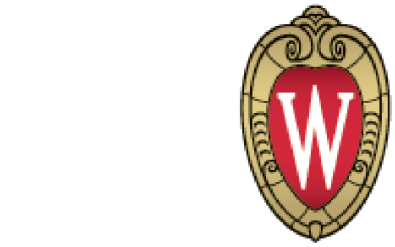

DEPARTMENT OF
Biomedical Engineering
UNIVERSITY OF WISCONSIN–MADISON

Self-Swab STI Test for Limiting Contamination

BME 200/300 Final Report

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Abstract

Routine testing for sexually transmitted infections (STIs) is not a common practice of many sexually-active people. As a result, common infections such as chlamydia and gonorrhea are highly prevalent, with four million cases of chlamydia occuring in 2018 [1]. In order to encourage routine testing of STIs and increase universal testing in general, STI screening needs to be less intimidating and more attainable. The primary way to accomplish this goal is through self-swab STI testing, which allows women to complete an intravaginal swab in the privacy of a clinic room, rather than experience the discomfort of being vaginally swabbed by a physician [2]. However, self-swab testing introduces the potential for contamination of the environment the test is administered in. Currently, self-collection STI tests involve a swab that must be inserted into the body, then removed and transported to an external vial of preservative media. In this process, there are many avenues of contamination, including the swab coming in contact with surfaces and the media vial spilling [2]. The goal of this project is to create a device that limits the potential contamination of the testing environment and of the swab. To do this, a proposed final design includes a swab housed in an external casing, a cap containing the media that screws onto the device, and an easy-to-handle structure. Ultimately, a STI self-swab test such as this would allow for increased universal testing while limiting contamination.

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I. Introduction

Chlamydia is the most frequently diagnosed bacterial sexually transmitted infection in the United States, affecting an estimated 1 in 20 young women from ages 14-24 [1]. Many cases go undiagnosed due to the commonly asymptomatic nature of the infection; between 50-70% of people diagnosed with chlamydia presented asymptomatically [1]. Sexually active women are recommended to be tested annually for chlamydia, but barriers to testing such as lack of transportation, concerns about confidentiality, cost, and violation of privacy limit the frequency of routine testing [2][3]. The most common method of testing is a vaginal swab that is either collected by the physician or patient. In recent studies considering the benefits of the self-swab method of STI testing, it was found that 84% of women prefer the self-swab method to traditional gynecological procedures, and 94% would be more willing to routinely test for STIs if self-swabbing was available [1]. If patient-collected STI tests were made more commercially available, or more commonly presented as an option for in-clinic testing, routine STI testing could become more typical.

One limitation of patient-collected STI samples is the potential for contamination of the testing environment and the swab itself during the collection process. The collection process involves the patient inserting a swab into the vaginal canal, which gives plenty of opportunity for vaginal fluid to transfer from the patient's hand to other surfaces of the examination room while handling the swab. Furthermore, contamination of the swab – which could happen if the swab simply touches the patient's leg or a clinic table – could lead to false-positives, as the sample may become contaminated by the surrounding environment [4]. A false-positive could lead to patients being treated for STIs that they do not have.

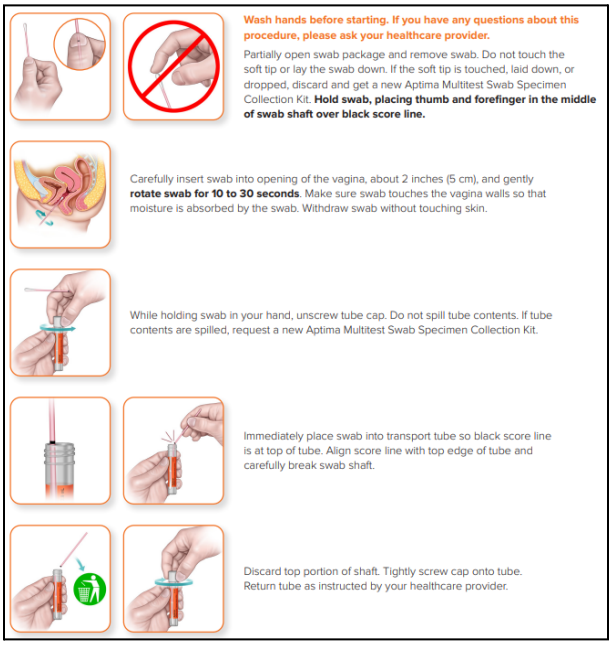


Figure 1: Aptima Multitest Swab Patient Instructions [5]

Manufacturers of STI self-swabbing kits exist both in the United States and internationally, but all commonly used methods involve at least a 2-component system. For example, as seen in Figure 1, the Aptima Combo 2 Assay by Hologic® employs the use of a proprietary swab for sample collection, and a small media-filled tube for sample preservation [5]. Competing design Mía by XytoTest® utilizes the same design and sample collection method [6]. During the transfer of the sample to the media tube, there is a high probability of contact contamination as the patient must first collect their sample, then hold the swab as they attempt to transfer it into the transport media. The swab could fall out of their hands, the media container could spill, or the patient could transfer vaginal fluid onto nearby surfaces as they undergo the process of handling both the sample and media at the same time. Therefore, the aim is to create a one-component device that limits contact of the patient's hands with their vaginal fluid as much as possible.

II. Background

Chlamydia results from infection with the Chlamydia trachomatis (CT) bacterium – a species of the chlamydophila genus [1] [7]. This bacteria is an anaerobic, gram-negative, obligate intracellular parasite that only naturally manifests in humans [8]. CT bacteria can be subclassified into 18 serologically variant strains (serovars), with serovars D-K leading to genital or neonatal infections [7]. The CT bacteria can spread during vaginal, anal, or oral sex with an infected person, and can be transferred to a newborn baby from an infected mother during childbirth [1]. CT bacteria have a unique infectious life cycle with an elementary body (EB) that is metabolically inactive and a reticulate body (RB) which is metabolically active [7]. When first coming into contact with CT bacteria, host cells take up the EB form which then differentiates into RB [7]. RB can then replicate to form additional EB and further spread the infection [7]. Chlamydia is typically asymptomatic, with only 30% of women developing symptoms [1]. Some of these symptoms include endocervical bleeding or discharge, urethritis (frequent urination), and pelvic inflammatory disease (abdominal or pelvic pain) [1]. In women, the CT bacteria initially infects the cervix but may spread to the urethra or upper reproductive tract [1]. If the bacteria spreads to the uterus and fallopian tubes, pelvic inflammatory disease can develop (PID) [1]. PID can lead to additional health complications such as chronic pelvic pain, tubal factor infertility, ectopic pregnancy, and Fitz-Hugh-Curtis Syndrome [1].

When testing for the CT bacteria using a swabbing technique, it is important that a non-toxic material is used. Any toxic materials can lead to bacteria death when using cell culture techniques or interference with non-culture methods like Nucleic Acid Amplification Tests (NAATs) [9]. As a result, any materials that have not been provided by a manufacturer should be tested for toxicity in cell culture and interference with non-culture testing methods [9]. The swab shaft can be made of plastic or wire, and the tip should be made of dacron or rayon as they are absorptive materials that will not inhibit the bacteria isolation during laboratory testing [10] [11]. All swab samples should be stored in a chlamydia transport media that do not contain antibiotics

[10]. Samples that are inoculated within 24 hours of collection should be stored at 4℃ while samples that are to be inoculated more than 24 hours after collection should be stored at -70℃ [10]. A material that can withstand this wide range of temperatures must be used to store the sample and the media.

The client, Dr. Jean Riquelme, is a family medicine specialist based in Madison with over 31 years of experience. Dr. Riquelme graduated from the Medical College of Wisconsin in 1993 and completed her residency in family medicine at Aurora Healthcare (Milwaukee). Dr. Riquelme has requested a vaginal self-swab device that limits contact contamination of the testing room for use in Chlamydia screening. Given that the device is to be used as a self-swab, it must be user friendly and should ultimately promote universal STI testing. As a result, the device will follow the design of a tampon, a product that about 42% of menstruating women regularly use [12]. The device must also allow for both swabbing and storage in a media in order to mitigate the contamination of the testing room [2]. This will be accomplished by employing a design that has a contained deployment, retraction, and sealing mechanism. The swab that is within the device must be deployed at least 5 cm into the vaginal canal to allow for adequate collection of CT bacteria [13]. All components of the device must be biocompatible as they will enter the vaginal canal and potentially come into contact with CT bacteria [9]. For a more detailed description of the design specifications, see Appendix B.

III. Preliminary Designs

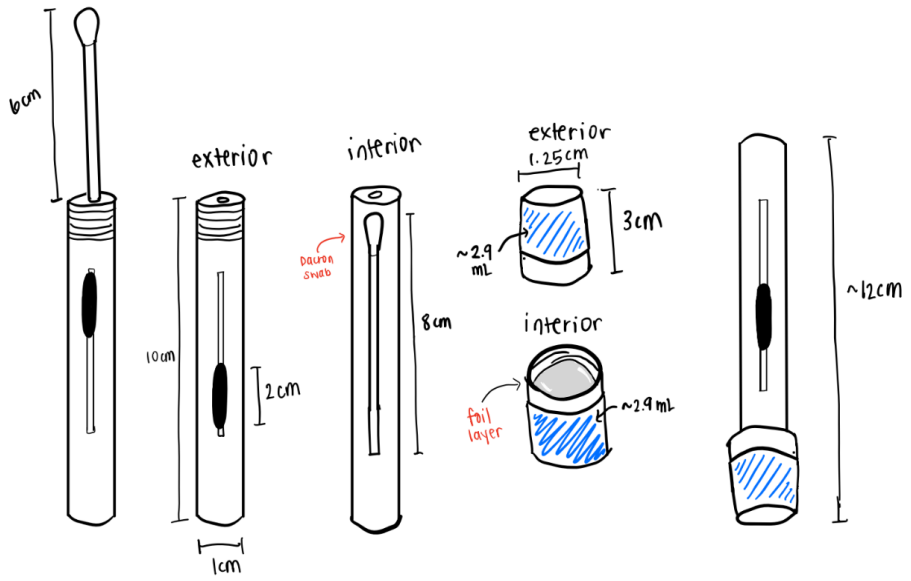


Figure 2. Screw-On Media with Slider

Design 1: Screw-On Media with Slider

The first design can be seen in Figure 2. This design idea includes a test-tube-like container made of an autoclavable material such as polypropylene or resin, that contains a proprietary swab. This design utilizes a slider mechanism to deploy and retract the swab from within the tube. Attached to the tube is a container filled with media that is able to be screwed and unscrewed from the tube by the user. The media is contained behind a foil layer that should be pierced by the swab after the sample has been collected and the container has been screwed back on. The main advantages of this design are its ease of production and processing. The design would be fairly easy to fabricate using 3D-printing, and the test-tube shape is similar to that of lab equipment and would not require a novel processing technique. The main benefit of this design is that the unscrewable media container would limit spillage of media as it is not pierced until it is screwed back on to the tube. However, the main drawback of this design is that it is not a single unit and is instead split into two components, increasing the opportunity for contamination when screwing and unscrewing the media container.

