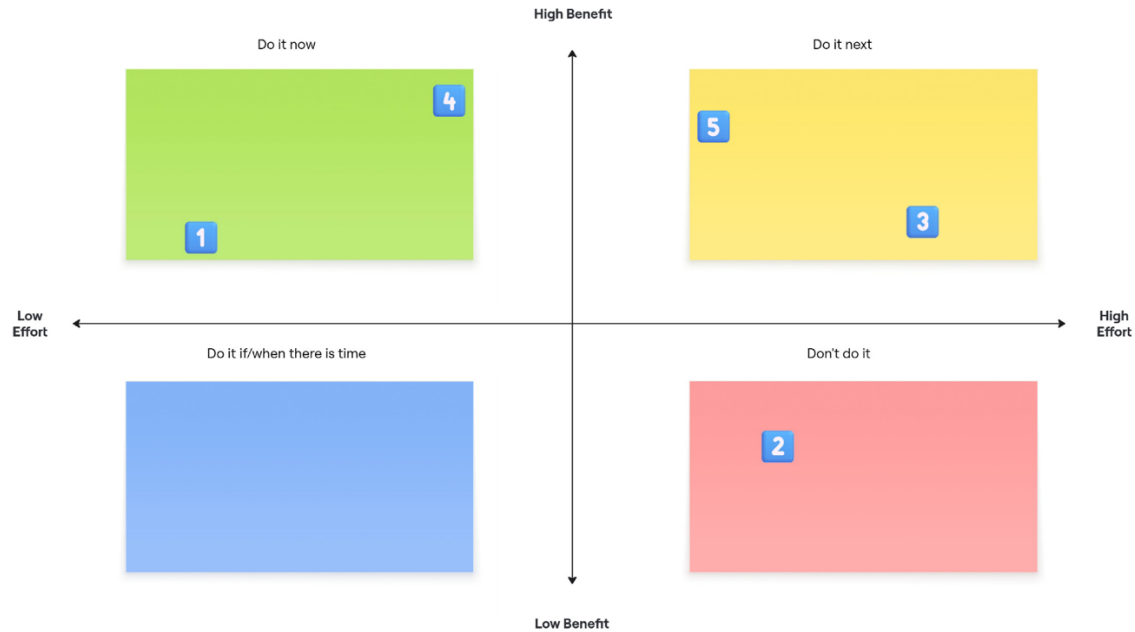


Figure 11. Benefit effort matrix addressing ideation prompt 3. (1)A built-in rescission tool with a trigger for retraction, (2)A sheath with a built-in rescission tool and a radial crank to retract rescission tool, and (3)A built-in rescission tool that could flip out from nested position in the sheath. (4)A built-in resection tool that could be dynamically sized during an operation and a built-in rescission tool that could be mechanically slid out from its nested position in the sheath.

It was decided that a built in rescission tool that was nested within the sheath to be later released through a mechanical mechanism could significantly increase the size taken up in the working channel of the sheath. A mix of concept 1 and concept 4 proved to be the most impactful whilst minimizing effort for a low-fidelity model.

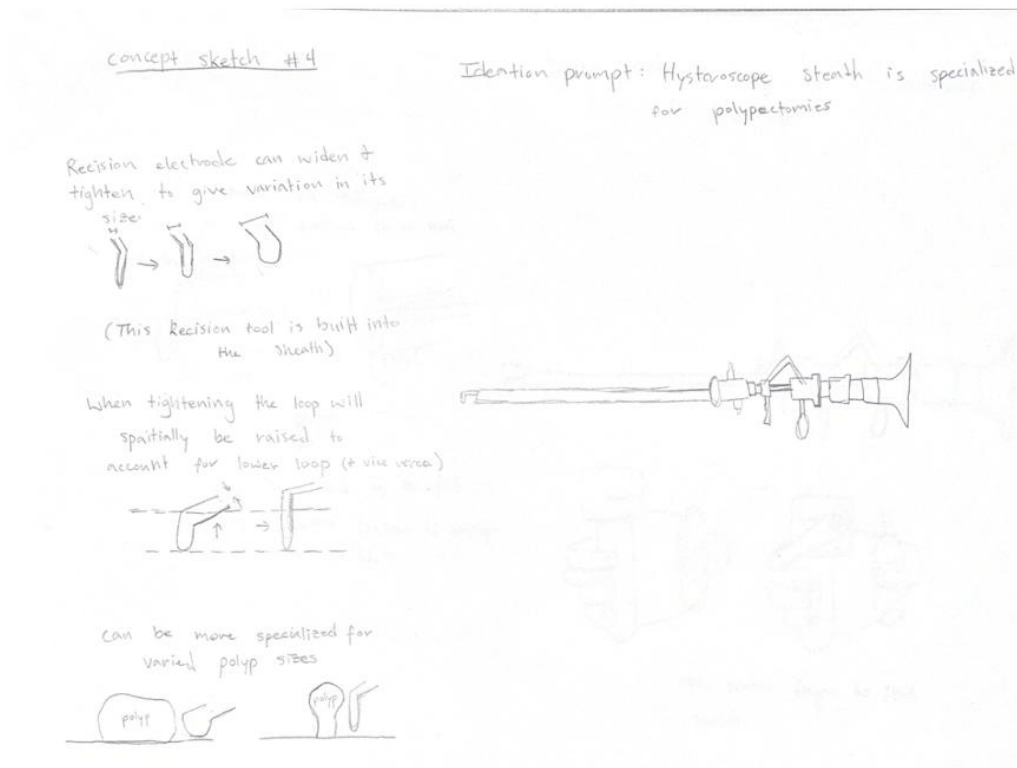


Figure 12. Sketch of the dynamically sized resection electrode loop. The built-in resection tool that can be resized during the operation allows for different sized polyps to be quickly and efficiently removed so that operation times are lower. This also allows for more consistent changing from an operational and diagnostic mindset.

The model was constructed using a hollow metal rod with two wooden sticks inserted within. On one end of the sticks, a loop of metal wire was wound around and secured with scotch tape. One of the wooden sticks was used to tighten or loosen the loop. On the end of this stick without the wire a golf tee was attached to act as a handle for pulling the stick back and pushing it back in.

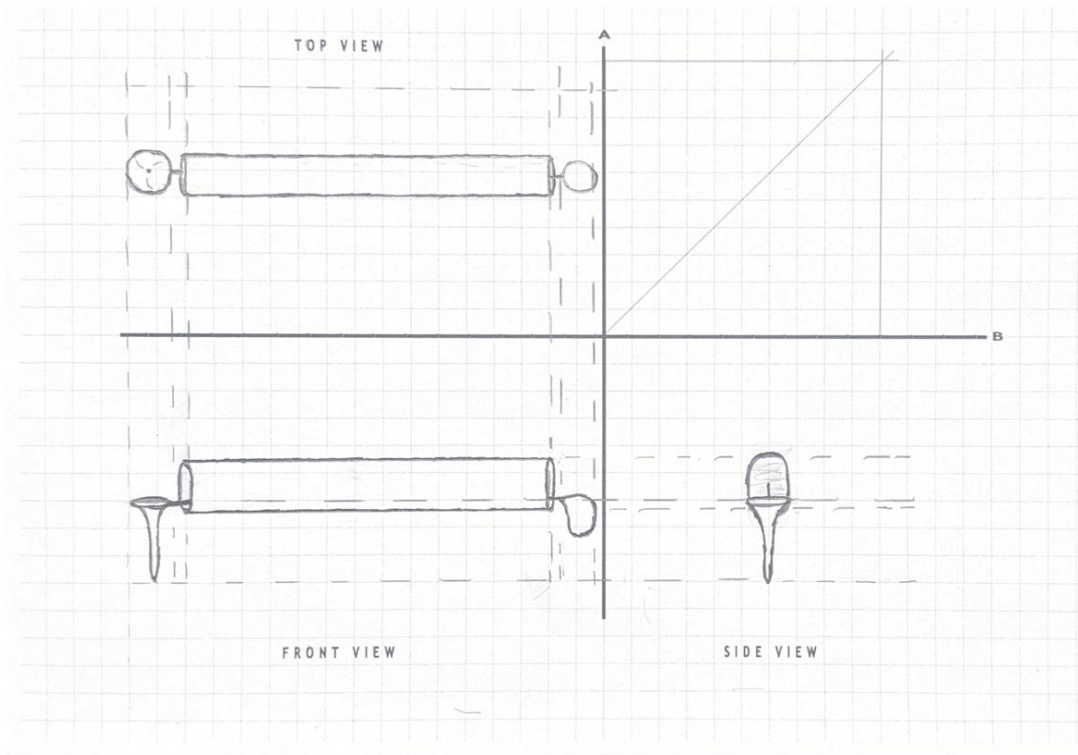


Figure 13. Orthographic drawing of the rapid prototype for concept 4



Figure 14. Rapid prototype of dynamically sized built-in resection electrode hysteroscope

