



ALIGNA - PAINLESS IUD PLACEMENT

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Biomedical Engineering 400

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ABSTRACT

Pain and anxiety during intrauterine device (IUD) insertion can discourage patients from choosing this effective, long-term contraceptive method. Conventional insertion requires a speculum to visualize the cervix, a tenaculum to grasp and stabilize cervical tissue, a uterine sound to measure depth, and a separate IUD inserter that can contribute to discomfort through tissue grasping and repeated instrument passage. While there are existing suction-based stabilizers that replace the tenaculum, these do not address uterine sounding and deployment together. Aligna aims to minimize avoidable pain by integrating cervical stabilization, adjustable sounding, and controlled insertion into one device. The proposed Articusound design uses syringe-generated suction around the ectocervix, the outward-facing cervical surface, with a twist-lock mechanism to maintain the vacuum. A steerable sounding component accommodates uterine orientation, while a locking depth slider and fixed stop shoulder guide deployment to the measured depth. The device should preserve cervical visibility and instrument access without compromising placement control. The device will be fabricated mostly with materials made of silicone and PLA. Planned testing will use anatomical models to evaluate suction retention under traction, depth-setting reliability, and IUD-surrogate placement within 20 mm of the uterine fundus. Fabrication and testing have not begun; mechanical performance and potential pain-reduction benefits remain unverified.

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I. INTRODUCTION

1.1 Motivation/Impact

Intrauterine device (IUD) insertion is a medical procedure performed to place an IUD into the uterus near the fundus to prevent conception. IUDs are among the most effective reversible contraceptive options, with fewer than 1 out of 100 users becoming pregnant during the first year of typical use; unlike daily pills, weekly patches, or monthly vaginal rings, they provide long-term protection without requiring ongoing user action after placement [1]. However, the steps of the procedure can be painful and intimidating for many patients. Anticipated insertion pain can prevent potential users from choosing an IUD: among 252 adolescents without prior IUD experience, 25% reported being uninterested in an IUD because of fear of placement pain [2]. Pain, anxiety, cervical manipulation with a tenaculum, uterine sounding, and variability in clinician technique can all contribute to a negative insertion experience, especially for nulliparous patients.

Therein lies the need for a device that minimizes painful steps and accommodates variation in cervical and uterine anatomy. By combining multiple steps of the insertion process into a single device, providers could simplify IUD placement while reducing the amount of cervical and uterine manipulation required. Ultimately such a device would improve procedural efficiency while reducing patient discomfort and anxiety during insertion.

1.2 Existing Devices & Current Methods

IUDs are considered one of the most effective reversible forms of birth control because they provide long-term pregnancy prevention without requiring daily or frequent action from the user. Unlike birth control pills, which must be taken every day, or patches and vaginal rings, which require regular replacement, an IUD provides continuous contraception after a single placement and can remain effective for several years depending on the type. Other user-dependent methods, such as condoms, also require use each time sexual activity occurs and can have lower typical-use effectiveness. IUDs can also be removed when contraception is no longer desired, with no significant impact on fertility. These advantages make IUDs a convenient and highly effective option for individuals who want reliable, long-term contraception without having to remember to use or replace their birth control on a regular basis. However, unlike many other contraceptive methods, IUDs require an insertion procedure, which can cause discomfort or anxiety for some patients and may discourage some individuals from choosing this highly effective option [1][2].

The traditional method for IUD insertion consists of the use of a speculum, tenaculum, uterine sound, and IUD inserter. The speculum is used to open the vaginal canal and provide visualization of the cervix. The tenaculum acts as a pair of forceps with inward-curving tips that are used to grasp and stabilize the cervix. A uterine sound is a metal or plastic, slightly curved rod that is used to measure the depth and position of the uterine cavity. This measurement is then used to set the IUD inserter to the appropriate depth before it is used to place the IUD near the fundus of the uterus [3]. These instruments can be seen in Figure 1.

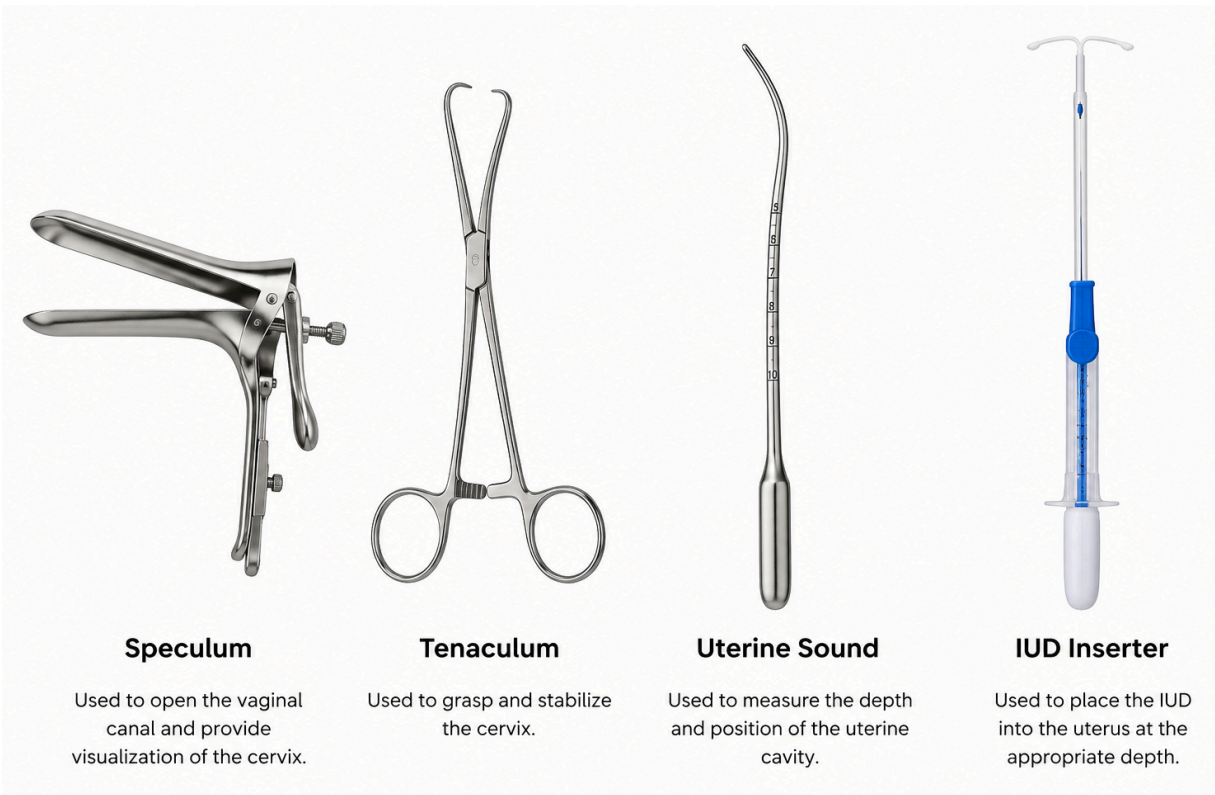


Figure 1. Instruments currently used in the IUD insertion procedure.
Image generated using OpenAI ChatGPT, 2026.

Carevix® is a sterile, single-use suction cervical stabilizer designed as an alternative to the traditional tenaculum. The device uses a horseshoe-shaped suction head that is positioned against the outer surface of the cervix, with the suction head shown positioned above the cervical os along the anterior portion of the cervix in Figure 2. Vacuum is then applied to create a seal with the cervical tissue, allowing the cervix to be stabilized and manipulated during transcervical procedures such as IUD insertion [4]. The FDA classifies Carevix as a uterine tenaculum and cleared it through the 510(k) process [5].



Figure 2. Placement of the Carevix® device on the cervix [4].

The Bioceptive® Cervical Suction Retractor Wand is a suction-based alternative to the traditional tenaculum that is designed to stabilize the cervix during transcervical procedures, including IUD insertion [6]. Unlike the Carevix® suction cervical stabilizer, which uses a localized suction head positioned against the outer surface of the cervix, the Bioceptive device uses gentle suction to engage the cervix at 360° around the cervical opening (Figure 3). This creates a stable, functional portal through the cervix that allows instruments to pass through the cervical canal while the cervix remains stabilized. The FDA's 510(k) record identifies the device as the Bioceptive Suction Cervical Retractor and classifies it as a uterine tenaculum [7].

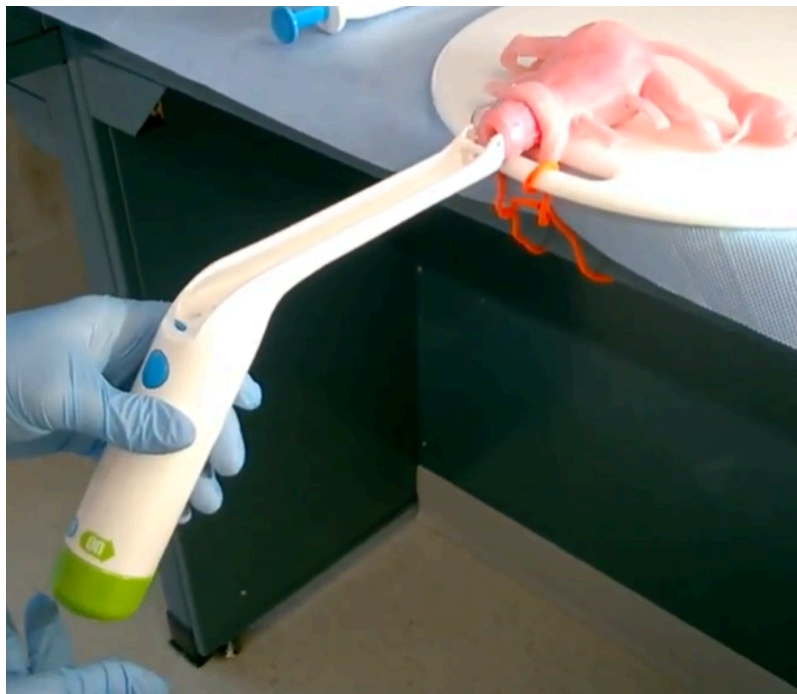


Figure 3. Placement of the Bioceptive® Cervical Suction Retractor Wand on the cervix [6].

