BME Design-Spring 2024 - KATHERINE KAFKIS
Complete Notebook

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KATHERINE KAFKIS

on

May 01, 2024 @06:18 PM CDT

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Team contact Information

ADAM BERDUSCO - Feb 16, 2024, 3:56 PM CST

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https://www.when2meet.com/?23357710-qXPHT

Project description

SARA MOREHOUSE - Feb 07, 2024, 4:37 PM CST

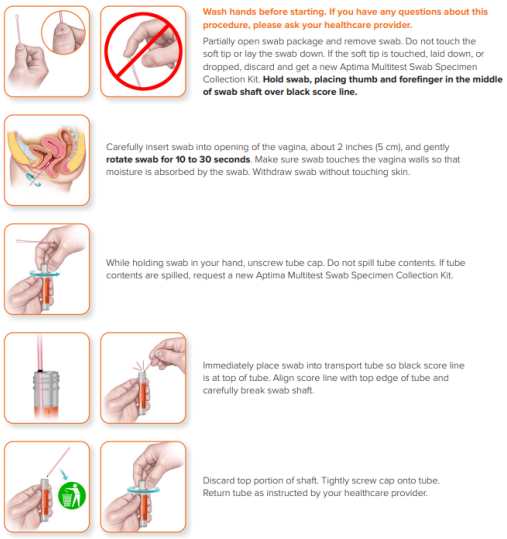
Course Number: BME 301

Project Name: Vaginal Self-Swab Device to Limit Contact Contamination

Short Name: Vaginal Self-Swab

Project description/problem statement:

Self-swabbing for sexually transmitted infections has been shown to increase early detection and treatment of STIs in women. Universal screening for chlamydia is recommended in all young women, but screening targets are seldom met in practice.
The current self-swab technology in the US involves the patient using the collection system employed by their provider, which commonly requires collecting a specimen from the vagina and transferring to a closed tube containing liquid media. This method is rife with the possibility of contamination due to improper transfer, spilling or splashing of the media, or vaginal fluids getting on the hands of a patient. As a result, the team has been tasked with designing a clean device that limits this potential contamination by employing a single unit for the swabbing and storing of test specimens.



Problem Statement:

Quality sexual health is important for every woman to sustain, but with women ages 15-24 accounting for 43% of undiagnosed STI cases, the system supporting women's sexual health could use some improvement (CDC). The team has developed a novel self-swab STI testing device that allows women the privacy of swabbing themselves without the potential discomfort of a physician present. This was conceived with the goal in mind of making STI testing more accommodating while reducing contamination of the testing environment. However, the current design has issues with media leaking from the device after use, as well as with the aesthetics of the design. Additionally, the device requires the addition of a thin, puncturable film to the cap to contain transport media. The team is tasked with modifying the original design to address the issues currently being faced while still seeking to limit contamination of the device and testing environment as well as account for patient comfort.

About the client:

Dr. 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.

2/5/24 Client Meeting

SARA MOREHOUSE - Feb 07, 2024, 4:30 PM CST

Title: Client Meeting 1

Date: 2/5/24

Content by: Sara Morehouse, Katherine Kafkis

Present: team and Dr. Riquelme

Goals: To gain a better understanding of any requirements for the project and touch base about next steps for the team.

Content:

Ask about getting in contact with the lab - she will get us in touch

What concerns do you have about the device as it is currently?

- Size seems good
- Main issue is delivering media (sealing, thin film, etc.)
- Material: used PLA. Thoughts on a compostable material:
    - Reasonable as long as it meets specifications
    - Will it still be comfortable?

What requirements do you have for the device going forward?

- No but should talk to lab processing people
    - East or west hospital labs
    - She will get us their info

Would you like us to continue with the plunger design or look into a slider?

- No preference
- Women aren’t dumb they can figure it out
- Can the cap be self sealing
- Slider increases cost

She has a rigid pelvic model in the anatomical position of someone who is upright

- Can use for testing
- Need it returned
- They use the fruit when they teach someone how to do this

She will be in South America the last two weeks of February

Conclusions/action items: We need to contact the sample processing lab as soon as we get their information and figure out what requirements they have for samples. We also need to update our PDS with these requirements.

2/27/24 Meeting With Dr. Accola

SARA MOREHOUSE - Feb 28, 2024, 4:54 PM CST

Title: Meeting with Dr. Accola

Date: 2/27/24

Content by: Sara Morehouse, Katherine Kafkis, Cherry Qiu

Present: Sara, Katherine, Cherry

Goals: To learn about the system in place for processing samples and figure out if we are able to test in the lab.

Content:

- How many STI swab samples get processed daily?
    - Each HPV test about 100 per day
    - CT/GH - probably 50-75 per day
        - Chlamydia being highest volume
        - Typically order both from same swab
    - How long does it take to process a single swab?
        - Depends on how they get the swab
        - Typically collected in the sample device that goes on the instrument
            - Hologic panther to test for all of the STIs
            - Swab that is collected and then goes into a tube, cap goes on, cap is typically pierceable which can go right on the instrument. Sample is labeled one time
            - Cap must come off before going to the instrument.
                - Instrument is height sensitive (presets???)
            - Want cap removed - whether the lab is removing it themselves or otherwise
            - Should fit in test tube rack
- What issues/shortcomings are there in this process from the lab's perspective?
    - Have to be careful not to contaminate the foil on the cap - if the cap is contaminated, then the sample is contaminated as the machine pushes through the cap to access the media.
    - Urine test has non-pierceable cap
- In order for you to receive the sample, are there any requirements for how it must be packaged/contained?
    - Aptima tubes have a rim on the cap that catches the swab to pull it out the way when the sample is being tested.
        - Best to use aptima caps?
        - Required for swab to be broken
    - Ideally instead of the cap with media, we'd want to push the swab directly into the multitest tube then break the swab at the perforation
- How would we realistically go about potentially testing our device?
    - Are we able to come into the lab to have one of our sample swabs processed?
        - As long as it is in a hologic tube
        - If interested we could come check out the instrument and see how it works - send an email to) a time. She will meet us outside and show us the process

- They don’t want to change the instrument and process at all

Develop assays that are used to test patient samples. PCR.

Conclusions/action items:

The major conclusion is that we have to find a way to either use the Aptima media tube or at least use the cap. This is probably going to involve going back to the drawing board a bit and redesigning our prototype.

3/13/24 Client Meeting

KATHERINE KAFKIS - Mar 13, 2024, 5:01 PM CDT

Title: Client Meeting

Date: 3/13/24

Content by: Katherine Kafkis

Present: Team

Goals: To inform our client of the changes we are making to the design and to get her feedback on these changes.

Content:

- changing the design to be compatible with the aptima media tube
- will have the swab exposed up to the breaking point with a mechanism of cleaving the swab at this breaking point that is similar to a cigar cutter
- Proceed to work with this lab and to refocus or continue down the path of something completely self-contained:
    - Up to us in her opinion
    - Push that question to exact sciences
        - other vaginal detection technologies
    - Goal: work with the UW system and then definitely adopt a specimen collection that goes with their technology
    - Make it so that they don't have to unscrew the cap and stick it in themselves
        - started focusing on contamination
        - get rid of opening the top, putting the specimen in, snapping it off, then sealing once again
- having to use something that has to be removed and processed is difficult and should be avoided
- should be able to done at home or in the bathroom of the clinic
- minimize the taking on and off of the top which seems to be the performance issue
- likes the idea of clipping the swab as it promotes universal testing
- make our device have talking instructions - interesting idea

Conclusions/action items:

Continue working on the clipping design. Investigate methods of cutting the swab and the amount of force that would be required to cut it at the breaking point.

1/26/24 - Initial Advisor Meeting

KATHERINE KAFKIS - Feb 02, 2024, 12:27 PM CST

Title: Initial Advisor Meeting

Date: 1/26/24

Content by: Katherine Kafkis

Present: Team

Goals: To get to know our advisor and new team members. To share information on what was accomplished last semester and some goals we have for this semester.

Content:

- Advisor meetings Friday 12:53 - 1:13 in 2349 EHall

Conclusions/action items:

Attend all future advisor meetings. Bring last years prototype to the advisor meeting next week.

2/2/24 Advisor Meeting

SARA MOREHOUSE - Feb 07, 2024, 4:35 PM CST

Title: 2/2/24 Advisor Meeting

Date: 2/2/24

Content by: Sara Morehouse

Present: team

Goals: To share what we worked on over the week and ask questions/for feedback on ideas

Content:

- Discussed sealing mechanism - could redesign plunger or switch to slider

- Discussed sustainable materials

- PDS will not change much

- Can do multiple design matrices to decide designs and materials

Conclusions/action items:

Work on PDS, continue research, brainstorm ideas

2/9/24 Advisor Meeting

SARA MOREHOUSE - Feb 13, 2024, 4:50 PM CST

Title: 2/9/24 Advisor Meeting

Date: 2/9/24

Content by: Sara Morehouse

Present: Cherry Qiu, Adam Berdusco

Goals: Discuss design ideas and upcoming design matrix.

Content:

- Don't worry about injection molding - just 3D print

- look into resin printing

- can't print threading very well - so either print cylinder and machine the threading with the lathe or try resin printing

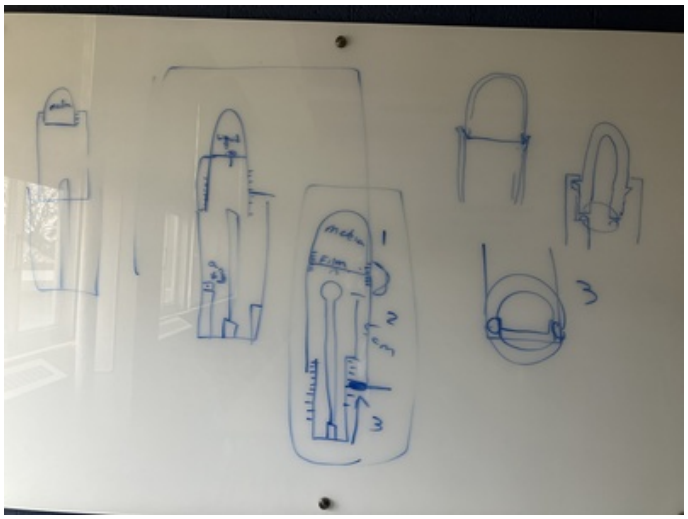
- Rethinking the plunger idea - could instead do a longer, thinner cap with a swab that gets inserted and punctures the film. Swab screws into cap - see image attached.

- Use Solidworks designs for design matrix

Conclusions/action items:

This meeting was helpful for taking a step back and rethinking the plunger. It seems like it makes the most sense to include 3 new overall designs for the matrix instead of doing 3 separate design matrices for each component. We will work on coming up with 3 designs and creating them in Solidworks this week.

SARA MOREHOUSE - Feb 13, 2024, 4:51 PM CST



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2/23/24 Advisor Meeting

SARA MOREHOUSE - Feb 28, 2024, 4:50 PM CST

Title: 2/23/24 Advisor Meeting

Date: 2/23/24

Content by: Sara Morehouse

Present: Team

Goals: To update on our progress and discuss design ideas.

Content:

- Discussed the ideas we got from Jesse from the Design Hub

- Discussed redesign of plunger

Conclusions/action items:

We need to continue to come up with design ideas and figure out how to simplify the design while still keeping the process contained.

2/15/24 - Preliminary Design Ideas

KATHERINE KAFKIS - Apr 25, 2024, 10:21 PM CDT

Title: Preliminary Design Ideas

Date: 2/15/24

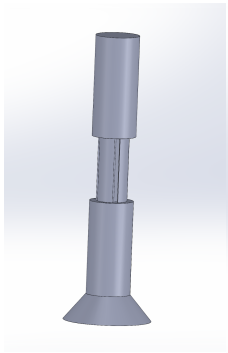
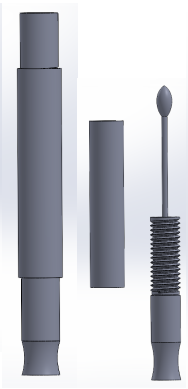
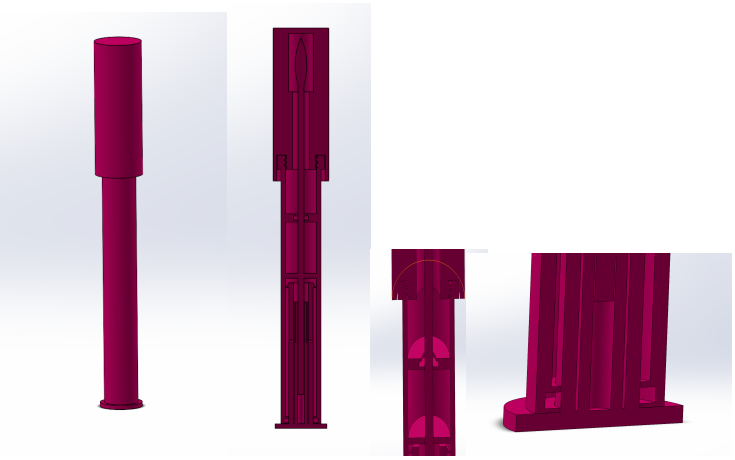
Content by: Katherine Kafkis

Present: Team

Goals: To evaluate our preliminary design ideas based off the criteria of leaking prevention and threading relocation.

Content: DESIGN MATRIX

Design Matrix:

iteria	**WeightDesign 1:**		**Design 2:**		**Design 3:**		
							
niting contamination	30	3/5	18	4/5	24	4/5	24
akage Prevention	25	3/5	15	5/5	25	3/5	15
se of use	15	5/5	15	4/5	12	4/5	12
se of fabrication	10	3/5	6	2/5	4	4/5	8
tient Comfort	10	3/5	6	3/5	6	5/5	10
fety	5	5/5	5	5/5	5	4/5	4
st	5	5/5	5	4/5	4	5/5	5
tal	**100**	70		80		78	

Conclusions/action items:

Continue discussing the different design ideas and meet with our advisors to get feedback on these ideas. Possibly print some preliminary prototypes to see how these ideas work in actuality.

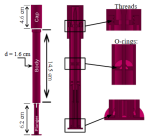
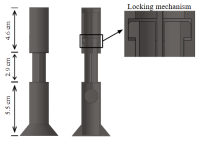
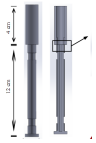
KATHERINE KAFKIS - Apr 25, 2024, 10:24 PM CDT

Date: 2/29/24

- Updated design matrix with more accurate rankings of the design ideas

- An additional design idea called the pull-back was fabricated and took the place of design idea 2 in the above design matrix. This new design would allow for the transfer of the swab into the aptima media tube which was discovered to be necessary in our meeting with Dr. Accola earlier this week.

Design Matrix:

Criteria	Weight	Modified Plunger 		Snap On 		Pull Back 	
Limiting contamination	30	5/5	30	3/5	18	5/5	30
Leakage Prevention	25	4/5	20	5/5	25	4/5	20
Ease of use	15	4/5	12	5/5	15	3/5	9
Ease of fabrication	10	1/5	2	5/5	10	3/5	6
Patient Comfort	10	5/5	10	4/5	8	4/5	8
Safety	5	5/5	5	5/5	5	5/5	5
Cost	5	5/5	5	5/5	5	5/5	5
Total	**100**	84		86		83	

2/21/24 - Ethical Considerations

KATHERINE KAFKIS - Feb 21, 2024, 2:21 PM CST

Title: Diversity and inclusion

Date: 21/02/2024

Content by: The whole team

Present: The whole team

Goals: Understand how diversity and inclusion affect the design

Content:

- Requires use of hands/arms
    - Different levels of dexterity in the hands
    - It is likely that people with limited mobility would not be booking a self-swab and would book an appointment with a doctor.
- The squatting position is likely the position to be used when testing
    - Another obstacle to inclusivity as people with limited mobility in the legs may have a more difficult time inserting the device
- Differences in vaginal anatomy
    - Design is based on the average unaroused vaginal canal
- It has a few moving components to the design which introduces complexity
    - Will require instructions to use: video, images, and multiple languages
    - Arrows to instruct the direction of screwing on
    - Lining up arrows to indicate a fully screwed-on device
    - Pictogram illustration of how to use the device
- Different age categories using the design
    - Ex: A 50-year-old female is likely going to be more comfortable using a medical device than a 13-year-old female. A 50-year-old female is also probably more likely to read the instructions thoroughly than a 13-year-old female
- Overall: inclusivity of the design should be worked on
    - Make sure it is not too complicated
    - Make sure it accommodates people with different levels of mobility to the greatest extent

Conclusions/action items: Some of these design considerations will be implemented into the design to increase overall inclusion.

3/4/24 - Modifications of Preliminary Design Ideas

KATHERINE KAFKIS - Apr 25, 2024, 10:39 PM CDT

Title: Modified Preliminary Design Ideas

Date: 3/4/24

Content by: Team

Present: Team

Goals: To modify our design ideas based off the meeting with Dr. Accola at the UW health lab who informed us that the aptima media tube must be used for diagnostic testing.

Content:

Design should:

- keep tube upright

- reduce amount of things in patient's hand

OR could shift purpose to be for physician use

- could be a stand for the tube and swab

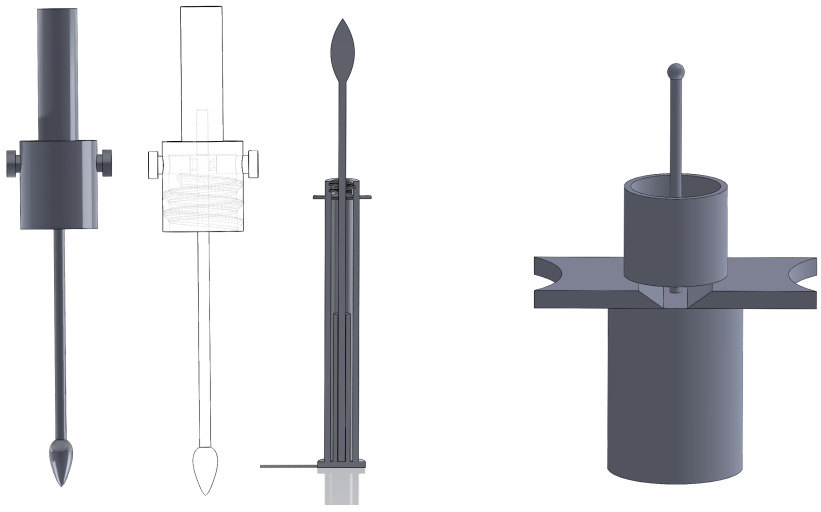
- could be a plunger where patient leaves the swab in the device and physician comes in and transfers to tube

- cigar cutter design integrated with the snap on design:

- remove the base
- add a cigar cutter style mechanism where patient pushes in tabs to cleave the swab
- swab holder screws directly on to the tube

The team worked on creating some SolidWorks designs today as seen below.

New Design Ideas:



- All of the new design ideas utilize a "cigar-cutter" design to break the swab off at its perforation point

- These would allow the patients to grip an external casing that can be safely set down on a surface with little risk of contamination

- The cigar-cutter component would then be used to transfer the swab into the aptima media tube after specimen collection

Conclusions/action items:

Discuss these new ideas with the advisors to get feedback on better ways to break the swab at its perforation point. Set up a meeting with Jesse from the design hub to get help generating ideas for a device that allows for the collection of samples and the transferring of the swab into the aptima media tube.