As shown in **Figure 15**, the loop was tested for its minimum and maximum achievable diameters and was cross referenced with the size ranges of polyps from literature, which varied from a few millimeters centimeters, with the latter being rarer. The electrode loop diameter should be able to range from 0.95-3.5 cm in diameter to effectively resect all commonly found polyps.



Figure 15. Rapid prototyping of the dynamically sized resection electrode loop testing. The left shows the largest diameter being measured to be 4cm. The right shows the smallest loop diameter being measured to be about 1cm.

While the prototype was relatively successful, the scope of this idea seemed greater than anticipated and didn't align with the theme of the other concepts, thus this thread was abandoned.

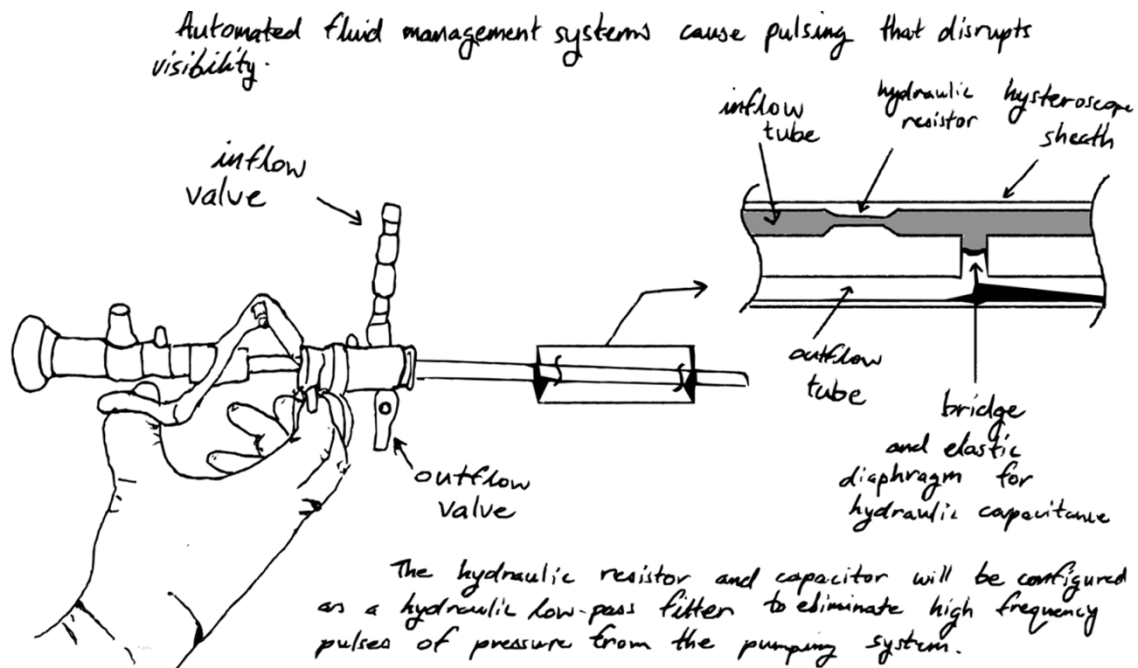


Figure 16. Fluidic low-pass filter to attenuate pulsing from automated fluid management systems. A constriction on the inflow tube is used to create a fluidic resistor while a membrane is placed in a bridge between the inflow and outflow tubes to act as a fluidic capacitor these act equivalently through their electrical analogs and thus form a low pass filter in this configuration.

Ideation Prompt 4

The fourth ideation prompt is aimed at improving the physician's control over distension fluid. Distension fluid is necessary to properly visualize the uterus for operative hysteroscopy, but it is also risky. Using too much hypertonic distension fluid or leaving distension fluid in the uterus for an extended period can lead to conditions like hypernatremia or hypovolemia. One solution to control the volumetric flow is to use an automated fluid management system, but the physicians we interviewed found that these systems pulse the fluid, which can disturb visibility. To attenuate this pulsing, concept 1 implements a fluidic low pass filter, as shown in **Figure 16**. If the physician still decides to use a more classical gravity based or manual fluid management solution, there is a risk of miscalculations of the amount of fluid used or the intrauterine pressure. Concept 2, shown in **Figure A3**, prevents this by adding a pressure gauge and stopper at the inflow valve of the hysteroscope to prevent the intrauterine pressure from exceeding an unsafe level. In the case of a perforation, distension fluid can leak into the abdominal cavity, further disturbing the tonicity of the patient's fluids. To prevent this, concept 3 adds a spring-loaded tip to block the inflow tube in case of excessive force. Concept 4 aims to reduce the risk of conditions like hypernatremia resulting from misuse of the distension fluid by adding a permeable membrane between the inflow and outflow channels. Any excess ions that might flow out of the patient will be collected in the outflow fluid, and concept 4 will allow for it to re-enter the uterus through the inflow tube. It also includes a sliding impermeable block that would be controlled by an osmolarity sensor to modulate the permeability of ions from the outflow fluid into the inflow fluid. Concept 5 provides the simplest means for the physician to control fluid flow by adding a valve at the distal end. This valve could build up pressure and release it in a burst to either displace any loose obstructions on the uterine wall or debris blocking visibility on the camera. It would also act as a final defense to prevent fluid inflow when it is not needed.