Both devices replace the mechanical grasping of a traditional tenaculum with suction-based stabilization, with the goal of reducing tissue trauma and discomfort. However, they do not address other painful aspects of the procedure such as the uterine sounding or need for preventive analgesia. LidoSound (seen in Figure 4) is a modified uterine sound designed to combine two steps of IUD insertion. LidoSound can both measure uterine depth and deliver lidocaine to the cervical and endometrial tissues. The device uses a hollow sound with openings near its tip to deliver the anesthetic as the device is withdrawn. The goal is to provide localized anesthesia while performing the uterine-depth measurement that is already part of the traditional IUD insertion procedure [8]. LidoSound is not currently an established commercial alternative to the tenaculum in the same way Carevix and Bioceptive are. It was developed as a Clemson University bioengineering design project and won the 2025 NIH/NIBIB DEBUT Challenge's *Technologies to Improve the Health of Women Prize* [9].



Figure 4. Lidosound components that come together to deliver lidocaine at the time of uterine sounding [8].

1.3 Problem Statement

Some patients may be deterred from choosing this highly effective, low-maintenance contraceptive option because of the pain and discomfort associated with IUD insertion [2]. The goal of this project is to improve the IUD insertion procedure by developing a device that combines the functions of the tenaculum, uterine sound, and IUD inserter while also incorporating a mechanism to reduce pain or discomfort during placement. Combining these functions into a single device could simplify the insertion process while improving patient comfort.

II. BACKGROUND

2.1 Anatomy and Physiology

The uterus is a hollow, muscular organ consisting of the fundus, uterine body, isthmus, and cervix. The cervix forms the lower portion of the uterus and contains the cervical canal, which connects the vaginal canal to the uterine cavity through the external and internal cervical os (see Figure 5). During IUD insertion, the device is guided through the vagina and cervical canal into the uterine cavity [10]. Once inside the uterus, the IUD is positioned near the uterine fundus, the broad upper portion of the uterus. For a T-shaped IUD, the horizontal arms should be fully extended at the fundus and oriented parallel to the uterine cornua, while the vertical stem should extend downward into the uterine cavity without entering the cervical canal. Correct positioning is important because an IUD located more than 2 cm from the fundus or partially or completely within the cervical canal may be considered malpositioned and may require removal and replacement [11]. The contraceptive effect of the IUD depends on its type: copper IUDs release copper ions that interfere with sperm movement and fertilization, while hormonal IUDs release levonorgestrel, which thickens cervical mucus and inhibits sperm from entering the uterus [12]. Therefore, accurate measurement of the uterine cavity and controlled placement of the IUD are important components of the insertion process.

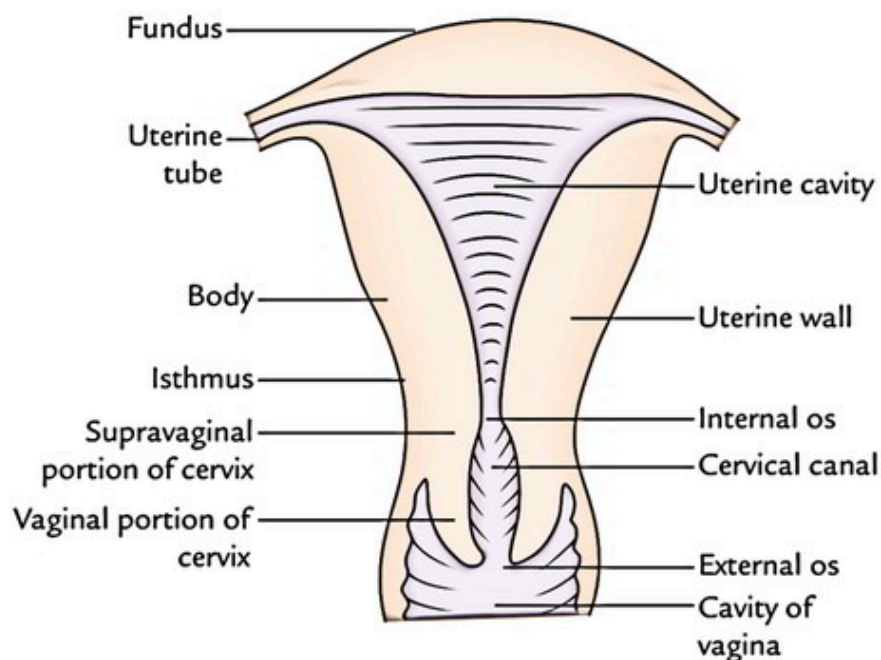


Figure 5. Anatomy of the uterus [13].

2.2 Client Information

The clients, Reshma Kandipati, ZiOnay Walker, Ashley Annah, and Emmanuel Sama, are a group of pharmacy students at the University of Wisconsin-Madison. The UW-Madison School of Pharmacy's annual entrepreneurship competition, SHARx Tank, allows PharmD students to pitch innovative, market-ready solutions to real-world healthcare problems to a panel of alumni judges. The clients submitted their idea for this innovation to the competition and hope to bring their idea to life.

2.3 Design Specifications

The IUD insertion device should be designed to safely and accurately place an IUD within the uterine cavity near the fundus for varying anatomical uterine structures. The distal portion of the device should have an outer diameter of less than or equal to 4 mm to allow for insertion through the cervical canal. The device should be operable using two or less hands and have a handpiece weight of less than or equal to 1.0 kg to allow for controlled use during the procedure (Appendix 10.1). The device should place the IUD less than 20 mm from the uterine fundus with a target success rate of 95% or better, consistent with the requirement for IUDs to be positioned high in the uterine fundus [14]. The device should also withstand at least 100 autoclave cycles at 121–134°C to allow for repeated sterilization (Appendix 10.1). The total procedure time should be roughly five minutes, while the cervical stabilization mechanism should maintain stabilization for at least three minutes. Finally, the design should address painful steps of the traditional IUD insertion procedure and use materials appropriate for contact with the body, following the applicable biological-safety considerations of ISO 10993-1 [15].

III. PRELIMINARY DESIGNS

3.1 Design 1: CerviPump

The CerviPump is an integrated, electrically assisted IUD-placement device that combines cervical stabilization, uterine sounding, depth control, and IUD deployment within one device. Its ribbed handle is designed to improve clinician grip and contain internal channels for the IUD insertion tube, suction tubing, and pressure-sensor wiring. A suction feature is positioned at the top of the cervix os to stabilize the tissue without using a tenaculum. The suction tubing connects to an electrically powered vacuum pump that is activated using a binary on/off switch. The distal end contains a telescoping, slightly curved component that performs the uterine sounding function before IUD deployment. A pressure sensor is intended to identify increased resistance when the distal tip reaches the uterine wall near the fundus. When this threshold is detected, an indicator light alerts the clinician that the selected insertion depth may have been reached. The clinician can then use a deployment slider to advance or release the IUD through the insertion tube. This integrated sequence could reduce the number of instruments introduced into the uterus and potentially shorten the procedure.

3.2 Design 2: Soundless Suction Assist

The Soundless Suction Assist is a comparatively simple design that replaces the tenaculum with a cervical suction device while continuing to use a standard IUD inserter. A single-use, medical-grade silicone suction cup is placed above or adjacent to the top of the cervical os. The clinician activates a hand pump to create suction and stabilize the cervix. A pressure indicator assists the clinician in applying an appropriate vacuum level, and a release button removes suction after the procedure is complete. Unlike the other two concepts, this design does not contain an independent uterine sounding mechanism. It is intended to reduce the number of invasive steps by eliminating the separate sound, which is traditionally inserted through the cervix to estimate uterine depth and orientation. The device would be used alongside an existing IUD inserter, allowing clinicians to maintain cervical stabilization while completing IUD placement with equipment already familiar in clinical practice.