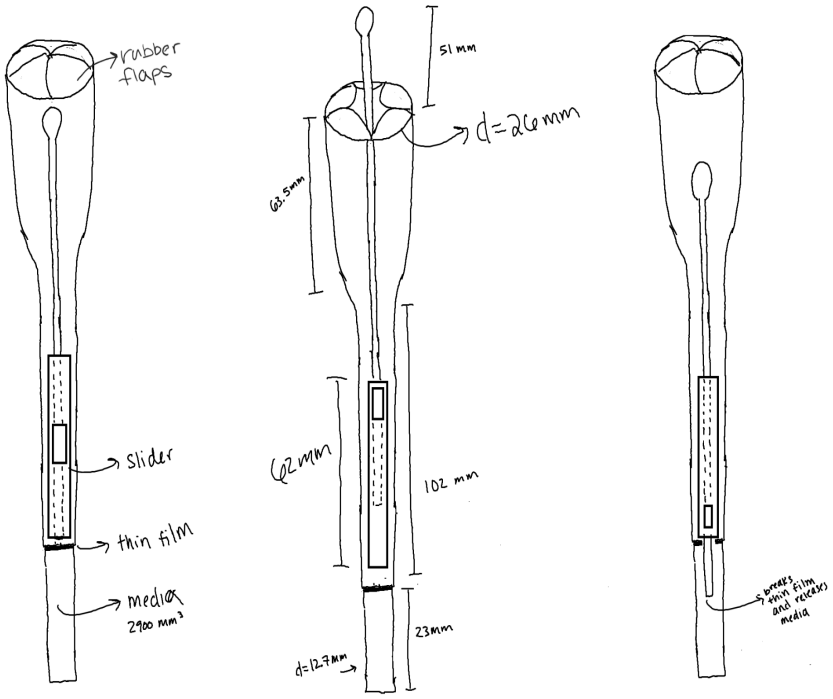


Figure 3. Slider swab design

Design 2: Slider Swab

The second design, as seen in Figure 3, utilizes a single unit design in order to limit contact contamination when self-swabbing. The design includes a slider for deployment and retraction of the testing swab, rubber flaps that will act as a sealing mechanism, and a media container that is separated by a thin film. When using the device, the patient will rest the top portion against the vaginal opening and push the slider forward to deploy the testing swab 5.1 cm into the vaginal canal. The patient will then rotate the device for 30 seconds in order to gather vaginal specimens. After collecting the specimens, the patient will pull the slider all the way down in order to break the thin film and release 2.9 mL of transport media. Some advantages of this design is that it will limit contact contamination of the testing room as the only portion of the design that must enter a potentially infected vaginal canal is to be contained in an external device. However, this design does introduce the risk for media spillage both before and after swabbing. If the patient were to pull the slider down prior to taking their swab, the thin film separating the media may break and the media would then be absorbed by the testing swab. Furthermore, the rubber flaps at the top of the device may not provide an adequate seal which could cause media to leak out the top of the device.

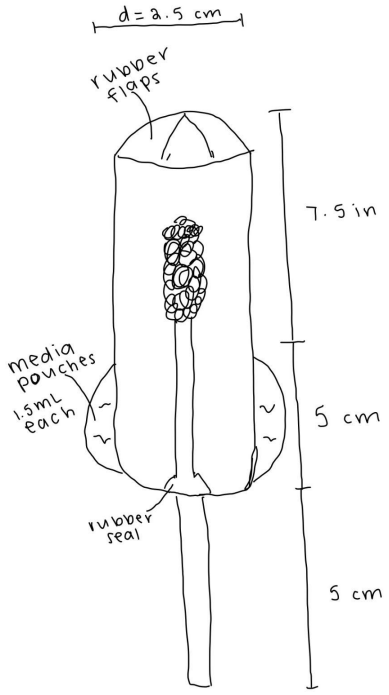


Figure 4. Plunger swab design with media pouches on the sides.

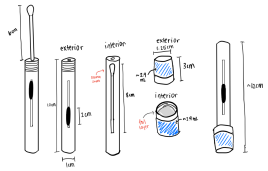
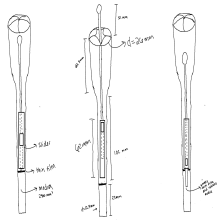
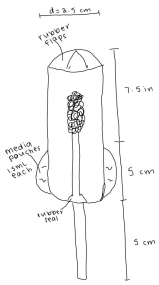
Design 3: Plunger Swab

The third design is also inspired by the structure of a tampon. Tampons are a familiar and easy-to-use device that many women are comfortable with, and this design seeks to translate that comfort into a simplistic STI test that encourages widespread testing. The upper body of this device is a shell that contains a swab, with the top portion consisting of rubber flaps that function similar to a valve. The bottom of the device is a plunger with a rubber seal and is connected to the rod of the swab. On the sides of the main body, there are two media pouches that contain 1.5 mL of transport media each and are enclosed with a thin foil or film. To use this device, the patient places the top of the device at the opening of their vagina. The plunger is pushed up, again, similar to how a tampon functions and the swab head is inserted 5 cm into the vagina. After swabbing, the patient pulls the plunger back down and the swab is retracted into the tube. The device can then be removed from the vaginal area. Next, the media pouches are squeezed and 3 mL of transport media is released into the body of the device in order to submerge the swab head. Overall, this design has the benefit of being extremely simplistic and user-friendly, making it more accessible to patients and maximizing their comfort in an uncomfortable process. However, the main drawback of this design is the potential for spillage and the close proximity of the media to the patient's body. As the top opening must allow for the swab to go in and out through it, it is challenging to completely seal it. Additionally, there is risk of the media pouches being broken prematurely.

IV. Preliminary Design Evaluation

Design Matrix

Table 1. Design Matrix for Self-Swab Device

Criteria	**Weight**	**Design 1:** Screw-on media 		**Design 2:** Slider 		**Design 3:** Plunger 	
Limiting contamination	30	3/5	18	4/5	24	5/5	30
Ease of use	20	3/5	12	4/5	16	5/5	20
Ease of fabrication	15	4/5	12	3/5	9	3/5	9
Patient Comfort	15	4/5	12	4/5	12	5/5	15
Safety	15	5/5	15	3/5	9	3/5	9
Cost	5	3/5	3	4/5	4	4/5	4
Total	**100**	**72**		**74**		**87**	

To determine the ideal design, six categories were evaluated for each proposed design idea. Limiting contamination refers to restricting the spreading of germs and other contaminants onto the swab or in the environment in which the test is being performed. Ease of use describes the degree of difficulty associated with performing a self-swab with the device, a metric preferred to be low. Ease of fabrication refers to the feasibility of fabrication within the constraints of ability and background of the engineer. Patient comfort details the degree of comfortability that the patient experiences when using the device to take a swab. Lastly, safety takes into account the potential biological and physical threats that are associated with device use, and cost refers to the price of manufacturing a singular unit.

Design three scores the highest (or ties) in four out of six categories, earning it the highest total score out of the three designs. It received a 5/5 in the limiting contamination

category because the swab is never exposed to the environment, and the media is contained within the device. Additionally, it scored highly in ease of use and patient comfort because the design is most similar to a tampon. Design three scored a 4/5 on cost due to its sleek, one-component design, although it does have the additional side pockets of media. Ease of fabrication is a bit lower scored because of the side pouches of media, and safety also scored similarly due to the close proximity of the media pouches to the user. Normally, scoring the highest in the design matrix would imply that design three would proceed to be the final design, but all three of these designs each have components that would be useful in the final design. Therefore, a combination of the three designs will be present in the proposed final prototype. The idea of a cap containing media from design one, the top, opening flaps from design two, and the push-stick idea from design three will all be incorporated.

Proposed Final Design

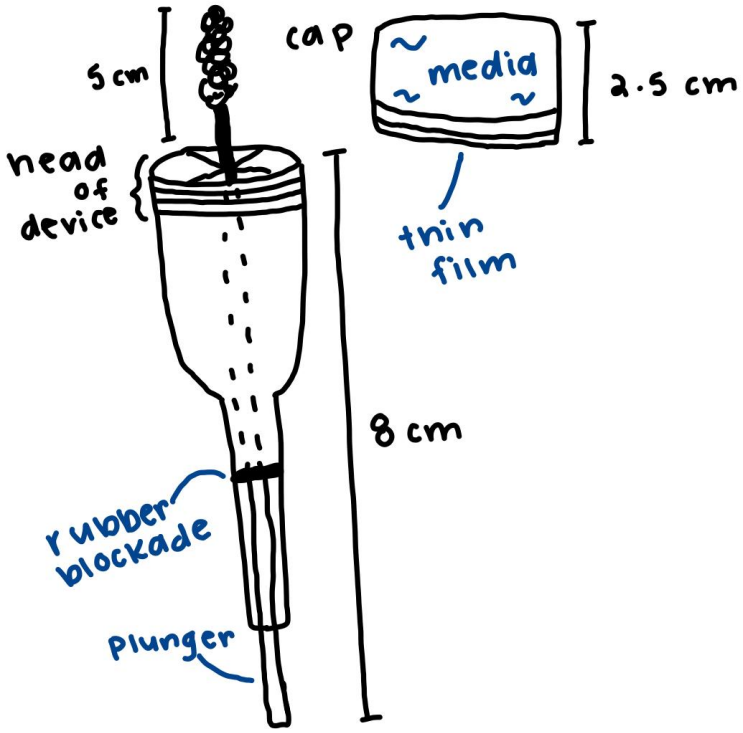


Figure 5. Proposed Final Design including device, swab and media cap

The proposed final design includes a plunger stick that attaches to the swab, a body to contain the swab, and cap that holds preservative media inside. The patient rests the head of the device on the entrance to the vagina (without inserting the device inside the body) and pushes the plunger up to insert the swab into the vagina. After completing a circular swab motion five times, the patient pulls the plunger down and the swab is removed from the body. At this point, the top of the device and the swab are contaminated, but the swab is housed in the device, so it is safe

from environmental contamination and will not taint any surfaces. To address the contamination of the top of the device, the user will screw on a media cap, as both the cap and the top of the device are threaded. At this point, the user will invert the device and deploy the swab once more. By pushing the plunger up and using the swab itself to break a thin layer of film on the bottom of the cap, the swab rests in the media and the bacteria of the sample is preserved. In its final position, the device will be resting on its cap, with the plunger stick fully deployed and the swab submerged in media. Keeping the device in an upside-down position will help mitigate the potential for leaking.