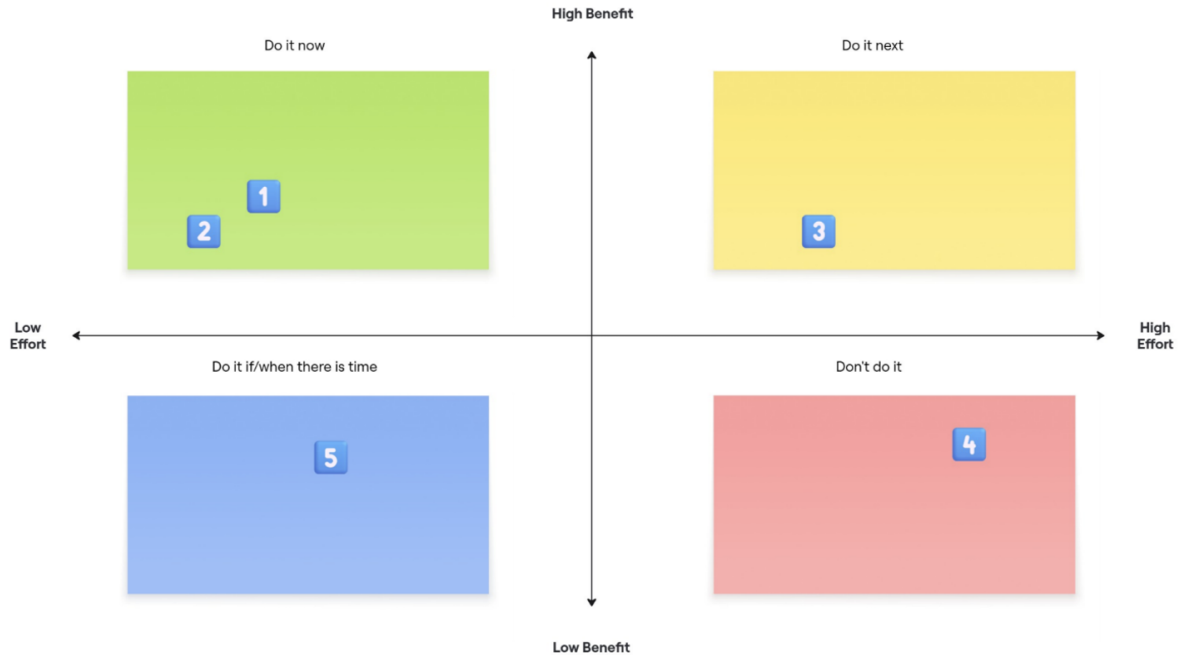


Figure 17. Benefit and effort matrix addressing ideation prompt 4. Concepts 1 and 2 involved the least effort and highest benefit. Concept 1, a fluidic low-pass filter, addresses a problem brought up during user interviews that could prevent the adoption of newer automated fluid management systems that improve the safety of fluid distension with the addition of static, non-moving parts. Concept 2, a pressure gauge tube with a stopper, also employs a relatively simple mechanism to directly prevent excess pressure in the uterus, thus mitigating the riskiest aspects of fluid distension. Concept 3, a spring-loaded locking mechanism to block fluid inflow on contact with the uterine wall, involves an intricate mechanism that may be difficult to implement in a small enough profile that wouldn't obstruct any other functions of the hysteroscope, but it does address a serious concern in the case of uterine perforation. Concept 4 has the highest complexity since it would involve semi-permeable membranes and an osmolarity sensors. Moreover, it would have relatively little benefit since an isotonic solution that is used for an appropriate period shouldn't pose a serious risk to the patient. Concept 5, a valve at the distal end of the hysteroscope sheath, is a relatively simple idea, but it doesn't directly address any problems and thus has relatively little benefit.

From this analysis, concept 1 was determined to be the most feasible and beneficial design to move forward with. A rapid prototype was constructed, as sketched in **Figure 18**, to test whether the basic topology of the fluidic capacitor and resistor would affect the relaxation time of a uterus modeled by a balloon. The relaxation time acts as an analog for the true attenuation at the cutoff frequency but is easier to measure. **Figure 19** shows the rapid prototype constructed from silicone tubing and plastic fittings. A small piece of plastic was fitted over two of the fittings to create a fluidic capacitor. Syringes were used to inject fluid into a balloon through the device and without it. This initial test showed qualitatively that the relaxation time of the balloon was reduced by the device, as expected.

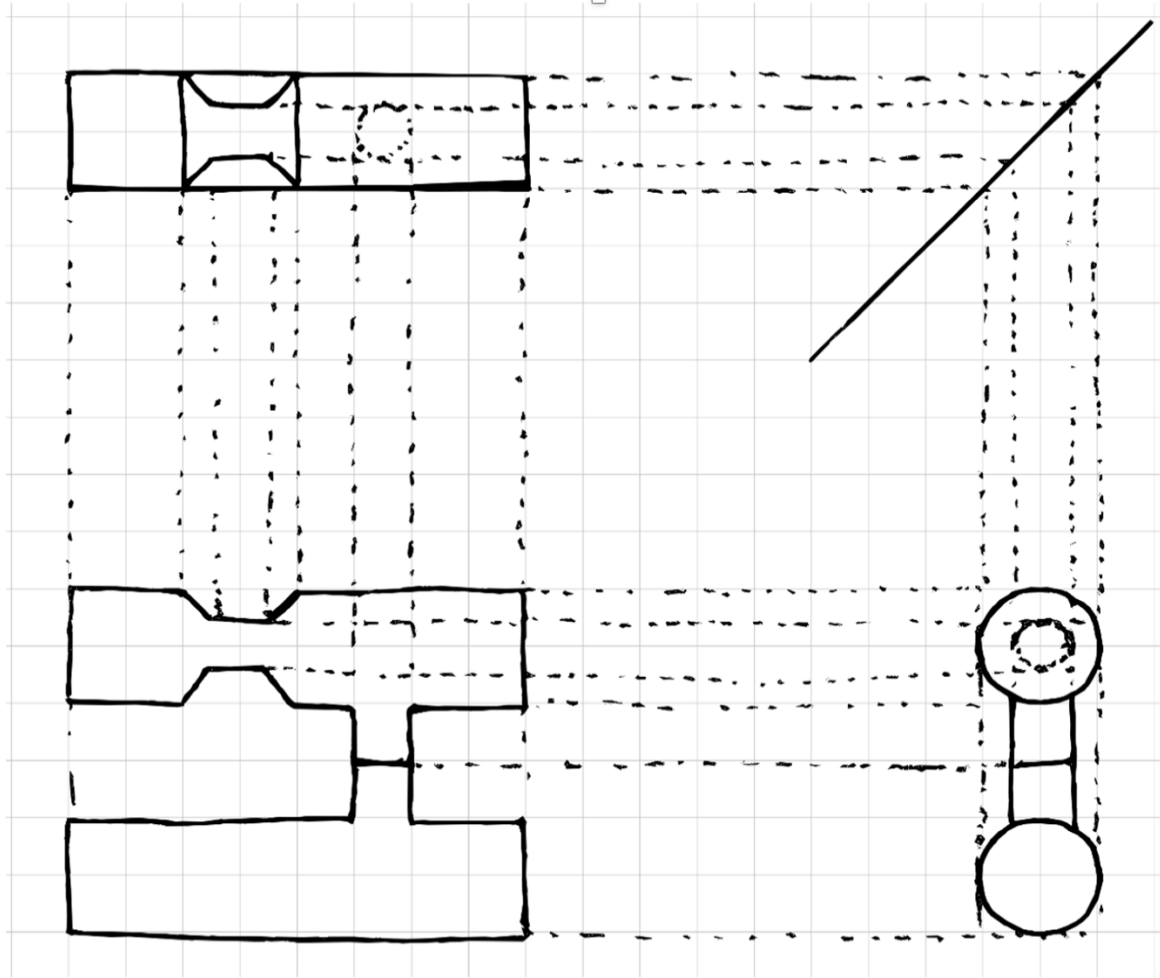


Figure 18. Orthographic sketch of rapid prototype for ideation prompt 4 concept 1.



Figure 19. Rapid prototype of fluidic low-pass filter.

Ideation Prompt 5

The fifth ideation prompt was “Interaction of the sheath with the cervix relays to the operator how much further the sheath can be advanced.” This addresses the user need requiring physical feedback to the physician from the device as the physician gets closer to the fundus upon insertion of the device, which is the most common point of perforation. The value of clear feedback to the user has been emphasized

throughout user interviews, as multiple OB/GYNs commented on the lack of clear or consistent feedback. Current on-market hysteroscopes require a high degree of experience-based inference for a user to understand risk of perforation through tactile feedback. Five concepts were developed from this ideation prompt. Concept 1 amplified the friction-based tactile feedback that physicians currently rely on through a gradient friction coating that increases frictional coating between the hysteroscope and the cervix as the scope moves further into the uterus. Concept 2 was the laser time-of-flight concept, which would send laser pulses through distension fluid and using the time frame it takes for them to be reflected as a method of estimating distance from the sheath tip to the fundus. Concept 3 had to do with a pre-measurement protocol, that utilizes the uterine sound, a preexisting tool used by OB/GYNs to measure the uterus, in combination with a marked hysteroscope to demonstrate the remaining depth of the uterus as the tool is inserted. Concept 4 was the computer-vision assisted procedure idea, which works by letting a computer algorithm estimate depth and iteratively develop a map of the uterine cavity. Concept 5, shown in **Figure 20**, builds on Concept 3 by developing a specialized tool, inspired by the uterine sound, that measures a path to the back of the uterus that the hysteroscope can then move along throughout insertion.

