DEPARTMENT OF
Biomedical Engineering
UNIVERSITY OF WISCONSIN–MADISON

Vaginal Self-Swab

Final Report

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BME 200/300: Biomedical Engineering Design

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Abstract:

Sexually transmitted diseases (STIs) can often be asymptomatic, therefore going undiagnosed and unreported [1]. Early screening and recognition of STIs are key in preventing disease progression and receiving treatment. Vaginal self-swabbing offers a non-invasive and less-intimidating way for more women to receive testing. The vaginal self-swab created by Hologic, the Aptima Multitest Swab Specimen Collection Kit, has the intention of increasing effective screening accessibility. However, it fails to ensure a low likelihood of contamination by disregarding the risk of false-positive nucleic acid amplification test results when samples are collected in an area that is contaminated with target nucleic acid [2]. The device created by Hologic has two components: the swab and a container with the transport media. The accuracy of the test results are jeopardized due to excessive external contact of surfaces to the swab, inaccurate breakage of the swab shaft, and the potential for the transport media to spill during the swabbing process; the goal of the final design, the "Tilt-and-Break", is to minimize contamination by these factors. By incorporating a handle component, swab-breaking accuracy testing revealed statistical significance (p-value of 2.776e-09) in swab-breaking accuracy improvement (Figure 9). However, until further testing, it is unclear whether the device reduces contamination from external surfaces, as contamination testing results yielded a p-value of 0.423 (Figure 10). Although the "Tilt-and-Break" device proved effective in swab-breaking improvement, additional contamination testing must be administered to obtain conclusive results on whether or not cross-contamination will be reduced in a clinical setting.

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1. Introduction

1.1. Motivation and Societal Impact

Vaginal infections are extremely undertested, especially in young women. Only 27% of sexually active females (15-25) reported being tested for a sexually transmitted disease [3]. Specifically, chlamydia is reported in the highest cases among young women. It is estimated that every one in 15 sexually active females (14-19) has chlamydia [4]. There can be serious long-term complications if untreated, including an increased risk of pelvic inflammatory disease, certain cancers, and even infertility [5]. However, many cases go undiagnosed due to the asymptomatic nature of these infections, which is shown in a recent study of the prevalence of bacterial vaginosis, vaginal candidiasis, and trichomoniasis. Researchers found that 48.37% of women with bacterial vaginosis were completely asymptomatic [6]. Sexually active women are recommended to be tested annually for vaginal infections, however, there are barriers to accessible testing. These barriers include the financial cost of the test, clinic locations, and even the concern of being stigmatized [7]. Although these barriers decrease the popularity of vaginal testing, one solution has been found in self-swab testing. Around 76% of women prefer a vaginal swab over a pelvic examination and 60% over a urine collection test [8]. Self-swabbing is a less invasive process that allows the patient to take control of their health without having to leave the comfort of their house. However, the self-swabbing and collection process allows for potential contamination of the testing environment and the swab itself. Possible contamination sources include the insertion and swabbing of the vaginal canal, as well as the transfer of the swab from the vaginal canal to the culture media tube. Furthermore, current vaginal self-swabbing tests require the patient to break the swab using their hands, which could lead to false positives. Overall, contamination leads to 67% of women receiving a false positive result [9]. This device will seek to minimize the contamination that comes with the current vaginal self-swabbing methods.

1.2. Competing Devices

This device is unique, meaning that there are no real competing devices. The device will be used in conjunction with the Aptima Multitest Swab Specimen Collection Kit, which is the test used by the UW-Health System clinics. This kit employs the use of a swab and a transport media-filled tube. After the user has swabbed, the swab is broken at the perforated line and placed into the media tube to be sent to the lab [10]. A similar design is the Evvy Vaginal Health Test, which utilizes the same sample collection method [11]. During the transferring process, there is a high probability of contamination. For both tests, the user has to collect a sample and then navigate the process of breaking the swab at the perforated line to place it into the culture media tube. Additionally, the transfer tube could spill, the swab could be dropped, and vaginal fluid could spread to other surfaces before being placed into the culture media.

Figure 1: Image displaying the Aptima Multitest Specimen Collection Kit by Hologic **[12].**

1.3. Problem Statement

Bacterial vaginosis, yeast infections, and sexually transmitted infections (STIs) can be detrimental to the well-being of an individual and cause a variety of health concerns, such as infertility, if left untreated. The vaginal self-swab device is to be utilized by patients to easily collect cervicovaginal mucus samples from the vaginal canal to diagnose infections and STIs. This device design aims to provide a convenient, accessible method of breaking the swab into the transfer tube while minimizing exogenous cross-contamination of the self-collected sample. Cross-contamination, with the surface and environment, typically occurs while transferring the sample to the culture media, which can alter the test results. In order to overcome this, the device will reduce contamination resulting from user-error by allowing the testing swab to break into the culture media solution directly, reducing swab-surface contact, and preventing media leakage.

2. Background

2.1. Background Research

The self-swab test, shown in Figure 1, is designed to detect bacterial vaginosis, yeast infections, and various sexually transmitted infections. The swab is used to collect vaginal fluid, which is contained in the culture media transfer tube. This fluid holds cells with vital information

on the health of the patient's vaginal canal [13]. Specifically, bacterial vaginosis is a poly-microbial condition of the vaginal canal which is caused by an increase in the vaginal pH. A typical vaginal pH is acidic, with a range of 3.5 to 4.5. Bacterial vaginosis is correlated to a pH greater than 4.5, although this can vary based on ethnic groups [14]. Sexually transmitted infections require immediate attention due to severe health complications, including pelvic inflammatory disease, increased risk of getting HIV, certain cancers, and even fertility [5].

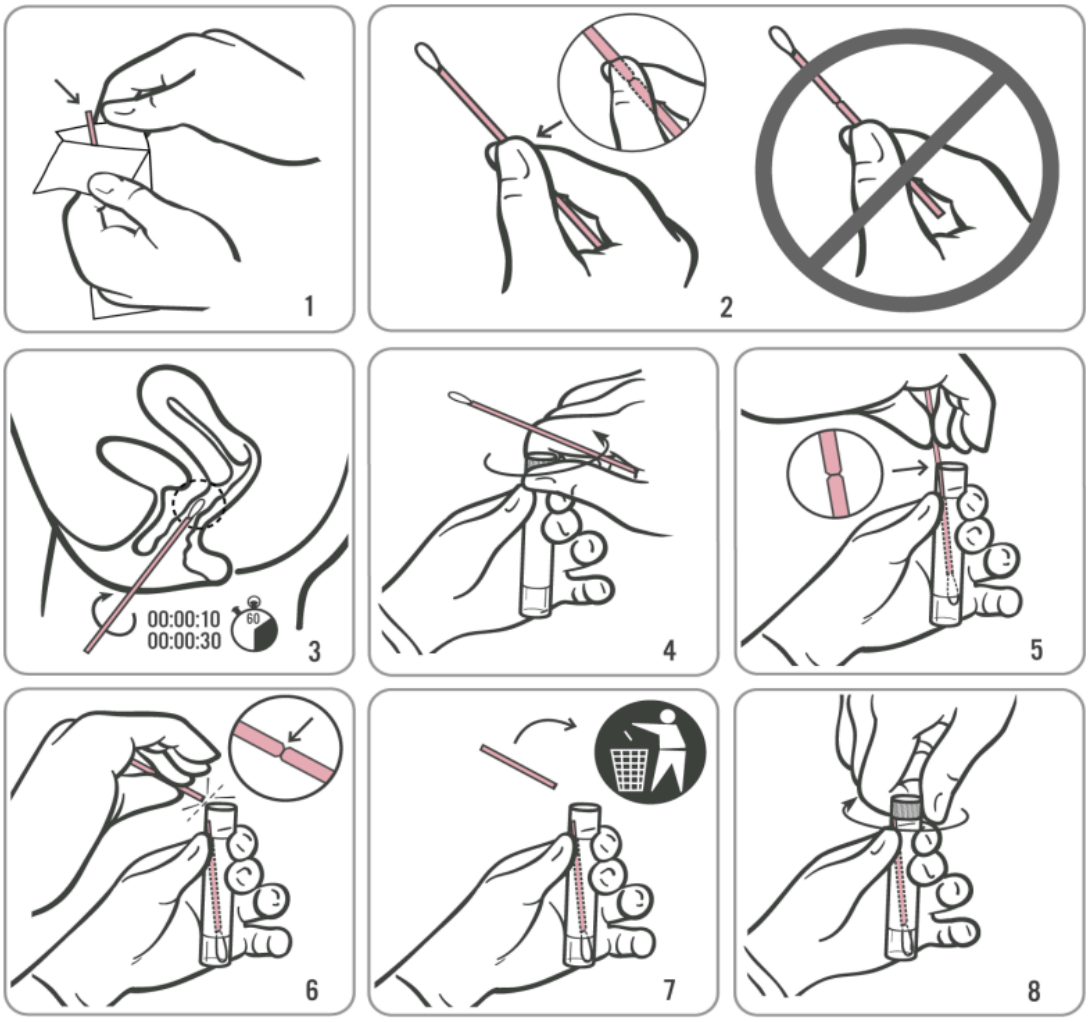


Figure 2: Schematic depicting the instructions for using the Aptima Multitest Collection Kit **[12]**.