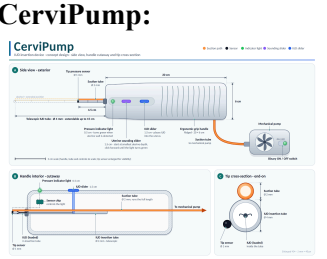
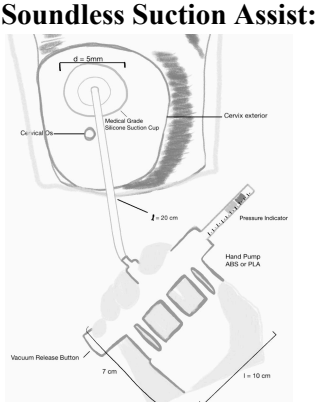
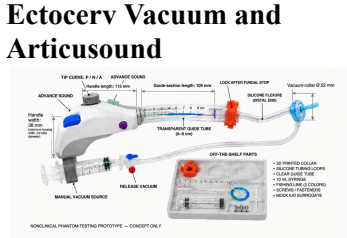
3.3 Design 3: Articusound

The Articusound combines a cervical suction stabilizer with an articulating uterine sounding and IUD-deployment mechanism. The suction component sits around the ectocervix and uses a syringe-style vacuum system. A twist-lock mechanism is intended to maintain the selected vacuum level without requiring continuous manual force. This approach is intended to stabilize the cervix while avoiding the tissue grasping associated with a tenaculum. The primary distinguishing feature of this design is that rather than using a rigid, straight sound, the device includes a steerable and rotatable sounding element that can be directed to better follow the patient’s uterine orientation. A patient’s uterus may be tilted forward (anteverted), tilted backward (retroverted), or positioned more neutrally. A device that can adapt its path may reduce the force required to advance through the cervical canal and uterine cavity, therefore reducing avoidable discomfort and potentially lowering the risk associated with forcing a rigid instrument against the uterine wall. After the device measures uterine depth, the clinician sets a marker, locking slider, or fixed stop shoulder at the measured position. The IUD is then advanced through the same sounding channel to the predetermined depth. The transparent guide tube allows the clinician to visualize depth markings, while the fixed stop is intended to prevent advancement beyond the selected distance. This design preserves the clinical value of uterine sounding while incorporating patient-specific adjustment and a controlled IUD-deployment pathway.

IV. PRELIMINARY DESIGN EVALUATION

4.1 Design Matrix

The three preliminary concepts were evaluated using six weighted criteria. Safety received the highest weight, at 25%, because the device must stabilize the cervix, preserve visibility of the cervical opening, and support accurate IUD placement without introducing unnecessary risk. Universality was weighted at 20% to assess each design’s ability to accommodate patient-to-patient differences in uterine dimensions and orientation. Ease of use was also weighted at 20% because the device should support a straightforward, standardized procedure without requiring excessive controls or complicated maneuvers. Feasibility received 15% to evaluate whether the team could fabricate, integrate, and test the proposed components within the project’s available resources and timeline. Cost was weighted at 10% to account for anticipated component and fabrication expenses while prioritizing clinical function over affordability alone. Originality also received 10% to assess how each concept differs from existing cervical stabilization and IUD-placement devices and contributes a distinct approach to the client’s goals.

Criteria	Weight	CerviPump:	Soundless Suction Assist:	Ectocerv Vacuum and Articusound
				

Safety	25	3/5	15	3/5	15	4/5	20
Universality	20	3/5	12	2/5	8	5/5	20
Ease of Use	20	4/5	16	5/5	20	3/5	12
Feasibility	15	3/5	9	5/5	15	2/5	6
Cost	10	3/5	6	4/5	8	5/5	10
Originality	10	4/5	8	3/5	6	4/5	8
Total	100	66		72		76	

Table 1: The preliminary design matrix was created to judge the three preliminary designs on the chosen criteria. The criteria weighted in importance are as follows: Safety, Universality, Ease of Use, Feasibility, Cost, and Originality. A final section of the total scores for each design which shows that the “Articusound” design scored the highest overall.

4.2 Design Matrix Criteria Analysis

The full design matrix can be found in the Appendix 10.4

4.2.3 Cervipump

CerviPump received an overall score of 66/100, primarily due to the advantages and development challenges of combining cervical stabilization, uterine sounding, and IUD deployment within one device. Its electric vacuum pump can be activated with an on/off switch, while separate sliders control insertion depth and IUD deployment. These controls are intended to reduce instrument exchanges and simplify operation, supporting an ease-of-use rating of 4/5. However, the clinician would still need to verify the sensor feedback rather than rely on the indicator alone to confirm correct positioning. Safety and universality each received 3/5 for distinct reasons. The sensor is intended to detect resistance near the fundus, the uppermost region of the uterus, and provide feedback for depth assessment. However, contact with tissue elsewhere along the insertion pathway could activate the indicator prematurely, making sensor reliability and interpretation important safety considerations. The universality rating reflects the device’s limited ability to actively adjust its direction to accommodate differences in uterine orientation. Although the depth setting allows some patient-specific adjustment, it does not provide the same directional adaptability as a steerable sounding component. Feasibility and cost also received 3/5 because the design requires integration of electrical and mechanical components. A commercially available pump could simplify sourcing, but the sensor would require calibration, and the sounding tube, sliders, suction tubing, and deployment mechanism would require repeated prototype revisions to function together reliably. These requirements increase both development effort and anticipated component expenses. Finally, originality received 4/5 because the sensor-based indicator adds feedback to the integrated sounding-and-insertion process, distinguishing CerviPump from concepts that primarily provide suction-based stabilization.

4.2.2 Soundless Suction Assist

Soundless Suction Assist received an overall score of 72/100, with its strongest performance in ease of use and feasibility, receiving 5/5 in both categories. Its manual suction pump and compatibility with an existing IUD inserter reduce the number of new mechanisms that must be fabricated and operated. While eliminating the sounding component also reduces instrument exchanges and procedural steps. These features make the concept comparatively straightforward to prototype, although the clinician would remain responsible for establishing and maintaining appropriate suction. Safety received 3/5, reflecting the lack of an accurate depth assessment before IUD insertion. The suction interface is positioned above the cervical os—the opening through which the inserter enters the cervix—to maintain access and preserve the

clinician's view. However, removing the separate uterine sound also removes the depth and orientation assessment provided by that instrument. Although the existing inserter includes depth markings, those markings do not themselves establish the patient's uterine dimensions or confirm that the instrument is following the appropriate pathway. The concept therefore simplifies the procedure without providing a dedicated replacement for sounding-based assessment. Universality received 2/5 because the design lacks an adjustable mechanism to accommodate differences in uterine depth and orientation. Unlike an articulating sound, it does not allow active modification of the insertion pathway to match patient-specific anatomy. Its comparatively simple construction and use of existing components supported a cost rating of 4/5, while its reliance on established suction and insertion mechanisms resulted in an originality rating of 3/5. Overall, Soundless Suction Assist prioritizes straightforward fabrication and operation, but these advantages come at the expense of anatomical adaptability and dedicated depth assessment.

4.2.3 Articusound

The Articusound received the highest overall score, 76/100, primarily because of its anticipated ability to accommodate patient-specific anatomy while retaining uterine depth assessment. Its steerable, rotatable sounding component earned a universality rating of 5/5 because the clinician can adjust its direction before and during advancement to account for differences in uterine orientation. This provides greater control over the insertion pathway than a fixed, straight instrument and is intended to support placement near the fundus, the uppermost region of the uterus. Safety received 4/5 because the concept combines sounding-based depth measurement with an adjustable pathway intended to follow uterine anatomy more closely. However, its suction interface surrounds the ectocervix, the outward-facing surface of the cervix, and may partially obstruct the cervical os—the opening through which the sounding component and IUD inserter must pass. The higher safety rating therefore reflects anticipated placement-control advantages, balanced against concerns about visibility and access, rather than a demonstrated reduction in injury risk. These functions introduce additional operational and fabrication demands. Ease of use received 3/5 because the clinician must coordinate suction, articulation, depth adjustment, and deployment rather than manage a simpler stabilization device. Feasibility received 2/5 because the adjustable sounding mechanism and deployment controls require substantial custom fabrication and repeated revisions to function reliably together. The syringe-style, twist-lock suction mechanism supported a preliminary cost rating of 5/5, although this inexpensive subsystem does not establish the cost of the complete assembly. Finally, originality received 4/5 because the adjustable sounding-and-placement pathway distinguishes Articusound from concepts focused primarily on suction stabilization. Overall, the design prioritizes anatomical adaptability and controlled placement, but achieving these advantages requires greater mechanical complexity.