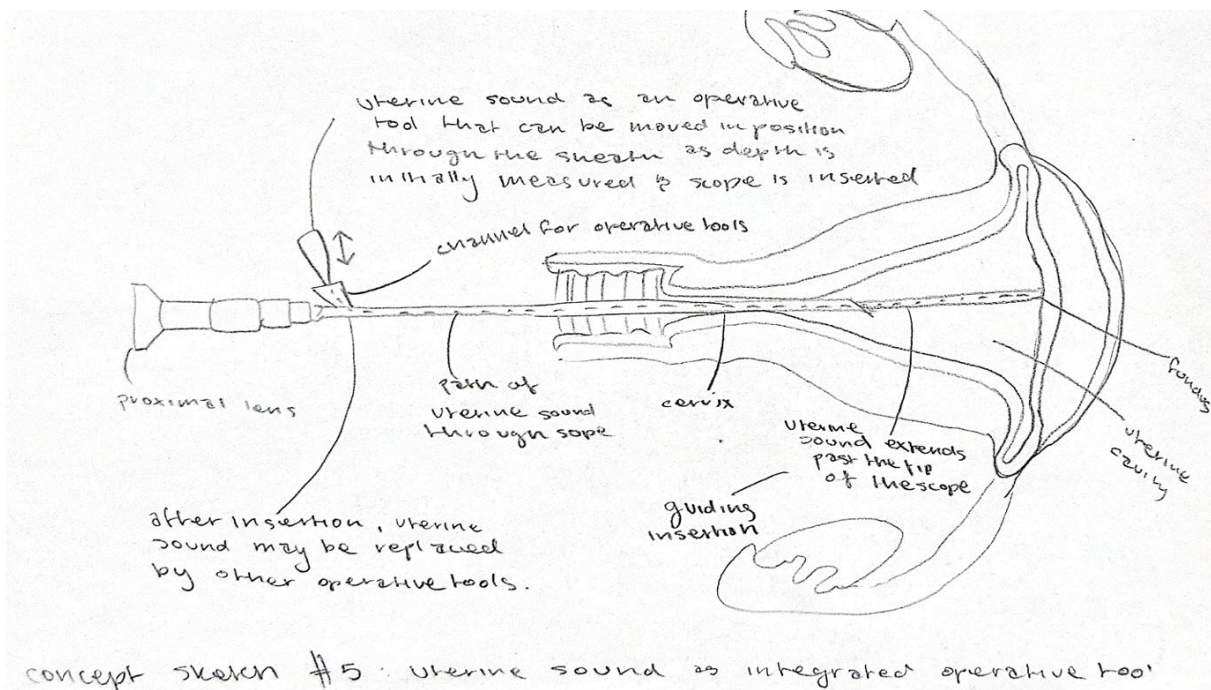


Figure 20. Sketch of concept 5, the uterine sound as an integrated operative tool.

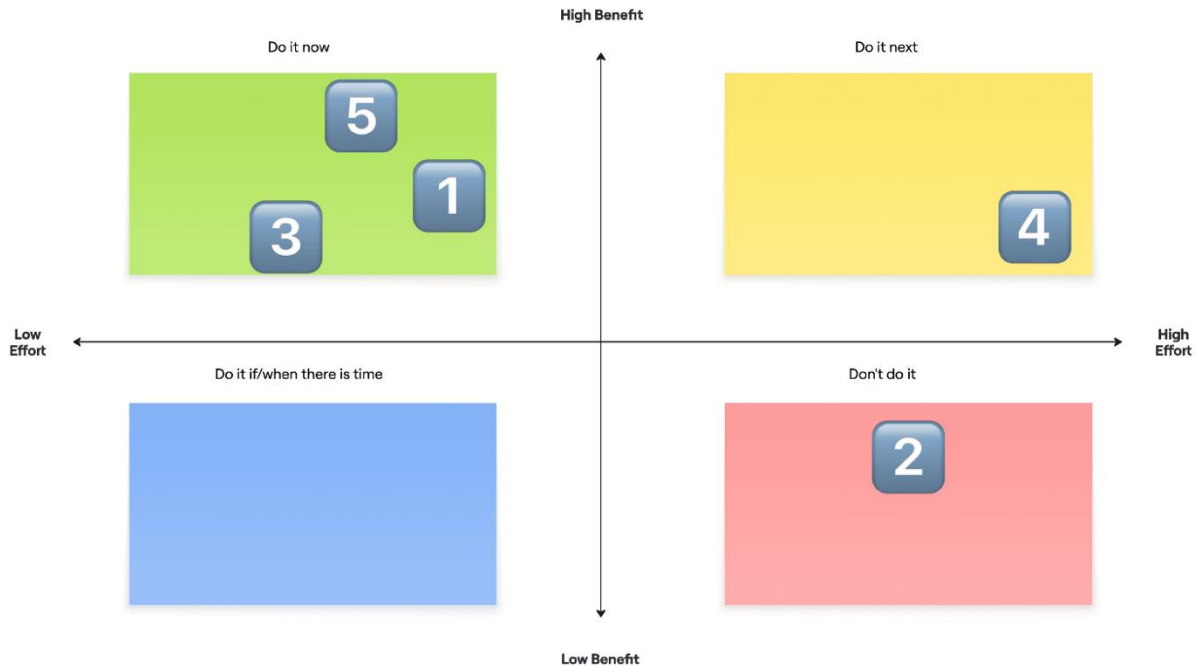


Figure 21. Benefit-effort matrix for concepts addressing ideation prompt 5.

Concepts were evaluated through a benefit-effort matrix. Concepts 2 and 4 were ruled out due to high effort and relatively low benefit. Both concepts require circuit and coding system development that are outside the scope of this course. Among the remaining concepts, concept 5 was found to have higher benefit than concept 4 because the integration of the uterine sound as an operative tool creates less opportunity for error or deviation from the path of measurement causing unintentional perforation. Concept 1 was also maintained as a way of improving the current standard method of feedback for physicians, requiring little training for the user but increasing the feedback they receive. However, the benefit for concept 1 was rated lower than for concept 5, as the feedback method for concept 1 is qualitative, rather than quantitative as in concept 5.

In addition to the benefit-effort chart, a Pugh matrix, included in the appendix, was constructed to justify subsequent design decisions. The main criteria promoting concept 5 included feasibility, feedback benefits, ease of use, and testability. Concept 5 had the most realistic path of designing and testing the design inputs given available materials and time, while giving the user clear and understandable feedback in a variety of uterine anatomies. Concept 5 could be used by OB/GYNs without requiring significant extra training or physical effort and had high translatability of quantitative testing results to user needs.