2.2. Design Research

Since this design will involve swabbing and transferring bacteria, a safe, nontoxic material must be used. Correct sterilization and decontamination processes must be followed, including the process of autoclaving. Autoclaving is used to kill bacteria and germs through heat, pressure, and saturated steam [15]. Since the main component of the self-swab design will be 3D

printed, the device must be made of autoclavable plastic. Possible autoclave-safe material is polycarbonate plastics (PC) or polylactic acid (PLA). Polycarbonate is effective in protecting the safety of the swab during transfer through heat resistance, chemical resistance, and 100% recyclable properties [16]. Further, polypropylene and polypropylene copolymers can be autoclaved without losing strength and are best known for being a low-cost, durable option [17]. This device is subject to requirements for the collection and transport of samples for medical laboratory examinations [18].

2.3. Client Information

The client, Dr. Jean Riquelme, is a family medicine specialist based in Madison. Dr. Riquelme graduated from the Medical College of Wisconsin in 1993, completing her residency in family medicine at Aurora Healthcare. Intending to promote safer, more accurate vaginal self-testing, Dr. Riquelme requests a vaginal self-swab device that limits contamination. This device should test for various vaginal diseases, including bacterial vaginosis, yeast infections, and sexually transmitted infections (STIs).

2.4. Design Specifications

This device will be used in conjunction with the self-swab process, so it must be user-friendly with clear instructions, easily hand-held, and ultimately promote universal testing. The design must be durable enough to prevent leakage and strong enough to break the swab consistently. The swab must be deployed at least 5 cm into the vaginal canal to allow for adequate vaginal testing [19]. Since this will be a sterile device, all materials must be biocompatible and nontoxic, following the toxicology risk assessment outlined by ISO-10993-17. Furthermore, the design must allow for both the swabbing and storage in the media while combating contamination of the testing environment. For more information on the design specifications, see Appendix I.

3. Preliminary Designs

3.1. The "Altered Bend" Design

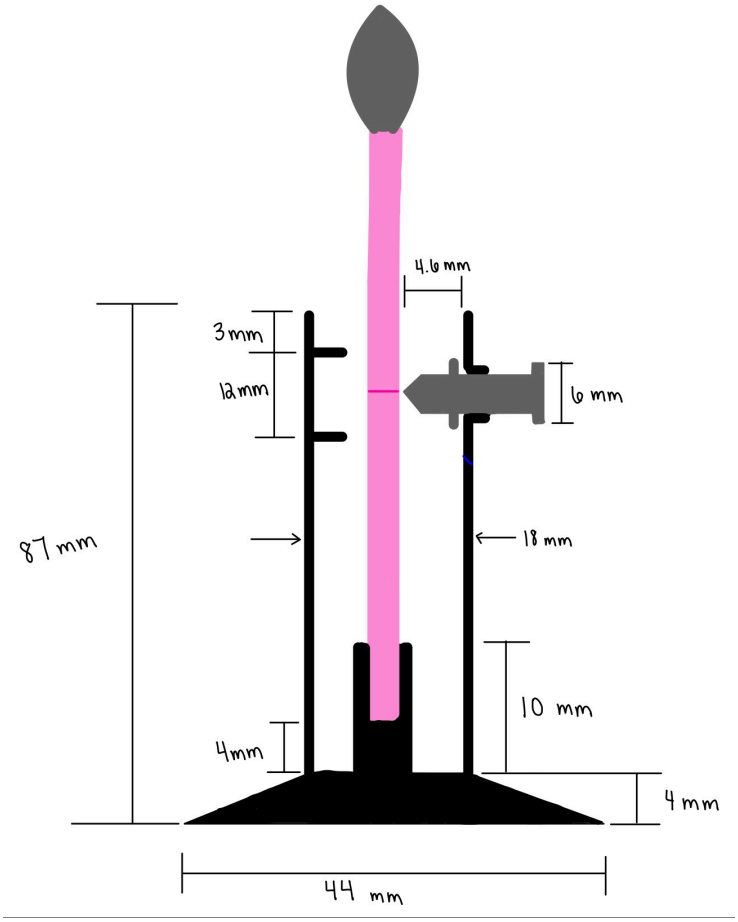


Figure 3: The "Altered Bend" design sketch.

The first design, called the "Altered Bend" Design, is an updated and altered version of the past semesters' design. This design features a larger base, providing more stability if the patient sets the device down on a countertop after swabbing (Figure 3). It also has a wider opening surrounding the perforation point to prevent spillage of the liquid media. The button mechanism was altered to be stationary instead of rotational, in order to consistently cut the swab at an accurate length.

This device would be attached to the bottom 6 mm of the swab to hold it in place. The patient would follow the self-swabbing protocol while holding onto the bottom 87 cm handle. After swabbing, the patient will rotate the device upside down, placing the swab into the media tube. The swab should be inserted approximately 5 cm into the media tube, or up to the first interior support. Then the patient should execute the cutting mechanism by pressing the button on the side of the device. This will cut the swab directly under the perforation point. The device is wide enough to simulate an umbrella over the liquid media to prevent any possible spillage from occurring. The patient will then screw back on the provided cap to the media tube and

dispose of the device containing the bottom of the swab. The media tube will then be sent to a physicians' lab to be tested.

3.2. The "Tilt-and-Break" Design

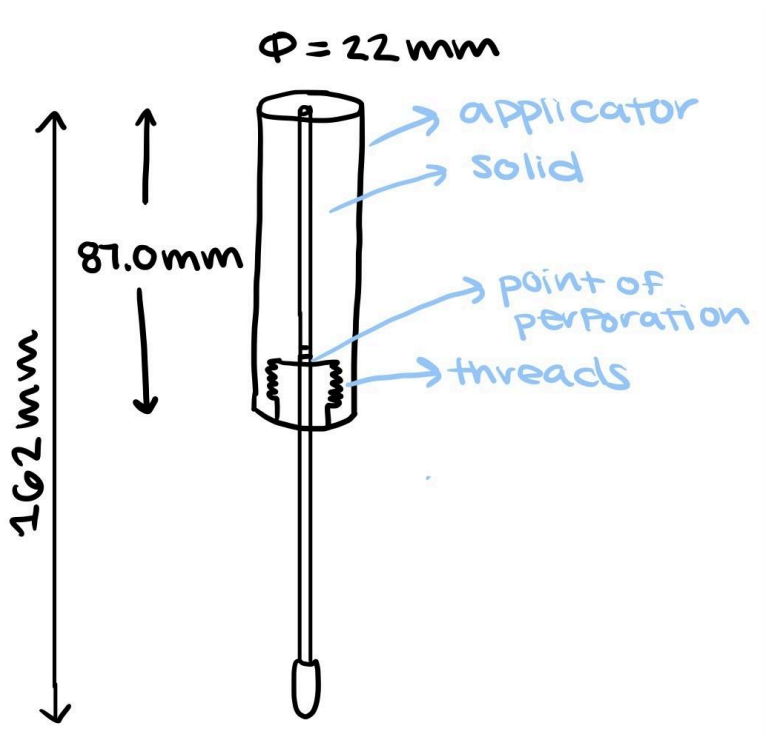


Figure 4: Sketch of the "Tilt-and-Break" design idea.

The second design idea, named the "Tilt-and-Break", is composed of Hologic's 'Aptima' Swab and a "handle" component. The handle component is a non-hollow, solid material into which the testing swab is pressure-fit into. The solid material extends for the portion of the swab which is above the perforation line. At the perforation line, the solid material ends and there exists a hollow void with threaded "walls", into which the media container can be securely screwed into (Figure 4).

To use this device, the patient must hold the device by the "handle" while swabbing themselves (as instructed by the typical self-swabbing protocol) [10]. Following the swabbing process, the patient must insert the end of the swab into the media container. Then, before screwing the handle onto the media container, the patient must hold the media container in place while tilting the handle of the device. This motion will produce a reaction force (by the solid material of the handle) onto the line of perforation of the swab, resulting in swab breakage. Once the swab is broken, the patient may then screw the handle component onto the media container, which will allow the healthcare provider to collect the specimen and send it to the lab for further testing.

3.3. The "Tunnel" Design

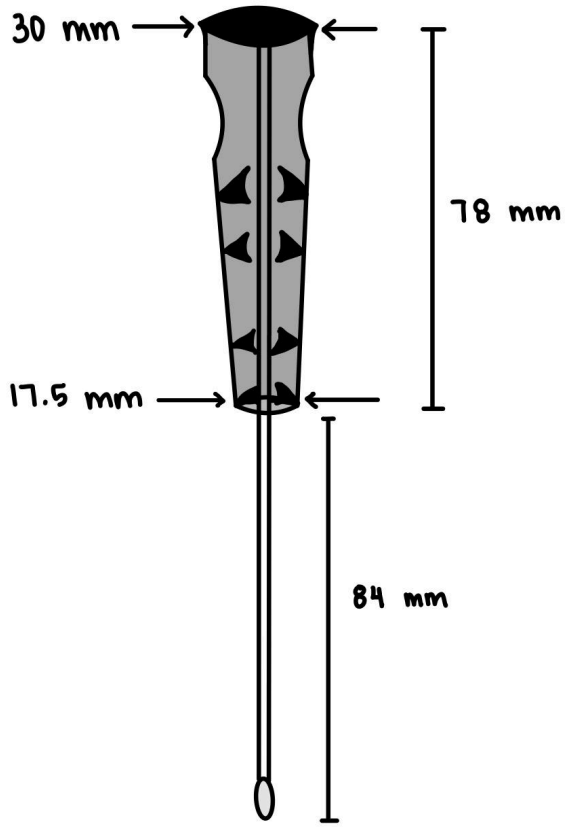


Figure 5: The "Tunnel" Design with the swab and holder.