4.3 Proposed Final Design

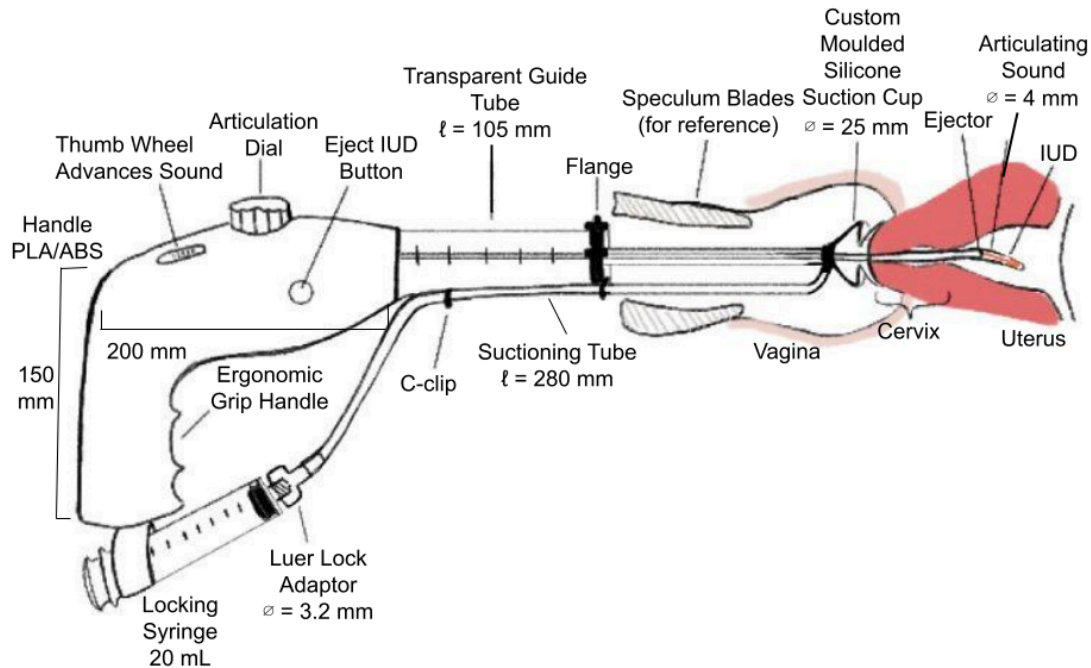


Figure 6. Articusound Device Drawing

Articusound was selected as the proposed final design because it addresses the client's objective of minimizing avoidable pain through coordinated changes to cervical stabilization, uterine sounding, and IUD insertion. Rather than modifying stabilization alone, the concept combines suction with an adjustable sounding and deployment pathway. A syringe-generated vacuum secures a suction interface around the ectocervix, the outward-facing surface of the cervix, to replace the tissue-grasping function of a traditional tenaculum. A twist-lock mechanism is intended to maintain suction without continuous manual effort. The steerable, rotatable sounding component accommodates the uterine pathway while measuring depth. A locking slider then preserves the selected depth, and a fixed stop shoulder limits advancement as the IUD passes through the sounding channel. The deciding advantage is the connection between anatomical adjustment, depth assessment, and deployment. Soundless Suction Assist simplifies stabilization but does not provide an adjustable replacement for sounding, while CerviPump emphasizes electronic feedback rather than active directional control. Articusound therefore offers the most comprehensive conceptual response to the client's requested procedural changes. However, its low feasibility rating remains a significant constraint. Articulation and deployment must not disrupt suction or alter the depth setting, and the surrounding suction interface must preserve visibility of and access to the cervical opening. Further development should simplify these mechanisms without sacrificing their intended functions. Articusound is the preferred approach for development, but reliable integration and pain-reduction benefits remain unverified.

V. DEVELOPMENT PROCESS

5.1 Materials

The Articusound will incorporate a combination of flexible tubing, a silicone suction interface, commercially available connectors and a syringe, and a custom-fabricated body to support cervical stabilization and controlled IUD deployment. Within the suctioning component of the device, the suction cap component of the device will be made of silicone. Medical-grade silicone has the ability to form a proper seal against internal organs, such as the cervix, and can be developed via micromolding or injection molding [16]. The cap will then be attached, via a luer lock connector, to a 280mm suctioning tube, 9.5mm outer diameter, made out of cured silicone [17]. The final component of the suctioning in the device is a disposable syringe, which can be commercially bought, to create the negative pressure vacuum system [18]. To connect the suctioning tube to the syringe and the cap, luer lock and luer slip connectors will be utilized [19,20].

The IUD itself will be stored internally on the device. It will be deployed through a much wider, flexible, and transparent guide tube, made of polyvinyl chloride (PVC), which will be able to withstand an autoclave environment of 206.8 kPa at 23°C or 103.4 kPa at 51°C[21]. The body of the IUD deployment device, including the buttons, thumb wheel, and the dial, will utilize PLA to sustain 3D printed CAD designs. This will allow adjustability of the design based on needs, sizes, and aesthetics provided by the client.

Silicone is a gold standard material utilized in many medical devices. Silicone is biocompatible, flexible, and able to withstand the harsh autoclaving environment [22]. Many medical grade syringes are made of a polycarbonate shell with a rubber seal attached towards the bottom of the syringe [18]. Within the prototyping stages, the body of the prototype will be made out of PLA due to the ease of 3D printing, however PLA is not autoclave safe, and therefore the body of the device will have to transition into 3D printed PEEK or 316 stainless steel [23].

5.2 Methods

The IUD deployment device will be fabricated through a combination of mechanics and CAD modeling. To create the body of the device, 3D printing and CAD will be utilized. Of the suctioning components, the syringe, tubing, and luer lock connectors will be bought and assembled without any modifications. The suction caps will be developed using cured liquid silicon and a 3D CAD mold of the cap. By using this method, different sized molds can be fabricated to accommodate for different sizes and shapes of the cervix. The entire suctioning system will be hooked onto the body of the device, allowing for secure attachment.

In order to fabricate the flexible sounding component of the device, it will follow an engineering design similar to a colonoscope. The PVC guided tube will be no more than 5mm diameter to accommodate for the 3-4mm diameter of the IUD tubing [24]. The distal end of the PVC tube will then be controlled via a manual push and pull mechanism. Attached to the PVC tube will be four 0.2mm copper wires on each side (every 90°) of the tube. These wires will be loaded onto a spin wheel, which will be mechanically attached to the exposed dial of the device, allowing for the user to mechanically pull on one side and bend in the direction that they intend [25]. For the final prototype, the team will look into using a nitinol or stainless steel vertebrae to surround the PVC tube and act as a backbone and prevent mechanical degradation. In addition, the team can consider automatic rotation instead of mechanical, to improve ergonomics of the device. A similar method, using a spin wheel, will be used to allow for deployment of the IUD and advancement/retraction of the sounding tube into the cervix.

5.3 Testing

Testing will evaluate the two main functions of the device; accurately placing the IUD and effectively stabilizing the cervix.

5.3.1 IUD Placement

The combined uterine sound and IUD inserter will be tested via a pass fail test. Figure 7 shows the combined model of the vaginal canal, cervix, and uterus that will be implemented in testing. In order to pass the test, the device must place the IUD within 20 mm of the uterine fundus [26]. The test will be repeated a minimum of 10 times and be timed to compare to average procedure times. In the case of failure the nature of the failure will be noted in Appendix 10.3.1

Given that the model is not adjustable to demonstrate the range of anatomical dimensions or orientations, future testing should consider these factors. Phantoms capable of simulating diverse anatomy, such as Preciso™ Intra-Uterine Device Simulator and GynoS™ IUD placement, exceed the current budget.



Figure 7. SimCoach IUD Insertion Training Model[28].

5.3.2 Suctioning Component

The model shown in Figure 7 does not mimic the viscoelasticity and surface friction of cervical tissue closely enough to test the suctioning component of the device. Instead, a cervical disc biopsy model (Figure 8) will replicate the properties of cervical tissue for the purposes of initial testing.

Testing for the suctioning component shall evaluate the amount of pressure applied via the vacuum over a 7 minute period across multiple trials with varying amounts of force at the handle. Special attention will be paid to the consistency of the pressure throughout the trial period accounted for by taking pressure values at the 0, 1, 3, 5, and 7 minute marks. This trial time is consistent with the average procedure time for an IUD insertion [28]. Any loss or release

of vacuum will be noted and no attempts to re-engage the vacuum will be made. Depending on orientation of the cervix and uterus varying levels of 1.5 - 6.5 newtons of traction force are required to pass the cervix with the uterine sound and IUD inserter [29]. Three weights across this force range (0.15, 0.4, 0.7 kg) will be hung from the prototype handle while the suctioning component is engaged with the cervical tissue model. This method of testing will inform the design in terms of avoiding premature release of the suction and maintaining pressure without any spikes or sudden drops. The tolerance range for the negative pressure applied to the ectocervix is between -300 to -375 mmHg (Appendix 10.3.2).



Figure 8. LifeLike BioTissue ©, Cervix Disc Biopsy Model

Neither of the tests evaluate compatibility with the speculum, patient comfort, or ease of use for trained providers. Yet, each of those parameters are identified in the design matrix as central to the project. Future testing should expand the anatomical diversity of the phantoms, survey trained providers on ease of use and ergonomics of the device, and verify the biocompatibility and sterilization processes.

VI. DISCUSSION

The primary focus of Aligna is to reduce avoidable discomfort during IUD placement while maintaining reliable cervical stabilization, uterine-depth measurement, and controlled deployment. Preliminary design evaluation identified Articusound as the preferred concept because its syringe-based suction system and adjustable sounding pathway offer

potential advantages in accommodating anatomical variation. However, its selection through the design matrix does not establish that these functions will operate successfully in an integrated prototype. The concept's relatively low feasibility score reflects the difficulty of combining articulation, depth control, suction, and deployment within one device. Initial development must therefore determine whether the anticipated benefits justify the additional mechanical complexity.

Existing research supports investigating suction as an alternative to conventional tenaculum grasping. A randomized study comparing a suction cervical stabilizer with a single-tooth tenaculum reported lower pain during cervical grasping, traction, and IUD insertion with the suction device[30]. This evidence supports Aligna's approach, but it does not ensure equivalent performance for the selected design's circumferential suction head. Differences in contact geometry, applied vacuum, and integration with the sounding mechanism may affect stabilization and access to the cervix. Furthermore, suction-based stabilization does not address every source of insertion pain. Aligna's potential contribution is therefore the combination of mechanical stabilization and controlled placement, rather than an assumption that replacing the tenaculum alone will make insertion painless.