3/12/24 - Three-point Bending Design Ideas

KATHERINE KAFKIS - Apr 25, 2024, 10:40 PM CDT

Title: Three-point Bending Design Ideas

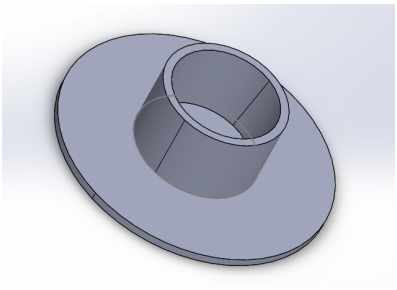
Date: 3/12/24

Content by: Team

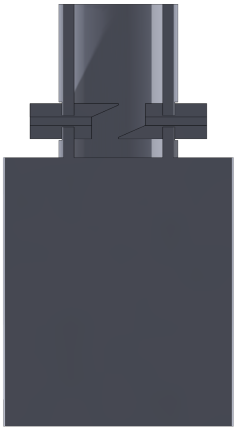
Present: Team

Goals: To fabricate rough CAD designs of a collection device that breaks the swab using a three-point bending mechanism as well as a media stand that can help stabilize the aptima tube during the transfer process.

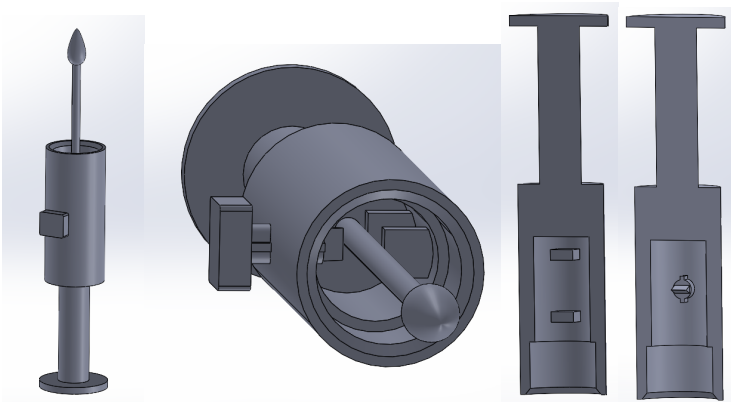
Content:



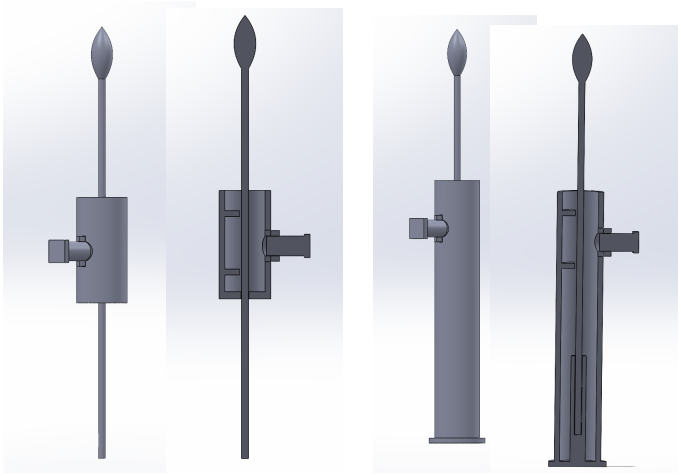
- This component is a base to house the Aptima tube while the patient conducts the test.



- This design is a potential solution to breaking the swabs. There are two edges that actuate to apply pressure and bend the swab. If enough force is applied to the swab it will break at the already perforated section via shear force.



- This design uses a 3-point bending mechanism to break the swab. When the patient is done swabbing, they press the device onto the uncapped Aptima tube and push the button to break the swab, causing it to fall into the tube. They would then remove the device and screw the Aptima cap back on.



- The middle design also utilizes 3-point bending to break the swab and uses a button to apply a central force at the swab perforation.

- The rightmost design is identical to the middle design except that it includes a full body that is the length of the swab and provides a base for it to stand up on.

Conclusions/action items:

Continue fine-tuning the above design ideas and 3D print the above prototypes to test their ability to break the swab and for use at show and tell.

3/22/24 - Show and Tell

SARA MOREHOUSE - Mar 22, 2024, 1:00 PM CDT

Title: Show and Tell

Date: 3/22/24

Content by: Team

Present: All

Goals: Get feedback.

Content:

- Check percentage of dyed area vs not dyed area for a dye/fluorescent testing to quantify results
- Full-body device gives you something to grip on
- Shorter design is cheaper, easier to package, less waste
- Survey people to see if they'd prefer the shorter or longer design
- Swab yeast
- Shorter design is preferred - less bulky
- On full design - difficult to feel resistance of the swab against the vaginal wall
- Hex cap - something for it to rest on, easier to make the button

Conclusions/action items:

The feedback was helpful.

4/8/24 - Proposed Final Prototype

KATHERINE KAFKIS - Apr 25, 2024, 10:41 PM CDT

Title: Proposed Final Collection Device

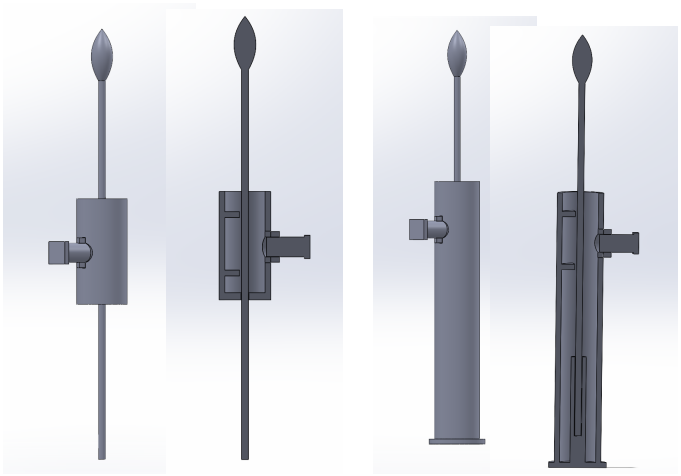
Date: 4/8/24

Content by: Katherine Kafkis

Present: N/A

Goals: To determine which final prototype to continue with, the shorter or longer design.

Content:



- These two prototypes both utilize 3-point bending to break the swab.

- Based on the feedback at show and tell, there is no conclusive preference for the longer or shorter design as we received differing opinions from each group we spoke to. As a result, a survey should be conducted to determine which prototype should be the final design.

Conclusions/action items:

Fabricate an instruction manual for the two prototypes and a survey. In the survey, ask questions regarding the shorter vs longer design as well as feedback on the fabricated instructions.

4/10/24 Ethical Considerations of design

SARA MOREHOUSE - Apr 10, 2024, 2:02 PM CDT

Title: Ethical Considerations

Date: 4/10/24

Content by: all

Present: all

Goals: To identify ethical considerations and brainstorm possible solutions.

Content:

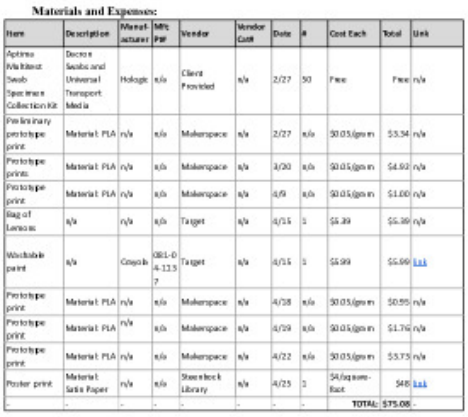
- A cheaper, but less environmentally friendly material could be used which lowers the overall cost of the device but harms the environment. It is a one time use device, so the waste aspect of the project is important to consider.
- Another component of the device that has an ethical dimension is that it requires a reasonable amount of mobility and dexterity.
- To address these ethical dimensions, we are trying to figure out a way to use an environmentally friendly material that can be recycled. To address the mobility issue, we can try to make the device as ergonomically friendly as possible and limit more difficult maneuvers such as screwing caps on.

Conclusions/action items:

We will consider these ethical dimensions as we move forward with designing and testing.

Materials and Expenses Spreadsheet

KATHERINE KAFKIS - May 01, 2024, 4:17 PM CDT



Materials and Expenses:

Item	Description	Manufacturer	Mfg PN	Vendor	Vendor Cost	Date	#	Cost Each	Total	Link
Aptima Multitest Swab Specimen Collection Kit	Dacron Swabs and Universal Transport Media	Hologic	n/a	Client Provided	n/a	2/27	50	Free	Free	n/a
Preliminary prototype print	Material: PLA	n/a	n/a	Makerspace	n/a	2/27	n/a	$0.05/gram	$5.34	n/a
Prototype prints	Material: PLA	n/a	n/a	Makerspace	n/a	3/20	n/a	$0.05/gram	$4.92	n/a
Prototype print	Material: PLA	n/a	n/a	Makerspace	n/a	4/9	n/a	$0.05/gram	$1.00	n/a
Bag of Lemons	n/a	n/a	n/a	Target	n/a	4/15	1	$6.39	$6.39	n/a
Washable paint	n/a	Crayola	081-0-4113-7	Target	n/a	4/15	1	$6.99	$6.99	Link
Prototype print	Material: PLA	n/a	n/a	Makerspace	n/a	4/18	n/a	$0.05/gram	$0.95	n/a
Prototype print	Material: PLA	n/a	n/a	Makerspace	n/a	4/19	n/a	$0.05/gram	$1.76	n/a
Prototype print	Material: PLA	n/a	n/a	Makerspace	n/a	4/22	n/a	$0.05/gram	$3.75	n/a
Poster print	Material: Satin Paper	n/a	n/a	Steenbeck Library	n/a	4/25	1	$4/square-foot	$48	Link
-	-	-	-	-	-	-	-	TOTAL:	$75.08	-

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Materials_and_Expenses_1_.pdf (53.2 kB)

3/16/24 - 3D Printing Procedure

KATHERINE KAFKIS - Apr 17, 2024, 8:46 PM CDT

Title: 3D Printing Protocol

Date: 3/16/24

Content by: Team Members

Present: Team Members

Goals: To generate a 3D printing protocol.

Content:

Timeline:

- SolidWorks drawing of hollow caps for thread size testing completed by 3/17/24
- Begin printing caps with different thread sizes by 3/18/24
- Test the thread sizes with the Aptima Media test tube. Make note of the thread size that fits the Aptima tube for use in the self-swab design by the morning of 3/19/24.
- SolidWorks designs completed by 2:00 pm on 3/19/24
- Begin printing 3/19/24
- Complete prints by 3/21/24

Materials and costs table:

Material	Quantity (g)	Cost Each	Total Cost
Ultimaker PLA	(obtain this value when filling out the Makerspace Google form prior to starting printing)	$0.08 per gram	(obtain this value when filling out the Makerspace Google form prior to starting printing)

Equipment used: Bambu Lab X1 Carbon printer, Ultimaker PLA Filament

Fabrication Details

Name of fabrication step/portion of prototype: 3D printing of Self-Swab device

Date to be completed: **03/19/2024**

Team member(s) fabricating:

Detailed sketch of portion of prototype being fabricated (Include dimensions):

Detailed bulleted steps of fabrication:

- Open the SolidWorks file of each design component
- Download STL files of each design component (ie. Body, Cap, Base, etc.)
    - Save STL files to a flash drive with an easily identifiable name
- Plug the flash drive into the MakerSpace computer
- Open up the software corresponding to the printer type being used
    - If a Bambu printer is used, open Bambu Studio
- Import the STL files into a new project to populate the build plate

- Click the lay-on face button and select the face with the largest diameter. This will place the selected face on the build plate and must be repeated for each component.
    - Ensure all components are 2-3 squares apart
- Select the printer to be used by opening the devices tab
    - Note that printer names can be found on the printer itself. Choose a printer that is available or nearly completing a print.
    - Additionally, make note of the filament types and colors loaded onto the printer being used. Ensure that PLA filament is loaded onto the printer of interest.
- Highlight all components of the print. Right-click on the mouse and select filament type. Select the PLA filament in an available color.
    - PLA filament should be 1.75 mm in diameter
- Click the enable supports button.
    - Select rectangular supports.
- Select a layer thickness of 0.16 mm
- Set layer speed to be 200 mm/s and support speed to be 150 mm/s
- Set infill to be 20%
- Click the slice all button. Make a note of the grams of material used and the print time.
- Download a 3MF file
- Navigate to Google Chrome and fill out the 3D print form
    - Note that the form should already be open; if not, consult a staff member.
- Consult a MakerSpace employee for loading the print onto the printer and for billing purposes.

Conclusions/action items:

Follow this protocol for printing moving forward. Include this protocol in an appendix for the fabrication section of the final report.

4/25/24 - Final Prototype

KATHERINE KAFKIS - May 01, 2024, 6:10 PM CDT

Title: Final Intravaginal STI Self-Swab Device

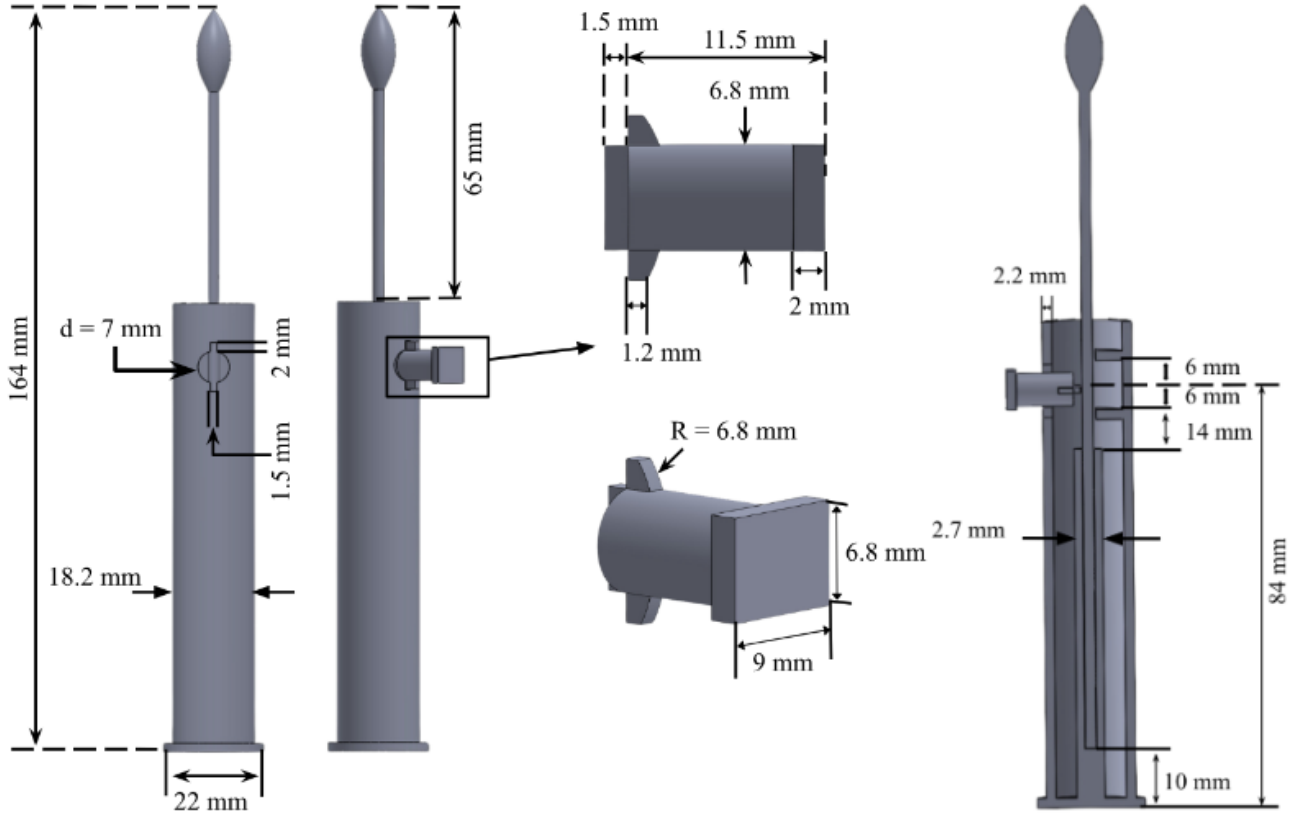
Date: 4/25/24

Content by: Katherine Kafkis

Present: N/A

Goals: Present the final device, shortcomings, and future directions.

Content:


164 mm
d = 7 mm
2 mm
1.5 mm
18.2 mm
22 mm
65 mm
1.5 mm
11.5 mm
6.8 mm
2 mm
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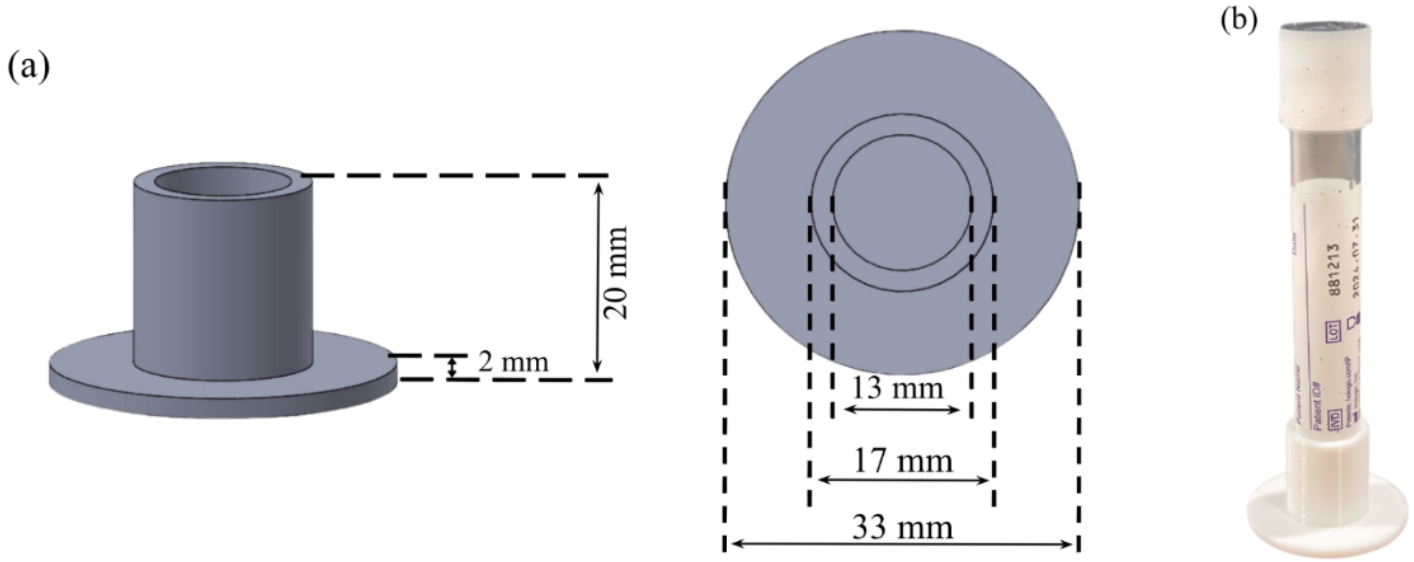
6 mm
14 mm
2.7 mm
84 mm
10 mm



Final collection device:

- external casing

- swab holder

Final transport mechanism:

- keyed push-button of the external casing

- upper opening of the external casing

- media stand

Conclusions/action items:

In the future, the design should be made to be compatible with different swab types as it is currently designed to house the Aptima swab. The keyed push-button can freely rotate within the casing of the device which could prevent the breaking of the swab in three-point bending. As a result, this rotation should be limited or completely prevented.