Figure 22. Rapid Prototype for concept 5, the uterine sound operative tool for insertion

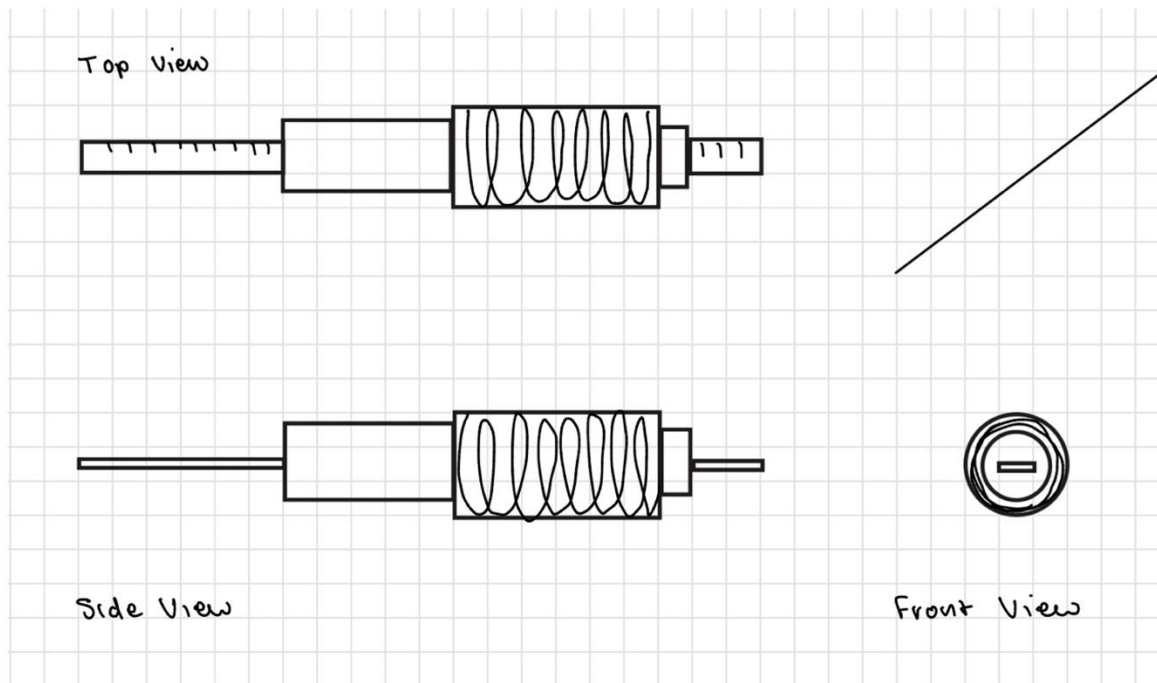


Figure 23. Orthographic sketch for concept 5, the uterine sound operative tool for insertion

A rapid prototype of concept 5 in conjunction with the telescoping spring compression model of the hysteroscope was constructed. The purpose of this prototype was to determine whether the operative tool developed in concept 5 could be integrated into the device along with a telescoping design, as it was determined that addressing the physician feedback component of main user needs alone would not comprehensively address the perforation risk factors that users highlighted in the user interviews, including size and stiffness of the device. As shown in **Figures 22 and 23**, the prototype was constructed by creating a flat measurement tool that passes through a spring compression sheath system that compresses at a force threshold. The operative tool was able to be used as a track for which the spring compression sheath travels along, without affecting the ability of the sheath to compress.

Design Process

After evaluating all design concepts and rapid prototypes for each ideation prompt, three design threads were determined to be the most influential towards developing a final design. More details regarding these threads among others can be found in the Design Evolution and Evaluation Matrix (DEEM).

Thread 1: Spring Sheath

As previously mentioned, the low-fidelity spring sheath prototype had the obvious design flaw of the spring being fastened to the outside of the distal sheath without any internal support to maintain proper alignment, causing the sheath to be flimsy. As discussed during a previous interview with OB/GYN Sarah Smith, it is critical that the sheath maintains alignment with the cervical canal to prevent perforation and facilitate an effective operation^[16]. Furthermore, the lack of alignment while testing the model invalidates the comparison of perforation forces between the spring and control sheaths. To address this, another iteration was designed with the spring located within the sheath. This design was inspired by the toilet-paper roll holder used in the rapid prototype addressing ideation prompt 5, as it

utilized a spring within two coaxial cylinders to allow the inner cylinder to retract into the outer cylinder upon contact with something. Furthermore, the spring closely lined the inner wall of the cylinders. Emulating this in the hysteroscope sheath would allow telescopes and operative tools to still be inserted through the sheath without impedance from the spring.

The new design involved two coaxial 3D-printed plastic sheaths, with the distal sheath having an outer diameter of 7.5 mm. The distal end of the proximal sheath had a recessed cylindrical portion where the spring and the proximal end of the distal sheath were inserted. Consequently, when force was applied to the distal sheath, the spring would compress as the distal sheath retracted into the proximal sheath. The same control sheath and test method were used as for the rapid prototype, as shown in **Figure 24**.



Figure 24. Generation 1 spring sheath perforation force testing. The same setup was used as for the low-fidelity spring sheath model. The mean and standard deviation of the perforation forces for the spring sheath and control sheath were 23.68 ± 8.18 N and 19.00 ± 2.61 N, respectively.

The spring group had a higher average perforation force than the control group, as expected, demonstrating the importance of the sheath maintaining alignment. Consequently, based on this data, the conformity of the spring in the experimental sheath allows the user to apply a larger force to the experimental sheath before perforation occurs. However, there are two main limitations to this test. Firstly, the distal spring sheath has a larger wall thickness and outer diameter and a smaller Young's modulus compared to the control sheath, which could act as confounding variables when determining the efficacy of the spring in increasing the perforation force. Additionally, paper may not be an appropriate substitute for uterine tissue. Therefore, in future iterations, both sheaths should have the same material and dimensions, and perforation force testing should be performed using a material that more closely simulates uterine tissue, such as soft silicone sponge rubber ^[28].

Thread 2: Graded stiffness hysteroscope tool with measuring ring.

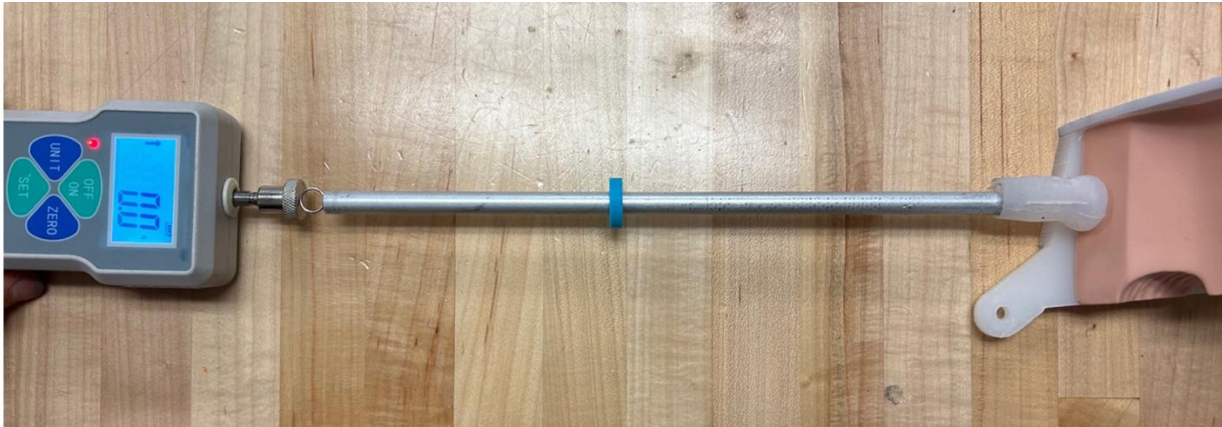


Figure 25. Generation 1 prototype of graded stiffness hysteroscope tool with external measuring ring. The prototype is shown undergoing testing with a force sensor to measure the deformation of the silicone tip.

This generation 1 prototype, as shown in **Figure 25**, combined leading concepts from ideation promotes 1 and 5 into a cohesive prototype: a sheath featuring an atraumatic graded-stiffness tip and an external measuring ring indicating uterine depth. These two subsystems work in tandem to address the major concern of uterine perforation during polypectomies by both mitigating excessive contact force and providing a physical reference for maximum safe insertion length, while providing haptic and visual feedback to the physician.

