Aligna-Painless IUD Placement

Product Design Specification

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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:

i. 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:

i. 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].

ii. 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 15-30 psi [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 3 lbs [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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