Contamination testing protocol - PRETEST

SARA MOREHOUSE - Apr 10, 2024, 10:25 PM CDT

Title: Contamination testing protocol (prior to testing)

Date: 4/10

Content by: Sara Morehouse

Present: n/a

Goals: To draft a protocol for contamination testing with and without the device.

Content:

Project Title: Vaginal Self-Swab To Limit Contact Contamination

Team members: Sara Morehouse, Adam Berdusco, Katherine Kafkis, Cherry Qiu

Timeline:

- Perform test on __/__/____

Materials and Costs Table:

Material	Quantity	Purpose	Manufacturer	Part #	Cost	Link
Realemon 100% Lemon Juice	1	Invisible ink to demonstrate contamination that occurs during swabbing.	Mott's LLP	203-14-0462	$2.99	Realemon 100% Lemon Juice - 15 Fl Oz Bottle : Target
Aptima Multitest Swab Specimen Collection Kit	6	Swabs to use for simulation of STI collection test.	Hologic		n/a (provided by client)	n/a
Plastic Vaginal Model	1	To act as the "patient's" vagina for STI test.	n/a (provided by client)	n/a	n/a	n/a
ImageJ software	1	To use for measuring surface area contaminated by self-swab.	NIH	n/a	$0	Download (imagej.net)
White paper 100cm x 60cm	6	To act as the testing environment in order to measure contaminated area while swabbing	any	n/a	$	n/a
Hairdryer	1	To use to heat up the lemon juice after performing testing.	any	n/a	variable	n/a
Nitrile gloves	8 pairs	For use with applying lemon juice to vaginal model and during tests.	Any (provided by BME Teaching Lab)	n/a	$0	n/a
Prototype	1	To be used to test contamination of the surface while swabbing.	n/a	n/a		n/a

Contamination Testing Protocol

Date to be Completed:

Images of Testing Setup:

Steps:

1. Lay white paper flat on a bench top or countertop.
2. Put on one pair of nitrile gloves.
3. In a separate area, open the lemon juice bottle and separate the vaginal model in half.
4. Pour a small amount of lemon juice into the palm of a gloved hand and apply to the interior of the vaginal model and on the exterior of the opening. Ensure the model is sufficiently coated on the interior and at the opening.
5. Dispose of gloves and re-cap the lemon juice bottle.
6. Carefully put the vaginal model back together and transport the model onto a chair.
7. Put on a second pair of nitrile gloves.
8. Open an Aptima Multitest Swab Specimen Collection Kit and DO NOT read instructions.
9. Perform the test with the vaginal model using best assumptions of how to take the test. Ensure that all transfer of swab and media uncapping and swab breakage occurs over the white paper.
10. When the test is complete, plug in the hairdryer and apply warm/hot air to the white paper over areas where lemon juice was spilled or dripped onto the paper. Ensure that the lemon juice turns light brown when heat is applied. If not, end the test here and obtain a water-soluble paint to be used for retesting.
11. Take a picture of the entire white sheet of paper with the brown lemon juice stains visible.
12. Upload the image into ImageJ and find the percentage of the total area that was contaminated with lemon juice during this test. Record this value in a table under the “Aptima Multitest Swab test NO directions” category.
13. Repeat test and record contaminated area value.
14. Read the directions for the Aptima Multitest carefully, and then perform two tests exactly following the instructions. Record the calculated area values under the “Aptima Multitest Swab test WITH directions” category.
15. Read instructions for the prototype swabbing device and perform two tests exactly following the instructions. Record the calculated area values under the “Self-swab device prototype WITH directions” category.
16. Use t-test to calculate p-values between each category to determine if there is a significant difference between the amount of area contaminated by each testing method.

Conclusions/action items:

The testing will take place early next week and we will update the protocol in detail during the process/after testing.

Prototype Instruction Manual + Survey Questions

KATHERINE KAFKIS - Apr 17, 2024, 8:38 PM CDT

Title: Proposed instructions for the use of the prototype during vaginal self-swab STI testing.

Date: 4/15/24

Content by: Katherine Kafkis

Present: N/A

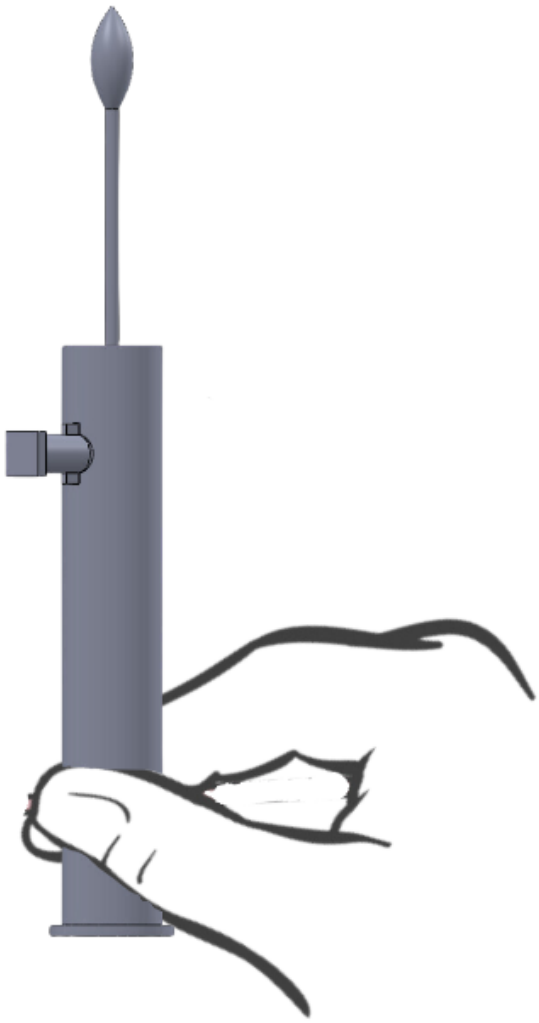
Goals: To generate a detailed instruction manual demonstrating the use of the device.

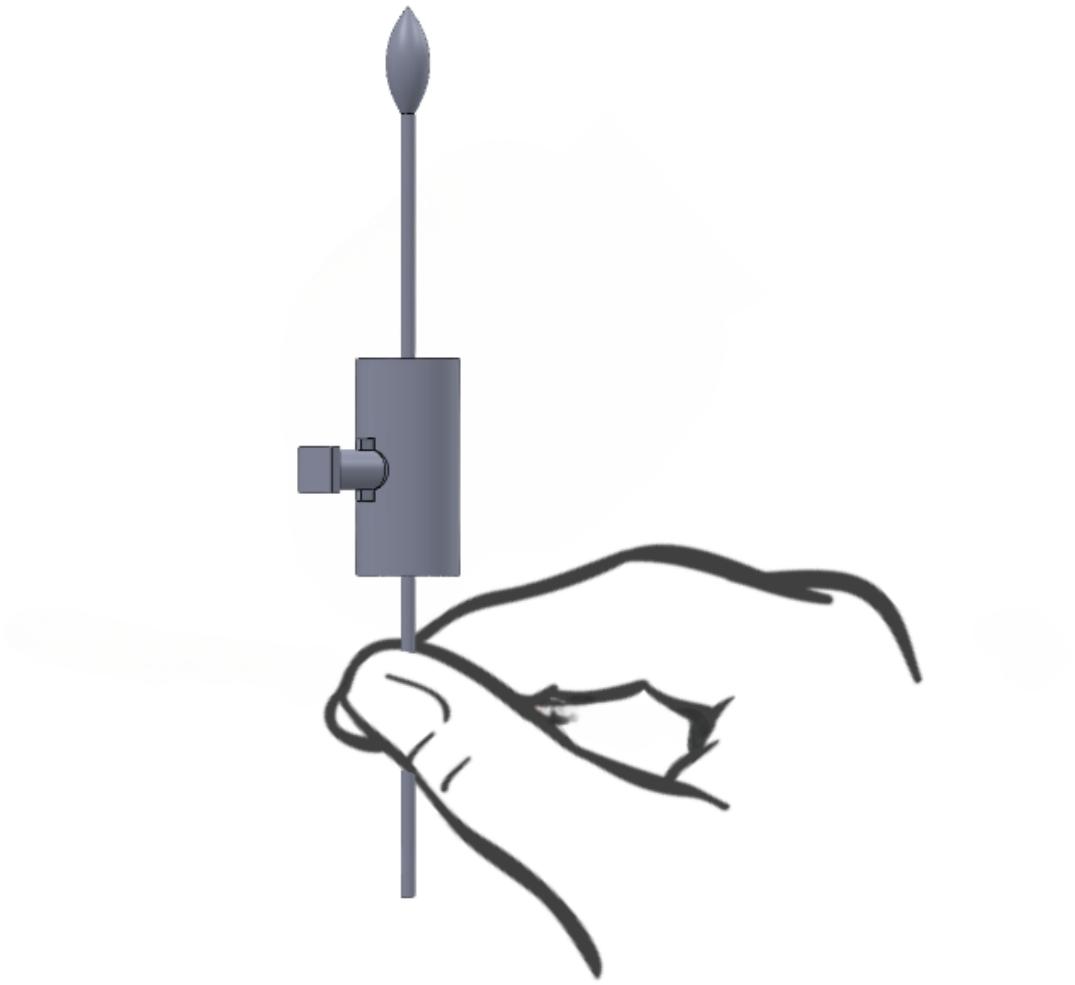
Content:

Instructions:

1. Wash hands.
2. Remove the media test tube from its packaging and place it in the stand as shown:

3. Remove the device from its sterile packaging and hold it as shown (for respective prototypes)

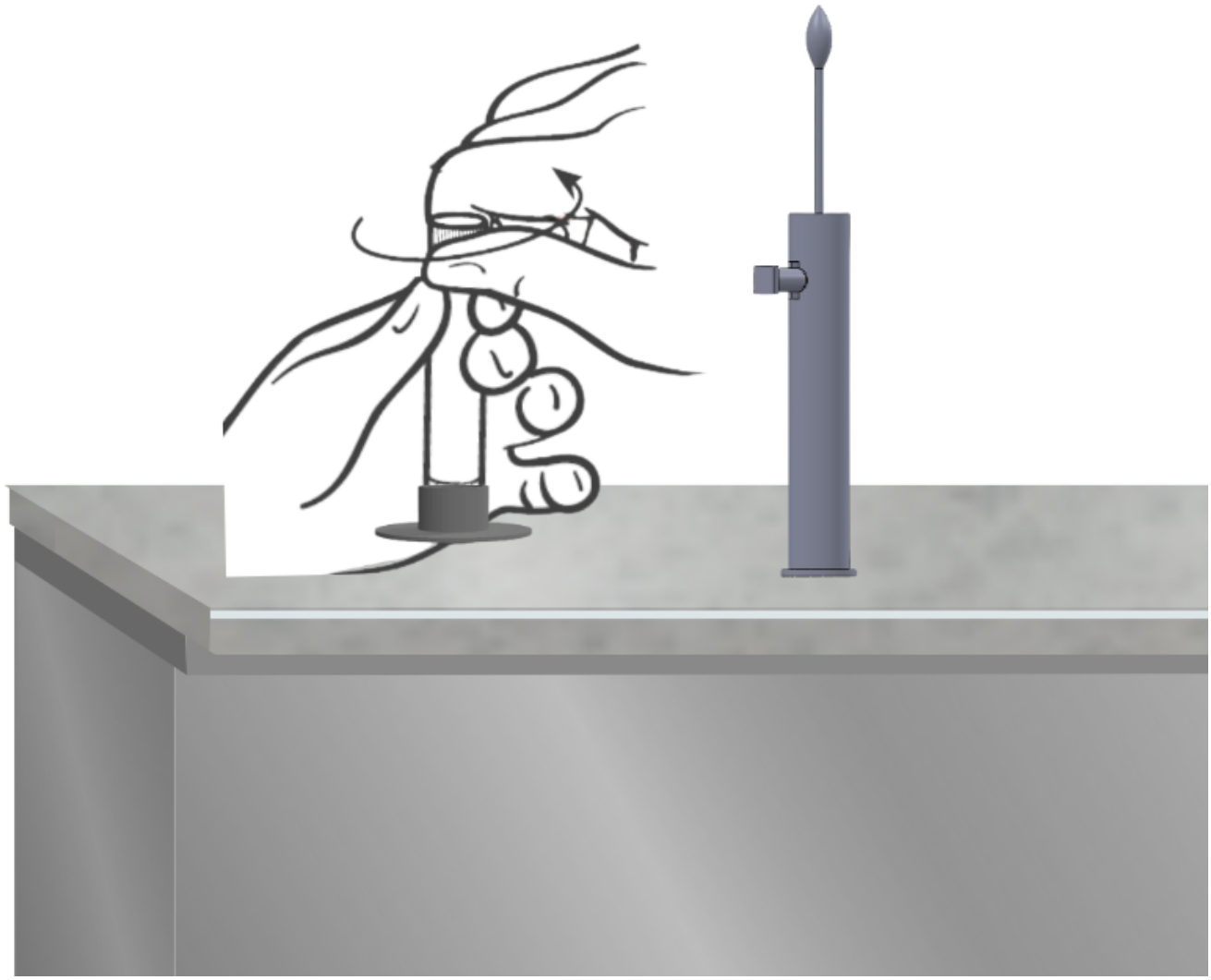




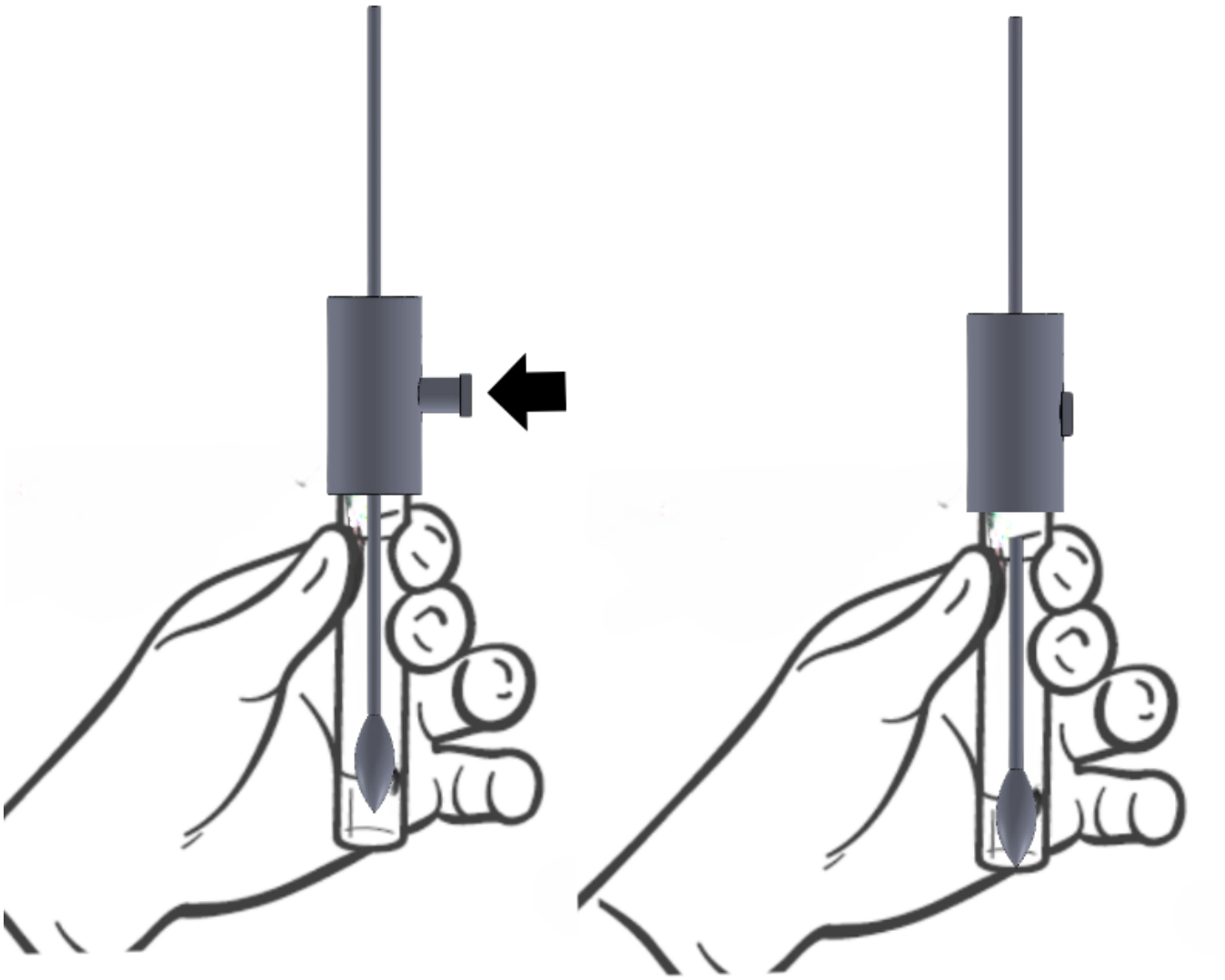
(A) (B)

4. Holding the bottom of the outer plastic casing, carefully insert 2 inches of the Dacron swab into the vagina - marked by the black line.
5. Gently rotate the swab against the vaginal walls for 10-30 seconds.
6. Remove the swab from the vagina

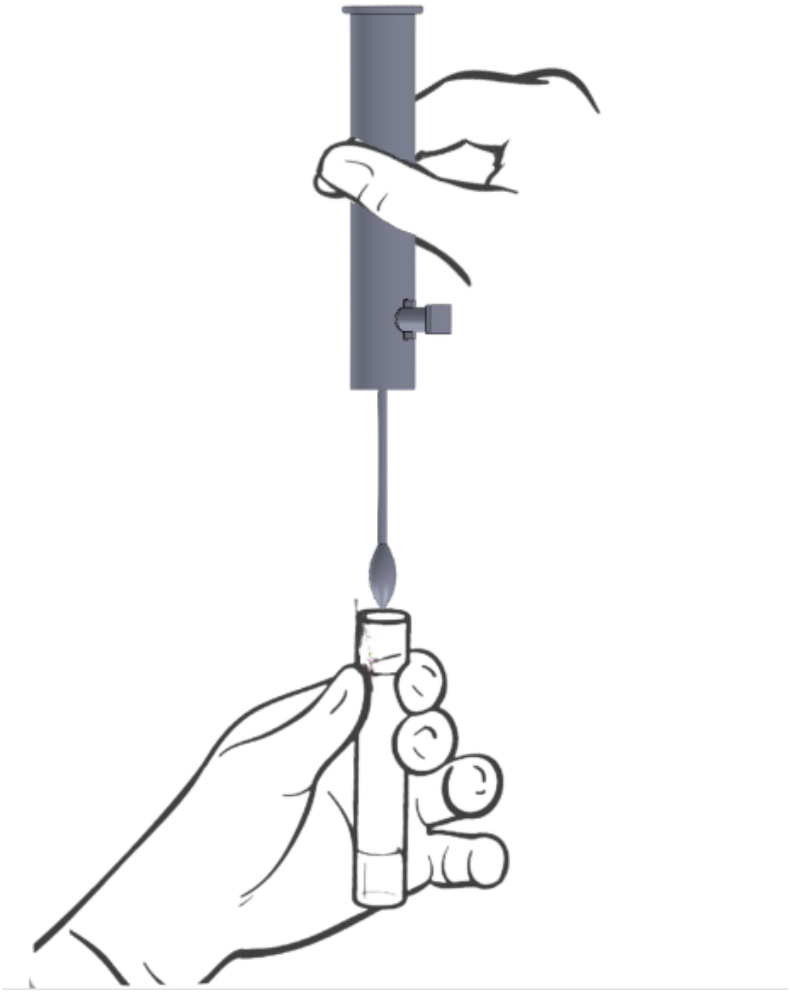
7. Prototype A: Set the device down on the counter. Keeping the media test tube in the holder, remove the cap and set it