The outer sheath was modeled using a 9 mm diameter hollow steel tube to simulate the typical geometry and rigidity of commercial hysteroscopes. A complementary internal tool was designed with a thin metal rod and a soft silicon tip to represent the atraumatic distal tip. To create the tip, a silicone mold was CAD-modeled, and 3D printed, then used to cast a silicone sleeve that fit securely over the distal end of the inner rod. Four longitudinal slits were cut along the silicone tip to allow controlled compression under applied loads. This design enabled the tip to deform when contacting tissue, dissipating force rather than transmitting it directly to the uterine wall. **Figure 26** illustrates how the silicone tip compresses under applied pressure, representing its intended mechanical response during insertion.

In parallel, a small measuring ring was CAD modeled and 3D printed to fit tightly around the hysteroscope sheath. This ring serves as a visual indicator of insertion depth. During simulated use, the physician would insert the hysteroscope with the silicone tipped tool extending beyond the distal end. Upon reaching the uterine wall the tip compresses elastically, allowing the physician to identify the end of the cavity without risk of perforation. The measuring ring can then be slid to the external reference point at the vaginal canal to mark the maximum safe insertion depth. This mechanism can be reapplied throughout a polypectomy, allowing the physician to reestablish the safe depth limit after repositioning or resection.

To evaluate the prototype, a mechanical test was conducted using a silicone slab to represent the uterine wall. a 10 N force was applied using a force sensor while the tip contacted the slab. For comparison, the same setup was repeated using the rigid sheath alone under a 10N applied load. The rigid sheath demonstrated no measurable compression, while the atraumatic tool compressed 16 mm under equivalent force. This deformation confirmed the concept's ability to absorb force and conform to tissue surfaces, validating its potential to reduce localized stress and perforation risk. Additionally, the measuring ring was tested for functionality by sliding it along the sheath to confirm smooth operation and stability during simulated insertion.

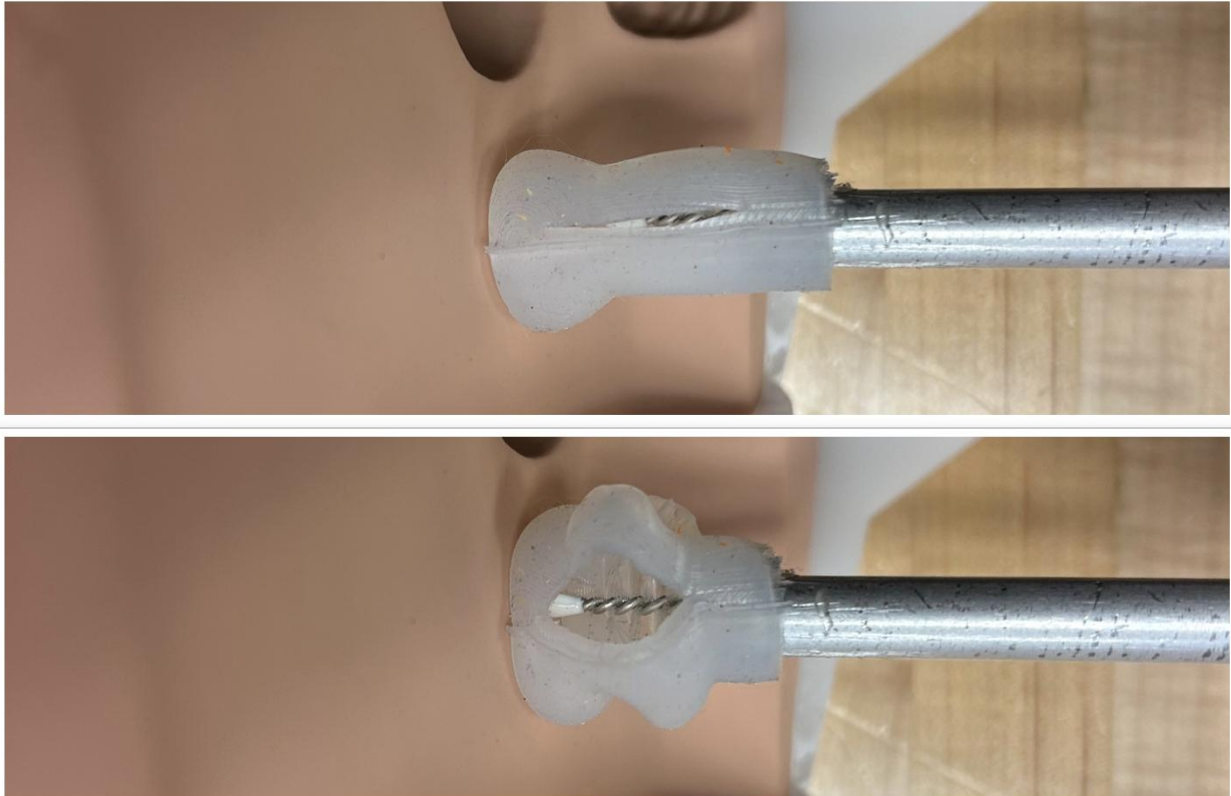


Figure 26. Generation 1 prototype of graded stiffness hysteroscope tool with external measuring ring. The prototype is shown with the atraumatic silicone tip in its relaxed state and pushed against a human tissue model. The silicone tip conforms by compressing by 16 mm when axially loaded with 10N.

User feedback was gathered through trials of peer observations while using the device. Users agreed the prototype retained the traditional hysteroscope design whilst incorporating accessory safety features. It was noted that although the measuring ring improved depth awareness, it should be redesigned as a more compact addition to avoid obstruction of the field of view or interfere with hand positioning. Additionally, users expressed difficulty threading the tool through the outer hysteroscope sheath due to bulkiness of the silicone tip, therefore, the silicone tip dimensions will be adjusted to reduce friction within the sheath and allow smoother insertion and removal. Considerations for future iterations of this prototype include deciding which kind of hysteroscopic sheath this system is most compatible with, how the measuring ring will accommodate other tools and barriers on the external sheath and ensuring the silicone tip won't obstruct the camera's view.

Future iterations will address these considerations and refine existing features to integrate feedback and measurement mechanisms into one design that minimizes perforation risk whilst maintaining intuitive user operation.

Thread 4: Fluidic Low-Pass Filter

The rapid prototype shown in **Figure 19** had arbitrary constriction sizes and membrane radius. Additionally, the balloon was not filled to a realistic pressure for the uterus during distension. To quantitatively test the device, it was determined by analyzing a video of pulsing during distension that a pulsation of about 9 Hz can be expected from automated fluid management systems^[29]. Thus, a cutoff frequency of 5 Hz was chosen. From this, the membrane area and silicone tubing length were determined to achieve this cutoff frequency. Initially, an attempt was made to fit the fluidic capacitor and resistor into the housing of the hysteroscope sheath, as shown in **Figure A4**, but this was not feasible to manufacture

since many of the details were below the tolerance of 3D printers. Instead, a much larger fluidic capacitor radius was chosen to fit in a housing external to the hysteroscope. The fluid management system would then pump into this housing through a fluidic resistor, and the output would be fed into a hysteroscope sheath. A testing setup with this prototype is shown in **Figure 27**.



Figure 27. Generation 1 prototype of fluidic low-pass filter. Two syringes are used, one at the input and one to limit outflow. The yellow box contains a membrane that acts as the fluidic capacitor. The yellow nozzle connected to the balloon is only to create a water-tight seal with the balloon. In practice, the cervix would provide this seal. Additionally, the contraption would be sitting out of the way with the automated fluid management system and its output would feed into the hysteroscope sheath.

For this prototype, the balloon was also inflated to a far greater degree to approximately achieve 70 mmHg, which is a realistic intrauterine pressure during an operation ^[23]. The results of testing this prototype were successful. The relaxation time with the prototype was below that without it, and the relaxation time was below 2 seconds, which meets the design input.