The third design consists of three components - the swab holder, Hologic's 'Aptima' swab, and 'Aptima' media tube. As seen in Figure 5, the swab holder is completely hollow with varying-sized disks in the interior. These disks align to stabilize the swab whilst being used to swab the vaginal canal. The base is wider than the bottom opening, serving as protection from tipping and spills. Additionally, there are cutouts at the top for ease of use for the patient.

When using this design, a patient would receive the device with the swab already placed inside the holder. In this orientation, the swab is secure in the holder and will limit contamination. The patient would then use the grips to hold the swab holder and insert the swab into the vaginal canal, collect the specimen, and remove the swab. After removing the swab from the canal, the user would then transfer the swab to the Aptima transport media tube by pinching the bottom opening to break the swab. Since the bottom-most disk is sharp, the swab will break at the perforated line due to the pressure. After the swab is broken and in the culture media, cap the tube and follow the transfer instructions. The advantages of this design include the ability to limit contamination and leakage/spillage. The holder acts as a barrier between the environment and the swab. The user can set down the swab without the risk of spreading contaminated vaginal fluids. However, this design has the opportunity to be dangerous for the user. Since the

inside contains a sharp disk, the patient could pinch or cut themselves in the swabbing and breaking process. Further, this design is not extremely user-friendly due to the force needed to break the swab by pinching.

4. Preliminary Design Evaluation

4.1: Design Matrix for Table Attachment

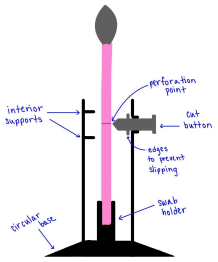
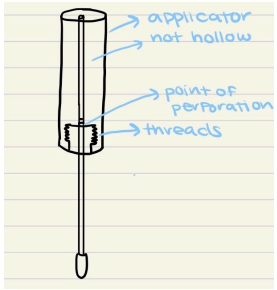
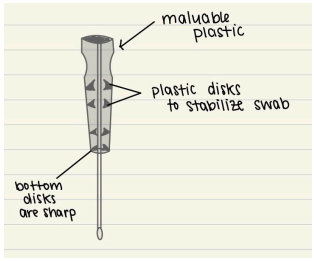
Design Criteria (weight)	Design 1: Altered Bend Design 		Design 2: Tilt - and - Break 		Design 3: The Tunnel 	
Limiting Contamination (30)	4	24	4	24	4	24
Leakage Prevention (25)	4	20	5	25	4	20
Ease of Use (15)	4	12	5	15	3	9
Ease of Fabrication (10)	3	6	4	8	2	4
Patient Comfort (10)	5	10	5	10	5	10
Safety (5)	4	4	5	5	2	2
Cost (5)	5	5	5	5	5	5
Total Score (100)		81		92		74

Table 1: Design matrix depicting the three design ideas and their respective scores.

The criteria chosen for the evaluation of the vaginal self-swab design ideas (from highest to lowest weight) include: limiting contamination (30/100 points), leakage prevention (25/100 points), ease of use (15/100 points), ease of fabrication (10/100 points), patient comfort (10/100 points), safety (5/100 points), and cost (5/100 points) (Table 1).

The first criterion, limiting contamination, refers to the ability of the device to prevent

cross-contamination of the sample by contact with an exogenous surface. All of the design ideas received the same score in this category. The second criterion, leakage prevention, is the ability of the device to prevent the leakage of media from the media-containing component. The "Tilt-and-Break" design scored the highest in this category (5/5) due to the threaded aspect of the design, which provides additional security once screwed onto the media-containing component. For ease of use, which is how intuitive it is for the patient to use the device, the design scoring the highest was the "Tilt-and-Break", due to its simplistic design and method of usage. Similarly to the previous category, due to its simplistic design, the "Tilt-and-Break" scored ⅘ points within the ease of fabrication category. All of the designs scored full points for both the patient comfort and cost categories, as they have similar swabbing protocols and are to be made of the same material. Finally, for the safety category, the design with the highest score (5/5) was the "Tilt-and-Break"; this is because unlike its counterparts, this device does not propose a potential method of pinching the patient (via buttons or internal disks).

4.4: Proposed Final Design

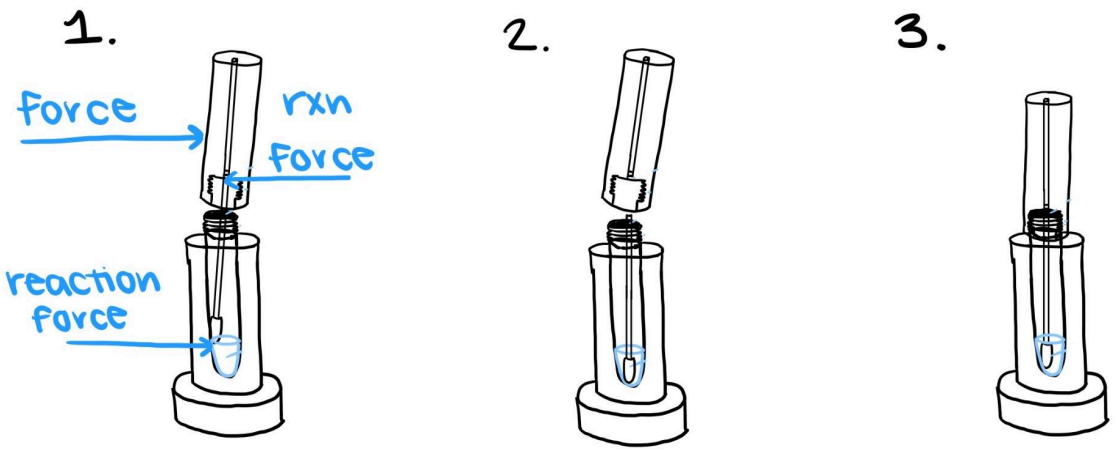


Figure 6: Sketch of the "Tilt-and-Break" design mechanism.

Following evaluation of the design matrix criteria, the design idea with the highest overall score (92/100) to be used for the final prototype is the "Tilt-and-Break" (Table 1). This design idea is intuitive and simple, leading to its high scores for ease of use and fabrication. Without any buttons or moving components, there is reduced risk of injury to the patient, resulting in a high safety score. The threaded aspect of this design allows the device to be securely screwed onto the media container, contributing to its high leakage prevention (Figure 4). The cost of this device is estimated to be within the $250 budget given by the client.

Although this design scored relatively high in the limiting contamination category, it did not receive full points. This is due to the fact that following the swabbing process, the device is

exposed, increasing the risk of exogenous contamination of the sample. This is to be mitigated by allowing the device to "stand" on the top portion of the handle while the patient handles the media container, or by inserting the swab into the media container immediately after swabbing (Figure 6).

Similarly to the limiting contamination category, this design scored highly for ease of fabrication, yet did not receive full points. This is because although the design does not have any difficult-to-fabricate buttons or internal components, the threaded aspect of the design still poses some difficulty in fabrication. This is due to the threading of the media tube being non-standard, which requires manual measurements to design the correspondent threaded component of the Tilt-and-Break cap.

5. Fabrication/Development Process

5.1. Materials

- **Swab:** The swab will be a dacron swab. It is a non-cotton, non-toxic, hydrophilic, synthetic fiber-wrapped swab [20]. The shaft of the swab is plastic [21]. 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:** A universal transport media will be used such as Vircell Transport Medium. 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 [22].
- **PLA swab holder:** One of the device prototypes will be 3D-printed using polylactic acid (PLA). PLA is a thermoplastic derived from an organic source such as sugar cane or starch. It is biodegradable and has similar characteristics to petroleum-based thermoplastics such as polypropylene or polyethylene [23]. Autoclaving PLA may result in partial degeneration of the model, having a melting point of 184 °C. Common autoclave processes typically run for 20 minutes at approximately 121 °C [15].
- **Clear Resin**: The final Tilt-and-Break prototype will be printed using clear resin. Clear resin offers high accuracy with precise tolerances to fine details which is necessary for the threading and the internal tube in the design. It also showcases the internal features of the design, promoting clarity for users. It demonstrates strong mechanical properties such as having a flexural strength of 105 MPa [24]. This is crucial for the design since the Tilt-and-Break encounters bending forces while the patient uses the device to snap the swab into the medium.
- See Appendix III for further information regarding cost of materials.

5.2. Methods

5.2.a. Swab Transport Media (STM) Base

Overview: The STM Base prototype was obtained from the pre-existing design created by the team from the previous semester. The SolidWorks part file was shared with the current team and certain measurements were modified to achieve the improved base design (Figure 8).
Process: The only change made to the STM Base design was increasing the bottom diameter to 49.5 mm. The previous semester had a smaller bottom base diameter, resulting in the STM to tip over and spill. The first prototype was printed at the UW Makerspace using the Bambu Printer and PC. The second prototype was printed using the same printer, but PLA. The material was changed after consulting with the MakerSpace staff and discovering that PC is a difficult material to 3D print due to its high melting point; typically, PC devices will fail during 3D printing.