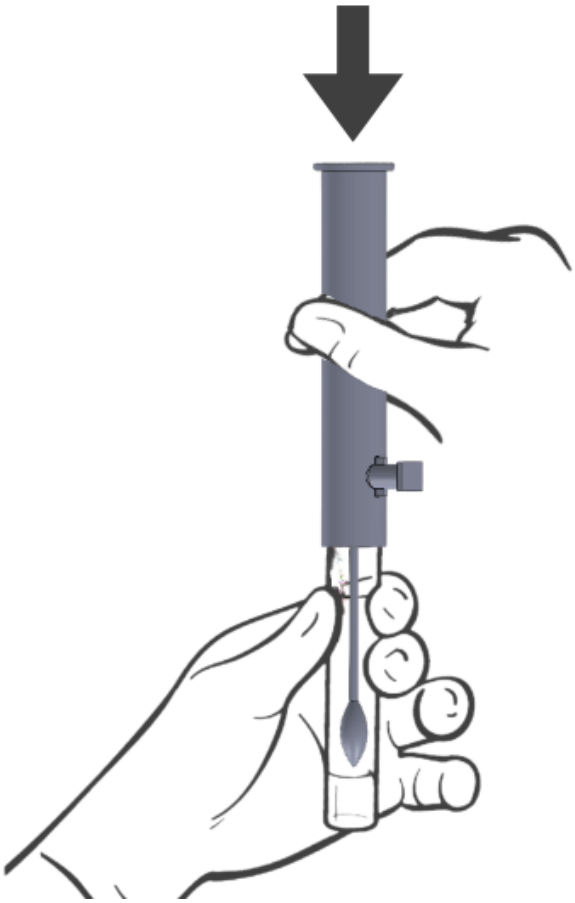


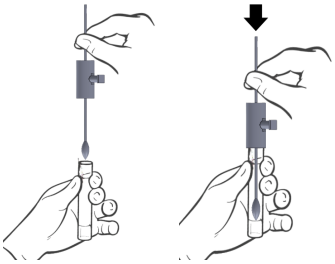
Prototype B: Hold the device in your hand. Keeping the media test tube in its holder, remove the cap and set it down on the counter.



8. Flip the device upside down and attach it to the test tube by firmly pressing the device over the opening of the tube.

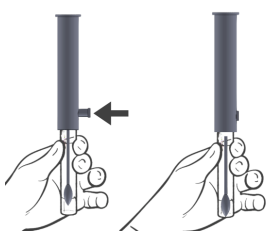


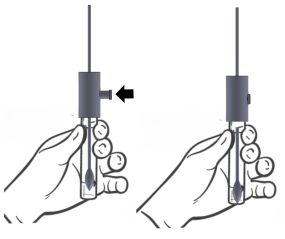




(A) (B)

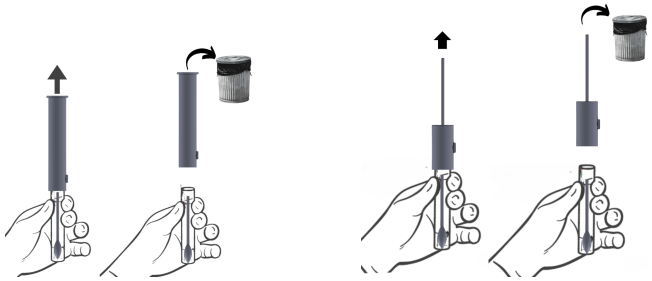
9. Press the button on the side of the device to break the swab.





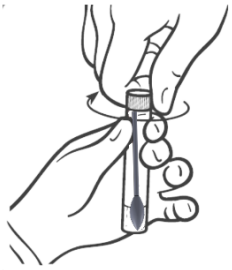
(A) (B)

10. Remove the device from the test tube by pulling up on the device. Discard the removed part of the device.



(A) (B)

11. Firmly screw the original cap to the test tube back on.



12. Wash hands.

Survey Questions: LINK TO SURVEY: https://forms.gle/NbnJDXw4ExQzvGZD9

1. Please open the document linked here for background information.
2. Instructions
3. Which prototype would you feel more comfortable using when conducting a vaginal self-swab in a clinic?
    1. Prototype A - Longer device
    2. Prototype B - Shorter device
    3. Other
4. On a scale of 1-5, how visually appealing is prototype A?
5. On a scale of 1-5, how visually appealing is prototype B?
6. On a scale of 1-5, how effective do you think the device is at limiting contamination?
7. Do you feel that the instructions effectively taught you how to use the device?
    1. Yes
    2. No
    3. Other
8. After reading over the instructions, how comfortable would you be with breaking off the swab using a push-button?
9. After reading over the instructions, do you think that screwing the device onto the media test tube would be more effective than just “sliding” it over with a friction fit?

10. Would you be able to use the instructions for either of the prototypes to conduct an STI swab test?
    1. Yes, with the help of a healthcare provider.
    2. Yes, after a demonstration from a healthcare provider
    3. Yes, after reading over the instructions I could use this device on my own
    4. No
11. Are there any aspects of either prototype that would discourage you from using the device?
12. Do you have any other feedback for our vaginal self-swab?

Conclusions/action items:

Incorporate the results from the survey into our final prototype and testing section of our final report.

Mechanical Testing Protocol

SARA MOREHOUSE - Apr 30, 2024, 2:54 PM CDT

Title: Swab Mechanical Testing Protocol

Date: 4/12/24

Content by: Adam Berdusco

Present: Cherry Qiu, Sara Morehouse

Goals: To clearly describe the process of testing the swabs in a 3-point bending configuration using an MTS machine.

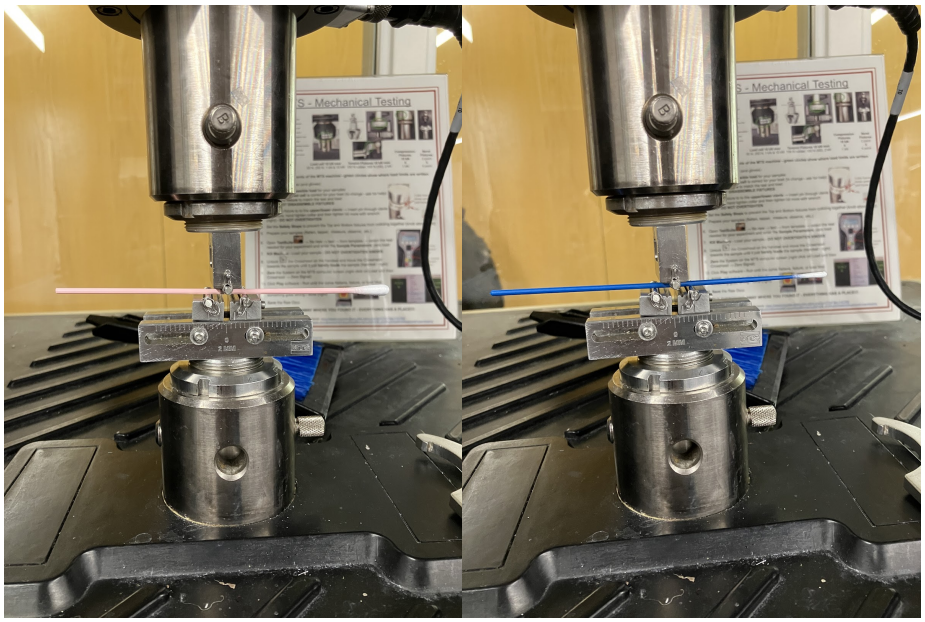
Content:

Project Title: Vaginal Self-Swab To Limit Contact Contamination

Team members: Sara Morehouse, Adam Berdusco, Katherine Kafkis, Cherry Qiu

Date performed: 4/12/24

Pictures of testing setup:



Materials and Costs Table:

Material	Quantity	Purpose	Manufacturer	Part #	Cost	Link
Swab	6	A three point bend test will be done on the swab to determine ins	Hologic	PRD-03546	n/a	https://www.hologic.com/hologic-products/collection-devices/aptima-multitest-swab

1. Log into the computer using the person's CAE account
2. Turn the MTS machine on using the power switch on the back right corner of the machine
3. Ensure the MTS machine is set up of three point bending
    1. Attach load cell - 1kN
    2. Attach 3-point bending fixture

3. Change the distance between supports to 16mm, each 8mm from center location of applied load
4. Open the TW Elite software
5. File→ New “Test From Template”
6. Click “Templates”
7. Choose “BME 315 3 Point Bend To Failure”
8. Ensure the control is connected to the program
9. Change the test rate to 2 mm/min
10. Move cross head up using the minute changer
11. Hit kill switch
12. Load the sample into the MTS Machine
13. Position the gripper so that it lightly touches the sample
14. Zero the force load by right clicking on the box and hitting “clear signal”
15. Undo kill switch (the yellow light should turn on)
16. Unlock the Machine again to gain control with the controller (hit lock button twice)
17. Record the gauge length
18. Press the lock button on the controller again to control the machine with the computer
19. Zero both the meters for load and for cross-head displacement with “clear signal”
20. Press the green play button and enter the diameter of sample
21. Hit OK
22. Watch graph and data collection until sample fails and graph beings to fall
23. Hit the red stop button
24. Press Return to Zero
25. Right-click on the Test Run and export raw data
26. Choose what path to export the data
27. Hit Export
28. Hit kill switch
29. Unload sample
30. Take a picture of graph
31. Repeat with the remaining samples starting at step 2
32. Clean up machine and station after all samples have been tested

Conclusions/action items:

The testing was successful. See results under "Experimentation" for more information about specific results.

Tipping Testing Protocol

SARA MOREHOUSE - Apr 30, 2024, 2:56 PM CDT

Title: Tipping Testing of Media Tube

Date: 4/22/24

Content by: Cherry Qiu

Present: Cherry Qiu, Katherine Kafkis

Goals: To describe the process of testing the angle of tipping required for the transport media tube to fall over with and without the supportive base.

Content:

Project Title: Vaginal Self-Swab To Limit Contact Contamination

Team members: Sara Morehouse, Adam Berdusco, Katherine Kafkis, Cherry Qiu

Date performed: 4/22/24

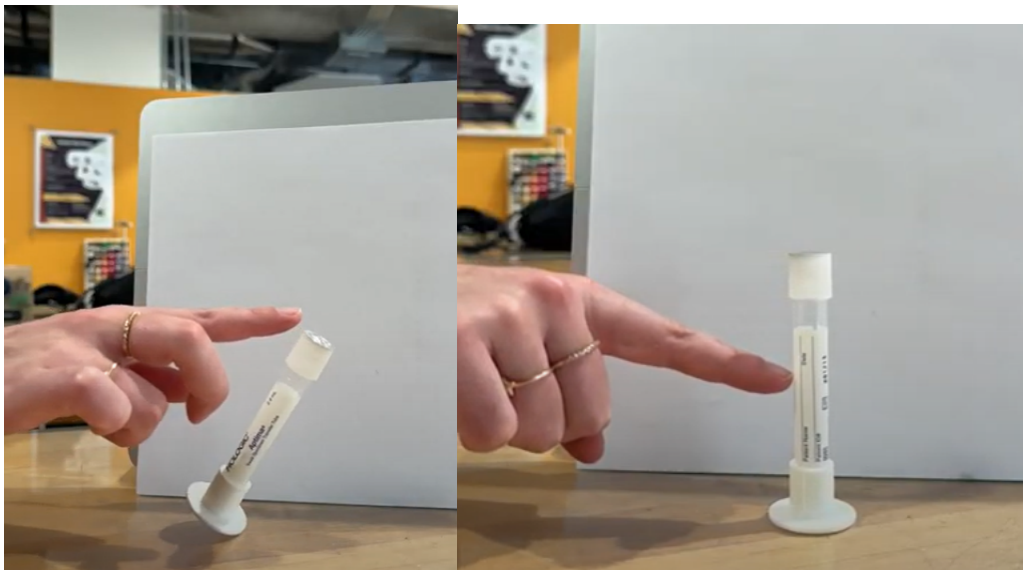
Materials and Cost Table:

Material	Quantity	Purpose	Manufacturer	Part #	Cost	Link
Aptima Hologic Tube filled with Media	1	Used to determine stability of Prototyped Base	Hologic	PRD-03546	n/a	https://www.hologic.com/hologic-products/collection-devices/aptima-multitest-swab
Prototype Base	1	Testing the base stability	Makerspace	n/a		n/a

Steps:

1. Place Hologic tube in prototyped base
2. Set up the camera to clearly show the tube and base level in frame.
3. Start recording.
4. Push the tube by the cap until the tube completely tips over.
5. Stop Recording.
6. Repeat steps 2-5 for remaining pushing by the cap tests.
7. Repeat steps 2-6 for pushing the middle of the tube tests.
8. Repeat for the tube without the base.
9. Upload images to ImageJ.
10. Draw a line following the angle of the tube at the tipping point.
11. Measure the angle of the line and record value.

Images of Testing Setup:



Conclusions/action items:

The testing was successful. See results under "Experimentation" section.

Final Prototype Instruction Manual

KATHERINE KAFKIS - May 01, 2024, 6:14 PM CDT

Title: Final Prototype Instruction Manual

Date: 4/23/24

Content by: Katherine Kafkis

Present: n/a

Goals: To modify the instruction manual so it just highlights the final prototype.

Content: see attached PDF

Conclusions/action items:

Include this instruction manual in the final report.

KATHERINE KAFKIS - May 01, 2024, 6:16 PM CDT

Description: The above prototype is designed to limit contamination when collecting vaginal self-swabs for STI testing. The prototype houses the Dacron swab that is to be inserted into the vaginal canal, rotated for 10-30 seconds, and then transferred into a media-containing tube for diagnostic testing. The transfer process for this design uses bending to break the swab, with the top of the device tightly fitting over the top of the media tube. As seen in the above figure, there is a push-button that aligns with a perforated point on the Dacron swab. When this push-button is pressed inward, the swab is forced to bend and will ultimately break.

Instructions:

1) Wash hands.
2) Remove the media test tube from its packaging and place it in the stand as shown:

3) Remove the device from its sterile packaging and hold it as shown

Download

Prototype_Instruction_Manual.pdf (665 kB)

Contamination Testing Updated Protocol and Results

SARA MOREHOUSE - Apr 20, 2024, 4:00 PM CDT

Title: Contamination Testing Updated Protocol and Results

Date: 4/17/2024

Content by: Sara Morehouse

Present: team

Goals: To test the ability of the prototype to limit contamination of the testing environment.

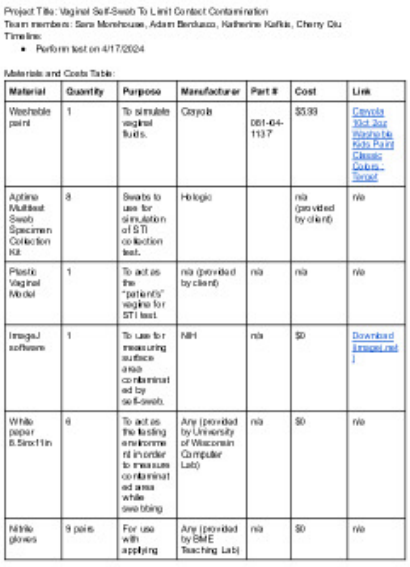
Content:

see attached pdf.

Conclusions/action items:

The test was successful. Results are summarized in attached pdf.

SARA MOREHOUSE - Apr 20, 2024, 4:00 PM CDT



Project Title: Vaginal Self-Swab To Limit Contact Contamination
Team members: Sara Morehouse, Adam Berdusco, Katherine Kaffka, Cherry Du
Timeline:

- Perform test on 4/17/2024

Materials and Costs Table:

Material	Quantity	Purpose	Manufacturer	Part #	Cost	Link
Washable paint	1	To simulate vaginal fluids.	Crayola	051-64-1137	$3.99	Crayola 10ct Jbr Washable Kids Paint Classic Colors - Target
Aptima Multitest Swab Specimen Collection Kit	8	Swabs to use for simulation of STI collection test.	Hologic		n/a (provided by client)	n/a
Plastic Vaginal Model	1	To act as the "patient's" vagina for STI test.	n/a (provided by client)	n/a	n/a	n/a
ImageJ software	1	To use for measuring surface area contaminated by self-swab.	NIH	n/a	$0	Download ImageJ.pdf
White paper 8.5inx11in	8	To act as the testing environment in order to measure contaminated area while swabbing	Any (provided by University of Wisconsin Computer Lab)	n/a	$0	n/a
Nitrile gloves	9 pairs	For use with applying	Any (provided by BME Teaching Lab)	n/a	$0	n/a

Download

Contamination_Testing_Protocol.pdf (913 kB)

Survey Results

KATHERINE KAFKIS - Apr 25, 2024, 10:47 PM CDT

Title: Survey Results

Date: 4/18/24

Content by: Katherine Kafkis

Present: N/A

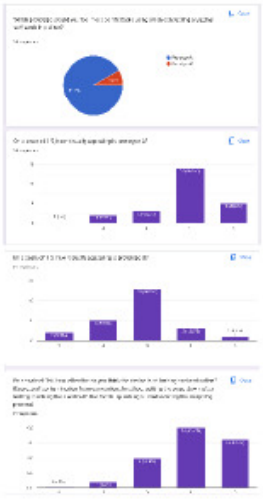
Goals: To gather the relevant results from the survey that should be included in the poster and final report.

Content: see attached pdf

Conclusions/action items:

Based off the survey results, the longer design is to be the ultimate final prototype. The instructions should be modified to only highlight the longer design and the results from the survey should be incorporated into the poster presentation.

KATHERINE KAFKIS - Apr 25, 2024, 10:47 PM CDT



Download

Survey_results.pdf (260 kB)

Mechanical Testing Results

SARA MOREHOUSE - Apr 30, 2024, 2:59 PM CDT

Title: Mechanical Testing of Swab Results

Date: 4/12/24

Content by: Adam Berdusco, Cherry Qiu

Present: n/a

Goals: To process data from mechanical testing and describe the results.