V. Fabrication/Development Process

Materials

Swab: The swab will be a Dacron swab. It is a non-cotton, non-toxic, hydrophilic, synthetic fiber-wrapped swab [14]. The shaft of the swab is plastic [15]. Dacron swabs are most commonly used for STI testing due to their non-toxic and hydrophilic nature. They are both safe for patients as well as most compatible with biological samples.

Transport media: Universal transport media increases the viability of the obtained specimen by keeping it in a non-dry environment and allowing the sample to be kept at room temperature [16]. Aptima Multitest Swab Transport Media (STM) was provided by the client and used solely for demonstration purposes [17]. This media will ultimately be contained within the cap of the device.

Red Dye: Red dye was used as an indicator for testing. Its vibrance allowed the results of both the Leak Test and Clinical Use Test to be clearly determined. A failing Leak Test visibly had red dye seeping out of the device onto the paper while a passing Clinical Use test visibly had red dye staining the swab. The red dye was also low cost and easy to acquire.

Foil: Aluminum foil was used solely to mimic the sealing of both the body of the device and the cap. It was a non-expensive material that allowed for a more complete demonstration of how a medical-grade film would be used once acquired. Sealing the swab within the body to maintain sterility before collecting a sample, and sealing media in the cap before being punctured were the two main criteria showcased with the foil [18].

Tube: The tube was used to mimic the vaginal canal in order to conduct Clinical Use Testing. It was 3D printed out of polycarbonate–as it was part of an early prototype–so it was readily available for use. The tube was also long enough and wide enough to

properly insert the swab the necessary depth for an STI test, approximately 5 centimeters [13].

Initial prototypes: All parts of each initial prototype (body, plunger, and cap) were 3D printed out of polycarbonate. It is an autoclavable, non-toxic, and biocompatible plastic [19]. Polycarbonate was primarily selected for its availability at the UW Makerspace.

Final prototype: All parts of the final prototype (body, plunger, and cap) were printed out of pink polylactic acid (PLA). PLA is a biopolymer that is commonly used in medical applications [20]. PLA is biocompatible and non-toxic, however it does not perform well at autoclave temperatures [21]. It was chosen as the material for the final prototype due to its availability at the UW Makerspace as well as for aesthetic purposes.

See Appendix A for information regarding the price of listed materials.

Methods

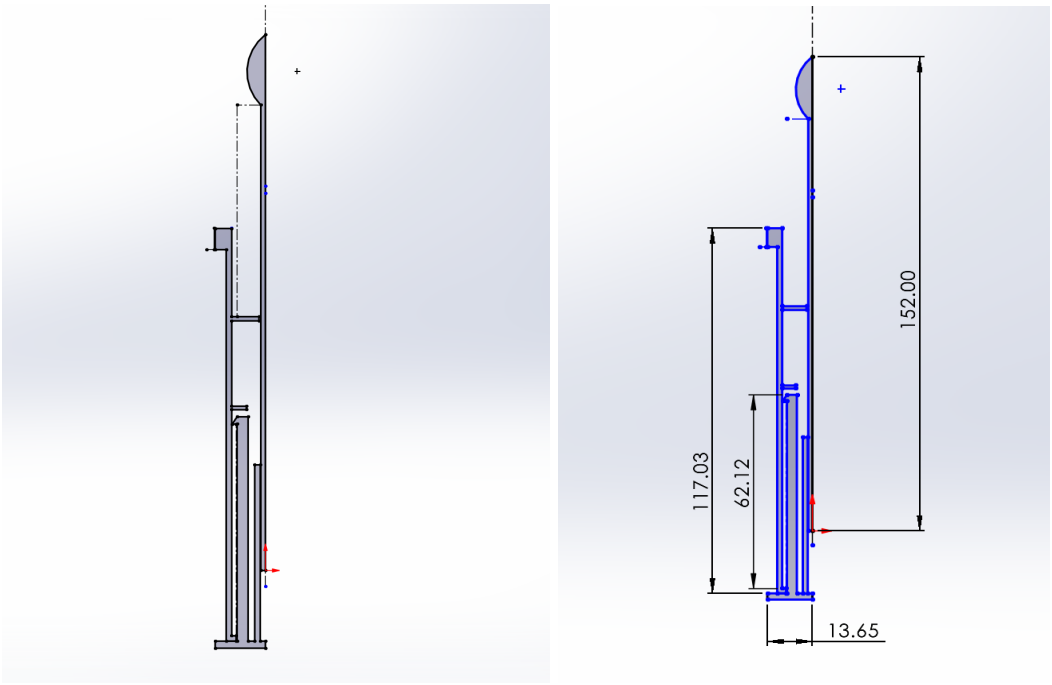


Figure 6. SolidWorks drawing of plunger and body of device centered about the mock swab prior to being revolved.

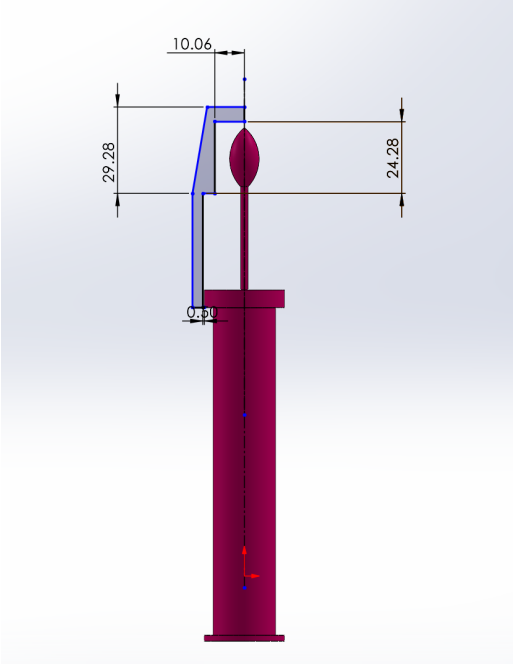


Figure 7. SolidWorks drawing of cap prior to being revolved with the swab fully enclosed while the plunger is fully deployed.

The three components of the device consisting of the plunger, the body, and the cap were first designed using SolidWorks. A mock swab, which can be seen in Figure 6, was first drawn and used as a reference to create the body and plunger of the device. Given that the swab is 15.2 cm in length, the body of the device was designed to entirely enclose the swab with the plunger in the retracted position [15]. With the known parameter of at least 5 cm of swab insertion into the vaginal canal, the plunger of the device was designed with 6.2 cm of vertical motion which directly translates to insertion into the vagina. The plunger of the device was also designed with a tight fit to the swab, which has a diameter of 2.4 mm, in order to inhibit the removal of the swab from the device during testing [15]. An insertion mechanism - which follows the design of a standard one-time snap - was added to the plunger of the device in order to assemble the plunger and the body [22]. A rim was also added to the bottom of the body in order to prevent the removal of the plunger during retraction. The SolidWorks drawing of the body and plunger was revolved about their center line to generate the 3D design seen in Figure 7. The cap of the device was then designed using the body and the needed 2.9 mL of media storage as a reference [17]. The cap was also designed to entirely seal the swab with the plunger in the fully deployed position as seen in Figure 7. The drawing of the cap was separately revolved about the same center line as the plunger and body. Standard threading of 0.5-13 inch was then added as an extrusion about the upper rim of the body and as a cut about the base of the cap.

Once the SolidWorks drawings were completed, stereolithography (STL) files of the body, plunger, and cap were created for the purposes of 3D printing. 3D printing was conducted at the UW-Madison MakerSpace using the Bambu Lab printers. The STL files were uploaded to

the MakerSpace computers and printing was conducted by the MakerSpace staff. Upon completion of 3D printing, supports were removed from each part of the device and the three components were assembled into a prototype.

Final Prototype

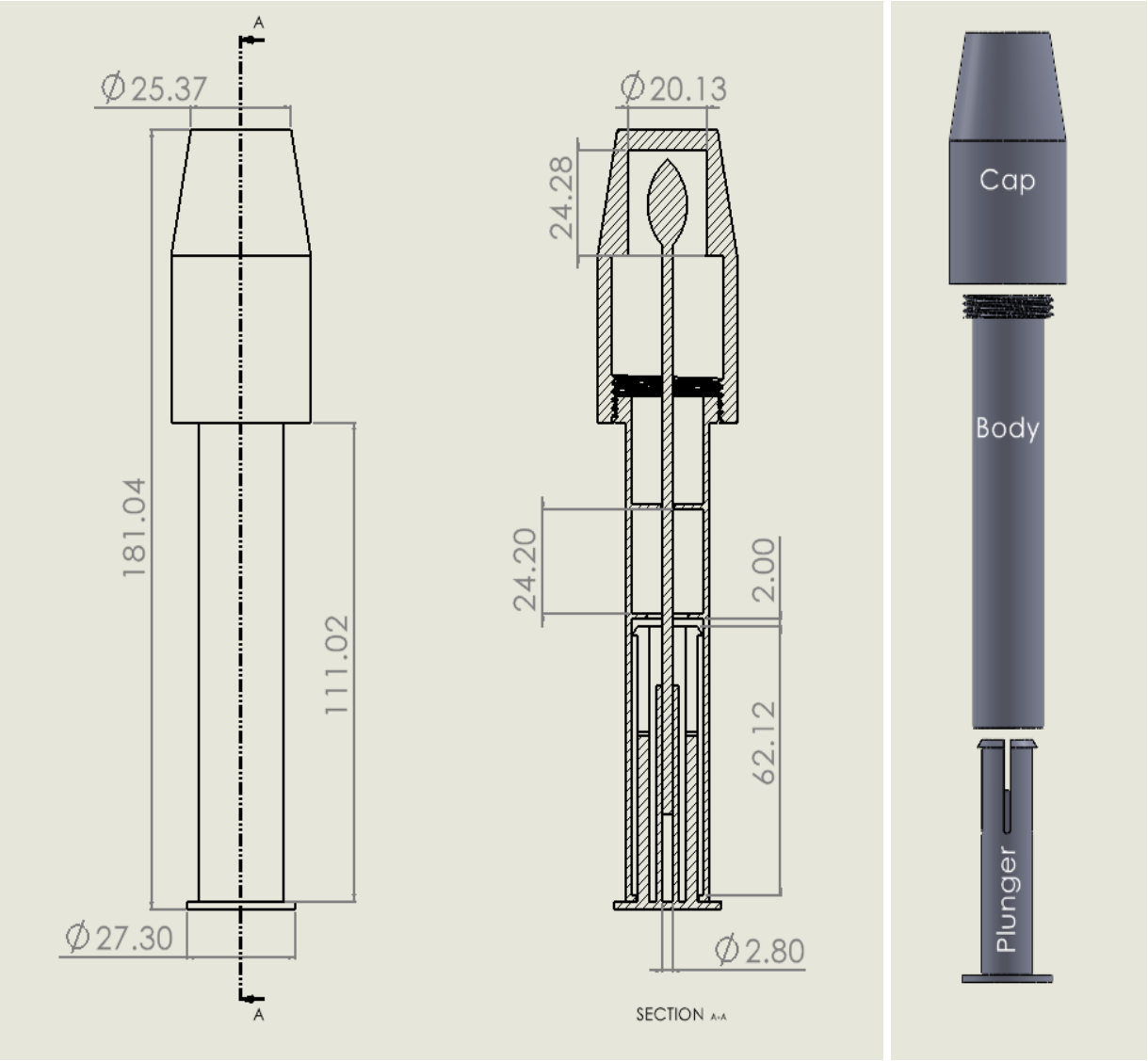


Figure 8. SolidWorks Drawing of Final Prototype, dimensions labeled in millimeters.