Appendix

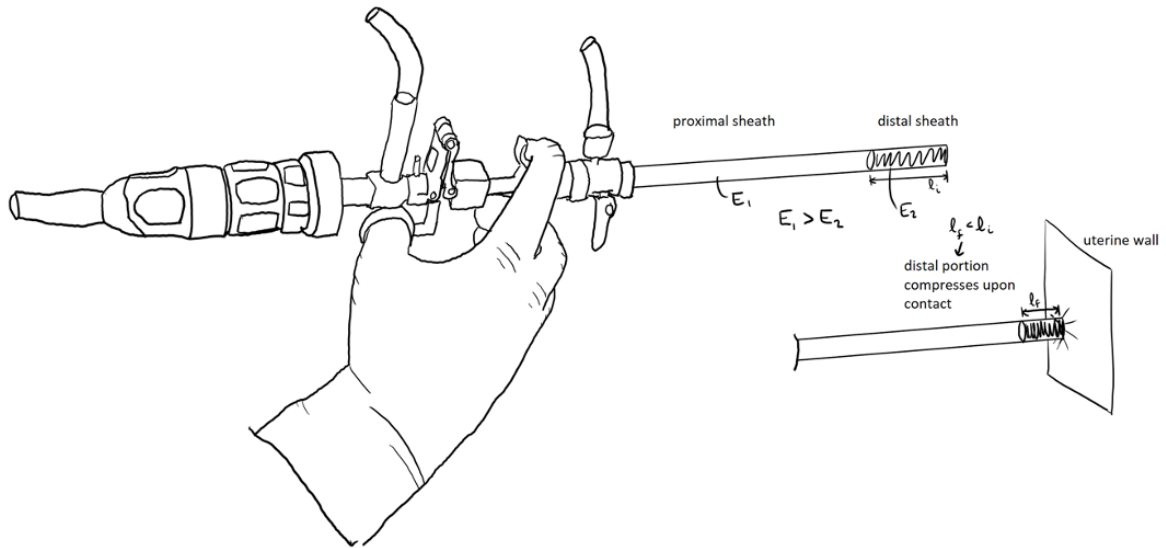


Figure A1. Sketch of the flexible tip sheath concept to address ideation prompt 1.

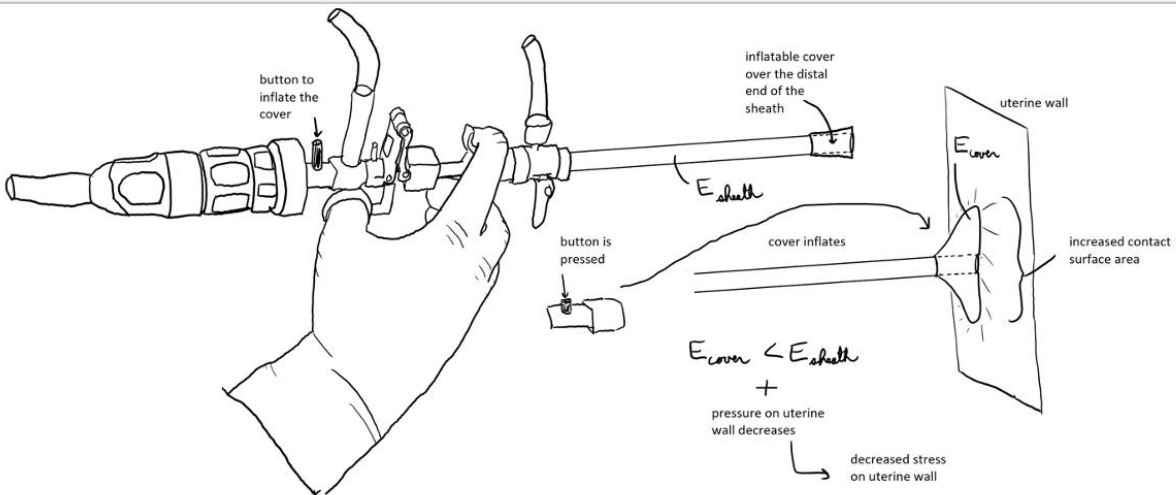


Figure A2. Sketch of the inflatable cover sheath to address ideation prompt 1.

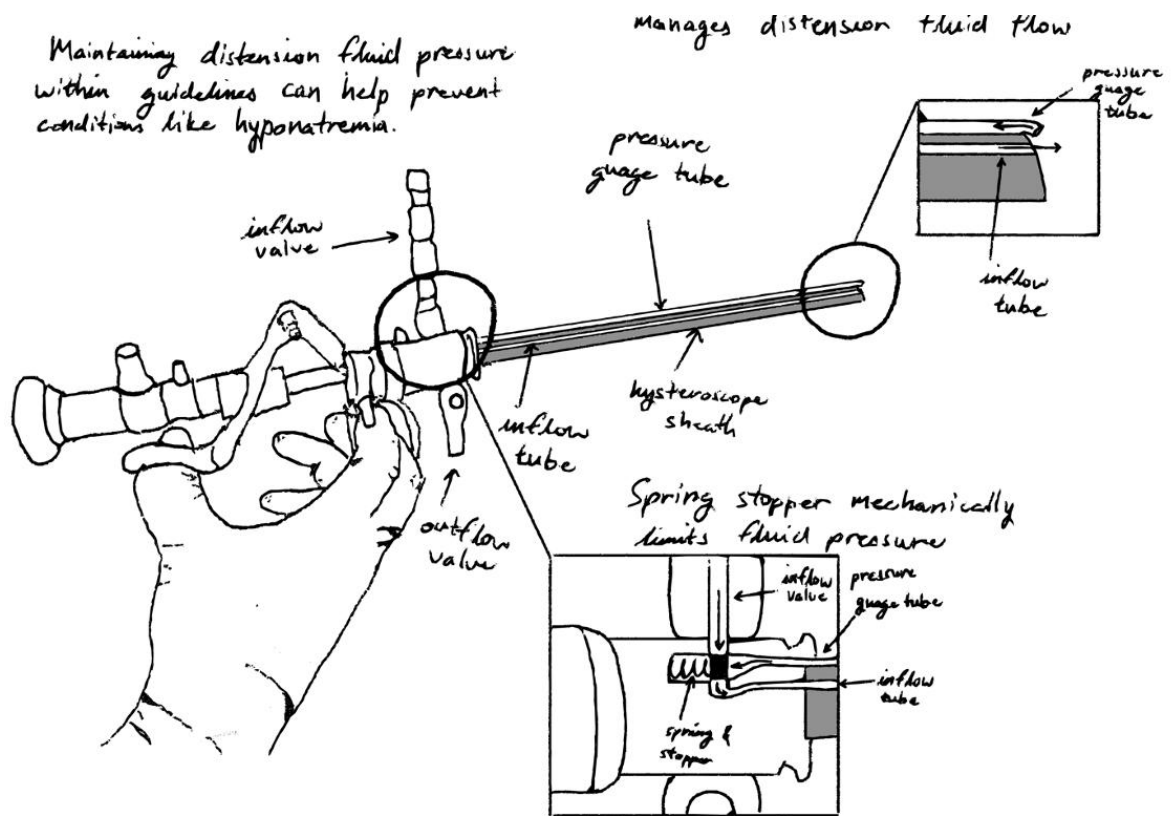


Figure A3. Concept sketch 2 for ideation prompt 4. Shown is a small tube that acts as a gauge of the intrauterine pressure. This tube reaches the base of the hysteroscope sheath where it will dislodge a spring-backed stopper if there is excess pressure, halting the flow of distension fluid into the inflow tube.