Content:

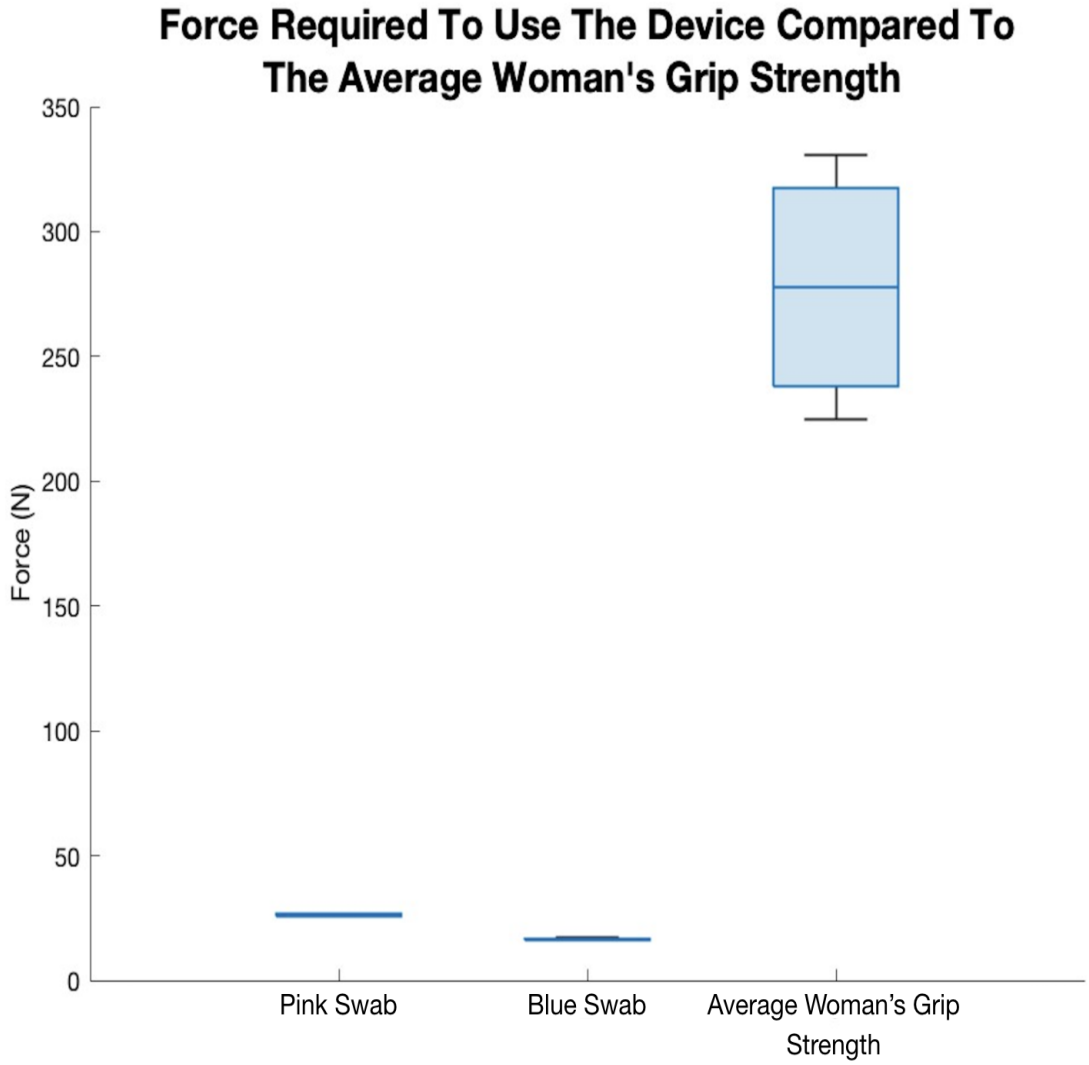
Test #	Swab	Notes	Force Required to Break (N)
1	Pink		25.45
2	pink		26.96
3	pink		26.62
4	blue	when it failed, it bent and started to press down on the fixture and an increased load was recorded	15.94
5	blue	when it failed, it bent and started to press down on the fixture and an increased load was recorded	16.97
6	blue	when it failed, it bent and started to press down on the fixture and an increased load was recorded	16.67

Mean hand-grip force of healthy young adult females: 277.8 ± 52.8 N

Maximal hand-grip force of healthy young adult females: 329.4 ± 57.7 N

Source: https://doi.org/10.1007/s00421-006-0351-1

[1] D. Leyk et al., “Hand-grip strength of young men, women and highly trained female athletes,” *European Journal of Applied Physiology*, vol. 99, no. 4, pp. 415–421, Dec. 2006, doi: https://doi.org/10.1007/s00421-006-0351-1. [Accessed: Apr. 21, 2024]



Conclusions/action items:

These results indicate that the swabs used in the device require minimal force to break in 3-point bending - approximately 20 Newtons. Compared to the average woman's grip strength, which is around 275 N, the force required to break the swabs is minimal and well within reason. This tells us that the device should be able to break the swabs in the current 3-point bending configuration.

Tipping Testing Results

SARA MOREHOUSE - Apr 30, 2024, 3:01 PM CDT

Title: Tipping Testing Results

Date: 4/22/24

Content by: Cherry Qiu

Present: n/a

Goals: To describe the results of the tipping testing performed.

Content:

Results

Test	Point of Contact	Tipping Angle Measured from the Horizon (Degrees)	Notes
1	Cap	56.78	
2	Cap	64.58	
3	Cap	61.99	
4	Middle	49.61	Tube stayed upright with applied force for a couple of seconds before beginning to tip.
5	Middle	57.01	Tube stayed upright with applied force for a couple of seconds before beginning to tip.
6	Middle	58.56	Tube stayed upright with applied force for a couple of seconds before beginning to tip.
7	Middle	83.7	No base
8	Middle	84.35	No base
9	Middle	81.16	No base
10	Cap	85.96	No base
11	Cap	86.58	No base
12	Cap	87.8	No base

Test	Mean (degrees)	Standard Deviation (degrees)
Cap with base	61.10	3.24
Middle with base	55.06	3.91
Cap without base	86.78	0.936
Middle without base	83.07	1.69

Conclusions/action items:

These results tell us that the base/stand that we designed for the media tube is successful in making it more difficult to tip the tube over. This means that it is less likely for the media tube to tip over and spill during testing, which should reduce the potential for contamination during testing.

4/29/24 - PDS

KATHERINE KAFKIS - Apr 29, 2024, 10:58 PM CDT

Vaginal Self-Swab Device to Minimize Contact Contamination

Product Design Specification

Client: Dr. Jean Riquelme
Advisor: Dr. Megan McClean
TA: Stephen Foley
Lab 303

Sara Morehouse (Leader)
Cherry Qiu (Communicator)
Katherine Kafkis (BWIG and BSAC)
Adam Berdusco (BPAG)

Date: February 8, 2024

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PDS_Spring_2024_1_.pdf (234 kB)

Preliminary Report

KATHERINE KAFKIS - Apr 29, 2024, 10:59 PM CDT

Vaginal Self-Swab Device to Minimize Contact Contamination

Preliminary Report

Client: Dr. Jean Riquelme
Advisor: Dr. Megan McClean
TA: Stephen Foley
Lab 303

Sara Morehouse (Leader)
Cherry Qiu (Communicator)
Katherine Kafkis (BWIG and BSAC)
Adam Berdusco (BPAG)

Date: March 6, 2024

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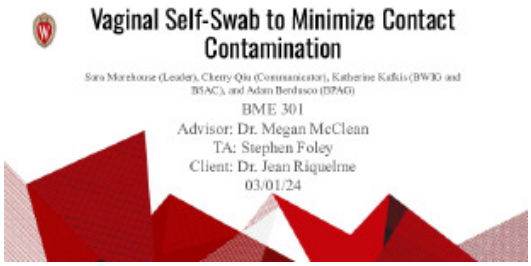
Preliminary_Report_3_.pdf (509 kB)

Preliminary Presentation

KATHERINE KAFKIS - Apr 29, 2024, 11:00 PM CDT



Download

Vaginal_Self-Swab_Preliminary_Presentation_2_.pdf (1.45 MB)

Executive Summary

KATHERINE KAFKIS - Apr 29, 2024, 11:01 PM CDT

301 - Excellence - 38 - Vaginal Self Swab Device - Executive Summary.pdf

According to the CDC, Chlamydia is the most frequently diagnosed bacterial sexually transmitted infection (STI) in the United States, affecting an estimated 1 in 20 young women from ages 14-24, with 43% of these women accounting for undiagnosed cases. Intravaginal self-swab STI testing has been found to increase the likelihood of routine testing and diagnosis, with one study conducted at the University of Pittsburgh's School of Medicine in 2011 finding 84% of women to prefer the self-swab method and 94% feeling more willing to routinely test for STIs through a self-swab. While self-swab testing methods appear to promote universal testing, the current self-swab testing method employed by most clinics introduces great potential for contamination of the testing environment.

Conventional vaginal self-swab STI tests provide patients with a Dacron swab and a test tube filled with chlamydia transport media to collect their specimens. This process requires patients to hold the swab in their hand, insert the Dacron swab 5 cm into the vaginal canal, rotate it for 10-30 seconds, and then transfer it into the media tube for diagnostic testing. The transfer process requires patients to physically break the swab into the media tube at a perforation point which can cause media or vaginal fluids to splash onto and contaminate surfaces. The contamination of surfaces has led to false positives, with one study conducted in 2020 at the Skaraborg Hospital's Department of Clinical Microbiology in Sweden finding 67% of women to receive a false positive due to surface contamination.

A modified testing device has been developed to limit the contamination of the testing environment during STI self-testing. The proposed method utilizes a device that houses and breaks the Dacron swab while limiting contamination via the external casing. The device firmly holds the plastic shaft of the Dacron swab, leaving the upper 6.5 cm available for specimen collection. The interior of the device contains 2 points of contact with the swab, one above and one below the swab's perforation point. The exterior of the device contains a push button that aligns with the perforation point - forming a three-point bend mechanism to break the swab. To use the device for self-swabbing, a patient holds the outer housing of the device and inserts the swab 5 cm into the vagina. After rotating the swab against the vaginal walls for 10-30 seconds, the patient removes the swab and places the device on the table with the swab tip in the air, providing the patient time to collect themselves after specimen collection. The patient then unscrews the top of the provided media tube while it stands in a supportive base, picks up the device, and pushes the device over the opening of the media tube where it is firmly held in place via a friction fit such that the head of the Dacron swab is submerged in the media. To break the swab and transfer it into the tube, the patient presses the button on the exterior of the device causing the swab to break and fall into the media. They then remove the device and re-cap the media tube, which can be sent to the lab for processing. The use of the external casing should limit contamination as it allows patients to safely set the device down and prevents vaginal fluids or media from being spilled or transferred to surfaces during the swab collection process.

Validation of this device's ability to reduce contamination is to be conducted via a cervical model coated with an invisible ink. Both the conventional method and the proposed device will be used to complete a mimetic self-swab on the model, with the spreading of the invisible ink being used to quantify the contamination of each method. The force required to break the swab will also be determined in a three-point bend test on an MTS machine. This test will be used to optimize the 3-point bending configuration which should require the least amount of force. The test will also be used to provide patients with intuition on the amount of force to be applied to the button. A survey is to be sent out to students within the BME design curriculum to gather data on the aesthetics, usability, and instructions fabricated for the device. Feedback from the survey will be readily incorporated into the device and its instruction manual. Altogether, the device offers a simple modification to the current STI self-swabbing process and successfully limits contamination of the testing environment by improving the ergonomics of the process of sample collection. By doing so, this novel device holds the potential to streamline STI testing and further promote universal testing to decrease rates of STIs across the population.

Download

301_-_Excellence_-_38_-_Vaginal_Self_Swab_Device_-_Executive_Summary.pdf (69.9 kB)

Final Poster Presentation

KATHERINE KAFKIS - Apr 29, 2024, 11:00 PM CDT

Download

Vaginal_Self-Swab-38-Poster_1_.pdf (1.1 MB)

1/31/2024 Towards sustainability for medical devices and consumables: The radical and incremental challenges in the technology ecosystem

SARA MOREHOUSE - Feb 01, 2024, 11:55 AM CST

Title: Towards sustainability for medical devices and consumables: The radical and incremental challenges in the technology ecosystem

Date: 1/31/23

Content by: Sara Morehouse

Present: n/a

Goals: To learn more about the possibility of choosing a more sustainable material for our device.

Search Term: "compostable materials for single use medical devices", Google

Citation: [2]S. Hinrichs-Krapels, J.-C. Diehl, N. Hunfeld, and E. van Raaij, “Towards sustainability for medical devices and consumables: The radical and incremental challenges in the technology ecosystem,” Journal of Health Services Research & Policy, vol. 27, no. 4, pp. 253–254, Jun. 2022, doi: https://doi.org/10.1177/13558196221110416.

Content:

- The market for medical devices prioritizes safety and infection control
- packing is laminated which makes it difficult to separate for recycling
- Single-use devices are prioritized --> however, no compelling evidence that it reduces healthcare-acquired infections
- There is a need and opportunity for evidence to demonstrate that it is not unsafe to reuse/recycle
- Hospitals seek to optimize efficiency and minimize cost when purchasing medical devices
- Hospital waste is usually incinerated rather than recycled

Conclusions/action items:

This article gave a background on what happens to medical waste and the reasons as to why there is not more recycling of medical waste being done. From here, I plan to look more into specific materials that can be used for medical devices that are recyclable or compostable.

SARA MOREHOUSE - Feb 01, 2024, 11:55 AM CST

Editorial

Towards sustainability for medical devices and consumables: The radical and incremental challenges in the technology ecosystem

SAGE

There is global recognition that health care is one of the most carbon-intensive sectors, accounting for 4.4% of global net greenhouse gas emissions and toxic air pollutants.[1] The International Panel on Climate Change and the World Health Organization have made a call to action to reduce health care's ecological impacts,[2] while 14 countries have pledged to develop carbon-neutral health systems.[3] In practice, this will mean reducing emissions from buildings and major infrastructure, encouraging public transport for staff and patients, reducing waste in hospitals, and using the 'purchasing power' of the health sector as a large purchaser of high-carbon products (including medical devices and consumables).

Purchasing environmentally sustainable medical devices and consumables is a worthwhile goal, but the realities of achieving this are challenging and require a better evidence base on, at the very least, further thinking and nuanced guidance. In this editorial, we follow the life of a medical device, equipment, or consumable from design and manufacture, to purchase, use and disposal to demonstrate key challenges and opportunities in achieving environmental sustainability within the wider technology ecosystem.

Design, manufacture and regulation

While external targets and incentives (such as extended producer responsibility policies) are generally moving towards environmentally sustainable manufacturing, part of the challenge is that the market for medical devices (rightly) prioritises safety and infection control. As a result, for example, consumables often have laminated packaging that are difficult to separate for recycling. The use of single-use devices or consumables over reusable ones has also been a subject of debate: single-use have been prioritised for decades but there is no compelling evidence that they reduce health care–acquired infections.[4] Disposable or single-use medical devices increase confidence, but also promote the consumption of raw materials and the creation of waste. This reliance has become a barrier for manufacturers to design sustainably, despite motivations to do so. There is an opportunity for industry and researchers to create the evidence base that demonstrates that reusing, remanufacturing or recycling is not necessarily unsafe. This can influence the regulatory landscape, allowing new devices to be decommissioned on the market, and create new business models in which consumables and devices can be repurposed and delivered back to the hospital, or at least integrated into closed-loop supply chains.

Purchasing and acquisition

Previous work has advocated the 'purchasing power' or leverage the health sector can use to influence suppliers.[5] However, there is not yet a solid evidence base on how purchasing functions in healthcare organisations can be improved, let alone whether they can be designed to include sustainability as a purchasing criterion. In a comprehensive review of literature of materials logistics in hospitals, studies focus on optimising efficiency and minimising cost,[6] and this is echoed by a study comparing medical device purchasing across five countries that found that there is more focus on cost-containment and less on quality and health outcomes.[7] One study focusing on the purchase of MRI scanning equipment found that environmental and social sustainability dimensions were 'personally relevant but professionally secondary to cost, performance, and ability to use the equipment in their organizations' physical infrastructure.'[8p418] Creating a strong evidence base for what is possible in improving environmentally sustainable hospital purchasing will be needed. This will balance any existing priorities and trade-offs in individual purchasing decisions (for example, between patient safety, cost, and environmental sustainability) and create new business models for suppliers, such as leasing contracts for equipment or 'pay per scan' models.[9]

Use, reuse, reduce or refuse

While measures such as the use of washable instead of single-use gowns could be regulated through standardised purchasing, others require behavioural changes by clinicians and nursing staff (for example, whether they choose to use gloves or disinfect their hands, or the frequency with which gloves are replaced). Behaviours, habits, and protocols once a product is in use can also drive or hinder environmental sustainability. This implies we also need behavioural research into how products are used once

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hinrichs-krapels-et-al-2022-towards-sustainability-for-medical-devices-and-consumables-the-radical-and-incremental.pdf (466 kB)

1/31/23 Design Engineers' O-Ring Size Guide

SARA MOREHOUSE - Jan 31, 2024, 11:34 PM CST

Title: "Design Engineers' O-Ring Size Guide"

Date: 1/31/23

Content by: Sara Morehouse

Present: n/a

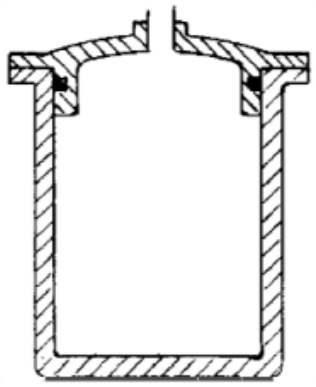
Goals: To better understand how o-rings work in order to create a compression seal and to understand how the correct size needed is calculated.

Search Term and Database: "o ring sizing for compression seal", Google

Citation: [1]“Design Engineers’ O-Ring Size Guide,” *www.pressureseal.com*. https://www.pressureseal.com/orings/oguide.pdf (accessed Jan. 31, 2024).

Content:

- you will need a different o-ring size depending on if the o-ring is sealing a liquid that has a low volume swell on the ring or a high volume swell on the ring
- Our device with the plunger and body would qualify as a static radial seal similar to the image below: where the black squares represent the cross-section of the o-ring



- Steps for choosing a ring for this design include finding an o-ring with an outer diameter closest to the inner diameter of the vessel

Conclusions/action items:

This guide was most helpful as it showed me what a compression seal with an o-ring looks like, so I can help to design this component within our device. Also, it will be helpful in the future for deciding the correct size of an o-ring to use as it has a lot of size and dimension tables with recommendations for each type of seal. We can use this to pick the correct size ring once we update our design to incorporate the grooves.

SARA MOREHOUSE - Jan 31, 2024, 11:34 PM CST

PRESSURE SEALS, Inc. 81 Commerce Way, South Windsor, CT 06074

DESIGN ENGINEERS' O-RING SIZE GUIDE

INTRODUCTION:

Substantially all O-ring manufacturers present their catalog data in the rotation of "groupings" or "families" of cross-sectional thickness first, then followed by dimensions of inside diameter. All sizes with 1/16" nominal wall are listed first, followed by rings with 3/32" wall, then 1/8" wall, etc. This is the same mode of presentation found in the AR® 568 Uniform-Numbering System, published as the Aeronautical Recommended Practice Report of the Society of Automotive Engineers. The same practice of detailing sizes by cross-sectional "families" is found in government specifications AN 6227, AN 6230, MS 9021, MS 15993, MS 28775, MS 29513, etc.