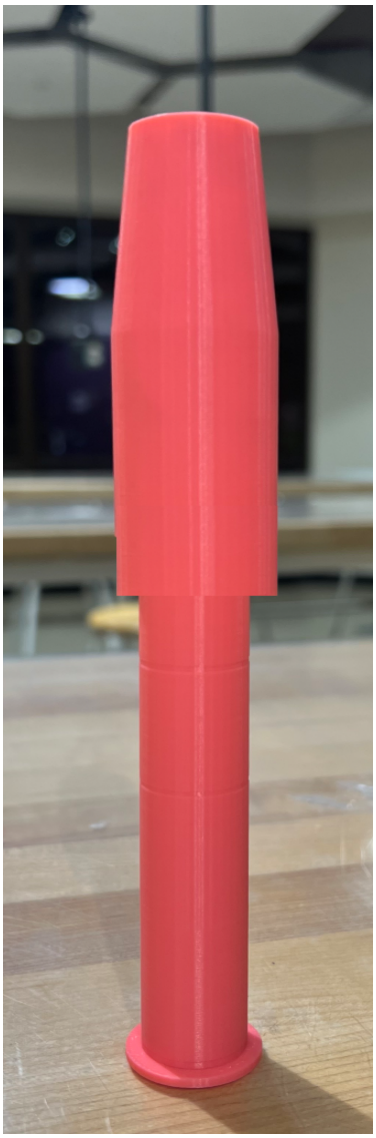


Figure 9. Final Prototype with the cap screwed on. All parts were made from 3D-printed PLA at the UW-Madison MakerSpace.

The final prototype, which can be seen in Figures 8 and 9, consists of a plunger, body, and cap. The plunger acts as the deployment and retraction mechanism necessary to insert the swab at least 5 cm into the vagina and to remove the swab from the vagina. The plunger also has a small hole as seen in Figure 8 that is 2.8 mm in diameter which allows for the attachment of the swab shaft to the plunger. The body provides the necessary containment of the swab in order to limit contamination of the environment and also acts as a guide for the swabs deployment path. Ideally, the swab is the only portion of the device that comes into contact with potentially infected vaginal fluids, but some fluid may get on the very top of the body. However, this contained contamination allows the patient to grip the body and plunger of the device without ever getting any vaginal fluids on their hands.

The body of the device also has two locations of support, one that is 2 mm above the plunger and a second that is 24.2 mm above the first (see Figure 8). These supports keep the swab stable as it is being deployed or retracted in order to ensure that it remains stiff during sample collection. The cap then acts as the final seal to the device, with a smaller container to hold the transport media as seen in Figure 8. There is a rim on the cap to allow for the addition of a thin film which will ultimately seal off the transport media. The cap and its containing media ensure that the specimen remains viable until testing in the laboratory.

The final prototype would be used during STI self-testing in a clinical setting. A patient using the final prototype would rest the top of the body against the vaginal opening, plunge the swab into the vaginal canal, grip and rotate the body to collect a sample, and then once again use the plunger to remove the swab from the vagina. The patient would then screw the cap onto the body of the device, flip the device upside down, and use the plunger one last time to puncture the thin film and soak the swab with media.

Testing

Leak Test

The goal of the leak test was to assess potential leakage from the self-swab device. The procedure was divided into three parts. In part 1, the device is tested for leakage with the cap-side facing down. The cap is filled with colored dye-stained water, and the swab is pushed into it. After each trial any visible color on the filter paper is recorded. Part 2 involves a similar process, but the device is placed plunger-side down to test for leakage in that configuration. Part 3 assesses leakage after shaking the device for a minute to simulate real life transportation where the device may be shaken around. The comprehensive testing protocol systematically assesses potential leakage scenarios from the self-swab device under the three different outlined conditions. The use of colored dye-stained water and filter paper allows for a clear visual indication of any leakage, with each part of the protocol addressing specific orientations and actions that may reveal vulnerabilities in the device's design. The Leak Test is considered passed if no red-colored liquid is visible on the filter paper. For a more detailed testing protocol and exact instructions, see Appendix C.

Ease of Use Test

In order to evaluate the feasibility of the final design being used by actual patients, students in BME Design were surveyed regarding the aesthetics of the device, the process of taking the swab, and the cleanliness of the device. Respondents were given the following directions for how to use the device:

> *This device functions similar to a tampon with a plunger at the end that is used to push the swab into the vagina and also retract the swab after use. After the swab is taken, a*

cap is screwed on that contains media to preserve the sample until further testing in the lab.

1. Wash your hands.

2. Place the top of the device at the opening of the vagina. Do not insert the tube into the vagina.

3. Push the plunger into the device and ensure the swab enters approximately 5 cm into the vagina.

4. Swab the sides of the vagina for 10-30 seconds by gently rotating the swab.

5. Pull the plunger out of the device until the head of the swab is inside the tube.

6. Move the device away from the genital area and obtain the cap.

7. Flip the tube upside-down and screw the cap on to the tube.

8. Once the cap is securely screwed on to the tube, keep the device upside-down and press the plunger down and into the cap to break a foil inside and release the media.

9. Place the entire device (tube and cap) into a sealable bag for transport. Keep the device in the upside-down position.

10. Wash your hands. Return device and bag to your healthcare provider.

Subsequently, they were asked the following questions:

- On a scale of 1 to 5, how visually appealing is the device?
- On a scale of 1 to 5, how comfortable would you be using this device?
- On a scale of 1 to 5, how clear are the directions?
- Would you be able to use this device to perform a self-swab?
- On a scale of 1 to 5, how clean do you think this new self-swab process would be in terms of contamination of the testing environment? (transfer of vaginal fluids to hands, counter, other surfaces in the room)
- Are there any aspects of the design that would prevent or discourage you from using the device?
- Do you have any other feedback about this new self-swab device?

These questions were chosen with the goal of evaluating specific criteria from the design specifications, which included that the device must be user-friendly, should make patients more comfortable with the self-swab process, and should have no risk of contamination when in use. Originally, the team intended to survey respondents about this device in comparison to standard STI self-swabs and ask if it would be easier to perform a self-swab with the new device. However, this could not be accomplished due to lack of approval from an Institutional Review Board (IRB) as it involves asking about medical history. Thus, the focus of the survey was shifted to ask solely about the new device. Additionally, the last two open-ended questions were included in order to gather general feedback about the design and to identify any limitations or drawbacks of the device that would affect how user-friendly it is. To view the entirety of the survey, see Appendix D.

Clinical Use Test

The main goals of the Clinical Use Test are to ensure that viable samples can be collected with the device and to assess the contamination of the device during use. In order to conduct this test, a tube that was coated with a red dye on its inner walls was used to mimic the vaginal canal. The device was then used to take a sample as if being done by an in-clinic patient. A passing test would result in the swab being stained with red dye, indicating specimens were collected from the walls of the 'vagina'. Furthermore, red dye only appearing on the swab and not the head of the body would demonstrate reduced contamination of the device itself. Overall, our client's goal of increasing universal testing and reducing contact contamination requires a fully functioning STI testing device that is able to give accurate results with minimal contact of vaginal fluids. The Clinical Use Test aims to discern whether these criteria can be met with our device.

See Appendix E for information regarding the specific instructions followed for this test.

Mechanical Strength Test

The goal of the mechanical strength test was to assess the mechanical integrity of the body and plunger of the device. Although the device is not expected to experience substantial loading, the possibility of the device being mishandled prompted a need for quantifying its mechanical strength. As a result, both compressive and tensile tests were conducted on the body and plunger of the device using a SolidWorks simulation. The compressive test consisted of a 10, 100, and 1000 N axial load, while the tensile test consisted of a 25, 50, and 75 N axial load. Stress distributions were generated for both the body and plunger of the device under each loading condition. The material used in this test was polypropylene (PP) as SolidWorks did not offer PLA. Additionally, PP is expected to be used in any future iterations of the device. For a detailed testing protocol, please look to Appendix F.

VI. Results

Leak Test

Part I: In part one of the leak test, the team filled the cap with colored beverage to assess leaking. Results were as follows:

Table 2. Leak test part one data

Trial #	1	2	3	4	5
Colored dye visible - yes or no? ***If yes, provide a detailed description.**	No Dye	No Dye	No Dye	No Dye	No Dye

As seen in Table 2, in all five trials no liquid was observed leaking from the cap. It is safe to conclude that the cap made from polylactic acid (PLA) does not allow any leakage, so the media can be stored in the cap with confidence.

Part II: In part two of the leak test, the team assessed if liquid would leak out the bottom via the connection between the body and the plunger. Results were as follows:

Table 3. Data from leak test part two

Trial #	1	2	3	4	5
Colored dye visible - yes or no? ***If yes, provide a detailed description.**	Yes. Nearly all the liquid came out of the bottom.	Yes. Nearly all the liquid came out of the bottom.	Yes. Nearly all the liquid came out of the bottom.	Yes. Nearly all the liquid came out the bottom.	Yes. Nearly all the liquid came out the bottom.