5.2.b. Tilt-and-Break

Overview: After taking initial measurements of the STM cap and tube using calipers, a preliminary design was constructed in SolidWorks. Measurements were altered throughout the fabrication process in order to create accurate threading and consistent swab snapping.
Process: The Tilt and Break was created with a hollow tube in order to pressure-fit the swab. The depth of the hollow tube (from the bottom of the swab to the perforation line) was 80 mm. At the perforation line the tube opening was made wider, simulating a cap to the STM tube. Manual threading was created on SolidWorks using sweep and circular pattern features. Aptima does not utilize standard threading on the media tube, so the creation of manual threading was necessary to ensure no leakage from the medium. The proposed final design was modeled in SolidWorks (Figure 7). The model featured the altered length and thickness specifications. After the part file of the final design was completed, it was exported as a stereolithography (STL) file to be 3D-printed. The 3D-printing process was conducted at the UW-Madison MakerSpace using the Bambu Lab printers. The STL files were uploaded to the MakerSpace computers and the MakerSpace staff members began the printing process. Once the prototypes finished printing, the supports added surrounding the base and threading of the Tilt-and-Break were removed.

5.3. Final Prototype

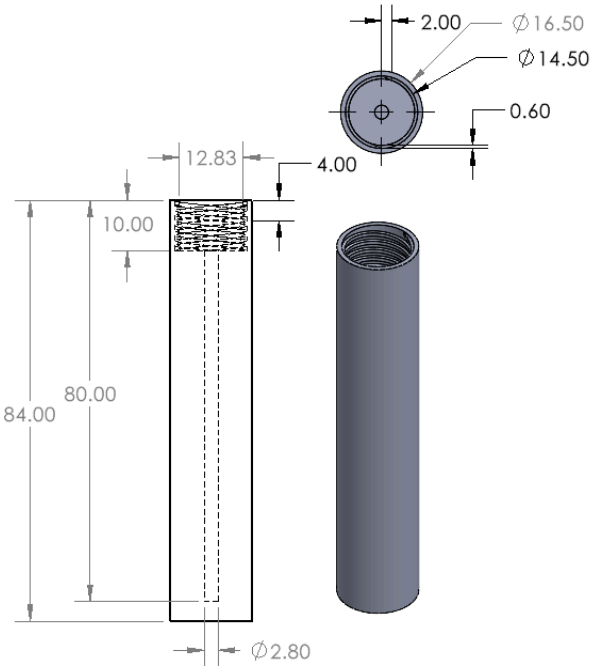


Figure 7: "Tilt-and-Break" SolidWorks model.

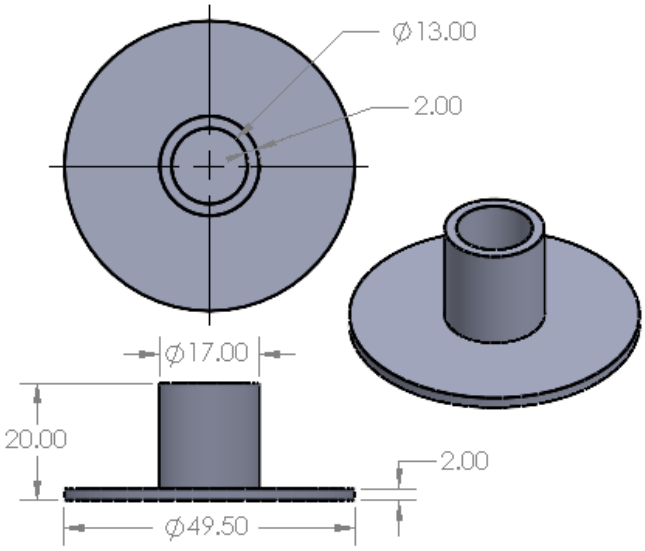


Figure 8: "Swab Transport Media Base" SolidWorks model

The final constructed prototype as demonstrated in Figures 7 and 8 consisted of two main components: the Tilt-and-Break and the STM base. Figure 9 shows an animated version of the Tilt-and-Break with the swab addition. The final prototype of the Tilt-and-Break was 3D-printed

using clear resin in the Formlabs printer. Clear resin was used due to its durability and the ability to showcase the internal features of the design. One model required 20.67 mL of material. The final prototype of the STM base was 3D printed using PLA in the Bambu Lab. PLA was used due to its biodegradable and inexpensive properties. One STM Base model required 6.6 g of product to print.

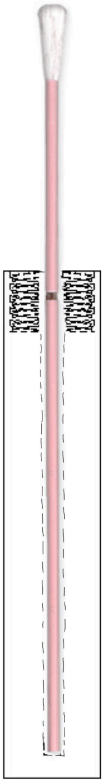


Figure 9: Animation of Tilt-and-Break with swab.

6. Testing

6.1. Swab-Breaking Accuracy

Of the device functions requested by the client, consistent swab-breaking at the line of perforation was one of the main considerations (Appendix I). It is crucial for the swab to break at the line of perforation due to the fact that the swab must be short enough to fit within the media tube after screwing on the cap, yet long enough to provide enough surface area for the bacteria to be collected at the laboratory [10].

To determine the swab-breaking accuracy of the device, ten trials were performed for each condition: for the Hologic Aptima as well as for the Tilt-and-Break device. In order to prevent user differences between trials, one participant was responsible for breaking the swabs for each trial of each condition. For both the Tilt-and-Break and Hologic Aptima devices, the

participant went through the general motions of using the device (without swabbing of the vaginal canal). Then, after breaking the swab into the media tube, the swab was removed with tweezers and placed onto a flat, dry surface. Using calibrated calipers, the distance between the line of perforation and the actual breaking point were measured, and recorded into a data table; this process was repeated for a total of ten trials for each condition.

6.2. Contamination Testing

One of the client requirements for the device was that it would limit external cross-contamination resulting from the process during which the swab is transferred into the media tube (Appendix I). Cross-contamination of samples often leads to a false positive result when analyzing the samples in the laboratory.

To identify whether the Tilt-and-Break device limits cross-contamination, the following testing protocol was adhered to: first, four testing conditions were identified: the Tilt-and-Break device, the Hologic Aptima device, a positive control, and a negative control. A positive control was put into place in order to ensure a 'baseline' value to compare the cross-contamination results to. Similarly, a negative control was administered to ensure that the agar plates which were used for this portion of the testing protocol were sterile, and that they did not interfere with the results. To prevent variance due to user factors, one participant performed the experiment for each trial of each condition.

For the Tilt-and-Break portion of the experiment, the participant went through the general motions of using the device (without swabbing the vaginal canal). Then, using a rotating motion, the swab was streaked onto an LB agar plate. This process was repeated for a total of three times, using a new agar plate and swab to limit potential cross-contamination between each trial. The same protocol was repeated for the Hologic Aptima device (for a total of three trials). For the positive control portion of the experiment, a swab was used to swab the surface of a phone screen. The sample was then streaked onto an agar plate (utilizing a rotating motion). This process was repeated for a total of three trials. For the negative control, three unopened, unstreaked agar plates were placed in the incubator; this was to ensure that the agar used for this experiment was in fact sterile.

Following the streaking protocol for each of the testing conditions, each of the agar plates was placed into an incubator set to 32 °C for a period of 48 hours in order to speed up the process of bacterial proliferation [25]. The agar plates were placed upside-down into the incubator to prevent condensation build-up on the agar plate lid, which could otherwise affect the proliferation rate of the bacterial colonies by increasing cross-contamination and dryness of the agar [26]. To prevent overheating or burning of the agar, the agar plates were placed as close to the center of the incubating platform as possible, since the edges of the incubator tend to reach higher temperatures.

Following the 48-hour incubation period, the agar plates were removed from the incubator, and the colonies were counted for every trial of each of the four conditions. In order to aid in the quantification of colonies, a colony-counting app called “ColonyCount” was used; in a study on colony-counting methods, it was found that this app was effective in quantifying the amount of colonies present on agar plates [27]. The data obtained in this experiment was then recorded in a data table, which was statistically analyzed for result-interpretation purposes.

7. Results

7.1. Swab-Breaking Accuracy

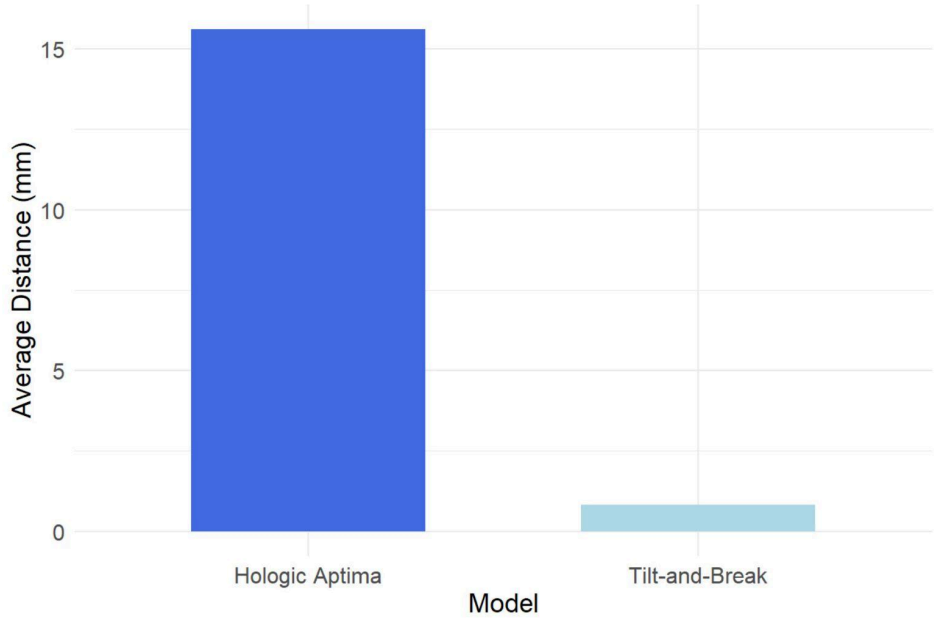


Figure 10: Plot depicting the average distance of breakage from the line of perforation of both the Hologic Aptima and Tilt-and-Break devices.