HEADACHE FOR DESIGN ENGINEERS:

A frequent result of this established mode of O-ring size presentation is the laborious task of "plowing through" several sections of specification data. In actuality, the design engineers usually are involved first with the outside or inside diameter in a sealing application before they want to make a determination as to what wall thickness or cross-sectional diameter of rubber seal they wish to consider in their design.

RESCUE OPERATIONS:

Many O-ring applications, of course, involve metal parts turned out on lathes and screw machines. Inevitably, some large production runs are found beyond tolerance. The established O-ring size will not perform its sealing function. Many dollars worth of expensive metal and material go down the drain. However, the resourceful design engineer can rescue the situation oftentimes by the use of a special size O-ring.

CIRCLE SIZE ROTATION:

We acknowledge gratefully the advice given to us by many design engineers that circle diameters are much more significant to them as their first level of consideration. In this GUIDE we have listed all Pressure Seals' O-rings, for which high production tooling is available, in progressive order by outside diameter first, followed next by inside diameter, and then by wall thickness or cross-section. The first three columns are in the regular English inch system to the nearest thousandth of an inch. In the same order, the data is repeated in the metric system. The final right-hand column gives the catalog number for ordering purposes, and the catalog page on which tolerances are

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oguide.pdf (1.3 MB)

2/1/24 Preparation and Characterization of Biodegradable Plastics Out of Food Wastes as Prospective and Eco-Friendly Medical Devices

SARA MOREHOUSE - Feb 01, 2024, 1:05 PM CST

Title: "Preparation and Characterization of Biodegradable Plastics Out of Food Wastes as Prospective and Eco-Friendly Medical Devices"

Date: 2/1/24

Content by: Sara Morehouse

Present: n/a

Goals: To learn about what is available for biodegradable/compostable plastics for use in medical devices.

Search Term: "Compostable plastic medical device", Google Scholar

Citation: [3]R. Mukhopadhyay, K. Divya Sree, and R. Saneeha, “Preparation and Characterization of Biodegradable Plastics Out of Food Wastes as Prospective and Eco-Friendly Medical Devices,” *International Journal for Research in Applied Science & Engineering Technology*, vol. 5, no. 12, pp. 134–142, Dec. 2017.

Content:

- plastics are petrochemical-based polymers, resistant to microbial degradation
- Biodegradable plastics degrade naturally by microbial action and much faster than petro plastics
- can be derived from things like cornstarch, pea starch, fruit/vegetable peels, vegetable fats/oils
- starch is a natural biopolymer, consists of amylose and amylopectin primarily
    - Ratio of amylose to amylopectin affects physical/chemical properties of the starch
- Techniques such as shearing, temperature, and plasticization during starch extrusion allow for a melted thermoplastic material to be created.
- using food waste that is rich in starch
- One such biodegradable plastic that can be 3D printed with is Biome3D - look into more later
- This article describes numerous methods for making bioplastics from easily-accessible materials such as banana peels, potatoes, corn starch, agar
- They tested the bioplastic materials for tensile strength, water permeability and water resistance, biodegradability (specifically halophilic degradability and soil biodegradability)
- the toughest materials were produced from corn starch and agar
- The composites were heat-sensitive, non-microwaveable, insoluble in water, insoluble in acids
- They state that if the bioplastics are fragile, as they found with the ones they made, that it can be dried, powdered, and colored to use for 3D printing

Conclusions/action items:

This article was really interesting and I thought it was fascinating how easily they made bioplastics from everyday waste products. While we would need a more tried/well-tested plastic for our device, it suggests to me that there is likely people out there who are 3D printing or injection molding with bioplastics such as these. I am going to look more into this as this is something that I would like to improve about our design.

Download

fileserve.php.pdf (5.56 MB)

2/1/24 About the Use of Recycled or Biodegradable Filaments for Sustainability of 3D Printing

SARA MOREHOUSE - Feb 01, 2024, 6:40 PM CST

Title: "About the Use of Recycled or Biodegradable Filaments for Sustainability of 3D Printing"

Date: 2/1/24

Content by: Sara Morehouse

Present: n/a

Goals: To better understand the use of compostable plastics in 3D printing - is it feasible for us to incorporate this in our project at this time?

Search Term: "compostable 3D print", Google Scholar

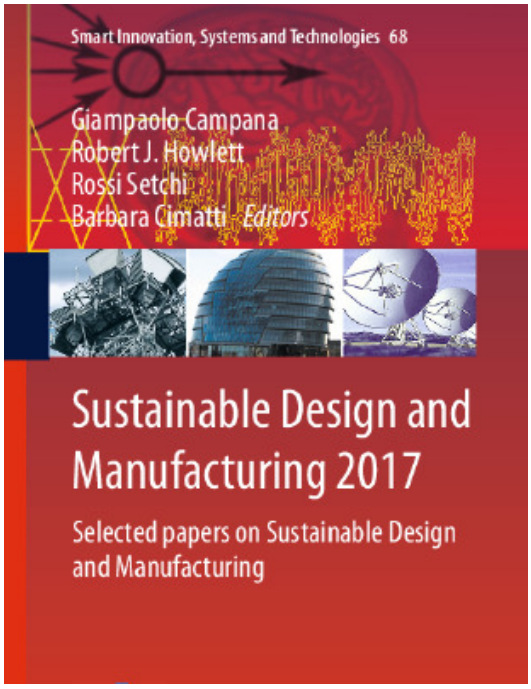
Citation: [4]J. Pakkanen, D. Manfredi, P. Minetola, and L. Iuliano, “About the Use of Recycled or Biodegradable Filaments for Sustainability of 3D Printing,” Sustainable Design and Manufacturing 2017, vol. 68, pp. 776–785, 2017, doi: https://doi.org/10.1007/978-3-319-57078-5_73.

Content:

- Bioplastics are derived from renewable sources (sugars and natural fibers)
- Fused Deposition Modeling (FDM) is known as 3D printing - it is low cost, and has a lot of potential for what can be printed, however it generates a lot of waste if material is not recycled.
- Estimates suggest that in the best case where efficiency and improvements are made, additive manufacturing can lead to 5% energy and CO2 emission savings by 2025
- There is however a lot of waste and excess material from supports/scraps in 3D printing
- There a currently a lot of polymeric materials available for 3D printing
- Requirements for FDM materials:
    - must have a low melting point
    - must have a reduced viscosity in order to flow out of the nozzle
    - It is key to have the proper extrustion temperature so that the right viscosity is achieved
- the most commonly used materials include: ABS, PLA, PC, PA, HDPE, PET, TPU (PLA is technically biodegradable and recyclable but requires recycling facilities, it won't degrade in your backyard if you bury it in soil)
- Other biodegradable plastic filaments used include: PHA, PVA, PET, and HIPS
- Instead of purely plastic filaments, bio-composite filaments are also available:
    - consist of a biodegradable polymeric matrix and bio-based fillers
    - fillers are fibers or particles - variable content up to 40%
    - filler can be sawdust, cellulose, other natural fibers
- potato and soy-based filaments have been developed as well
- use of fillers decreases the mechanical properties of the 3D prints - increase melt viscosity so get issues with flowability, fusion of layers, porosity, swelling
- As far as improving the sustainability of 3D printing, the thermoplastic scraps can be reused as new feedstock for printing (however my thoughts are that the likelihood of this happening with medical waste is zero)
- Should try to do one or two recycling cycles of materials

Conclusions/action items:

This article was somewhat helpful. It gave me a better understanding of the basics of 3D printing and how plastic selection works. However, it didn't talk about compostable materials which is really what I was interested in/looking for, so I will keep looking for more info on that.



978-3-319-57078-5.pdf (137 MB) pp. 776-785

2/8/24 Injection Molding of Medical Plastics

SARA MOREHOUSE - Feb 08, 2024, 11:27 PM CST

Title: "Injection Molding of Medical Plastics"

Date: 2/8/24

Content by: Sara Morehouse

Present: n/a

Goals: To understand the process of injection molding and how it is used in the medical device industry

Search Term: Injection molding medical devices, google scholar

Citation: [1]Karim Amellal, Costas Tzoganakis, A. Penlidis, and G. L. Rempel, “Injection molding of medical plastics: A review,” vol. 13, no. 4, pp. 315–322, Jan. 1994, doi: https://doi.org/10.1002/adv.1994.060130407.

Content:

- (The source is from 1994 so not super up to date but some of the information is still relevant)
- The process requires a cavity that is filled with molten polymer
- then once the cavity is full then extra polymer is injected in to account for possible shrinkage of the polymer as it hardens
- The molded part is allowed to cool and then the part is ejected
- Almost all plastic medical devices are injection molded
- Material properties to consider include chemical resistance, water absorption, oxygen transmission, elasticity, impact strength, and deflection temperature
- Two common sterilization techniques for medical devices include ionizing radiation (gamma radiation or electron beam) and ethylene oxide gas

Conclusions/action items:

This article was helpful to just get a background understanding of what injection molding is but was not very recent so further research will be required.

SARA MOREHOUSE - Feb 08, 2024, 10:54 PM CST

SPECIAL REPORT

Injection Molding of Medical Plastics: A Review

KARIM AMELLAL, COSTAS TZOGANAKIS*, ALEXANDER PENLIDIS, and GARRY L. REMPEL

ABSTRACT

Introduction

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Adv_Polym_Technol_-_Winter_1994_-_Amellal_-_Injection_molding_of_medical_plastics_A_review.pdf (779 kB)

SARA MOREHOUSE - Feb 08, 2024, 11:29 PM CST

read next:

Rapid and Low-cost Prototyping of Medical Devices Using 3D Printed Molds for Liquid Injection Molding (wisc.edu)

Common thermoplastics in injection molding - BMPMedical - Plastic Injection Molding Services Massachusetts

2/8/24 How to Design an O-Ring Gland: Compression

SARA MOREHOUSE - Feb 08, 2024, 11:28 PM CST

Title: "How to Design an O-Ring Gland: Compression"

Date: 2/8/24

Content by: Sara Morehouse

Present: n/a

Goals: Better understand how to design a compression seal

Search Term: Compression seal o-ring, Google

Citation: [1]“How to Design an O-Ring Gland: Compression,” www.gallagherseals.com. https://www.gallagherseals.com/blog/how-to-design-an-o-ring-gland-compression (accessed Feb. 09, 2024).

Content:

$$Percent\ Squeeze = \frac{d_{CS} - t_{gland\ depth}}{d_{CS}} \times 100$$

Formula for Squeeze

- Want less squeeze for dynamic applications and more squeeze for static applications
- want zero percent compression set (want the o-ring to completely recover after the seal is released)
- A higher force is required to seal the hardware for a higher squeeze
- Can design a lead-in chamfer between 15-20 degrees to decrease the necessary compression force

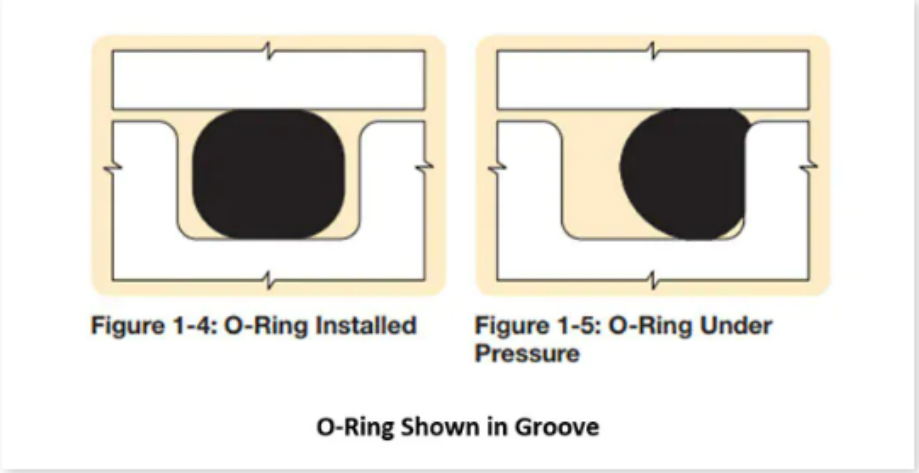


Figure 1-4: O-Ring Installed

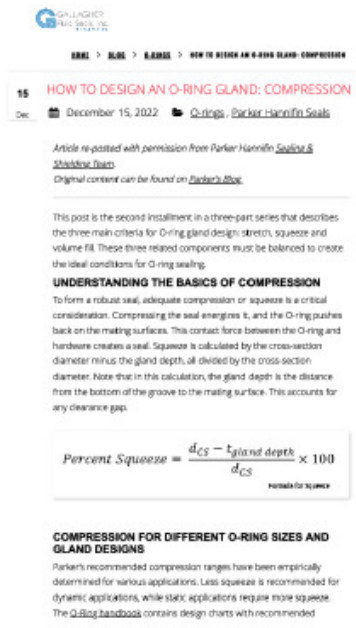
Figure 1-5: O-Ring Under Pressure

O-Ring Shown in Groove

Conclusions/action items:

This was helpful to understand some of the calculations behind designing an o-ring compression seal, and to visualize the seal.

SARA MOREHOUSE - Feb 08, 2024, 11:25 PM CST



HOW TO DESIGN AN O-RING GLAND: COMPRESSION

15 Dec December 15, 2022 O-rings , Parker Hannifin Seals

Article re-posted with permission from Parker Hannifin Sealing & Shielding Team.
Original content can be found on Parker's Blog.

This post is the second installment in a three-part series that describes the three main criteria for O-ring gland design: stretch, squeeze and volume fill. These three related components must be balanced to create the ideal conditions for O-ring sealing.

UNDERSTANDING THE BASICS OF COMPRESSION

To form a robust seal, adequate compression or squeeze is a critical consideration. Compressing the seal energizes it, and the O-ring pushes back on the mating surfaces. This contact force between the O-ring and hardware creates a seal. Squeeze is calculated by the cross-section diameter minus the gland depth, all divided by the cross-section diameter. Note that in this calculation, the gland depth is the distance from the bottom of the groove to the mating surface. This accounts for any clearance gap.

$$Percent\ Squeeze = \frac{d_{CS} - t_{gland\ depth}}{d_{CS}} \times 100$$

formula for squeeze

COMPRESSION FOR DIFFERENT O-RING SIZES AND GLAND DESIGNS

Parker's recommended compression ranges have been empirically determined for various applications. Less squeeze is recommended for dynamic applications, while static applications require more squeeze. The O-Ring handbook contains design charts with recommended

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o-ring.pdf (885 kB)

2/29/24 Hologic Panther Research

SARA MOREHOUSE - Feb 29, 2024, 10:12 PM CST

Title: Hologic Panther Research

Date: 2/29/24

Content by: Sara Morehouse

Present: n/a

Goals: To learn more about the machine used to process STI samples and how it works.

Link: Panther® System | Hologic

Content:

- fully automated system for running assays
    - all you have to do is load samples and they will run themselves.
    - can run multiple tests from the same sample at the same time
    - Load primary sample tubes directly into the machine
    - Can run overnight
    - Can run over 1000 tests in 24 hours
    - Can automatically generate reports

Conclusions/action items:

This was helpful to better understand what the Hologic Panther is, and how it is used in the lab and why exactly we need to redesign our device to work with this system. It is very efficient and it doesn't make sense to disrupt this system, so we need to find a way to work within the system.

Design Idea - No Plunger

SARA MOREHOUSE - Feb 14, 2024, 6:09 PM CST

Title: Design with no Plunger

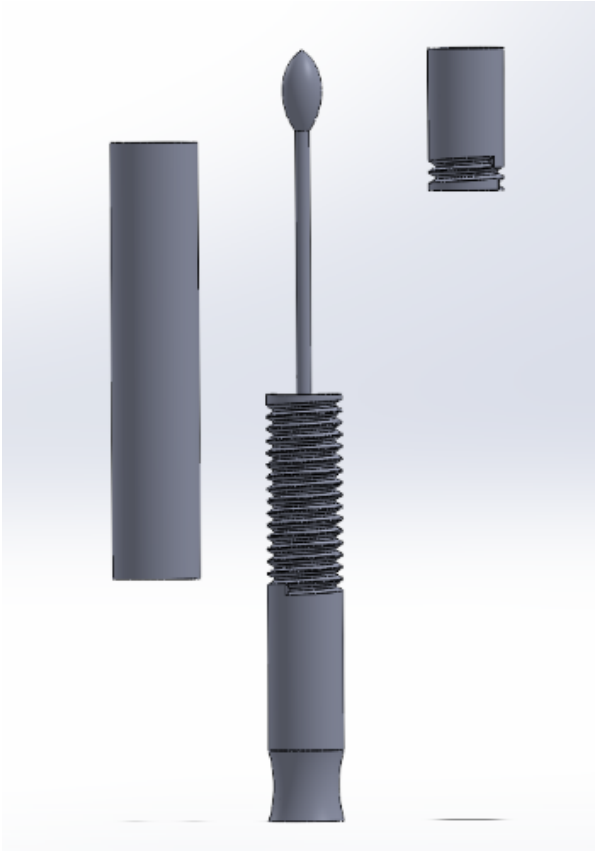
Date: 2/14/24

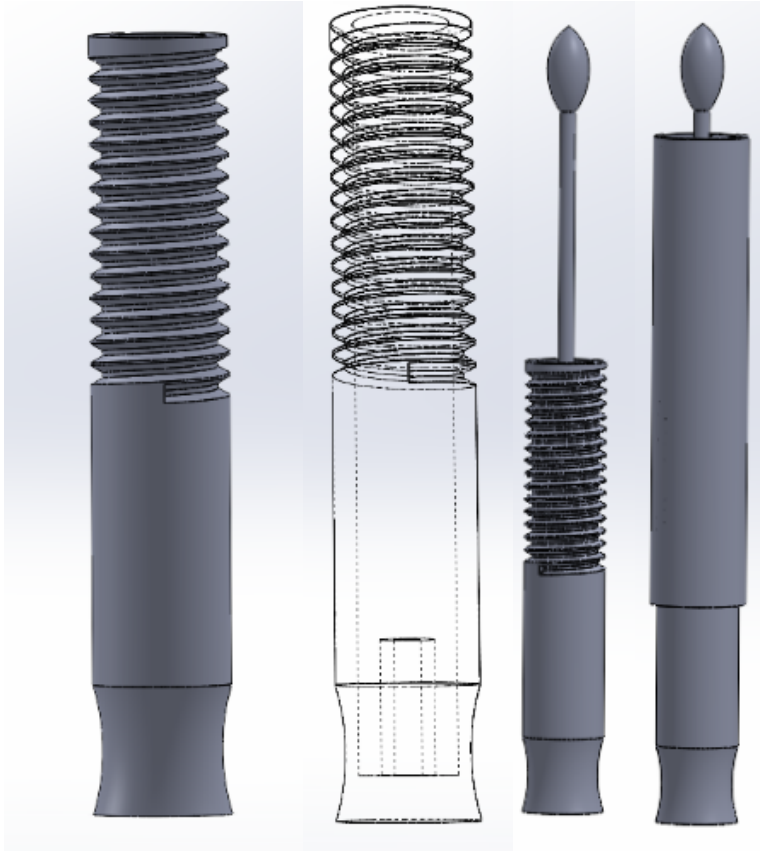
Content by: Sara Morehouse

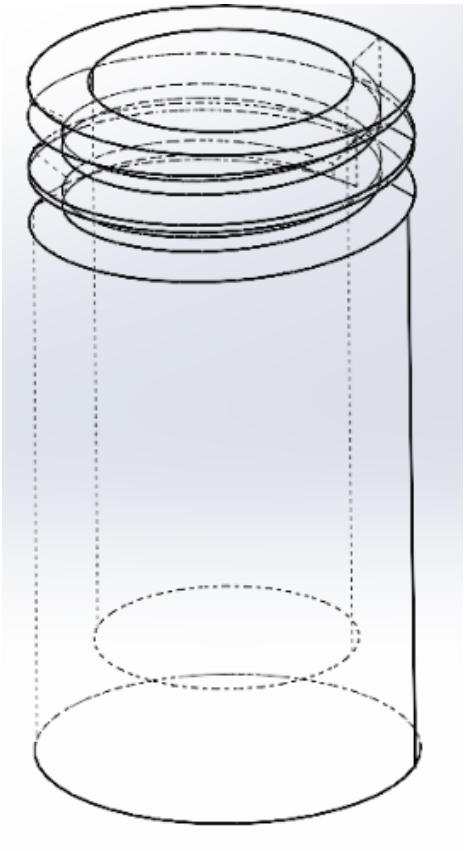
Present: n/a

Goals: Describe a new design idea

Content:







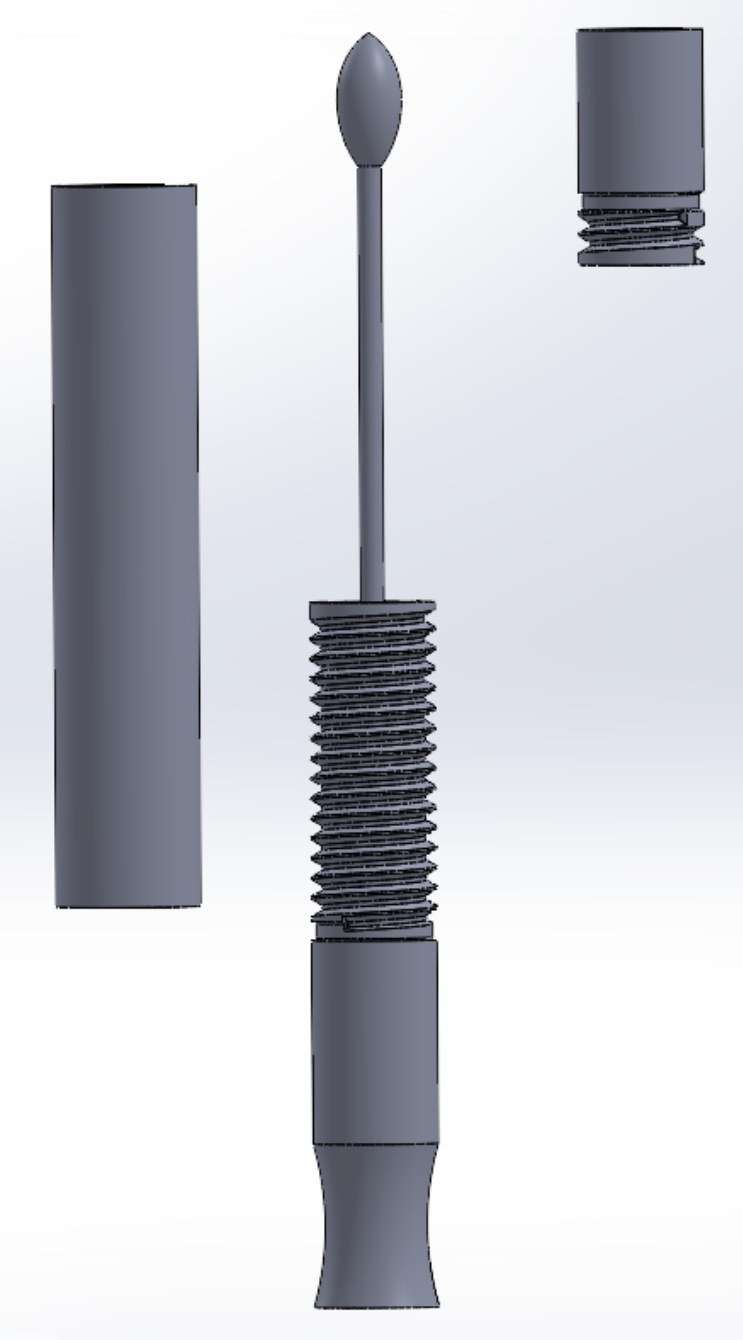
all components (base with swab, middle cap, top cap with media base^ base ^(transparent) base ^with swab, base ^with middle cap media^ top cap(transparent)

Consists of a base with a grooved grip on the bottom with the swab sticking out. Then the media component is screwed on to the cap at the top, and the cap/media combination is screwed onto the base to contain the device.

Conclusions/action items: Need to add o-ring on the base piece below the threading and on the top cap piece above the threading.

SARA MOREHOUSE - Feb 15, 2024, 1:33 PM CST

Added o-ring grooves on the base piece and the media cap piece. Also added an offset on the threading of the middle piece to add space for the o-ring



SARA MOREHOUSE - Feb 15, 2024, 1:37 PM CST

Evaluations of this design:

- improved sealing mechanism with the o-rings on the top and bottom

- simpler design with no plunger

- might be harder to fabricate with 3D printing but can try resin printing or machining the grooves

- would limit contamination well as all the patient has to do is screw the middle cap on (because it comes connected to the media cap already)

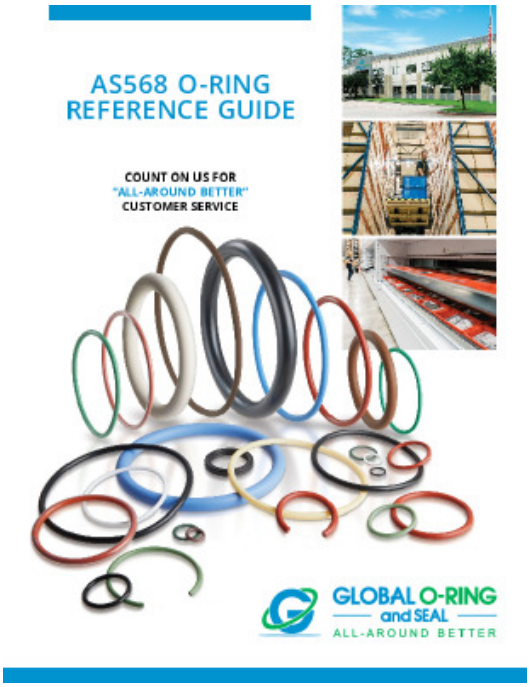
- should be simple to use then also

- safety - no more or less safe than the old design. Could say that it is safer because it won't leak

- cost - smaller amount of material so cheaper than the old design

O-ring

SARA MOREHOUSE - Feb 23, 2024, 12:37 PM CST



Download

Global_O-Ring_AS568_Guide.pdf (1.49 MB)

SARA MOREHOUSE - Feb 23, 2024, 12:38 PM CST

Date: 2/23/24

By: Sara Morehouse

Content: This is an o-ring guide and has the sizing/dimensions/tolerance of a bunch of o-ring sizes, and contains the specific one that my SolidWorks design uses.

Conclusions: Print designs, test with this o-ring

Button Cutter

SARA MOREHOUSE - Mar 11, 2024, 10:19 PM CDT

Title: Button Cutter Design

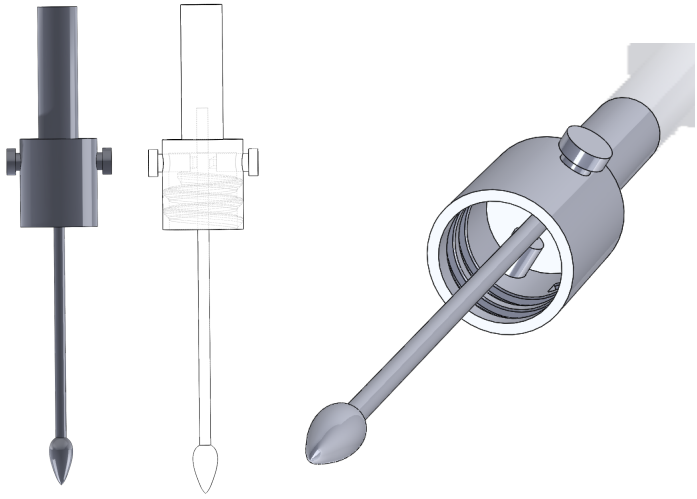
Date: 3/11/24

Content by: Sara Morehouse

Present: team

Goals: To come up with a modified design to account for the need to incorporate the Aptima tube.

Content:



Conclusions/action items:

Need to discuss designs/get feedback, get help with the cutter mechanism

1/31/24 - Compostable Materials in Flexible Tampon Applicators

Title: Compostable materials for the manufacturing of flexible tampon applicators

Date: 1/31/24

Content by: Katherine Kafkis

Present: N/A

Goals: To learn about materials that may be more environmentally friendly to be incorporated into our design as it will be a one-time-use product and add to medical waste.

Search Terms: ScienceDirect - "degradable biopolymers"

Citation: G. Cappiello, C. Aversa, and M. Barletta, “Design of compostable materials for the manufacturing of flexible tampon applicators,” *Procedia CIRP*, vol. 110, pp. 342–347, 2022, doi: https://doi.org/10.1016/j.procir.2022.06.061.

Content:

- Plastic tampon applicators contribute to single-use plastic waste.
  - Improper disposal of plastic applicators, particularly those made of polyethylene (PE), leads to environmental problems due to their low biodegradability
- Compostable Bioplastics:
  - Bioplastics derived from renewable sources, such as polylactic acid (PLA), have reduced carbon emissions and are biodegradable
  - PLA Properties:
    - Good stiffness and strength (we have previous research on the mechanical properties)
    - PLA has drawbacks such as poor processability and brittleness, which can be addressed through blending with other polymers like polybutylene adipate terephthalate (PBAT) or polybutylene succinate (PBS).
    - Adding minerals or natural fibers to bioplastic blends can enhance mechanical properties and processability.
- Polymer Selection:
- - PLA (Polylactic Acid):
    - Grade L105 from Total Corbion PLA,
    - selected for its low molecular weight (important for injection molding)
    - Melt flow index (MFI) of 50g/10 min (indicates its flowability characteristics)
  - PBS (Polybutylene Succinate):
    - Grade FZ71 from MCC Biochem
  - PBAT (Polybutylene Adipate Terephthalate):
    - Grade C1200 from BASF selected for its compatibility with PBS and mechanical properties.
- Polymer Blends:
  - A. PLA/PBS Binary Blend
    - Ratio of 1:4 (PLA to PBS) chosen to balance brittleness of PLA with flexibility of PBS.
    - Incorporation of drop structure intended to enhance flexibility and mitigate PLA's brittle behavior.
  - B. PLA/PBS Blend with Preponderance of PLA
    - Added more PLA
  - C. PLA L105 Mixed with PBAT
    - Combination aimed at achieving high elongation at break and low modulus of elasticity similar to thermoplastic elastomers.
    - PBAT's properties expected to complement PLA L105 for mechanical performance.
  - D. PBS/PBAT Blend with Predominance of PBS
    - Intended to maintain desired mechanical properties while minimizing potential drawbacks of PBAT content increase.
- Additives:
  - HAR W 92 Micro-Lamellar Talc (Imeris Talc, Switzerland):
    - Added to all formulations to enhance mechanical properties and processing characteristics.
  - PDLA Luminy D070 (Total Corbion PLA):
    - Added to promote crystalline content in PLA fraction through stereo-complex formation with PLLA in PLA L105.
  - Process and Product Additives:
    - Included to facilitate compounding and molding processes, ensuring consistency and quality in final product.

process.

Nomenclature

PLA: Poly Lactic Acid
PBS: Poly Butylene Succinate
PBAT: Poly Butylene adipate terephthalate
MFI: Melt Flow Index
DSC: Differential scanning calorimetry

Materials	Type	#A	#B	#C
PLA L105	Polymer	16	64	16
PBAT C12	Blend-polymer	0	0	62
PBS FZ71	Blend-polymer	62	15	0
Talc	Mineral filler	18	17	18
PLA-D070	Crystallization promoter	0,8	0,8	0,8
BPMS-265	Melt strenght enhancer	2	2	2
Joncryl	Chain extender	0,2	0,2	0,2
EBS	Slip agent	1	1	1

2. Experimental

- Materials were extruded without drying treatment through a corotating twin-screw extruder.
  - Parabolic temperature patterns were kept within the extrusion barrel, with the head temperature increased to prevent obstructions.
  - Optimal temperatures were set to facilitate incorporation between powder additives, mineral filler, and melt polymer phase.
  - Made from the extruded compound using a benchtop injection molding machine
    - we would need to make a mold and find somewhere to do injection molding
  - **NOTE: We could reach out to one of the labs in Engineering, my old CBE 320 professor does polymer extrusion in his lab so I could send him an email to see if he has injection molding machine**
- Thermal Characterization:
  - Thermo-rheological properties were analyzed using a DSC3 calorimeter under a nitrogen atmosphere.
  - Measured enthalpies of melting, cold crystallization, and crystallinity
  - Crystalline fraction of each polymer phase was calculated using standard molar enthalpy of fusion values

- Heat Deflection Temperature (HDT) Test:
  - The HDT/V-1113 machine was used to determine the deflection temperature under load (DTUL) according to ISO 75-B method.
  - Specimens were loaded with 8 gram weights and immersed in oil before testing.
- Izod Impact Test:
  - The Izod impact test was conducted to determine notch toughness using an impact pendulum.
  - Specimens identical to those used in the HDT test were used.
  - followed ISO 180
- Tensile Test:
  - Used an MTS machine and performed according to ISO 527-2-1A
- Process parameters, including thermal profile and injection pressure, ensured successful processing of the formulations without degradation, shrinkage, or adhesion to the mold.
  - Formulations A, C, and D exhibited good processability during molding, with formulation D being particularly successful and not requiring silicone spray for mold extraction.
  - Formulation B, with a higher PLA content, experienced some molding issues, resulting in fragile applicator petals and breakages during extraction.

Figure 2 Molded applicators realized with A, C and D formulations

  -
  - **NOTE: Now that I'm thinking about tampons we could fix the wobbliness of our plunger by tapering the bottom of the body of the device inward, like the design of a tampon.**
- Thermal Analysis (DSC Results):
  - The results showed the formation of a two-phase system due to polymer incompatibility.
  - Subzero glass transition temperatures were observed for formulations A, C, and D due to the presence of PBS and PBAT.
  - nucleating agents influenced the crystalline fractions differently in each material.
- Heat Deflection Temperature (HDT):
  - A and D had higher thermal resistance due to their PBS-rich polymer matrix.
  - A exhibited the highest HDT, while B and C had lower values influenced by the PLA polymer phase.

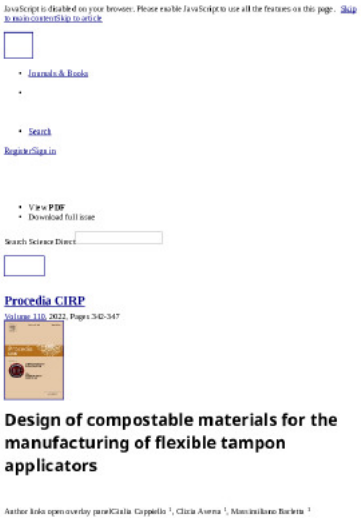
Mechanical Properties:

- high toughness for all samples
  - D had the highest toughness because of the PBS and PBAT.
  - B showed moderate toughness .
- D had the highest elastic modulus, followed by B and A.

Conclusions/action items:

Look into mechanisms to do injection molding on campus, especially with a compostable polymer as that would help reduce the waste from single-use plastics in the medical field. Continue rese
biopolymers and injection molding. Discuss tapering the bottom of the body of the device (like a tampon applicator) with the team to reduce the wobbling of the plunger.

KATHERINE KAFKIS - Jan 31, 2024, 11:30 PM CST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Procedia CIRP

Volume 110, 2022, Pages 342-347

Design of compostable materials for the manufacturing of flexible tampon applicators

Author links open overlay panel Giulia Coppiello [1], Clizia Aversa [1], Massimiliano Barletta [1]

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2/1/24 - Injection Molding: Polypropylene Polymer

KATHERINE KAFKIS - Feb 02, 2024, 12:47 AM CST

Title: Injection molding. Influence of process parameters on mechanical properties of polypropylene polymer. A first study.

Date: 2/1/24

Content by: Katherine Kafkis

Present: N/A

Goals: To better understand how injection molding a polymer may impact the material's mechanical properties.

Search Term: ScienceDirect - Injection Molding Polymers

Citation: E. Farotti and M. Natalini, “Injection molding. Influence of process parameters on mechanical properties of polypropylene polymer. A first study.,” *Procedia Structural Integrity*, vol. 8, pp. 256–264, 2018, doi: https://doi.org/10.1016/j.prostr.2017.12.027.

Content:

- The primary objective is to assess the mechanical properties of a commercial PP polymer.
- A specialized mold is manufactured to facilitate quasi-static and dynamic standard tests on polymeric specimens.
- Pressure and temperature sensors are strategically placed near the mold to directly monitor the filling and packing phases of the injection molding (IM) process.
- Controlled input parameters include mold and melt temperatures, packing pressure, and cooling time
- The study exclusively focuses on conducting tensile tests as the primary mechanical evaluation method.
- Injection molding machine specifications:
  - maximum screw stroke: 100 mm
  - maximum injection flow: 146 cm3/s
  - maximum injection pressure: 139 MPa
  - screw diameter: 30 mm
  - maximum clamp force: 50 t

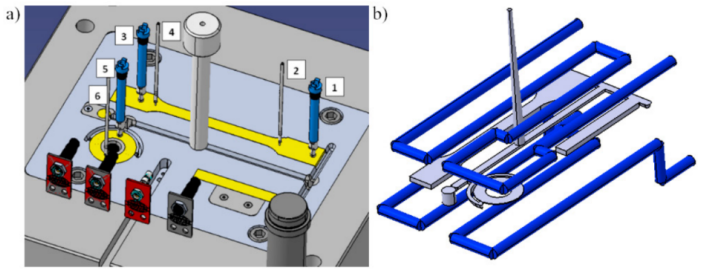

Fig. 2. (a) Possible sensor positions: 1-3-5 pressure, 2-4-6 temperature; (b) Part and cooling channels CAD models

- Polypropylene material properties:
  - density: 905 kg/m3
  - melt flow rate: 20 g/10 min
  - tensile modulus: 1500 MPa
  - tensile strain at yield: 9%
  - tensile stress at yield: 34 MPa
  - Charpy impact strength: 3 kJ/m2

Conclusions/action items:

The material properties of injected molded polypropylene appear to be suitable for the purposes of our design as it doesn't need to withstand any excessive loading. Additional research on the cost of injection molding as well as where we could do this should be considered. As a team, we should look into designing a mold that can be filled with a ploymer as injection molding is likely the production method that would be used in a design like ours. Further research on the types of molds that can be used to set a polymer should be conducted as this paper didn't detail the fabrication of the mold itself.