Figure 10. Leakage observed from plunger connection

As Table 3 and Figure 10 detail, liquid was clearly seen leaking from the bottom of the device in all five trials. Although the protocol for the device usage calls for the device to remain inverted after the sample is collected, part two of the leak test showed that if the device was accidentally flipped upright, the media would leak out. The clear conclusion is that design modifications will have to be made in order to allow the strict containment of the preservative media in the device.

Part III: In part three of the leak test, the device would have been shaken and placed upside down to observe any further leakage. However, this part of the test was not executed because the results in part two clearly demonstrated that liquid readily leaks from the bottom of the device. Therefore, if the device was shaken, liquid would spray out from the bottom. In an effort to be conscious of the cleanliness of the testing environment, the team opted to not perform this test.

Ease of Use Test

Overall, respondents (n=12) rated the aesthetics, usability, and cleanliness of the device fairly high. ⅔ of respondents rated the device as either very visually appealing or moderately visually appealing. ⅝ of respondents stated they would be moderately or very comfortable with using this device. All respondents felt able to perform the self-swab with the device after either reading the instructions or seeing a demonstration, and ⅔ thought the directions were either moderately or very clear to understand. ⅝ of respondents felt that the new device would be moderately or very clean and prevent contamination of the testing environment. These results are displayed visually in Figures 11 through 13.

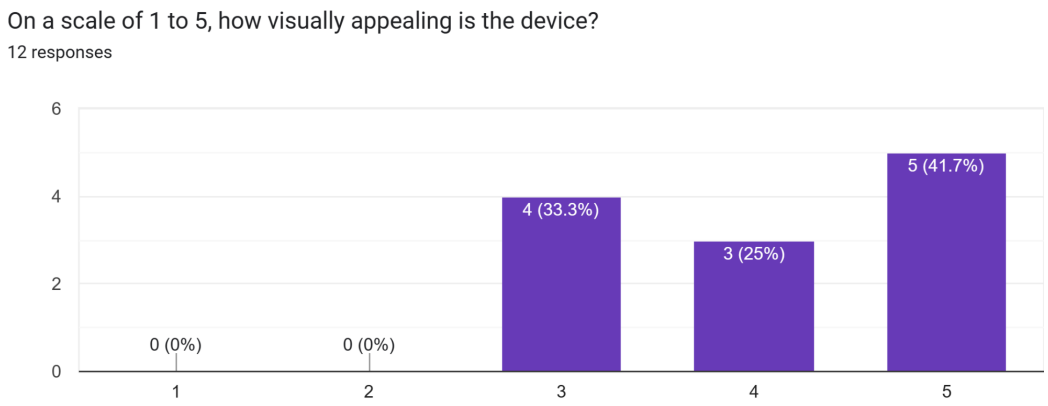


Figure 11. Bar graph results on visual appeal of the device, with 1 being very unappealing and 5 being very appealing.

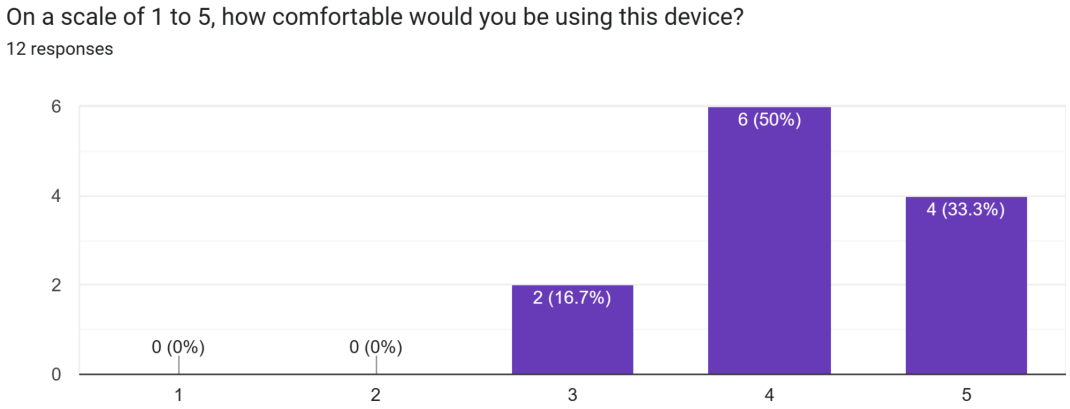


Figure 12. Bar graph results on level of comfort with using the device, with 1 being very uncomfortable and 5 being very comfortable.

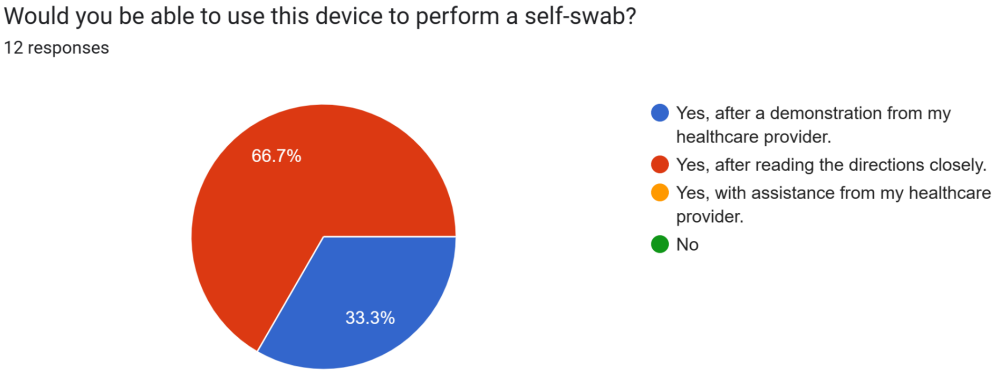


Figure 13. Pie graph results showing respondents' ability to perform a self-swab using the device.

Regarding the open-ended questions, some of the most common responses about aspects of the design that were unappealing included the threading on the outside of the tube and the white color of the initial prototype. Other feedback included flaring the top edge of the tube out to prevent accidental insertion into the vagina, adding grips to the bottom of the tube, altering the directions to include more specific language, and extending the cap. To see each response to the open-ended questions, see Appendix D.

Clinical Use Test

In the clinical use test, a swab was taken in a simulated vagina using the device. The results were as follows:

Table 4. Ease of use testing results

Trial #	1	2	3	4	5
Colored dye visible on swab - yes or no? ***If yes, provide a detailed description.**	Yes, swab is clearly stained red	Yes, swab is clearly stained red	Yes, swab is clearly stained red	Yes, swab is clearly stained red	Yes, swab is clearly stained red

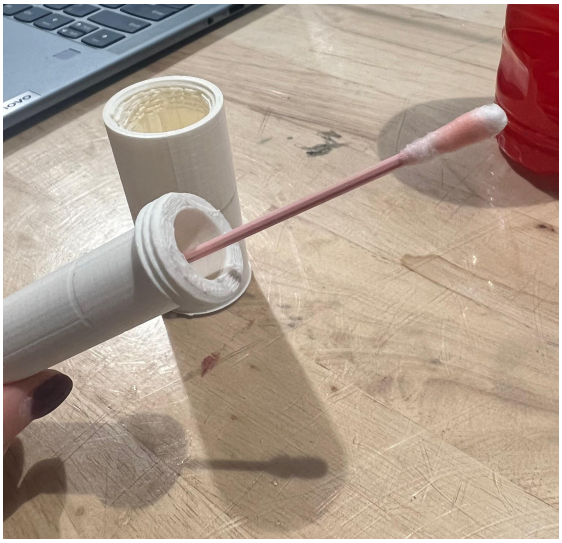
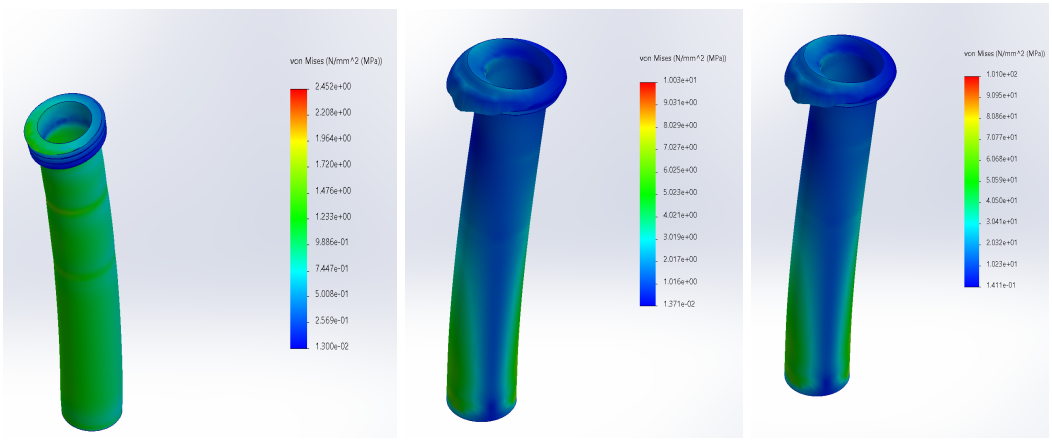


Figure 14. The red dye on the swab after the clinical use test was performed

As laid out by Table 4, the swab picked up a significant amount of the red coloring of the liquid in the test tube in all trials. Figure 14 demonstrates the dye on the swab after a singular trial. Furthermore, the body of the device did not have any red dye on it, proving that it did not come in contact with the simulated vaginal fluids. This test proved that only the swab comes in contact with the vagina fluids, and the body of the device does not. Therefore, contamination of the body is minimal, and since the user only touches the body of the device and the plunger, their hands are not contaminated. When the user goes to touch any part of the testing room, their hands should not be contaminating the area. Since limiting contamination was a main goal of the project, this test proved the team to be quite successful. Additionally, the results from this test show that the swab is able to get a sufficient sample for STI testing due to the presence of the dye on the swab. It is important that the device is able to be functional in a clinical setting, and this testing proves that it does.

Mechanical Strength Test

Body: The body of the device was able to withstand compressive loads greater than 1000 N and tensile loading greater than 75 N. Testing was done with incremental loading until those values were reached, but complete failure was never achieved. However, there was significant, visible deformation of the body, as shown in Figures 15-17.



Figures 15-17: Stress distribution with a 10, 100, 1000 N (left-to-right) compressive axial load

The average stress values were computed by taking the three highest values on the simulation and computing the average. For the body, the compressive stress average was 6.6 MPa. The average American woman weighs about 700 N with a standard deviation of 36 N, so even if a patient were to step on the device, it would not break [23]. The maximum tested compressive value of 1000 N has a statistically significant failure resistance, with a p-value of less than 0.0001.