Localized pain management presents an additional workflow challenge. Topical lidocaine and a paracervical block are distinct approaches, and CDC guidance indicates that either might reduce IUD-placement pain, although effectiveness varies [31]. A paracervical block requires injection access to tissues around the cervix, which could be restricted after Aligna's suction head is attached. Some studied block protocols also use a tenaculum during administration; therefore, performing the block first does not automatically establish a tenaculum-free procedure. Administering anesthesia before applying suction is a potential solution, but the sequence must be reviewed with a gynecologist to determine whether adequate visualization, stabilization, and injection access can be maintained. For the initial prototype, compatibility with separately administered anesthesia is more appropriate than adding an integrated injection mechanism. In future work, topical and paracervical pain management methods will be explored as well as dosing consistency if incorporated into the device itself.

Potential sources of error must be considered before fabrication begins. The first prototypes will use inexpensive printable polymers and commercial flexible components to establish proof of function before medical-grade materials are purchased. This approach allows affordable iteration, but differences in stiffness, surface finish, and seal compliance may limit how accurately the prototype represents a later clinical assembly. Printing tolerances, channel misalignment, slider friction, and imperfect connections could cause vacuum leakage, depth-setting errors, or deployment resistance. Critical dimensions should therefore be measured, fabrication settings documented, and each subsystem evaluated independently before integration. Mechanical performance must subsequently be reassessed after any transition to different materials.

Testing may also introduce measurement and model-related error. Inconsistent initial placement, and variation in applied vacuum could make suction performance appear more or less reliable than it is. Similarly, the available anatomical models do not fully reproduce living tissue properties or the range of cervical and uterine geometries. Successful placement in one model would not demonstrate equivalent performance across patients, and separate suction and placement tests would not establish that stabilization remains secure during integrated operation. Future trials should include combined-function testing, varied anatomical configurations, and simulated cervical surface conditions.

Ethical considerations include both responsible research conduct and the eventual use of the device. Early prototypes must remain limited to nonclinical testing because low-cost materials and unvalidated fabrication methods cannot be assumed to be biocompatible or sterile. Experimental failures must be reported alongside successful trials, and existing research, patented concepts, and assisted design illustrations must receive appropriate credit. Although "painless" is part of the project title, pain reduction remains an intended outcome rather than an established finding. Clinical use must preserve informed consent, individualized pain-management decisions, and the clinician's ability to discontinue or modify

the procedure. Human-participant evaluation would require appropriate institutional review and applicable regulatory oversight.

Affordability, anatomical inclusivity, and environmental impact must also inform later design decisions. A reusable handle with a disposable patient-contact cartridge may provide a practical architecture, but its cost and waste implications should be compared with the resources required for validated reprocessing and autoclavability. Interchangeable suction cups could help accommodate cervical variation, while compatibility with different IUD inserters would improve the design's applicability. These additions should be evaluated without allowing convenience or cost reduction to compromise access, stabilization, or placement control. Ultimately, Aligna's value will depend on demonstrating that its integrated functions offer a meaningful improvement over existing instruments while remaining feasible to manufacture and use.

VII. CONCLUSION

Aligna addresses the need for a less painful and more standardized IUD-placement procedure without compromising necessary clinical access or controlled positioning. The proposed Articusound design combines syringe-generated cervical suction with an adjustable sounding and IUD-deployment pathway, a locking depth slider, and a fixed stop shoulder. Preliminary evaluation identified this concept as the strongest candidate for further development, but its stabilization, placement accuracy, and potential pain-reduction benefits remain unverified because fabrication and testing have not yet begun.

The design process successfully narrowed the alternatives and clarified important clinical constraints. However, eliminating the speculum is not supported by the current configuration, and incorporating anesthesia remains an unresolved workflow consideration. The selected concept also introduces mechanical complexity that must be addressed before its functions can be reliably combined. In a subsequent iteration, the team would establish clinical access requirements earlier and evaluate individual mechanisms before developing a fully integrated assembly.

The next phase will involve CAD development, low-cost prototyping, and anatomical-model testing of suction retention, articulation, depth control, and IUD-surrogate deployment. Observed failure modes will guide revisions before investment in medical-grade materials and evaluation of biological safety and sterilization requirements. Future work will include interchangeable suction cups for differing anatomies, compatibility with different IUD types, assessment of miniature cameras and their sterilization feasibility, integration of pain relief medication, and approaches to reducing speculum-related discomfort. These developments will determine whether Aligna can provide a practical improvement in insertion workflow; any claim of improved patient comfort will require subsequent appropriately reviewed clinical research.

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X. APPENDIX

10.1 Product Design Specifications

Function

The Aligna Painless IUD Placement device is intended to provide a more comfortable, simplified, and standardized method for clinician-performed IUD placement. IUDs are among the most effective reversible contraceptive options, with fewer than 1 out of 100 users becoming pregnant during the first year of typical use; unlike daily pills, weekly patches, or monthly vaginal rings, they provide long-term protection without requiring ongoing user action after placement [1]. Despite these benefits, anticipated insertion pain can prevent potential users from choosing an IUD: among 252 adolescents without prior IUD experience, 25% reported being uninterested in an IUD because of fear of placement pain [2]. Pain, anxiety, cervical manipulation with a tenaculum, uterine sounding, and variability in clinician technique can all contribute to a negative insertion experience, especially for nulliparous patients. Aligna is designed to address these barriers through a tampon-style insertion system with a smooth atraumatic tip, lubrication, controlled alignment, clear orientation cues, adjustable insertion-depth control, simplified IUD deployment, and a topical lidocaine-delivery component that applies a controlled amount of anesthetic formulation to the intended genital or cervical site before insertion. CDC guidance indicates that topical lidocaine might reduce placement-related pain, although its benefit varies among patients [3]. Aligna is not intended to replace required clinical assessment, including pregnancy screening, bimanual examination, cervical inspection, informed consent, or identification of contraindications; instead, it aims to improve the insertion portion of the procedure, reduce avoidable discomfort, and make a highly effective, low-maintenance contraceptive option more acceptable to patients.

Client Requirements

- The device must provide a more comfortable, less intimidating IUD-placement experience by reducing pain and anxiety associated with conventional insertion instruments and steps, particularly speculum use, tenaculum traction, blind uterine sounding, and cervical passage.
- The device should reduce or eliminate the need for a separate tenaculum while still allowing the clinician to locate, stabilize, and align with the cervix for IUD insertion.
- The device should incorporate an atraumatic, small-profile, and potentially flexible distal tip to minimize tissue trauma and discomfort during insertion.
- The device should support controlled and repeatable insertion depth and IUD placement because uterine dimensions vary among patients and placement consistency can depend on provider experience.
- The device should include a simplified IUD-deployment mechanism that enables the clinician to place an IUD with fewer procedural steps and less dependence on complex manual technique.
- The device should combine improved mechanical insertion with localized pain management, including exploration of topical lidocaine delivery to the cervix.

- The device may incorporate features such as vacuum-based cervical stabilization and distal visualization to reduce reliance on conventional cervical-grasping and visualization tools, but these features must be evaluated for feasibility, safety, and effectiveness.
- The prototype should be evaluated in an anatomical phantom to assess insertion alignment, cervical stabilization, depth control, IUD-surrogate deployment, repeatability, and workflow simplification before any consideration of clinical use.

Design Requirements:

1. Physical and Operational Characteristics

a. Performance Requirements:

- This device must provide an effective mechanism for delivering an IUD into the uterus while offering an alternative to the uterine sounding and a tenaculum. The mechanism should also allow for stable, adjustable, yet precise control for the user while minimizing pain in the IUD placement procedure. This device should have characteristics for measuring or visualizing the uterine space, and the ability to act as a tenaculum for the IUD to be delivered simultaneously. It must be functional in a procedural setting where it can be sterilized and reused, or instead disposable for single use. It is required for the design to be safe for the user (practitioner) and receiver (patient) while also being ergonomically suited for quick adjustment and insertion. Performance requirements, such as insertion placement accuracy and stabilization of the cervix, should align with those of the standardized IUD insertion. It should be able to repeatedly achieve fundal intrauterine placement of the IUD, meaning the IUD is approximately 2.0 cm or less from the uterine fundus and does not stick into the cervical canal [4]. If an anesthetic characteristic should be added, the device should properly execute numbing of the cervix to reduce pain with the insertion procedure. This would include proper loading and dosing of the medication to be administered during the procedure.

b. Safety:

- The U.S. Food and Drug Administration (FDA) regulates intrauterine contraceptive devices and their introducers as medical devices. The device classification and applicable regulatory requirements must be considered when evaluating the safety and effectiveness of an IUD insertion system [5].
- IUD insertion presents several potential mechanical risks, including uterine or cervical perforation, incorrect placement, embedment, and expulsion. These risks make controlled insertion and appropriate placement important safety considerations. A device used for IUD insertion should therefore minimize the potential for excessive force, uncontrolled movement, or unintended advancement during the procedure. The insertion system must maintain its structural integrity throughout the procedure. Breakage, deformation, or separation of an insertion component could result in patient injury or retention of a device component. The system should therefore be evaluated for mechanical strength and reliability under the forces expected during insertion and deployment [6].