The objective of the swab-breakage accuracy test was to assess whether the Tilt-and-Break model achieved closer mean distance from the breakage point to the line of perforation than the Hologic Aptima test, which would indicate higher precision. The swab-breaking test revealed a clear difference in variability between the Hologic Aptima device and the Tilt-and-Break device. The mean distance from the perforation point for the Tilt-and-Break model was 0.863 mm with a standard deviation of 0.576 mm, indicating a relatively small and consistent distance. In comparison, the Hologic Aptima model had a mean distance of 15.601 mm with a standard deviation of 2.830 mm, showing a larger and more variable distance from the perforation point. A one-sided t-test was employed to evaluate the hypotheses at a 5% significance level. The null hypothesis states that the mean distance from the perforation point for the Tilt-and-Break model is equal to or greater than the mean distance for the Hologic Aptima model. The alternative hypothesis states that the mean distance from the perforation point for the Tilt-and-Break model is less than the mean distance for the Hologic

Aptima model. The test yielded a p-value of 2.776e-09, which is significantly below the 0.05 threshold, concluding that there is sufficient evidence to reject the null hypothesis. This result strongly indicates that the Tilt-and-Break model achieves a significantly smaller mean distance from the perforation point compared to the Hologic Aptima model, suggesting that the Tilt-and-Break model is more reliable and precise than the Hologic Aptima model. These findings underscore the potential for improved mechanical performance in swab breakage, reinforcing the efficacy of the Tilt-and-Break device.

7.2. Contamination Testing

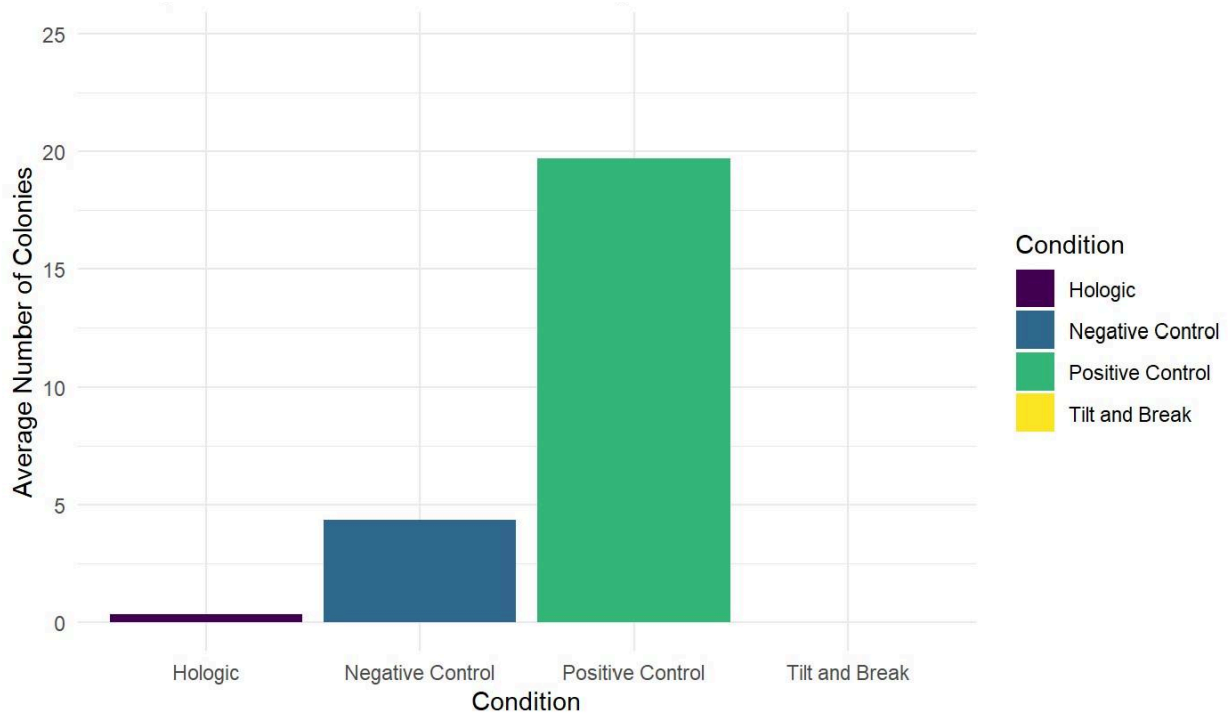


Figure 11: Bar graph displaying the number of colonies present on the agar plate for three trials of four different testing conditions.

The objective of the cross-contamination testing was to assess whether the Tilt-and-Break model limits cross-contamination from external surfaces, resulting from the process during which the swab is transferred into the media tube. The experiment yielded an average number of colonies as follows: the positive control displayed 19.667 colonies (standard deviation of 10.504 mm), the negative control showed 4.330 colonies (standard deviation of 7.500 mm), the Hologic Aptima method yielded 0.330 colonies (standard deviation of 0.570 mm), and the Tilt-and-Break showed no colonies (standard deviation of 0). A two-sided t-test provided a p-value of 0.423, which is greater than the significance threshold of 0.05. These results indicate that the observed differences among the groups are statistically insignificant, leading to a failure to reject the null hypothesis that there will be no difference between the Hologic Aptima and Tilt-and-Break conditions. Overall, there is no significant evidence to support that the Tilt-and-Break model limits cross-contamination under the conditions listed.

8. Discussion

The primary goal of this project was to design a device that provides a more convenient and accurate STI swab test for women to be used in conjunction with Hologic Aptima's current self-swab (Appendix 1). The Tilt-and-Break design was made with the intention of practicality and minimizing contact with external surfaces, thereby enhancing the accuracy and reliability of test results. To assess and quantify the effectiveness of this design, two tests were conducted: the first on swab-breaking accuracy and the other to examine the extent of cross-contamination from external surfaces. The swab-breaking accuracy testing of the device revealed statistically significant results, indicating that the Tilt-and-Break improves the accuracy of swab-breaking (Figure 10). Accurate swab-breaking allows for a sufficient length of swab to fit into the media tube, which is required by the laboratories to be used for PCR analysis of the sample. A sufficient swab length will allow the nucleic acid amplification test (NAAT) to proceed seamlessly as the specimen-containing swab must be a specific length [10].

The second test was conducted with the intention of identifying whether the Tilt-and-Break design reduced cross-contamination more than the Hologic Aptima during the sampling process. The rationale for comparing the bacteria collected during the sampling processes of the devices is rooted in the critical importance of proper specimen collection, which ensures the accuracy of diagnostic tests. Contamination during the collection phase can compromise the entire testing process, leading to false-negative or false-positive results which cannot be rectified once the sample is contaminated [28]. Following statistical analysis of results obtained, the data was found to be statistically insignificant (Figure 11). The statistical insignificance of the results implies that the Tilt-and-Break device did not show to be notably effective at reducing cross-contamination by external surface contact.

During the design process of the Tilt-and-Break, ethical considerations were made to ensure the device's accessibility and safety. In designing the device, it was crucial to use affordable materials to ensure widespread availability and encourage more people to get tested. A significant number of women (76%) state that they prefer self-sampling methods over physician examinations, highlighting the importance of an accurate and user-friendly design [8]. However, current methods of swabbing tests result in 67% of women receiving false-positive results [9]. This underscores the paramount importance of reducing contamination to increase the accuracy of results. However, it is important to note that ease of use is just as crucial as reducing contamination. The device is designed to accommodate a diverse range of patients, ensuring versatility and inclusivity in its application. The seamless and strain-free process of breaking the swab not only simplifies the testing process but also enhances the user-friendliness of the design. By addressing these key factors, the design aims to make testing more accessible, reliable, and inclusive for all users.

As a result of evaluation, several changes were made to the device throughout the semester. Initially, modifications in the prototyping process included the adjustment of

measurements such as custom threads to allow for a leak-proof lid, an increase in the canal length to 80 mm, and a decrease in the outer diameter to enhance the device's functionality. Additionally, the design was altered to incorporate a two-point bend mechanism after determining that the initially-proposed breaking mechanism needed improvement. This modification relocated the line of perforation from just below the end of the canal to 3 mm below it. These changes were implemented to improve the overall performance and reliability of the device, ensuring more consistent and accurate breakage of the swab.

The outcome of the insignificant test results of the cross-contamination testing can be attributed to several factors. Notably, in the cross-contamination testing of the device, the negative control exhibited bacterial growth, indicating contamination of the agar plates prior to testing. This unexpected contamination was not a result of the testing protocol, but rather originating from the supplier or during delivery. Such contamination compromised the integrity of the negative controls, which are critical for validating the accuracy of the test results. Consequently, this issue likely skewed the overall results, as it introduced an uncontrolled variable into the experiment. Additionally, the cross-contamination test was administered by a team member who had become highly proficient with the procedure over the semester, thereby reducing user error which is common in patients unfamiliar with the swabbing protocol. Moreover, user variability—referring to differences in how users interpret and follow instructions—remains an unquantifiable factor that can only be addressed through testing in clinical settings. Due to the fact the testing was conducted in different conditions than in the clinic (which is where the self-swab will officially be administered), the statistical evidence may have not accurately represented the environment in which the device will be implemented. Future testing in a clinical setting, preferably with a larger, randomized sample, will likely be key in identifying the efficacy of the Tilt-and-Break design.