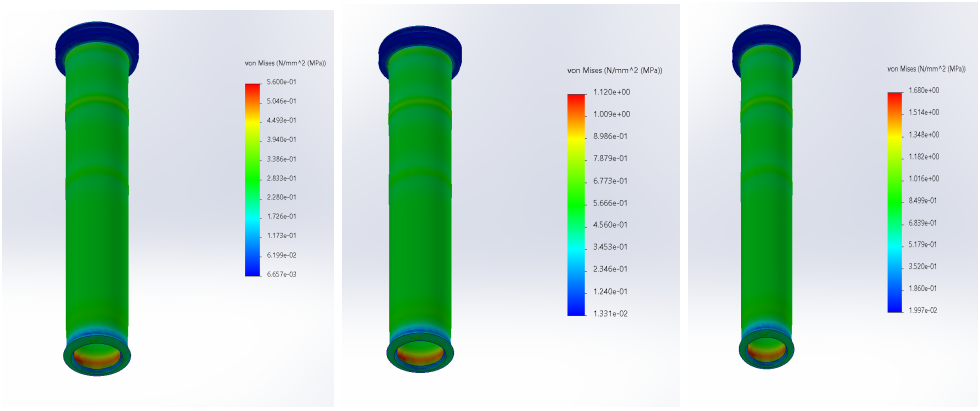
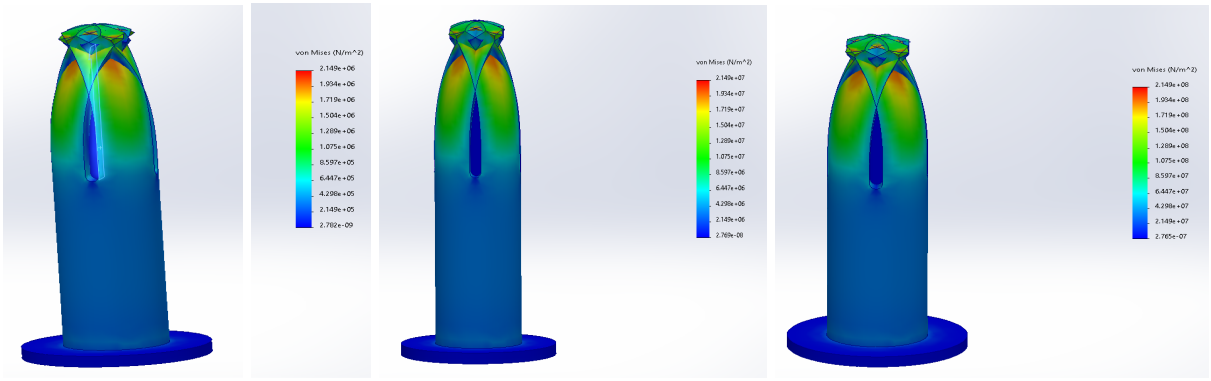


Figure 18-20: Stress distribution with 25, 50, 75 N (left-to-right) tensile axial load

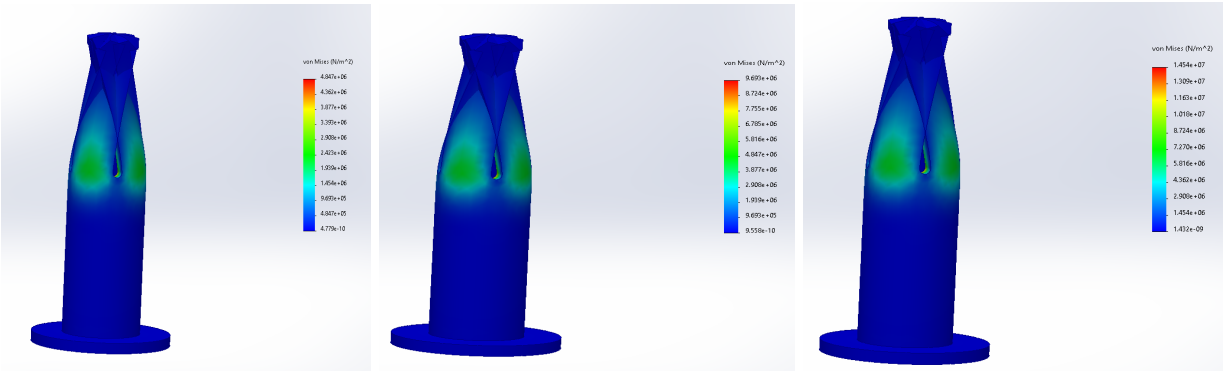
The average tensile strength of the body was 0.56 MPa, which was determined from simulations shown in Figures 18-20. The average seated woman has a pulling strength of 75 N, which was imitated in our testing [24]. Even at this 75 N tensile load, the body did not fail at any point, although deformation is evident. If for any reason, a patient placed the device in axial tensile load, the integrity of the device would be preserved. As observed from Figures 18-20, significant deformation is only visible at the 75 N load. Since 25 N is significantly lower than the mean ($p=0.0455$), the lack of visible deformation in that simulation is expected. However, the 50 N load is not significantly lower than the mean ($p=0.3173$), so lack of visible deformation was a bit unexpected.

Plunger: The plunger was able to withstand compressive loads greater than 1000 N and tensile loading greater than 75 N. Testing was done with incremental loading until those values were reached, but complete failure was never achieved. However, there was significant, visible deformation of the plunger, as seen in Figures 21-23.



Figures 21-23: Stress distribution under compressive axial loads of 10 N, 100 N, 1000 N (left-to-right)

For the plunger, the average compressive strength, as seen in Figures 21-23, was 72.4 MPa. This compressive strength simulates the attachment of the plunger into the body, as the relief feature needs to be squeezed together to fit it into the one-time snap component of the device. Deformation is evident around the relief feature, where the stress is concentrated. During assembly of earlier prototypes, these pieces were especially flimsy and were prone to snapping when the plunger was fitted into the body. Adjustments were made to the SolidWorks drawing so the pieces in the area of relief were thicker and more resistant to snapping.



Figures 24-26: Stress distribution of axial tensile loads of 25 N, 50 N, and 75 N.

The average tensile stress of the plunger was 4.85 MPa. Again, the stress is concentrated on the relief feature, but more towards the base of each component, as seen in Figures 24-26. This test was performed to simulate the stress distribution if a woman was to pull down on the plunger with excessive force. At the average pulling strength of a seated woman of 75 N, the plunger stays intact and does not fail.

VII. Discussion

The end goal of this design was achieved as it limits environmental contact contamination by keeping the swab enclosed and unexposed to the environment. This proves beneficial because the design ensures that the testing room does not become contaminated when transferring the swab into the media. The contained design not only decreases the potential for environmental contamination, but also the likelihood of a false positive due to a contaminated room [4]. In regards to STI testing, there is a severe lack of STI knowledge in young adults. STIs are under-tested with one in four sexually active adolescent females in the U.S. having an STI [25]. Clinical settings that are non-inclusive to LGBTQ+ patients, stigma around testing, lack of awareness of resources, religious beliefs, and many more factors are key barriers to STI testing [26]. Additionally, some people cannot afford doctor's visits or health care insurance and therefore, cannot get tested [4]. To address this socio-economic aspect of STI testing, using high-quality yet inexpensive materials is crucial to making STI testing more widely available. As a result, it's essential to recognize that our device - by incorporating more material than already existing designs - may contribute to increased waste. Sustainable practices should be considered,

such as exploring biodegradable or recyclable materials, and encouraging responsible disposal or reuse. The overarching goal of the design is to enhance comfort, encouraging sexually-active women and girls to undergo STI testing. Aesthetics and user-friendly features play a pivotal role in achieving this objective. Balancing cost-effectiveness with environmental responsibility and non-intimidating design is key to ensuring that the benefits of increased testing accessibility do not come at the expense of heightened environmental impact.

VIII. Conclusion

Contamination of STI self-swab testing environments with chlamydia or gonorrhea is prevalent, with one study finding that 13% of testing rooms had at least one of these bacteria on the surfaces [27]. Although the threat of infection to other patients is low, this contamination of surfaces has led to false positives, with one study finding that 67% of women who tested in the clinic received a false positive [4]. As a result, there is a need for extensive cleaning of the testing rooms in between patients, which requires both time and resources. The goal of the project was to limit contamination of the clinical environment for vaginal self-swab STI tests. To address this issue, a device was created that consists of a design similar to that of a tampon. The swab is contained in a plastic body and the patient uses a plunger to push the swab into the vaginal canal. After the swab is complete, the woman contracts the swab by pulling the plunger down and screwing a cap onto the top of the body of the device. Then, she flips the device upside down, and pushes the plunger in to rest the swab inside of the cap.

Through testing, comfortability using the device and effectiveness of limiting contamination were determined. In both those categories, the prototype performed well. Early on, modifications were made to the design to prevent mechanical failure, as components of the plunger were prone to snapping. After those changes, the device also performed well in mechanical strength testing. On the other hand, the prototype did not perform well in the leak testing, with simulated media readily leaking out the bottom. In the future, leaking prevention measures will be taken, including the addition of O-rings to the plunger and the cap and adding a twist-lock mechanism between the plunger and the body. Furthermore, changes will be made to make the design more aesthetically pleasing and less intimidating, including reducing the diameter of the body, moving the threading to the interior of the device, and changing the material to polypropylene. Further in the future, the method of fabrication could be changed from 3D-printing to injection molding to lower costs and time.

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X. Appendix

Appendix A: Expense Spreadsheet

Table 1. Expensive spreadsheet including the material, the cost per unit, the total cost, the vender, and the part number.

Material	Price per Unit	Total Cost	Place Purchased	Part Number
Polycarbonate	$3.74/device (on average)	$29.92	Makerspace	-
Polylactic Acid	$5.82/device (on average)	$23.28	Makerspace	-
Transport Media	-	-	Provided by client	-
Red Dye Testing Liquid	$2.50	$2.50	Makerspace Vending Machine	-
Foil	-	-	Already owned	-
Dacron Swab	-	-	Provided by client	-

Appendix B: Product Design Specifications

Function:

This device should be a vaginal self- swab used for STI testing in the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. A swab such as this would allow women to test and screen for these common STIs in the comfort of their own home or in a clinic. Current self-swab studies have found that 84% of women prefer this self-swab method of testing to getting swabbed by a clinician [1]. However, the current methods provide many avenues for contamination of not only the swab itself but also of the environment. If the swab touches any exterior surfaces, such as the leg or table, it is considered contaminated and results can be faulty [2]. Furthermore, liquid in the testing kit can easily spill and contaminate the testing space in a clinic [1]. A design in which the swab is deployed and contracted back into the device while remaining inserted in the vagina would decrease the probability of contamination.