- iii. Any portion of the device that directly or indirectly contacts the patient must be evaluated for potential adverse biological responses. Materials and processing methods should therefore be selected to minimize the potential for irritation, sensitization, cytotoxicity, or other adverse biological responses [7].
- c. Accuracy and Reliability:
 - i. Accuracy and reliability must be held to high standards, as this device will be used in a medical setting where proper and repeatable IUD placement is essential. The device should consistently guide the IUD into the uterine cavity and achieve proper fundal positioning without causing unnecessary movement or repeated attempts. Proper positioning is important because incorrect placement can reduce contraceptive effectiveness and increase the risk of complications [4]. The device should also be able to stabilize the cervix during insertion, potentially through a suction-based mechanism, while minimizing discomfort to the patient. The stabilization mechanism should reliably secure the cervix on the first attempt and maintain adequate stability throughout the insertion process. Testing will be essential to determine whether the device can repeatedly achieve proper IUD placement and cervical stabilization while maintaining consistent performance between uses.
- d. Life in Service:
 - i. The targeted life in service of the product if it is multi-use will be 5 years of use before requiring replacement to ensure performance requirements are continued to be met. The life in service timeframe revolves around the stresses that the device will endure on a day-to-day basis. The device needs to last for this period of time with proper cleaning and upkeep. The product must allow for storage in dry conditions with little temperature and humidity fluctuations to reduce mechanical degradation. The parts of the device that are in contact with biohazardous materials (are being inserted into the cervical canal and delivering the IUD) should be single use and their life in service would be for the one use on a patient.
- e. Shelf Life
 - i. The device should be able to maintain a shelf life of, at minimum, 12 months provided that the main material that makes up the device is PPSU [5]. Storing the device in a cool (15-25°C) and dry environment, away from UV light, and within its package seal will enhance its shelf life significantly [5].
 - ii. The device should maintain an unlimited shelf life provided that the main material making up the device is PEEK, and that the device is sealed and stored away from UV light and in a 15-25°C environment with less than 65% humidity [8].
- f. Operating Environment:
 - i. This device will mainly be exposed within a sterile environment of the operating room while making temporary contact within the patient.
 - ii. The device should be able to withstand temperatures of 20-24°C and humidity levels between 20-60% [9].

- iii. In cases of reusability, the device must be able to withstand an autoclave environment, operating at 121-134°C and pressures of 103.4-206.8 kPa [10].
- g. Ergonomics:
 - i. To maintain ease of operation, the device must be handled by the physician easily. The device will consist of three different buttons to allow for adaptive and all encompassing use. Each of the three buttons will be designated for IUD placement, a camera, and a replacement for the tenaculum.
 - ii. The device should be operated by the physician, using at most two hands or either. It should not require any direct contact between the patient and physician.
- h. Size:
 - i. The device itself must be at minimum the length of 30-36 mm and the width of 3-4 mm to ensure proper fitting of the IUD inside [11]. The device must be able to extend 6-9 cm in order to reach entirely across the uterus [12].
- i. Weight:
 - i. Current market IUDs weigh no more than a gram [11]. This device must be easy to use for its operators, and therefore should not exceed more than 1.36 kg [13].
 - ii. Depending on the final materials chosen to produce this device, the exact weight will vary.
- j. Materials
 - i. Prototype phase: The initial integrated prototype shall be fabricated from low-cost, readily machinable or printable materials suitable for repeated bench testing. Rigid housings, handles, triggers, and alignment fixtures may be produced from PLA, PETG, ABS, or comparable engineering-prototype polymers; flexible seals and atraumatic-tip concepts may be represented using commercial silicone tubing, silicone sheet, or TPU. Material selection in this phase shall prioritize rapid iteration, dimensional fit, visibility of failure modes, and total prototype cost rather than clinical biocompatibility or validated sterilization performance. All early prototypes made from non-medical-grade polymers, unvalidated photopolymer resins, commercial adhesives, or non-traceable components shall be clearly identified as nonclinical prototype and shall not contact human tissue or be represented as biocompatible, sterile, or reusable for clinical procedures. Biocompatible materials will be incorporated with the complete finished device.
 - ii. Clinical design phase: The preferred clinical material architecture shall separate the product into (1) a reusable, non-patient-contacting actuator/handle and (2) a sterile, clearly removable patient-contact cartridge. Components that are hardest to clean, especially narrow insertion, suction, optical, and lidocaine-delivery channels, shall be disposable unless the device permits sufficient access for cleaning and the complete reprocessing protocol is validated. FDA recommends smooth surfaces, disassembly where needed, disposable components in hard-to-clean areas, and clear identification of parts that must be discarded after use [14].
 - iii. Reusable structure path: Candidate materials for a reusable handle and load-bearing mechanism shall include medical-grade PPSU for the primary housing, passivated 316L/316LVM stainless steel for localized high-load shafts, pins, or springs, and medical-grade silicone for seals or compliant interfaces. PPSU is preferred over PEEK for most polymer structural components

because it tolerates repeated steam sterilization while carrying a substantially lower raw-material cost; supplier testing reports more than 1,000 steam cycles at 132°C without cracking or crazing [15]. PEEK may be reserved for small components requiring exceptional wear, chemical, or dimensional performance because medical-grade PEEK is reported at approximately \$500–\$800/kg, which exceeds our ideal budget[16]. Medical 316LVM is standardized under ASTM F138 and provides strong resistance to pitting and crevice corrosion in physiological environments [17].

- iv. Disposable structure path: Candidate materials for the single-use cartridge shall include medical-grade polypropylene for low-cost rigid molded bodies and plungers; medical-grade silicone or Pebax MED for the flexible, atraumatic distal tip and catheter-like shaft; and medical-grade PTFE only where a very low-friction liner is functionally necessary. Arkema states that Pebax MED grades are intended for catheter and tubing applications, and are sterilizable by gamma, steam, and EtO [18]. Medical silicone is commonly used for tubing, catheters, seals, and other components requiring flexibility, biocompatibility, and sterilization resistance, while PTFE provides low friction and chemical resistance [19].

k. Aesthetics, Appearance, and Finish:

- i. Safety, function, sterilization, and operation shall take priority over decorative styling. Consistent with the client’s stated creative freedom, no mandatory brand color or ornamental form is required at this stage; aesthetic choices shall support a less intimidating patient experience and a clear clinician workflow.
- ii. Color: The preliminary color scheme is not relevant and will not be taken into consideration when prototyping. In the future, the three critical functions of cervical stabilization/suction, lidocaine delivery, and IUD deployment shall use distinct control colors and/or distinct shapes or tactile features for clear differentiation between features and functions. FDA human-factors guidance supports clear contrast, legible labels, consistent control-display relationships, and design measures that reduce use-related hazards [20].
- iii. Form: The device shall use a compact, single-hand-compatible form with rounded external transitions, no exposed pointed components when not in use, and no unnecessary visual resemblance to a tenaculum or other grasping surgical instrument. The reusable and disposable components shall be visibly and mechanically distinct so the user can immediately identify which components require reprocessing and which require disposal.
- iv. Finish: External clinician-contact surfaces shall have a finish that is easy to wipe and grip while wearing gloves. Patient-contact surfaces shall be smooth, continuous, atraumatic, and free of visible seams, burrs, sharp transitions, and print-layer ridges. Reusable surfaces and internal passages shall avoid unnecessary recesses, dead-end cavities, and narrow inaccessible gaps as compliant with standards and regulations for related devices [14].

2. Production Characteristics

a. Quantity:

- i. The project shall produce one complete, functioning prototype evaluated on alignment, cervical stabilization, controlled insertion depth, and IUD-surrogate deployment in an anatomical

phantom. The device will be accompanied by a simplified workflow that prioritizes patient comfort and successful placement. After feasibility is demonstrated, the design shall be revised to ensure biocompatibility and sterilization requirements are met.

b. Target Product Cost:

- i. The direct material and externally purchased fabrication cost for the first functioning prototype shall not exceed \$120, although this number is subject to change and a concrete budget has not been established by the client. A bill of materials shall track each component's material, supplier, quantity, unit price, shipping, fabrication charge, and whether the item is reusable or consumable. The cost estimate shall be revised after each major prototype iteration and again after the reusable-versus-disposable architecture is finalized as this is all subject to change as the project progresses.
- ii. Prototype allocation: Low-cost PLA, PETG, or ABS should be used for rigid proof-of-concept parts whenever their mechanical behavior is adequate; UW-Madison pricing is approximately \$15-\$20/kg plus \$2 per printing hour [21]. Expensive certified materials should not be purchased for the first geometry iteration unless their unique physical behavior is essential.
- iii. Cost market comparison: Existing sterile IUD procedure kits provide a useful per-procedure benchmark but do not offer Aligna's proposed integrated suction, deployment, anesthetic, or visualization functions. A Gynex catalog listed a 12-kit box for \$185.95, or approximately \$15.50 per kit, while SouthPointe listed 10 single-use kits for \$390, or \$39 per kit. Aligna aims to create a product that falls within this range upon finalized design [22, 23].