9. Conclusions

Bacterial vaginosis, yeast infections, and sexually transmitted infections (STIs) are common diseases that threaten the health and well-being of individuals. In 2022, more than 2.5 million cases of syphilis, gonorrhea, and chlamydia were reported in the United States; all of which can have devastating effects on reproduction, even in asymptomatic women [29]. Vaginal self-swabs offer a non-invasive way for women to ensure a healthy vaginal microbiome and identify undesirable microorganisms [30].

Hologic's vaginal self-swab, the Aptima Multitest Swab Specimen Collection Kit, has allowed for women to gain greater access to testing [10]. However, this device currently faces several challenges which have negatively impacted the accuracy of results by allowing excessive room for user error. This includes a higher risk of contamination due to external surface contact to the swab, improper breakage of the swab, and a greater potential for the transport media to be spilled during the collection process. The goal of this project is to design a device to minimize contamination, preventing misdiagnosis to women seeking healthcare.

According to the design matrix evaluation, the Tilt-and-Break demonstrated the highest potential for effectively reducing cross-contamination and enhancing result accuracy. To induce an accurate break of the swab, the internal canal, which tightly fits the swab shaft, ends approximately 3 millimeters above the perforation point. This measurement ensures stress is consistently applied to the perforation point, providing a consistently accurate break. To mitigate cross-contamination from external contact, this device enables users to manipulate the swab while minimizing contact with external surfaces (and the hands of the patient) by acting as a barrier. This will limit the risk of potentially infected vaginal fluids from spreading to other surfaces in the testing room, as well as protect the sample specimen from contamination from the hands of the patient. Additionally, if the swab is placed on a surface (horizontally or vertically), the barrier-like mechanism of the Tilt-and-Break handle will prevent contact of the swab with the surface in multiple orientations.

Testing of the Tilt-and-Break device found that it significantly improves the accuracy of swab breaking, making it easier for the patient to use the device. In addition to improving user-friendliness, the improved swab-breaking accuracy allows for more accurate results during PCR analysis of the sample in the laboratory. This is due to the fact that the PCR mechanism used for sample analysis requires a specific length of swab to be in the media container. On the other hand, the contamination testing of the Tilt-and-Break did not yield any statistically significant results, making it unclear whether or not the device reduces cross-contamination by external surfaces during sample collection. Insignificant results for this criterion are likely due to the fact that a portion of the agar plates used for the experiment were contaminated. Furthermore, the participant conducting the testing was familiar with the protocol, and only one participant was used for each trial, possibly skewing the results to yield less growth for both the Hologic Aptima and Tilt-and-Break testing conditions.

In the future, to obtain a conclusive result for cross-contamination testing, sterile agar plates should be used for the experiment. Additionally, having a randomized sample of multiple participants who are able to perform the experiment for each of the trials could reduce potential skew in results, and provide a statistically-significant value to conclude whether or not the Tilt-and-Break reduces external contamination. Further, a set of instructions highlighting common user error could be created and included in the Tilt-and-Break kit to increase user-friendliness. Adding a list of possible sources of contamination onto the instructions could influence the user to be more careful throughout the procedure. Additionally, in future terms, clinical testing of the Tilt-and-Break would be useful. This is especially true with regard to cross-contamination testing, as most of the current self-swab contamination is seen at the laboratory, and PCR is more effective at detecting the contaminating bacterial strains commonly seen in self-swab testing. Subsequently, clinical use requirements and legal processes such as IDA and FDA regulations should be reviewed. Moreover, while the materials chosen for the final prototype have satisfactory qualities, utilizing injection molding in order to optimize materials will be implemented into future manufacturing practices. Lastly, initiating the patenting process

for the device is a progressive step in ensuring public access to the Tilt-and-Break and promoting accurate, accessible STI testing.

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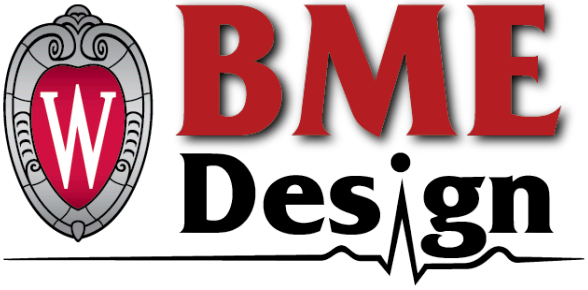
10. Appendix I

10.1. Product Design Specifications



Vaginal Self-Swab Device

BME 200/300 PDS

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Function:

The vaginal self-swab is a device to be utilized by patients to self-collect samples from the vaginal canal in the diagnosis of vaginal infections and STIs. The aim of this device design is to provide a convenient method of sample collection, while minimizing cross-contamination of the self-collected sample. Although studies have shown that vaginal self-swabbing has an accuracy similar to that of a physician-collected sample, self-swabbing poses a risk of sample cross-contamination [1]. Cross-contamination of the sample typically occurs during the process of transferring the sample to the culture media, which can alter the results. In order to overcome this, the device should allow the testing swab to directly break into the culture media solution, and to prevent media leakage.

Client Requirements:

- The vaginal self-swab should easily fit within the transfer tube.
- The base of the stand should be stable in order to withstand the general process of using the device.
- The device should limit cross-contamination resulting from transferring the sample into the culture media.
- The self-swab should directly break into the culture media solution.
- There should be no media leakage from the device.
- A budget of $250 should be observed.

Design Requirements:

1. **Physical and Operational Characteristics**
    - **a.** *Performance Requirements*:

i. The swab and holding device must be designed for one-time use and intended to function solely for the duration of the swabbing and subsequent testing process.

ii. The device must break the swab at the line of perforation consistently.

iii. The holding device must show sufficient durability to ensure secure containment during transport.

    a. No risk of spillage or leakage of culture media.

iv. The holding device must be capable of remaining upright autonomously, both when empty and when the swab is inserted.

v. The swab must be easily insertable into the holding device, with a secure fit that ensures stability.

vi. The support structure within the holding device should secure the swab in an upright position, minimizing the risk of cross-contamination during handling and transport.

vii. The swab head will need to be inserted at least 5 cm into the vagina in order for specimen collection [2].

b. *Safety*:

i. The swab head of the device must be 1-2 cm to collect an effective sample size without causing discomfort.

ii. The shaft must be no longer than necessary (5 cm) to prevent pushing the swab excessively into the vagina to collect an adequate sample.

iii. The transport media used must be non-toxic to prevent irritation or bodily reaction in the case that the media stand is spilled onto the skin.

iv. Materials that compose the vaginal self-swab must be biocompatible. It is important that all components be reviewed by a toxicology risk assessment outlined by ISO-10993-17 to ensure the device does not contain harmful elements that may leach into the vaginal canal and cause irritation in any way [3].

c. *Accuracy and Reliability*:

i. The swabs must show a sensitivity of 94.1% for Chlamydia and 96.5 % for Gonorrhea in order to ensure precision in the detection of the infections [4].

ii. Insert the swab 5 cm into the vagina and rotate, making contact with the vaginal walls for 10 to 30 seconds to provide reliable results.

iii. In order to guarantee accurate results, the patient must dispose of the kit and restart if the swab is touched by the skin, placed on any surface, or the contents of the tube are spilled [5].

iv. The tip of the self-swab devices should be approximately 1 cm in length for optimal collection of vaginal discharge samples [6].

d. *Life in Service*:

i. The swab and holding device should be designed for only one use, intended only for the swabbing and immediate testing process.

ii. Distance traveled is undefined.

iii. Before use, tests should be kept within a dry environment between 2-8 °C (36 – 46 °F) and out of direct sunlight [7].

iv. After use, the sample will be sent back to the lab.

a. The sample can be stored in the lab for 14 days at room temperature or up to 180 days if kept frozen (-20 °C) [8].

e. *Shelf Life:*

i. The swab sample should be stored and transported within a 50 mL centrifuge tube.

ii. The swabs should be transported and tested within 14 days and stored in between 2-30° C [6].

iii. To ensure the preservative liquid holding the sample remains effective, the STI kit should be used within 30 days of receiving it [9].

f. *Operating Environment*:

i. The vaginal self-swab device should be fully-functional at room temperature (20-22°C), as it will be administered in a clinical testing environment.

ii. The self-swab should be contained and administered in a sterile environment to prevent cross-contamination of samples.

iii. To ensure that the device is leak-proof and structurally sound, it must withstand aqueous conditions due to the containment of the transport medium.

iv. The swab portion of the device should withstand the acidic vaginal environment (pH 3.8-4.5) [10].

g. *Ergonomics*:

i. The device should be user-friendly and easy to use, and the self-swab will be provided with clear instructions [5].

ii. The self-swab should be a minimal device that can be easily handheld. The device should provide a comfortable grip to maneuver it easily without slip.

iii. The shaft portion of the device is to be inserted 5 centimeters into the vaginal canal, which will be made clear with a stopper. It should be slender and flexible for easy insertion [5].

iv. The swab proportion of the device should be soft and large enough to collect an effective sample yet still be minimally invasive.

h. *Size*:

i. The device must be able to fit the swab comfortably, with room for support.

a. The Aptima swab measures 15 cm in length with a circumference of 3 to 5 mm [11].

b. The average depth of an unaroused vaginal canal is approximately 9 cm [12].

ii. Adequate sizing is required for the swab to fit without contamination.

iii. Device size should accommodate easy transportation.

iv. The device should be measured in comparison to the standard lab procedures and equipment found within the client's laboratory.

i. *Weight*:

i. It is necessary for the device to be lightweight with a balanced weight distribution in order for the user to be able to handle the device easily.

a. The device will have a weight of approximately 5-15

grams, including the casing and swab.

j. *Materials*:

   i. The testing swab portion of the self-swab device to be used in the final prototype will utilize a pre-existing self-swab design called ‘Aptima Multitest Swab’, which is manufactured by Hologic [11].

   ii. The swab containing the vaginal sample should be stored in transport media to maintain bacterial/viral viability, which allows for greater testing accuracy [13].

   iii. The main component of the self-swab device, into which the swab will be broken and in which the culture medium will be contained, must be composed of an autoclavable plastic.

k. *Aesthetics*, *Appearance, and Finish*:

   i. A separate slender container will be needed alongside the swab that contains transport media.

   ii. The swab shaft will be slender and smooth to ensure easy insertion. The casing of the swab will be smooth and biocompatible as well to prevent pinching or irritation to the skin

   iii. The shaft will have a safety stopper or marker to show the patient when they have reached 5 centimeters.

   iv. The swab itself will have a soft, woven sampling brush head [14].

   v. The portion of the device that the patient holds should have appropriate ridges to provide better grip.

   vi. The color of the case of the self-swab should look appealing and clean to

patients and the swab itself will have no color. The container holding transport media will be clear so the patient can see inside.