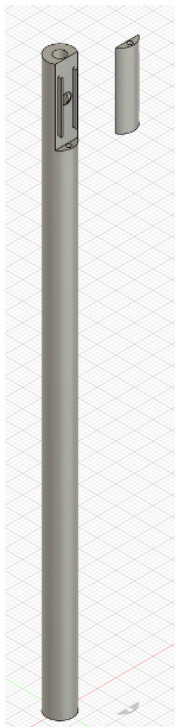


Figure A4. Prototype model of fluidic low-pass filter embedded in hysteroscope sheath.

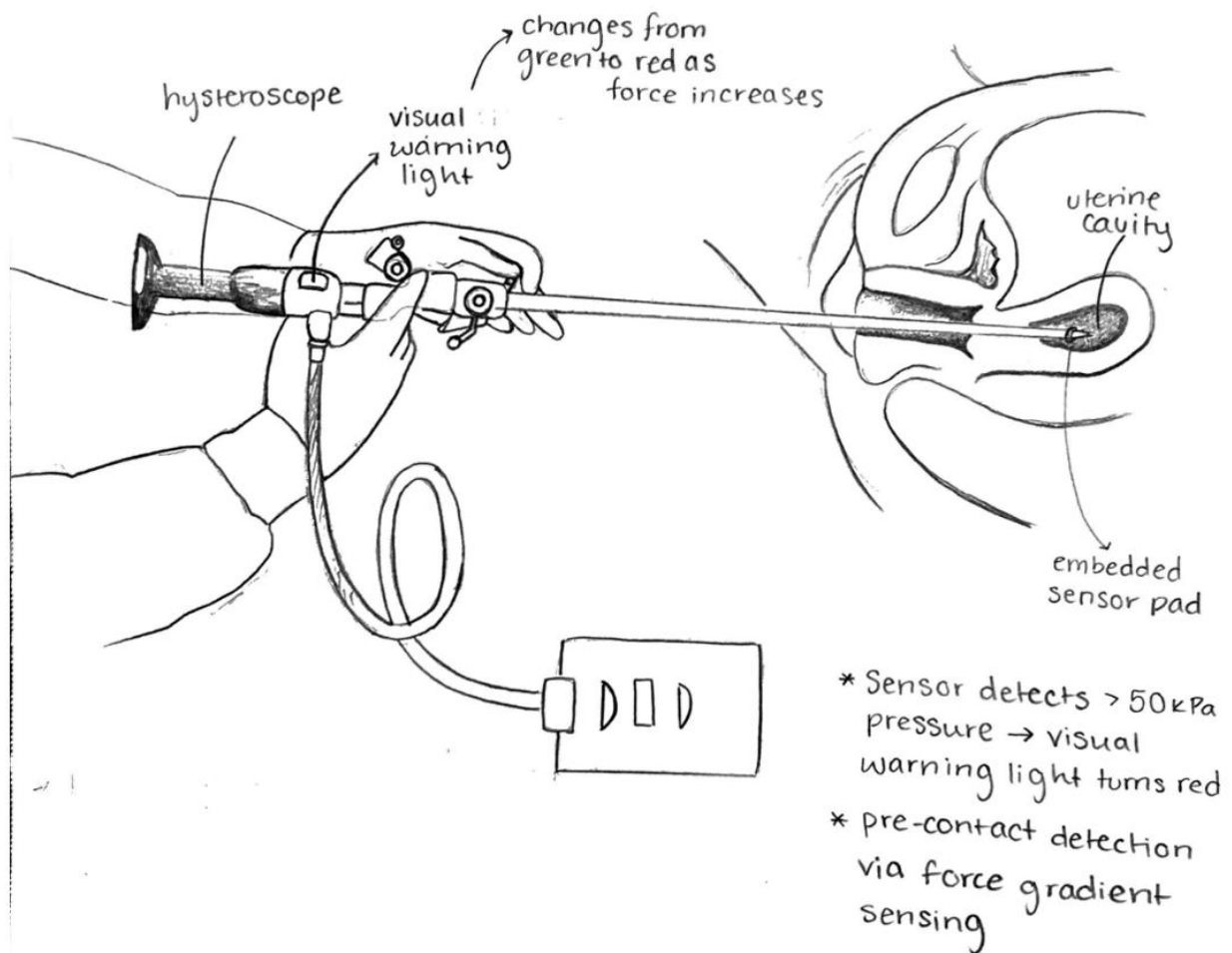


Figure A5. Concept sketch of a pressure-sensing tipped hysteroscope with visual feedback to address Ideation Prompt 2.

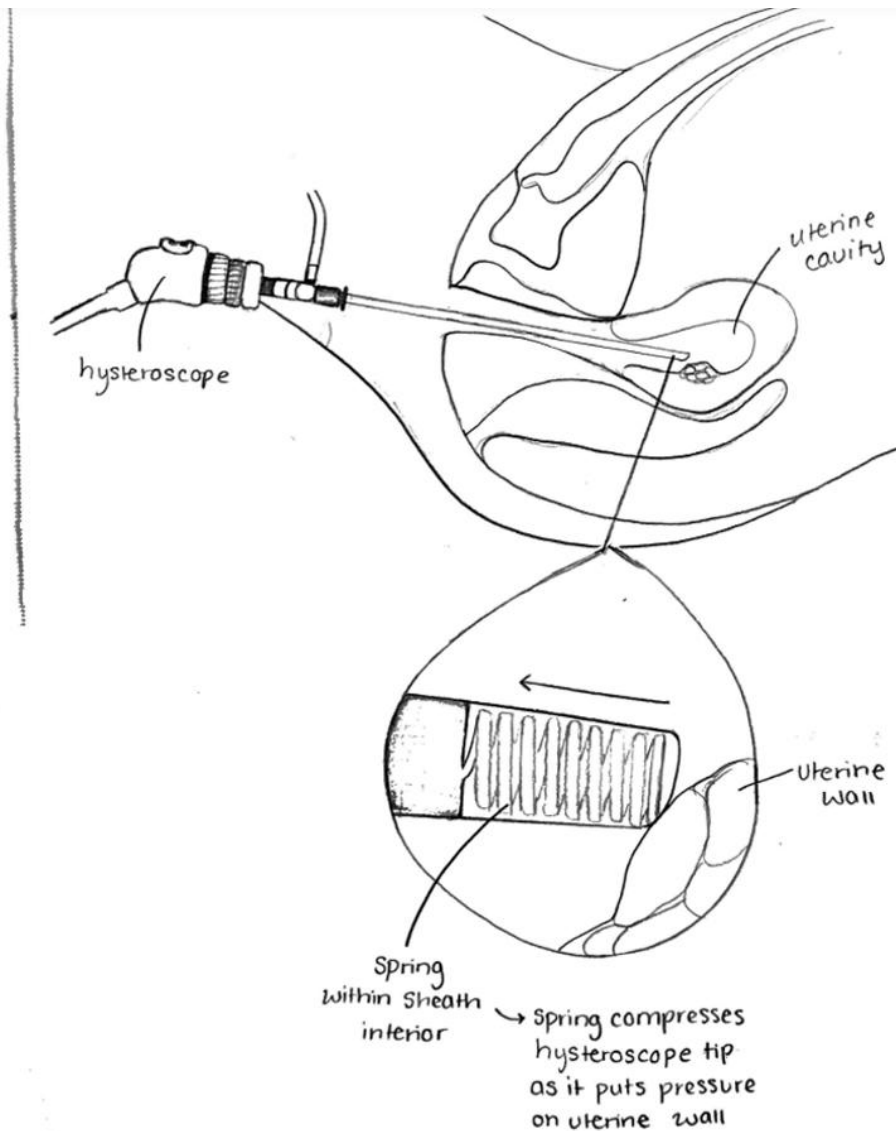


Figure A6. Concept sketch of a force limiting compliant hysteroscope tip with an internal spring system to address Ideation Prompt 2.

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