3. Miscellaneous

a. Standards and Specifications:

- i. 21 CFR 884.5360 - Contraceptive Intrauterine Device (IUD) and Introducer:
 1. IUDs and their introducers are classified as Class III devices requiring rigorous pre-market approval based regulatory pathways. 21 CFR 884.5360 underlines regulation of devices in this category and the premarket path [24].
- ii. ISO 10993-1 - Biological evaluation of medical devices - Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process:
 1. This standard provides a risk-based framework for evaluating the biological safety of patient-contacting device materials. During the insertion process the device will interact with mucosal tissue causing potential irritation or disruption. The short, limited contact as opposed to implantation is important to note. ISO 10993-1 will guide characterization of the material and biological endpoints [25].
- iii. ISO 17665-1: Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices:
 1. The device is intended to be sterilized via autoclaving between patient use. ISO 17665-1 will be used to design and implement a protocol to do so [26].
- iv. CFR Part 4- Regulation of Combination Products:

1. As the device will combine insertion with the delivery of lidocaine it is considered a combination product, evaluated under CFR part 4 which establishes relevant Good Manufacturing Practice [27].
- b. Customer:
- i. The device should ease patient concerns over inadequate pain relief and severe-insertion pain.
 - ii. Aligna must effectively place the IUD to reduce risk of expulsion and the burden of repeat visits for patients.
 - iii. Materials-selection should avoid that contribute to anxiety before and during the procedure. Such as materials that are uncomfortable to the touch (i.e rough texture or highly thermally conductive) and/or that produce loud noises such as clanking or clicking.
 - iv. Underlying perceptions of reusable medical devices as unhygienic cause fear during procedures, the design must assure patients of cleanliness and safety [28].
 - v. The device should accommodate a wide range of hand sizes and strength levels for practitioners, especially because women physicians report difficulty using medical instruments at a higher incidence due to androcentric design [29].
- c. Patient-Related Concerns:
- i. To reduce the incidence of cross-contamination and infection the device must be sanitized between uses.
 - ii. Aligna must be tested on an anatomically accurate model of the cervix and uterus.
- d. Competition:
- i. Aligna will combine the functions of the tenaculum, uterine sound, and IUD inserter. No device available on the market combines these functions into a singular product. Therefore, the main competitors for Aligna are the individual tools currently used during the procedure. This section pays special attention to product developments and patents aimed at reducing patient pain and reducing procedure duration.
 - ii. Tenaculum:
 1. Carevix produced by Aspivix is a suctioning device that works in place of a tenaculum during the procedure to stabilize the cervix. In a 2025 study evaluating the device, researchers found 73% of patients reported less pain than expected and 83% providers reported satisfaction. The device is touted as easy to use, provides adequate visibility, and lowers patient discomfort [30].
 - iii. Uterine sounding device
 1. Patent US8348864B2, "Uterine cavity length measurement", describes a device that provides direct measurements of the uterus rather than relying on tactile feedback from

the physician. It does so by measuring changes in fluid flow marking when the device moves from uterine cavity, to internal os, to external os. The device features an atraumatic distal tip and reduces procedure duration [31].

2. A group of students at Clemson University adapted the traditional uterine sound to numb parts of the uterus and cervix. LidoSound delivers lidocaine anesthetic through small holes at the distal tip during the measurement of the uterus [32].
3. Transvaginal ultrasounds offer an alternative to uterine sounding. In a 2018 study the SonoAce X6 machine with a transvaginal probe attached was tested against classical uterine sounding. The ultrasound technician summed endometrial and cervical stripes lengths to find the length of the uterus. Participants reported lower pain and higher satisfaction compared to the classical uterine sounding method [33]. Incorporating an ultrasound component to the design would greatly exceed the budget and is out of scope for this project.

iv. IUD Inserters

1. Proposed by Bayer Oy in 2017, US9668912B2 describes an IUD inserter that temporarily immobilizes the IUD string, eliminating the need to manipulate the removal string. Key aspects of the patent include a moveable slider that controls the release of the string and stop members that prevent premature release. This design improves hygiene, the ease of use for practitioners, and overall deployment control of the IUD [34]. Although greater deployment control could improve outcomes this design does not directly address patient comfort.
2. Proposed by Bayer Oy in 2020, US10561524B2 offers one-handed slider operation, an adjustable flange for patient-specific insertion depth, and automatic string release [35]. These features are informative to the Aligna design in terms of engineering the practitioner experience and ease of use.
3. Patent US3889666A describes an inserter prepackaged with the IUD inside of it. The narrow insertion tube reduces patient discomfort. This is achieved because the IUD folds immediately before insertion to maintain the structural integrity. Once properly placed the IUD is ejected and expands [36]. Overall this design simplifies the insertion process and is valuable for considering packaging for Aligna.

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10.2 Expenses

N/A, no current expenses

10.3 Testing Protocols

10.3.1 IUD Placement Accuracy

Test Apparatus and Materials Required

- SimCoach IUD Insertion Training Model
- Prototype preloaded with IUD model
- Callipers
- Timer

Protocol:

1. Set up training model on lab bench
2. Start timer

3. Position the prototype at the vaginal opening with the suction cup encompassing the ecocervix
4. Advance the uterine sound to measure the uterus depth
5. Adjust the lock collar according to the measurement
6. Eject the IUD to the measured depth
7. Remove device from model and stop timer
8. Measure the distance of the IUD from the fundus using the callipers
9. Record the distance and the procedure time
10. Mark pass or fail based on criteria and define failure mode if applicable

Trial	IUD Distance from Fundus (mm)	Procedure Time (s)	Pass/Fail	Failure Mode
1				
2				
3				
...				
10				

Failure Modes:

- The IUD is placed more than 20 mm from the uterine fundus.
- The IUD is not successfully deployed.
- The device cannot pass through the simulated cervix to reach the uterus.
- The device becomes stuck or cannot be withdrawn.

10.3.2 Cervical Stabilization and Suction Performance

Test Apparatus and Materials Required

- Cervix Disc Biopsy Model
- Cervix Disc Base
- Hook weights: 0.15, 0.4, 0.7 kg
- Prototype
- Timer
- Pressure gauge or traceable digital manometer
- Calliper
- Foam/cushioning pad

Procedure

1. Place a crash pad underneath the testing site
2. Secure the disc model to the base
3. Secure the base upside down such as to the bottom of a cabinet
4. Center the suction cup at the distal end of the device on the model
5. Measure the distance of the suction cup from the edge of the model with a calliper

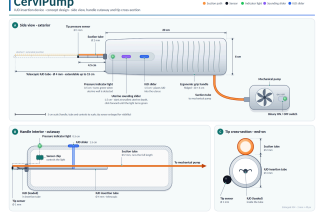
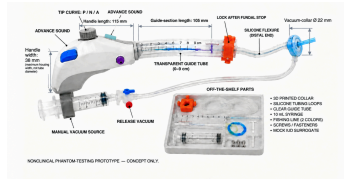
6. Engage vacuum
7. Attach weight and start timer
8. Measure the pressure at $t = 0, 1, 3, 5$, and 7 minutes
9. In the event of vacuum loss record the time of vacuum loss
10. Evaluate the trial based on failure modes and record on data sheet
11. Repeat 3 trials for each of the three weights (0.15, 0.4, and 0.7 kg)

Weight (kg)	Trial	Initial Pressure (mmHg)	1 minute	3 minutes	5 minutes	7 minutes	Time of Vacuum Loss	Pass/Fail
0.15	1							
0.15	2							
0.15	3							
0.4	1							
0.4	2							
0.4	3							
0.7	1							
0.7	2							
0.7	3							

Failure modes:

- Premature vacuum release
- Inability to establish a vacuum
- Pressure outside the -300 to -375 mmHg operating range
- Sudden pressure drop >50 mmHg within 1–2 seconds
- Pressure fluctuation exceeding ± 25 mmHg from the initial pressure
- Cervical tissue slipping from the suction component
- Device displacement >2 mm from original position
- Damage to the tissue surrogate

10.4 Design Matrix

Criteria	Weight	CerviPump:	Soundless Suction Assist:	Ectocerv Vacuum and Articusound
				

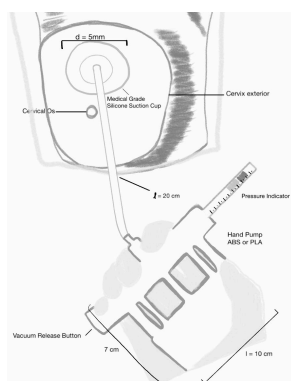
							
Safety	25	3/5	15	3/5	15	4/5	20
Universality	20	3/5	12	2/5	8	5/5	20
Ease of Use	20	4/5	16	5/5	20	3/5	12
Feasibility	15	3/5	9	5/5	15	2/5	6
Cost	10	3/5	6	4/5	8	5/5	10
Originality	10	4/5	8	3/5	6	4/5	8
Total	100	66		72		76	

Table 1: The preliminary design matrix was created to judge the three preliminary designs on the chosen criteria. The criteria weighted in importance are as follows: Safety, Universality, Ease of Use, Feasibility, Cost, and Originality. A final section of the total scores for each design which shows that the “Articusound” design scored the highest overall.