2. Production Characteristics

a. *Quantity*:

i. By the end of the semester, the team will design and fabricate one usable prototype.

b. *Target Product Cost*:

i. The total budget of this project, as specified by the client, is approximately $250.

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 [15]. The media contained within the media tube is a transport culture medium and a Class I (general controls) device as specified in Sec. 866.2390 [16]. 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 [17].

b. *Customer*:

i. The customer would like to increase the accessibility of testing for vaginal infections and STIs. More testing availability will decrease the prevalence of certain vaginal infections, many of which are associated with infertility. Self-collection of vaginal samples is not only as reliable as physician-collected samples, but it is arguably more accessible and convenient for the patient [1].

ii. The customer intends for the device to increase testing accuracy by the reduction of the risk of cross-contamination associated with current self-collection methods. The device should limit the swab from external surface contact, as well as prevent the transport medium from leaking from within the apparatus.

c. *Patient-related concerns*:

i. Currently, testing for HPV must be done in a healthcare facility, even if the patient collects a self sample. This could be a concern if a patient does not have access to a healthcare facility [18].

ii. Currently, screening for cervical cancer or gonococcal infection requires a cervical exam performed by a physician which cannot be done with a vaginal self-swab; vaginal self-swabs cannot test for every vaginal-related condition [19].

iii. It has been proven there is no difference in accuracy whether a person self collects versus going to an OBGYN for a test for yeast infection and bacterial vaginosis [20].

iv. Vaginal self swabs are generally used for testing for bacterial vaginosis

and yeast infection and they make it a more accessible and equally as effective process than getting a test from a healthcare professional [21].

d. *Competition*:

    i. There are self collection swabs that require transport media such OSOM rapid diagnostics COVID-19 tests [22] and BD Onclarity fecal swab [23]. However there are no other vaginal self swabs that prevent contamination through the use of transport media.

    ii. The current collection tube used by the client is from Hologic, the Aptima Multitest Swab Specimen Collection Kit. This tube requires the patient to break off the swab head into the collection tube with transport media and secure it with a screwable lid [24].

        a. There are plenty of companies that make vaginal self-swabs for testing bacterial vaginosis and yeast infection, however, they differ from Hologic's Aptima Test because they do not require the patient to snap the swab head into the collection tube.

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11. Appendix II

11.1. Original Design Matrices

Vaginal Self Swab - BME 300/200

Design Matrix

September 26, 2024

Section 312

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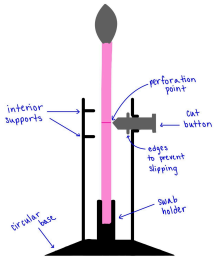
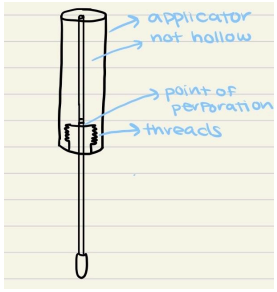
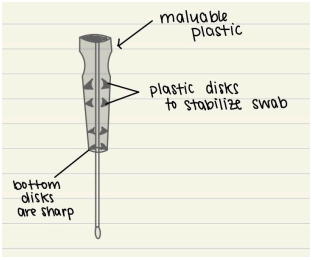
Table 2: Design matrix

Design Criteria (weight)	Design 1: Altered Bend Design 		Design 2: Tilt - and - Break 		Design 3: The Tunnel 	
Limiting Contamination (30)	4	24	4	24	4	24
Leakage Prevention (25)	4	20	5	25	4	20
Ease of Use (15)	4	12	5	15	3	9
Ease of Fabrication (10)	3	6	4	8	2	4
Patient Comfort (10)	5	10	5	10	5	10
Safety (5)	4	4	5	5	2	2
Cost (5)	5	5	5	5	5	5
Total Score (100)		81		92		74

Determination of Criteria and Weights:

Limiting Contamination (30): Leaking contamination refers to the ability to inhibit the spread of microorganisms from biological fluids or the testing environment. This criterion was discussed in the *Accuracy and Reliability* section of the PDS, and was assigned a weight of 30/100 due to its significance of being an accurate measurement. The device must demonstrate a consistent snapping mechanism while transporting the swab into the culture media. This requires the minimization of contamination caused by the patient's own bacterium, such as their hands, or from the environmental bacterium, such as a countertop.

Leakage Prevention (25): Leakage prevention refers to the degree to which spilling of contained culture media is prevented. This criterion was assigned a weight of 25/100 because it is of paramount importance that the culture media does not leak. Leakage of

the contained culture media can lead to inaccurate testing results, due to partial loss of the sample or external contamination. Additionally, skin contact with the culture media should be avoided, as it could lead to injury of the patient.

Ease of Use (15): This section focused on the simplicity of the process using the device. Relevant information was covered in the *Life in Service* and *Shelf Life* sections of the PDS. This criterion was given a weight of 15/100 because it is important that a patient would be able to understand and correctly use the device. A simple testing process is essential since the self-swab would be done without a doctor or physician's guidance.

Ease of Fabrication (10): This criterion assesses the ease of fabricating the insertion and stand mechanism, including the production and assembly of its components. Ease of fabrication was given a 10/100 because it's crucial that the design is feasible within the given time frame, both for prototyping and potential commercial manufacturing. A higher score in this category reflects a design that aligns with our fabrication skills and can be more readily scaled for commercial production.

Patient Comfort (10): Patient comfort refers to the comfort level of the patient while using the product, notably to which degree discomfort and pain are avoided. This criterion was assigned a weight of 10/100, as it is not an essential component of device functionality, but it is vital in the marketability and convenience of the product. Due to its convenience, patients are more likely to self-swab than to obtain a physician-collected sample [1].

Safety (5): Safety refers to risks (specifically to the user) associated with the product. This category ensures that the shaft portion of the swab can only be inserted 5 cm to prevent mechanical-induced tissue injury to the user [2]. Every material to be used is known to be biocompatible with the human body to reduce the risk of hypersensitivity [3].

Cost (5): The cost portion of the matrix is used to determine whether the cost of the materials are justifiable and within the client's budget. Points off in this category indicate costs exceeding the budget.

Justification of Assigned Scores:

Limiting Contamination (30): The "Altered Bend" design scored a ⅘ because although the base was extended to provide more stability, the device still has the potential of being knocked over, which could lead to contamination if the swab comes into contact with an external surface. The "Tunnel" design scored a ⅘ in limiting contamination because the mechanism is made out of malleable plastic, meaning it could tip easier without the added weight. Similarly to the other two design concepts, the "Tilt-and-Break" design received a score of ⅘. This is because although the design consists of a solid "handle" (as compared to the hollow "handles" of the other two designs) making it less prone to

tipping over, there is still the possibility of the device being knocked over and becoming contaminated after unintentionally coming into contact with a surface.

Leakage Prevention (25): The "Altered Bend" design scored a ⅘ in the leaking prevention category because of its inability to screw onto the device containing the transportation medium. The patient could accidentally knock over the tube containing the medium, leading to the potential spilling of viable bacterium through the crevices of the device. Similarly to the "Altered Bend" design, there is a possibility for tipping with the "Tunnel" design, so it is ranked a ⅘. Since there is no solid divide between the swab-holder and the tube, the culture media could spread throughout the hollow holder and escape the container. The "Tilt-and-Break" design scored full points in this category, because the "handle" component of the device is solid, and has no hollow voids for fluid to seep into if the device is not upright. Additionally, this design utilizes threads to allow for a secure, "screw-on" tightening of the two components.

Ease of Use (15): The "Altered Bend" design was given a score of ⅘ for ease of use because the button mechanism could malfunction, leading to inconclusive results. The "Tunnel" design was ranked the lowest, with a ⅗, because of the need to apply substantial, and variable (due to the user), pressure in order to break the swab. Finally, the "Tilt-and-Break" design scored full points in this category. This is because the device solely consists of a simple "screwing-on" mechanism, making it simple to use.