Client Requirements:

- The swab head should be contained in an external tube that is safe to enter the vagina.
- The swab head should be deployed from the external tube into the vagina and retracted back into the tube.
- The tube should seal upon retraction.
- The device should ultimately make universal STI testing more accessible and limit contamination of the testing room.
- A budget of 500 dollars should be observed.

Design Requirements:

1. **Physical and Operational Characteristics**

    a. Performance Requirements:

        i. The external tube must comfortably rest against the vaginal opening.

ii. The external tube must have a mechanism for deployment, retraction, and sealing of the test specimen.

1. Deployment and retraction will be accomplished via a slider mechanism or plunger mechanism.

2. Sealing will be accomplished via a cap.

iii. The head of the swab must be deployed 5 centimeters into the vaginal canal [2].

iv. The swab must remain connected to the external tube and allow patients to self-swab for up to 30 seconds [2].

v. The overall device must also contain a transport media in order to limit the contact contamination caused by the transfer of the specimen into the media [1].

b. Safety:

i. The swab head and shaft must be biocompatible and bioinert so as to prevent any irritation or immune response.

ii. The transport media used must be nontoxic and biocompatible in case of device malfunction or splashing that could cause it to come in contact with skin or internal vaginal tissue.

iii. The device must pass toxicological risk assessment as defined by ISO-10993-17 to ensure that the device will not have any harmful chemical or biochemical interactions with the vaginal or bodily components that it comes in contact with [3].

c. Accuracy and Reliability:

i. The swab device needs to be reliable at detecting Chlamydia and Gonorrhea STIs for every test.

ii. To ensure accuracy, the swab must be able to be inserted about 5 centimeters into the vagina and be rotated for 10-20 seconds each time to collect the sample [1].

iii. The tip of the self-swab device should be approximately 1 cm length for optimal collection of vaginal discharge samples [1].

d. Life in Service:

i. Fully assembled STI tests should have a shelf life ranging from 12-18 months. The exact standard cellular media used will further dictate the precise storage longevity of the test as a whole [4].

ii. Tests should not be stored in direct sunlight and should be kept between 2 – 8 °C (36 – 46 °F) for maximum shelf life before use [5].

iii. After samples have been collected, the test will be in service until the lab has gathered cells from the swab. Swabs can be stored at room temperature in the lab for a maximum of 14 days [6].

iv. Tests done at home will be transported to the lab.

v. Each test will only be used once.

e. Shelf Life:

i. The STI test should be used within 30 days of arrival [7].

ii. Swabs should be transported and/or tested within a 14 day period after the test is administered [6].

f. Operating Environment:

i. The STI swab must be user friendly and able to withstand room temperature (20-22°C) for several hours before and after use.

ii. The swab should have no risk of outside contamination or environmental contamination when in use.

iii. The device must be able to insert into the vagina and withstand the acidic environment of the vagina (pH of 3.8-4.5) [8].

g. Ergonomics:

i. The swab should insert and fit comfortably inside the vagina, submerged approximately 5 centimeters [2].

ii. All materials used in the swab and applicator should be compatible with the intravaginal environment.

iii. The fluid within the cap should be biocompatible but contained within the device.

h. Size:

i. The overall device will not exceed 17 centimeters in length. This provides the patient with enough grip length to comfortably swab the vaginal canal.
    1. The average depth of an unaroused vaginal canal is 9 centimeters [9].

i. Weight:

i. The overall device will not exceed 7 grams. This includes the weight of the external tube, the swab shaft and head, and the cell culture media within the device.

j. Materials:

i. As the design will consist of multiple sections, a variety of materials must be used to construct the sample collector.

ii. The head of the swab must be made of a non-cotton fiber that will not shed in the process of sample collection or analysis. The material must have chemical resistance and biocompatibility so as to withstand both the physiological environment of the vagina as well as the chemical processing involved with experimentation [10]. The swab head material must be highly absorbent for water and proteins so as to collect many specimens, and must allow for their release and collection in medium for testing [11]. Per CDC recommendation, suggested materials include rayon, dacron, or cytobrush [12].

iii. The shaft of the swab should consist of an easily-manufactured and autoclavable material such as a biocompatible resin or plastic that can be manufactured with 3D printing [10].

iv. An appropriate transport media must be used to store the sample following insertion into the vaginal canal. Commonly used, commercially-available media includes M4 media or Vircell Transport Medium [13]. Use of a transport media will allow for improved microorganism viability when testing is performed [14].

v. The body of the sample collector should be manufactured from an autoclavable, single-use plastic. The material must not irritate the vaginal canal or induce an immune response. Possible materials include polyethylene or polypropylene, similar to the composition of a plastic tampon applicator.

k. Aesthetics, Appearance, and Finish:

i. The finished product will be similarly shaped to a standard tampon applicator or IUD insertion device.

ii. The exterior finish of the product will be smooth and sleek as to prevent damage to internal tissue during insertion into the vagina.

iii. The product will be long enough to allow swab insertion of at least 5 centimeters into the vagina for sample collection purposes [2].

2. Production Characteristics

a. Quantity:

i. One self-swab device prototype will be developed for purposes of the project.

ii. Design should be replicable for potential to be mass-produced for either at-home or in-clinic use as per client's request.

b. Target Product Cost:

i. The end cost of the design process should not exceed the client's budget request of $500.

1. $55-100 is the estimated cost for one STI swab test (including projected materials for the device, the swab itself, and the liquid media) [15].

3. Miscellaneous

a. Standards and Specifications:

i. As defined by the FDA in the Code of Federal Regulations, Title 21, Sec. 866.2900, the vaginal sample collector is classified as a microbiological specimen collection and transport device and a Class I (general controls) medical device [16]. The media contained within the device is a transport culture medium and Class I (general controls) device as specified in Sec. 866.2390 [17]. This classification means that the device is exempt from premarket notification 510(k), but is still subject to registration and listing, labeling, and good manufacturing practices.

ii. The device is subject to requirements for the collection and transport of samples for medical laboratory examinations as outlined by ISO 20658 [18].

b. Customer:

i. The customer would like to limit cross contamination of the environment with a product that is able to seal the swab, so it is no longer necessary to transfer from the vagina to the tube.

ii. The customer would like to make universal testing of Chlamydia more accessible (ideally doubling the existing 6%-8%) in order to both prevent infertility as well as the spread of disease. The customer would also like to reach younger women who are more typically under-tested [19].

c. Patient-Related Concerns:

i. This product will ideally make patients more comfortable with regular STI screening.

ii. Barriers to universal testing will still exist (socioeconomic, location, age, etc) [19].

iii. Proficient self swabbing is important in collecting vaginal samples to be tested.

d. Competition:

i. There exist similar products to a self-swab for *Chlamydia Trachomatis*, none of which address the client's concern for contamination as they all require the screwing/unscrewing of sample containers [20].

ii. A design for a swab with a detachable head exists, yet the collection process still involves a separate entity, the collection tube, being unscrewed to place the head into. [21]

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Appendix C: Leaking Testing Protocol

Materials:

- Prototype of self-swab device
- Water (to simulate liquid media) and Color Dye
- Filter paper
- Timer

Leaking test: Plan for testing if the media contained inside the device leaks at any point, mostly focusing on the top with cap and the bottom of the device with the syringe. Broken up into three parts for testing.

Part 1 - Testing for leakage while the device is stationary cap-side down.

Step 1: Unscrew cap. Fill the prototype cap with colored dye-stained water. Screw cap back on device.
Step 2: Push swab into the cap while the device is cap-side down.
Step 3: Place filter paper on the table and set the device cap side down.
Step 4: Let the device sit out for 5 minutes, remaining in the cap-side down position.
Step 5: After 5 minutes, remove the device from the filtered paper. Record if any color is visible on the filter paper.
Step 6: Repeat process for 4 more trials.

Table for Part 1:

Trial #	1	2	3	4	5
Colored dye visible - yes or no? ***If yes, provide a detailed description.**					

Part 2 - Testing for leakage while the device is stationary plunger side-down.

Step 1: Unscrew cap. Fill the prototype cap with colored-dye stained water. Screw cap back on device.

Step 2: Push swab into the cap while the device is cap-side down.

Step 3: Place filter paper on the table and set the device plunger-side down.

Step 4: Let the device sit out for 5 minutes, remaining in the plunger-side down position.

Step 5: After 5 minutes, remove the device from the filtered paper. Record if any color is visible on the filter paper.

Step 6: Repeat process for 4 more trials.

Table for Part 2:

Trial #	1	2	3	4	5
Colored dye visible - yes or no? ***If yes, provide a detailed description.**					

<u>Part 3</u> - Testing for leakage after the device has been shaken for a minute.

Step 1: Unscrew cap. Fill the prototype cap with colored-dye stained water. Screw cap back on device.

Step 2: Push swab into the cap while the device is cap-side down.

Step 3: Place filter paper on the table.

Step 4: Shake the device for one minute over the filter paper.

Step 5: After 1 minute of shaking, place the device on the filter paper cap side down.

Step 6: Let the device sit for 5 minutes, remaining in the cap-side down position on the filter paper.

Step 7: After 5 minutes, remove the device from the filtered paper. Record if any color is visible on the filter paper.

Step 6: Repeat process for 4 more trials.

Table for Part 3:

Trial #	1	2	3	4	5
Colored dye visible - yes or no? ***If yes, provide a detailed description.**					

Appendix D: Ease of Use Testing Survey and Results

View the following images of a new vaginal self-swab device and read the directions, then answer the questions below.

Directions:

This device functions similar to a tampon with a plunger at the end that is used to push the swab into the vagina and also retract the swab after use. After the swab is taken, a cap is screwed on that contains media to preserve the sample until further testing in the lab.

1. Wash your hands.
2. Place the top of the device at the opening of the vagina. Do not insert the tube into the vagina.
3. Push the plunger into the device and ensure the swab enters approximately 5 cm into the vagina.
4. Swab the sides of the vagina for 10-30 seconds by gently rotating the swab.
5. Pull the plunger out of the device until the head of the swab is inside the tube.
6. Move the device away from the genital area and obtain the cap.
7. Flip the tube upside-down and screw the cap on to the tube.
8. Once the cap is securely screwed on to the tube, keep the device upside-down and press the plunger down and into the cap to break a foil inside and release the media.
9. Place the entire device (tube and cap) into a sealable bag for transport. Keep the device in the upside-down position.
10. Wash your hands. Return device and bag to your healthcare provider.