Safety:

Safety was weighted the highest at 25% because it ties directly into patient comfort and the success of the procedure. For sake of clarity, safety is divided into two criteria; visibility and accuracy. Visibility describes whether the device enhances or obstructs the practitioner’s view of the cervical opening. Minimized visibility could lead to extra maneuvering and extended procedure time or even insertion failure. The Ectocerv Vacuum suctions around the ectocervix potentially obstructing the view of the cervical os itself (where the inserter must enter to pass through the cervix and deploy the IUD in the uterus) which docked the safety score to 4/5. CerviPump and Soundless Suction Assist place the suction above the cervical os, maintaining visibility. Accuracy refers to the placement success once the inserter has already passed through the cervix into the uterus. Currently, a uterine sound is implemented to determine the orientation and depth of the uterus. Inserting the IUD at the improper depth or orientation can cause expulsion or perforation, though the sound itself also poses a risk of perforation. CerviPump integrates the sound with the inserter reducing the procedure time and the amount of instruments inserted into the uterus. However, the electronic mechanism for the suction increases the risk to the patient earning CerviPump a 3/5. Soundless Suction Assist removes the sound all together which eliminates potential perforations from the sound, but sacrifices the information on uterus orientation and depth giving it a 3/5 in terms of safety. Ectocerv Vacuum and Articusound adapts the sound to articulate according to the patient's anatomy therefore maintaining the benefits from the sound while reducing perforation caused by instrument rigidity thus the design upholds a score of 4/5 for overall safety.

Universality:

Universality was weighted at 20% because the device must accommodate patient-to-patient anatomical variation rather than applying a single standardized insertion approach. In particular, uterine dimensions and orientation can differ among patients, so the design should enable controlled, adjustable insertion and reliable fundal placement while reducing unnecessary force and pain throughout the uterine sounding process. This criterion therefore evaluates how well each alternative can be individualized to a patient's uterine anatomy before and during insertion. CerviPump received a score of 3/5 because its integrated sounding and IUD-placement process provides some patient-specific adjustment. Its distal sensor identifies when the fundus has been reached, allowing insertion depth to concretely reflect the individual patient's uterine length in a passive manner. However, the device offers limited ability to actively adapt its path or geometry to variations such as anteverted, retroverted, or neutral uterine orientation. Soundless Suction Assist received the lowest score, 2/5, because it relies on blind advancement until the fundus is encountered through resistance; this approach is a standardized procedure that does not include any adaptable mechanisms to accommodate individual patient variability. Ectocerv Vacuum and Articusound received the highest score, 5/5, because it can be adjusted both before and during the procedure: the clinician can preconfigure the device to match the anticipated uterine orientation and steer the sounding component during advancement toward the fundus. This combination of pre-procedure configuration and real-time directional control provides the greatest capacity to adapt placement to each patient's anatomy.

Ease of Use:

The next criterion, which was also weighted at 20%, was the ease of use by providers performing the IUD insertion. This criterion was considered important because the client requested that the device create a more standardized approach to IUD insertion, which is currently dependent on provider skill and technique. The device should be comfortable and straightforward for the provider to operate, allowing an IUD to be inserted without unnecessarily complicated steps or difficult maneuvers. Ease of use was primarily evaluated based on the complexity of the suction mechanism, whether a uterine sounding component was required, and the number of additional functions the provider would need to manage during the procedure. CerviPump received a score of 4/5. The suction mechanism is relatively simple because it uses an electric pump that can be turned on and off with a switch. However, one point was deducted because this design requires a uterine sound with a sensor. The sensor is intended to detect when the sound reaches the fundus of the uterus, but the path through the reproductive tract is not a straight, hollow path. Therefore, there is a possibility that the sensor could be triggered before the provider has confirmed that the sound has reached the appropriate location. This would require the provider to interpret the sensor reading and determine whether the sound has actually reached the fundus, potentially using their knowledge of typical uterine sounding measurements. Soundless Suction Assist received the highest score of 5/5 for ease of use. This design uses a relatively simple hand-pump mechanism for suction and does not require a separate uterine sounding component. Instead, the typical IUD inserter already contains depth measurements on the insertion tube, allowing the provider to use the same component to assess depth and perform the insertion. This reduces the number of components and steps that the provider must manage, making the overall process more straightforward. Ectocerv Vacuum and Articusound received a score of 3/5. The syringe and twist-to-lock mechanism provide a relatively simple method for controlling suction. However, two points were deducted because the design includes a sounding component as well as a mechanism for steering the sound and IUD to accommodate different anatomies. Although the steering mechanism could be beneficial because it allows the device to adapt to differences in patient anatomy, it also introduces an additional function that the provider must learn and control. Additionally, the provider must complete multiple steps for sounding before proceeding with IUD insertion, which makes the procedure somewhat more complex.

Feasibility:

Feasibility was ranked next because this category focuses primarily on the complexity of each device, the ability to fabricate its components, and the likelihood that the device can function as intended. This evaluation considers both the initial 3D-printed prototypes and the commercially available components that can be purchased and integrated into each design. Because the first prototypes will focus primarily on structural function and will use a combination of 3D-printed and purchased parts, all three concepts are feasible; however, they vary in fabrication difficulty, component integration, and the amount of iteration required. Therefore, feasibility was assigned a lower overall ranking priority than other evaluation categories.

CerviPump: CerviPump was ranked 3/5 because the design is moderately complex. The device uses an electrically actuated pump with a binary on/off control switch, along with a dual-function component intended to perform uterine

sounding and IUD placement sequentially. Because the electrical pump can be purchased rather than fabricated, the suction subsystem is relatively feasible to obtain and incorporate into the prototype. However, the dual-function sounding and placement component is more complex because it requires a slider mechanism to measure uterine depth and a sensor intended to help prevent uterine puncture during sounding. These features will require multiple components to be integrated into a single system and will likely need iterative CAD and 3D-printing revisions. For the device to function as intended, the pump must provide sufficient suction to stabilize the cervix without causing excessive discomfort, and the sensor must be calibrated to detect an appropriate resistance threshold and illuminate an indicator when the uterine wall is reached.

Soundless Suction Assist: Soundless Suction Assist was ranked highest in this category at 5/5 because it has the simplest overall structure and uses several components that already exist. The design incorporates a hand-pump suction system and a standard IUD inserter, reducing the number of new mechanisms that need to be designed and fabricated. The primary fabricated component would be a holder that secures the IUD insertion tool while incorporating the suction feature into the same device. This component can likely be produced through a relatively simple CAD model and 3D-printed as a single structural piece. Unlike an automated pump, the hand-pump mechanism places greater responsibility on the clinician or operator to maintain the correct suction pressure. However, if appropriate pressure is achieved and maintained, the device should be able to stabilize the cervix and allow the IUD insertion tool to be introduced afterward.

Ectocerv Vacuum and Articusound: Ectocerv Vacuum and Articusound was ranked lowest at 2/5 because it combines the largest number of mechanical features into one device. This concept includes a syringe-based suction system with a twist-lock mechanism intended to maintain the appropriate pressure while stabilizing the cervix. It also includes a dual-function component for uterine sounding and IUD placement that can rotate to accommodate different uterine orientations. Both the sounding mechanism and IUD deployment mechanism would be operated through sliders integrated into the device. Nearly all major components would require fabrication, making this design the most time-consuming and customizable option. In particular, the rotatable sounding and placement mechanism, along with its slider-based deployment systems, would likely require several CAD revisions and 3D-printing iterations before a functional prototype could be produced. The syringe suction system would be comparatively easier to develop because an existing twist-lock syringe could be adapted and combined with a custom suction tip. If successfully fabricated and integrated, the device's adjustable components could provide greater flexibility for different uterine positions; however, its multiple interconnected mechanisms make it the most difficult concept to prototype reliably.

Cost:

The Cost category compares the production cost across the three devices. Cost was weighted at 10%, the lowest weighted category since all three designs will undergo 3D printing for the first phase of fabrication, which is relatively cheap to produce. In addition, as expressed by our client, the goals of this device heavily outweigh the concern for cost, although the client has mentioned some concerns behind securing a final budget for when we move past the initial prototyping stages.

The Cervi Pump was rated at 3/5. This device received the lowest score due to its complexity of requiring multiple parts. The Cervi Pump combines parts sourced for the electronic component of the device, a uterine sounding component, the suction, and the actual component serving to release the IUD. The Soundless Suction Assist, requires fewer components than the Cervi Pump, by removing the sounding portion of the device. However the Soundless Suction Assist does also include a mechanical pump component of the device, which while more complicated than the twist and lock-in mechanism used in the Ectocerv Vacuum and Articusound, it is relatively cheaper to fabricate compared to the Cervi Pump's electronic component. Therefore the Soundless Suction Assist was rated at 4/5. Ectocerv Vacuum and Articusound was rated 5/5. The device's ability to utilize a "twist-lock" feature significantly reduces production costs of the suctioning component of the device, making the only cost of the device the electronic component of the device, which is used to move the sounding pipeline around.

Originality:

Originality across the three devices was also considered due to a large number of competing devices on the mark. Some components included in the three devices are specifically requested by our client despite being found on the market. However not all components have the same mechanisms performed by the three devices patented,

Since all three devices maintain a suction component to replace the tenaculum, a design that has been recently patented by Aspivix, the devices reduced a point deduction from the design. The Soundless Suction utilizes a pump device to create a suction, which is less commonly found in medicine. This specific component is not unique, however combined with the IUD placement, the device features a more innovative design, giving it a rating of 3/5. The CerviPump utilizes a new feature of utilizing an indicator light to allow the user to detect when they have hit the uterus wall giving it a rating of 4/5. The Ectoverve Vacuum and Articusund also utilizes an innovative feature that allows the uterine sounding probe to move around, making it flexible to the shape of the uterus, giving it a rating of 4/5.