Ease of Fabrication (10): When it comes to the ease of fabrication, the "Altered Bend" design was assigned a score of ⅗ because, in previous semesters, the button had issues with rotating, providing an inaccurate breaking of the swab (either too long or too short). Fabricating a "button" mechanism and assembling it in a non-rotational manner would be difficult. Ranked ⅖, the "Tunnel" design would be difficult to fabricate due to the incorporation of sharp inserts within the holder used to stabilize the swab. Lastly, the "Tilt-and-Break" design was given a score of ⅘; this device would be relatively easy to fabricate due to its simplistic design, but it may be difficult to create a "handle" into which the swab can be sufficiently pressure-fit. Additionally, the "Tilt-and-Break" design utilizes threads, which is an added component of difficulty with regard to the ease of fabrication.

Patient Comfort (15): Each of the designs scored full points for patient comfort because all of the designs have a similar mechanism in terms of specimen collection by the patient. During the process, the patient must insert the swab 5 cm into the vaginal canal, which provides little-to-no discomfort to the patient if done correctly [2].

Safety (5): The "Altered Bend" design received a score of ⅘ for safety because the button could potentially malfunction and pinch the user if not pressed correctly. The "Tunnel" design ranked the lowest, with a ⅖, due to the sharp insert at the bottom of the holder. This can be dangerous to the user during the swabbing process, as well as while breaking the swab. The simplistic design of the "Tilt-and-Break" mechanism leaves little room for

the user to injure themselves, which is why this design received a full score in this category.

Cost (5): Each of the designs received full points within the cost category because all of the proposed design ideas require a minimal amount of material for fabrication, leading to affordability. All of the costs required to manufacture either device are anticipated to be within the $250 budget of the client.

12. Appendix III

12.1. Expense Spreadsheet

Table 3: Projected materials and their costs

Item	Description	Manufacturer	Mft Pt#	Vendor	Vendor Cat #	Date	QTY	Cost Each	Total	Link
Base	3D print - PLA	n/a	n/a	Makerspace	n/a	10/29	1	$0.33	$0.33	n/a
Base	3D print - PC	n/a	n/a	Makerspace	n/a	10/29	1	$0.33	$0.33	n/a
Tilt-and-Break	3D print - clear	n/a	n/a	Makerspace	n/a	11/25	1	$4.96	$4.96	n/a
Tilt-and-Break	3D print - PLA	n/a	n/a	Makerspace	n/a	10/29, 10/30	4	$0.45	$1.80	n/a
Tilt-and-Break	3D print - PC	n/a	n/a	Makerspace	n/a	10/29	1	$0.45	$0.45	n/a
Dacron Swab	n/a	Hologic	n/a	Provided by client	n/a	n/a	n/a	Free	Free	n/a
Transport Media	n/a	Hologic	n/a	Provided by client	n/a	n/a	n/a	Free	Free	n/a
Agar Plates	testing agar plates	EZ BioResearch	n/a	Amazon	n/a	11/20	3	$22.10	$66.30	Amazon
Total Cost: $74.17										

13. Appendix Ⅳ

13.1. Swab-Breaking Protocol

Steps:

1. Go through the motions of using the Tilt-and-Break device.
2. After breaking the swab into the media tube, remove the swab from the media tube.
3. Lay the swab onto a flat, dry surface and measure the distance between the breaking point and the line of perforation using calipers; record the value in a data table.
4. Repeat this process for a total of ten times for the Tilt-and-Break device.
5. Repeat the same procedure for the Hologic Aptima device (for a total of ten times).

Results:

Table 4: Swab-Breaking Accuracy Testing Results

Test #	Hologic Aptima Distance from Line of Perforation (mm)	Tilt-and-Break Distance from Line of Perforation (mm)
1	14.27	-0.64
2	8.42	-2.43
3	20.51	-0.47
4	15.59	-0.57
5	16.72	-0.45
6	16.32	-0.95
7	15.81	-0.67
8	17.71	-0.62
9	14.71	-0.77
10	15.96	-0.59
Average	-0.816	15.602

13.2. Contamination Protocol

Steps:

1. Without swabbing anything, go through the motions of using the Tilt-and-Break.
2. Streak the sample contained on the swab onto the surface of an agar plate; rotate the swab while streaking to ensure even distribution of bacteria along the agar surface.

3. Repeat this process for a total of three trials, using a new agar plate and swab for each trial.
4. Repeat steps 1-3 for the Hologic Aptima device.
5. For the positive control, swab the surface of a phone screen.
6. Streak the sample contained on the swab onto the surface of an agar plate; rotate the swab while streaking to ensure even distribution of bacteria along the agar surface.
7. Repeat this process for a total of three trials, using a new agar plate and swab for each trial.
8. For the negative control, place three unopened agar plates into the incubator.
9. Place all of the agar plates upside-down in the incubator to prevent condensation build-up; make sure that the agar plates are positioned near the center of the incubator to prevent potential over-heating of the agar plates.
10. Set the incubator to 32°C for a duration of 48 hours.
11. Following the 48-hour incubation period, use the colony-counting app called "ColonyCount" to quantify the colonies present on each agar plate.
12. Record the data in a data table.

Results:

Table 5: Contamination Testing Results

Trial #	Positive Control # of Colonies	Tilt-and-Break # of Colonies	Hologic Aptima # of Colonies	Negative Control # of Colonies
1	30	0	0	13
2	9	0	0	0
3	20	0	1	0
Average	19.667	0	0.333	4.333

14. Appendix V

14.1. STM Base SolidWorks Protocol

Objective: Create a 3D model of the STM Base in SolidWorks.

Steps:

1. In SolidWorks, begin a new part file.
2. In the bottom right corner of the screen, change the units to MMGS.
3. Begin a new sketch on the top plane.
4. Use the circle feature to draw a circle centered at the origin.
5. Dimension the sketch to have a diameter of 49.5 mm.
6. Exit the sketch.
7. Use the Extruded Boss/Base feature to extrude 2 mm down.
8. Start a new sketch on the top of the cylinder.
9. Use the circle feature to draw two circles centered at the origin.
10. Dimension one of the sketches to have a diameter of 17 mm.
11. Dimension the other sketch to have a diameter of 13 mm.
12. Exit the sketch.
13. Use the Extruded Boss/Base feature to extrude the feature 18 mm up.

15. Appendix VI

15.1. Tilt-and-Break SolidWorks Protocol

Objective: Create a 3D model of the Tilt-and-Break in SolidWorks.

Steps:

1. In SolidWorks, begin a new part file.
2. In the bottom right corner of the screen, change the units to MMGS.

Shaft:

3. Begin a new sketch on the top plane.
4. Use the circle feature to draw a circle centered at the origin.
5. Dimension the sketch to have a diameter of 16.5 mm.
6. Exit the sketch.
7. Use the Extrude Boss/Base feature to extrude 84 mm down.

Cap:

8. Start a new sketch on the top of the cylinder.
9. Use the circle feature to draw a circle centered at the origin.
10. Dimension the circle to have a diameter of 14.5 mm.
11. Exit the sketch.
12. Use the Extruded Cut feature to cut 10 mm of material out of the shaft.

Internal Tube:

13. Start a new sketch on the 14.5 mm circle.
14. Use the circle feature to draw a circle centered at the origin.
15. Dimension the circle to have a 2.8 mm diameter.
16. Exit the sketch.
17. Use the Extruded Cut feature to cut 70 mm of material out of the shaft.

Threading:

18. Click on the Helix/Spiral feature and the inner cap.
19. Defined by Height and Pitch with Constant Pitch parameters.
20. Make the height 10 mm.
21. Make the pitch 4 mm.
22. Check the reverse direction box.
23. Make the start angle clockwise 0 degrees.
24. Check the green arrow.
25. Start a new sketch on the right plane.
    a. The plane chosen should align with the top of the shaft, tip of the cap, and beginning of the spiral.
26. Click on the line feature and draw a line from the tip of the spiral in a downward diagonal direction toward the center of the cap. Click to end the line.
27. Click to begin another line from the ending of the first straight down toward the bottom of the cap. Click to end the line.

28. Click to begin another line from the ending of the second line toward the side of the cap. Click to end the line.
29. Click to begin a fourth line from the ending of the third line straight up and click on the beginning of the first line. This will connect the first and third lines.
30. Add a centerline from the midpoint of the fourth line to the midpoint of the second line.
31. Add a relation to the centerline to make it horizontal.
32. Add a relation to the second and fourth lines to make them vertical.
33. Dimension the fourth line and make it 1 mm.
34. Dimension the centerline and make it 0.6 mm.
35. Dimension the first line and the centerline to create a 10 degree angle.
36. Exit the sketch.
37. Use the Sweep feature to extrude the threading.
38. Make the Profile and Path a Sketch Profile.
39. Click on the trapezoid made in the previous sketch as the profile.
40. Click on the Helix/Spiral made previously in steps 18-24 as the path.
41. The profile orientation should follow the path and the profile twist should have minimum twist.
42. The boxes should be checked for the following: Merge tangent faces, Show preview, and Merge result.
43. Click on the green check mark.
44. Click on the Chamfer feature.
45. The items to chamfer should be the Edges 1 and 2, these were the first and third lines drawn in the trapezoid.
46. The chamfer parameters should have a distance of 2 mm with a 10 degree angle.
47. Click the green check mark.
48. Click on the chamfer feature to start another chamfer.
49. The item to chamfer should be Edge 1, or the second line drawn in the trapezoid.
50. The chamfer parameters should have a distance of 2 mm with a 25 degree angle.
51. Click on the green check mark.
52. Click on the circular pattern feature.
53. Under the Direction tab the face chosen should be the inner tube in the cap. The equal spacing should be checked. The angle should be 360 degrees. The amount should be 2.
54. Under the Features and Faces tab click on both chamfers and the sweep feature.
55. Click on the green check mark. There should now be a total of 2 starting threads.