On a scale of 1 to 5, how visually appealing is the device? *

	1	2	3	4	5	
Very unappealing	○	○	○	○	○	Very appealing

On a scale of 1 to 5, how comfortable would you be using this device? *

	1	2	3	4	5	
Uncomfortable using this device	○	○	○	○	○	Very comfortable using this device

On a scale of 1 to 5, how clear are the directions? *

	1	2	3	4	5	
Not clear at all	○	○	○	○	○	Very clear

Would you be able to use this device to perform a self-swab? *

- ○ Yes, after a demonstration from my healthcare provider.
- ○ Yes, after reading the directions closely.
- ○ Yes, with assistance from my healthcare provider.
- ○ No

On a scale of 1 to 5, how clean do you think this new self-swab process would be in terms of contamination of the testing environment? (transfer of vaginal fluids to hands, counter, other surfaces in the room) *

	1	2	3	4	5	
Very Unclean - a lot of contamination	○	○	○	○	○	Very Clean - no contamination

Are there any aspects of the design that would prevent or discourage you from using the device? *

Your answer

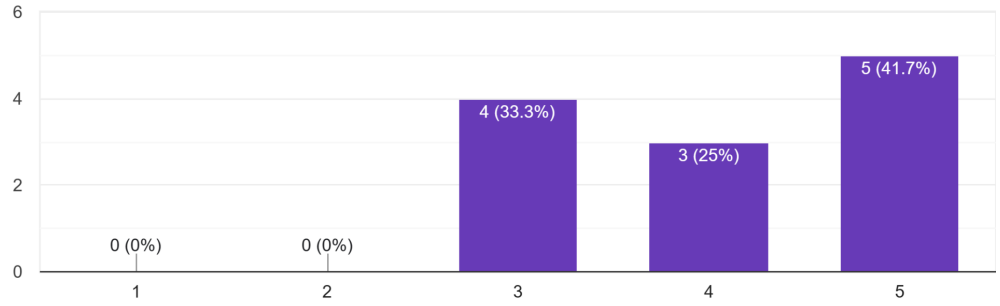
Do you have any other feedback about this new self-swab device?

Your answer

Results:

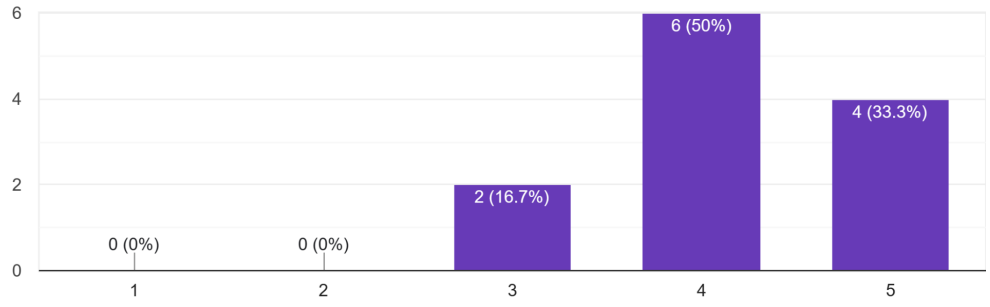
On a scale of 1 to 5, how visually appealing is the device?

12 responses



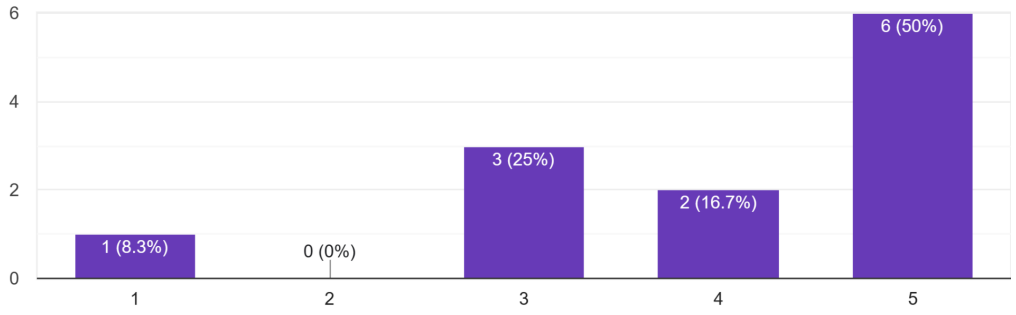
On a scale of 1 to 5, how comfortable would you be using this device?

12 responses



On a scale of 1 to 5, how clear are the directions?

12 responses

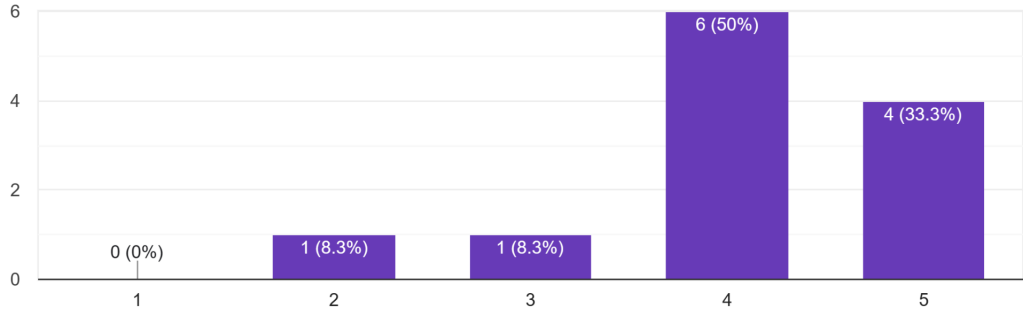


Would you be able to use this device to perform a self-swab?

12 responses

On a scale of 1 to 5, how clean do you think this new self-swab process would be in terms of contamination of the testing environment? (transfer...ids to hands, counter, other surfaces in the room)

12 responses



No

2 responses

The ridges on the top of the device makes me a bit uncomfortable

1 response

not really the threads could be uncomfortable if someone put it in too far. Also, I'd be slightly worried about aim since it does not go inside.

1 response

N/a

1 response

Even though it is just a model, the color white for the device is a little unappealing to me

Not that I can think of!

1 response

Harsh materials may appear intimidating

1 response

Not really

1 response

No, seems pretty straightforward

1 response

Even though the treaded portion of the tube wouldn't be inserted into the vagina, I would be a little concerned about if the edge of the treads would be sharp or feel uncomfortable if it touches the opening of the vagina.

1 response

I think it would be helpful to flare the edge of the tube out so it would contain more fluids from escaping and discourage insertion of the tube into the vagina. I also think that in addition to including written instructions, a visual guide of how to use the device would be helpful for patients using the device.

1 response

Adding grips to the tube, like a tampon might make the swab insertion process easier/more comfortable

1 response

n/a

1 response

When the instructions say to "push the plunger into the device" or "pull the out of the device" it may be more helpful to use directional language like "push the plunger upward into the device" and "pull the plunger downward away from the vagina"

1 response

if someone did put it inside a bit the cap doesn't go down a lot to cover that part so maybe extend the cap to prevent contamination.

1 response

Appendix E: Clinical Use Testing Protocol

Materials:

- Prototype of self-swab device
- Tube (to mimic the vaginal canal)
- Red dye
- Marker

Clinical Use Test: Plan for testing if the device performs as intended and could reasonably be used to take an intravaginal swab

Step 1: Using a tube (approximately the size of an average vaginal canal - about 4 inches long and 2 inches wide), coat the interior edges with a thin film of red dye. Be sure that it is not dripping and covers the interior evenly.

Step 2: Mark the tube at 2 inches from the opening with a marker. This will indicate when the swab has reached the depth necessary for collecting samples.

Step 3: After preparing the tube, the prototype self-swab device will be used to swab the interior of the tube as if it is a patient's vaginal canal.

Step 3a: Deploy swab into the tube using the plunger until the swab reaches the marked line. Be sure that the body of the device rests at the opening but does not enter the tube.

Step 3b: Rotate swab for 30 seconds allowing it to contact the walls of the tube.

Step 3c: Retract the swab from the tube back into the body of the device using the plunger.

Step 5: If food coloring stains the swab, the test is considered passed.

Appendix F: Mechanical Strength Testing Protocol

Materials:

- Individual SolidWorks parts of the body and plunger of the device.

Mechanical Strength Test**:** Plan for testing the ultimate compressive and tensile strength of the plunger and body of the device.

- ☐ Step 1: Generate a SolidWorks part of the body and plunger by saving the respective component as a separate SolidPart.
- ☐ Step 2: In the corresponding SolidPart file, navigate to Tools > Add-Ins.
  - ☐ Step 2a: If applicable, deselect SolidWorks Simulation.
  - ☐ Step 2b: Select SimulationXpress Analysis Wizard.
- ☐ Step 3: Perform a compression test.
  - ☐ Step 3a: Add a fixture to the part.
    - ☐ If testing the body, add a fixture to the surface of the rim without threading.
    - ☐ If testing the plunger, add a fixture to the solid bottom surface.
  - ☐ Step 3b. Apply a 10 N compressive load to the top of the part.
  - ☐ Step 3c: Apply the material, either polypropylene or a resin, to the part.
  - ☐ Step 3d: Run the simulation.
  - ☐ Step 3e: Select the Von Mises Stresses option to generate the stress distribution
  - ☐ Step 3f: Take a screenshot of the stress distribution and make note of the greatest stress.
- ☐ Step 4: Repeat step 3, increasing the force load by 10 fold until the device breaks or excessive deformation is observed. Ensure that a load of at least 700 Newtons is applied to the part as this is about the average weight of females ages 15 and older [x].
- ☐ Step 5: Perform a tensile test.
  - ☐ Step 5a: Add a fixture to the part.
    - ☐ If testing the body, add a fixture to the surface of the upper rim with threading.
    - ☐ If testing the plunger, add the same fixture as used in the compression test.
  - ☐ Step 5b: Apply a tensile force of 25 N to the part.
    - ☐ If testing the body, apply the load to the surface of the rim without threading.
    - ☐ If testing the plunger, apply the load to the underside of the one-time snap mechanism.
  - ☐ Step 5c: Apply the material, either polypropylene or resin, to the part.
  - ☐ Step 5d: Run the simulation.
  - ☐ Step 5e: Select the Von Mises Stresses option to generate the stress distribution
  - ☐ Step 5f: Take a screenshot of the stress distribution and make note of the greatest stress.
  - ☐ Step 5g: Increase the force by 25 N until the device breaks. Ensure that a load of 75 N is applied to the part as this is the average pulling strength of a seated woman [x].
- ☐ Step 6: Use the data to determine the average greatest stress of the body and plunger of the device.