KATHERINE KAFKIS - Feb 01, 2024, 7:35 PM CST

AIAS 2017 International Conference on Stress Analysis, AIAS 2017, 6-9 September 2017, Pisa, Italy

Injection molding. Influence of process parameters on mechanical properties of polypropylene polymer. A first study.

E. Farotti**, M. Natalini*

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2/1/24 - Rubber Cover vs O-ring Seal in Syringes

KATHERINE KAFKIS - Feb 01, 2024, 8:17 PM CST

Title: TIME FREQUENCY ANALYSIS OF DYNAMIC SYRINGE FRICTION - THE BENEFITS OF AN O-RING PLUNGER SEAL DESIGN

Date: 2/1/24

Content by: Katherine Kafkis

Present: N/A

Search Terms: Google Scholar - O-rings in medical devices

Citation: “Time frequency analysis of dynamic syringe friction - the benefits of an O-ring plunger seal design | IEEE Conference Publication | IEEE Xplore,” *ieeexplore.ieee.org*. https://ieeexplore.ieee.org/stamp/stamp.jsp?tp=&arnumber=1216118 (accessed Feb. 02, 2024).

Goals: To learn about the types of sealing systems being incorporated in medical devices and the ideal mechanism to be used in our design.

Content:

- Compares the dynamic friction properties of a specific syringe design featuring a 4 lobe, O-ring plunger seal with the traditional rubber cover plunger seal.
- Utilization of the Short Time Fourier Transform (STFT) to examine friction properties

$$S(t,\omega) = \frac{1}{\sqrt{2\pi}} \int s(\tau) h(\tau - t) e^{-j\omega\tau} d\tau \qquad (1)$$

- Focused on investigating the friction behavior at various flow rates
- Each syringe type underwent testing using a universal testing machine, which advanced the piston and plunger through a syringe barrel at linear velocities corresponding to different flow rates (0.5, 1.0, 3.0, 5.0, and 7.0 cm^3/s).
- Groups of five syringes were randomly selected and tested at each flow rate, with the reaction force against the plunger sampled at 167 Hz.
- Spectrograms generated from the friction data revealed distinct differences between the two syringe designs.

Rubber Seal vs O-ring

- The friction exhibited by the rubber cover plunger seal displayed periodic sawtooth function harmonics
- The friction of the O-ring seal plunger appeared smoother, with lower magnitude and lacking discernible periodic harmonic content.
- Analysis of the spectrograms highlighted that the O-ring plunger seal design showcased superior frictional performance compared to the traditional rubber cover design.
- The absence of significant periodic harmonic content in the friction of the O-ring seal suggests reduced stick-slip effects, contributing to smoother operation and potentially improved injection system performance. (Injection performance is not relevant to our design, however, superior friction and leak prevention is)

Conclusions/action items:

Overall, the incorporation of an O-ring to our design would definitely be beneficial to prevent leaking of media out of our design. Further research into how an O-ring should be included in our design should be conducted as it will need to fit snugly around the plunger as well as the swab while still allowing for smooth operation. Plausibly book a meeting with Jesse from the Design Hub to discuss re-working our SolidWorks to include an O-ring.

KATHERINE KAFKIS - Feb 02, 2024, 1:02 AM CST

TIME FREQUENCY ANALYSIS OF DYNAMIC SYRINGE FRICTION – THE BENEFITS OF AN O-RING PLUNGER SEAL DESIGN

I.P. Kalafut

Rubber Cover Plunger Design

4 Lobe, O-Ring Plunger Seal

Download

Time_frequency_analysis_of_dynamic_syringe_friction_-_the_benefits_of_an_O-ring_plunger_seal_design.pdf (189 kB)

2/1/24 -Do Single-Use Biopolymers for Medical Devices Reduce Environmental Considerations of Surgical Procedures.

KATHERINE KAFKIS - Feb 02, 2024, 1:01 AM CST

Title: Single-use Medical devices and biopolymers - Environmental Considerations

Date: 2/1/24

Content by: Katherine Kafkis

Present: N/A

Goals: To better understand the environmental impact of the production of biopolymers and petroleum-based polymers. o cross-reference the findings of a previous paper on PLA biopolymer blends.

Search Terms: PubMed - biopolymer AND sustainability

Citation: S. R. Unger *et al.*, “Do single-use medical devices containing biopolymers reduce the environmental impacts of surgical procedures compared with their plastic equivalents?,” *Journal of Health Services Research & Policy*, vol. 22, no. 4, pp. 218–225, May 2017, doi: https://doi.org/10.1177/1355819617705683.

Content:

Rise of Plastic Use:

- Medical device manufacturers embraced plastics due to their efficiency and cost-effectiveness in production, leading to a surge in plastic usage in healthcare.
- This transition revolutionized medical device manufacturing, usage, and disposal processes, with single-use plastic devices becoming prevalent, replacing reusable items like woven cotton products. This shift also escalated the generation of hospital waste due to the disposable nature of plastic medical devices.
- Studies indicate that polyethylene content in medical devices ranges from 7% to 88% of total weight

Biopolymers:

- Biopolymers, derived from renewable feedstocks, have emerged as an eco-friendly alternative to petroleum-based plastics.
- Recent advancements have enabled biopolymers to mimic the physical properties of synthetic plastics.
- Biopolymers like guayule-derived latex rubber and polylactide (PLA) are viable substitutes for traditional plastics in various medical applications, offering compostable alternatives.
- Using biopolymers may reduce reliance on non-renewable resources and curb hospital-generated waste, especially if biopolymers are composted.

- This study uses a comparative life cycle assessment (LCA) to evaluate single-use medical products containing plastics versus those with biopolymers
- Plastics were substituted with suitable biopolymers based on their physical properties and functional requirements.
    - Guayule-derived latex was chosen as a substitute for nitrile, neoprene, or polyisoprene-containing products
    - PLA replaced LDPE and PP.
    - Thermoplastic starch replaced cardboard
- Environmental and human health impacts resulting from inputs and outputs were evaluated using the Tool for Reduction and Assessment of Chemical and Other Environmental Impacts (TRACI) 2.1.
    - categories: ozone depletion, global warming, smog, acidification, eutrophication, carcinogenics, non-carcinogenics, respiratory effects, ecotoxicity, and cumulative energy demand (CED).

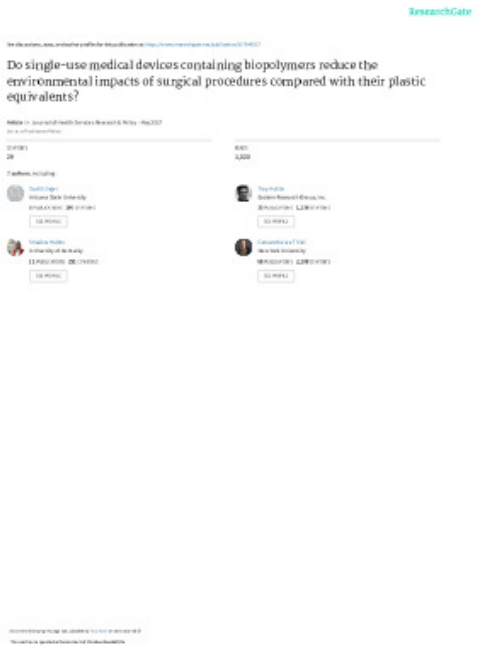
Results:

- Biopolymers showed advantages in several impact categories like acidification, ecotoxicity, carcinogenics, respiratory effects, and CED.
    - Agricultural activities associated with biopolymer manufacturing exacerbated impacts related to global warming, eutrophication, ozone depletion, and smog
- Petroleum-based plastics performed better in categories such as global warming, eutrophication, ozone depletion, and smog.

Conclusions/action items:

The findings of this article appear to demonstrate how biopolymers can be both advantageous and damaging towards the environment, slightly contradicting a previous paper I found. Additional research should be conducted on biopolymers to minimize environmental harm. Additionally, the material used in the design should be able to be manufactured following typical practices for single-use medical devices.

KATHERINE KAFKIS - Feb 02, 2024, 1:05 AM CST



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2/13/24 - Rod Seal O-Ring

KATHERINE KAFKIS - Feb 15, 2024, 5:27 PM CST

Title: Rod Seal O-ring - Necessary Equations

Date: 2/13/24

Content by: Katherine Kafkis

Present: N/A

Goals: To better understand the calculations that should be considered when incorporating an O-ring seal into our design**.**

Citation: "Rod Seal Application Example," *Minnesota Rubber & Plastics*. https://www.mnrubber.com/tools-resources/design-guide/rubber-standard-parts/rod-seal-application-example/ (accessed Feb. 13, 2024).

Content

Seal Groove Diameter:

- Groove Diameter = Min Shaft Diameter + (2 x Dynamic Gland Depth)
- Necessary diameter of the groove where the seal will be placed.

Minimum Gland Cross-sectional Area:

- Minimum Gland Volume = ((Min Groove Dia. – Max Rod Dia. / 2) x Min Groove Width)
- Gives the minimum volume of the groove space available for the seal to fit into.

Maximum Cross-sectional Area:

- Maximum Seal Volume = (Max Quad-Ring Cross-section)^2 x 0.8215
- Gives the maximum volume that the seal can occupy.

Seal Squeeze Calculation:

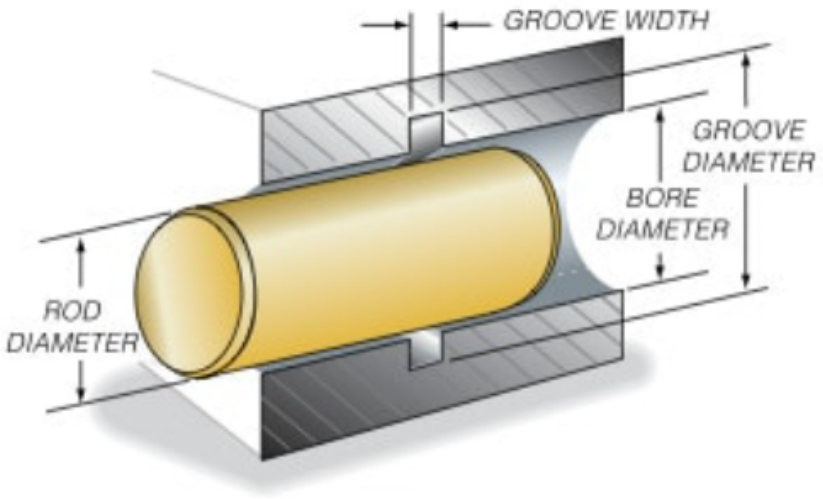
- Max Seal Squeeze = 1 – (Min Gland Depth / Max Seal Cross-section)
    - Calculates the maximum compression that can be applied to the seal.
- Min Seal Squeeze = 1 – (Max Gland Depth / Min Seal Cross-section)
    - Calculates the minimum compression that can be applied to the seal.

Maximum Clearance Calculation:

- Max Radial Clearance = (Max Bore Dia. – Min Rod Dia.) / 2
- Calculates the maximum allowable radial clearance between the rod and bore (tolerance to be included in the design so that it can still slide)

Installed Seal Stretch Calculation:

- Stretch % = ((Installed Seal ID – Original Seal Inside Diameter) / Original Seal Inside Diameter) x 100
- Percent the seal diameter stretches when installed compared to its original diameter.



Conclusions/action items:

Attempt to design an O-ring seal that is similar to the one in the figure. Pick out two O-rings and then modify the design to include an O-ring seal at the bottom of the device and near the cap.

2/14/24 - Modified Plunger Design with O-ring and New Cap

KATHERINE KAFKIS - Feb 15, 2024, 5:36 PM CST

Title: Updated Plunger Design

Date: 2/14/24

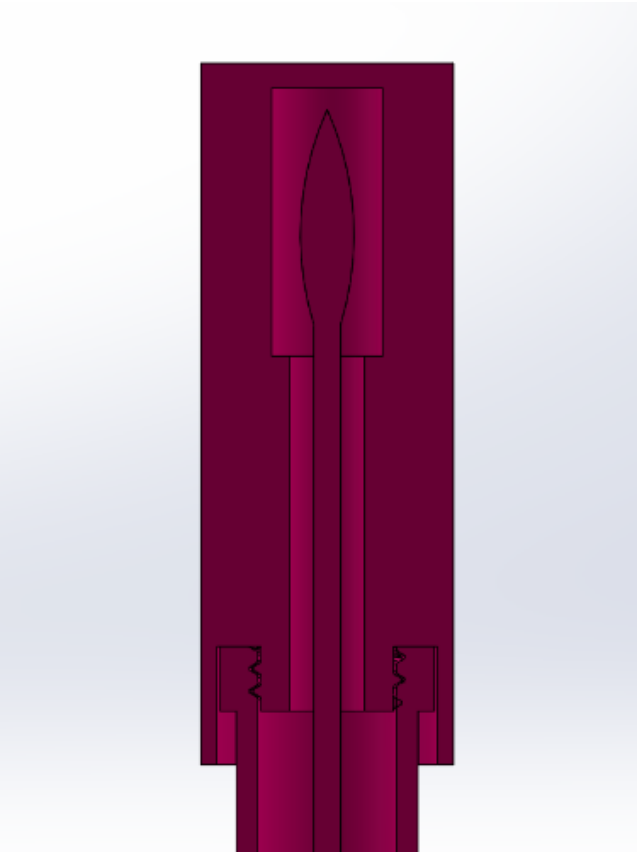
Content by: Katherine Kafkis

Present: N/A

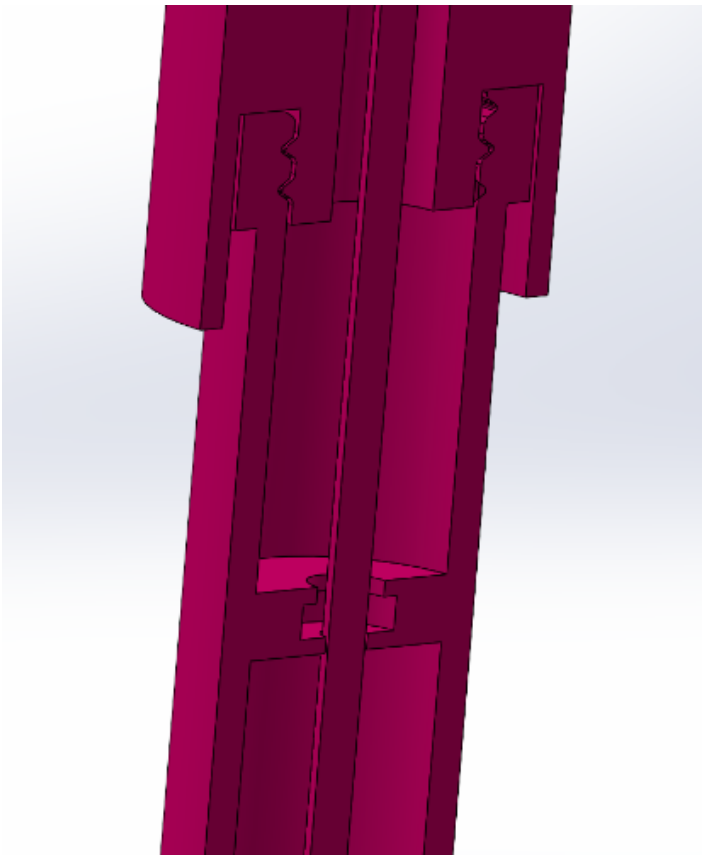
Goals: To modify the existing device such that it is thinner, has the cap screwing into the inside of the device, and has two sites for O-ring attachment to prevent leaking and promote sealing at the bottom of the device.

Content:

- Cap that screws onto the inside of the device:

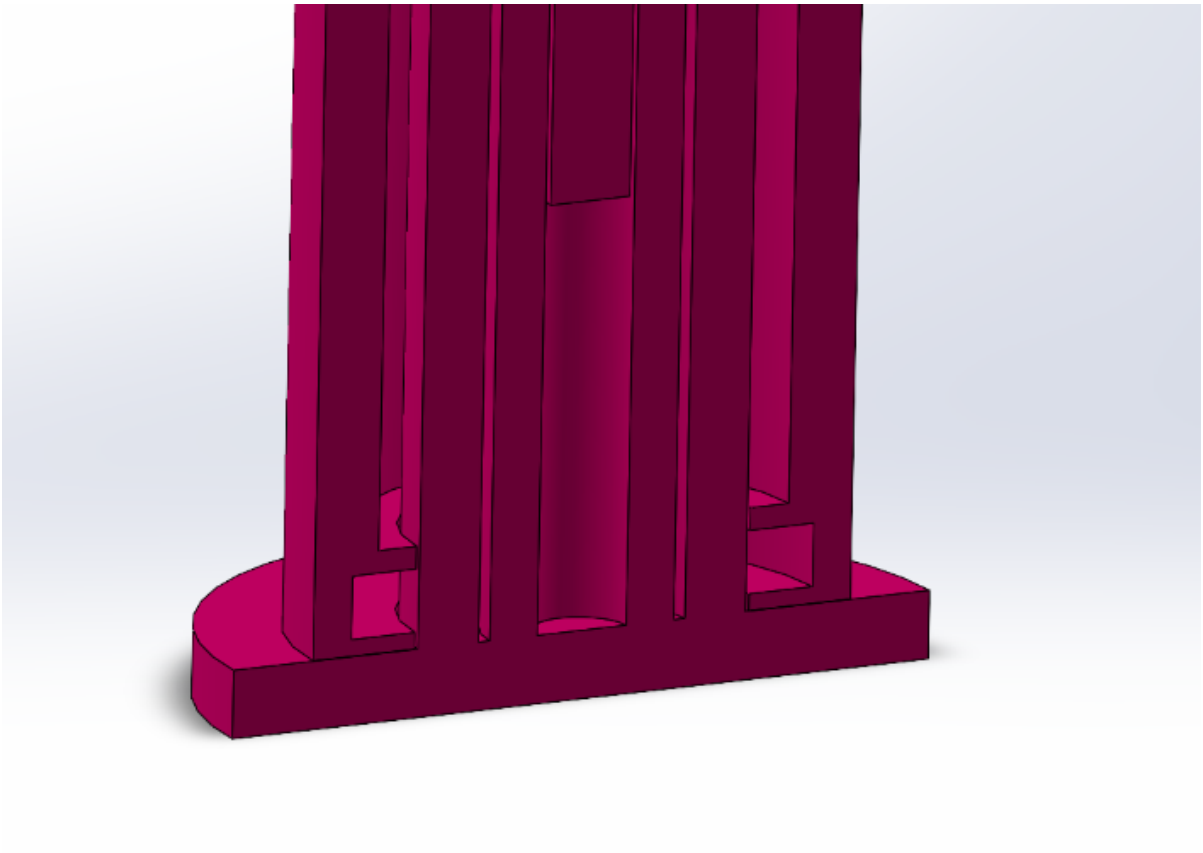


- O-ring site one: AS568-005



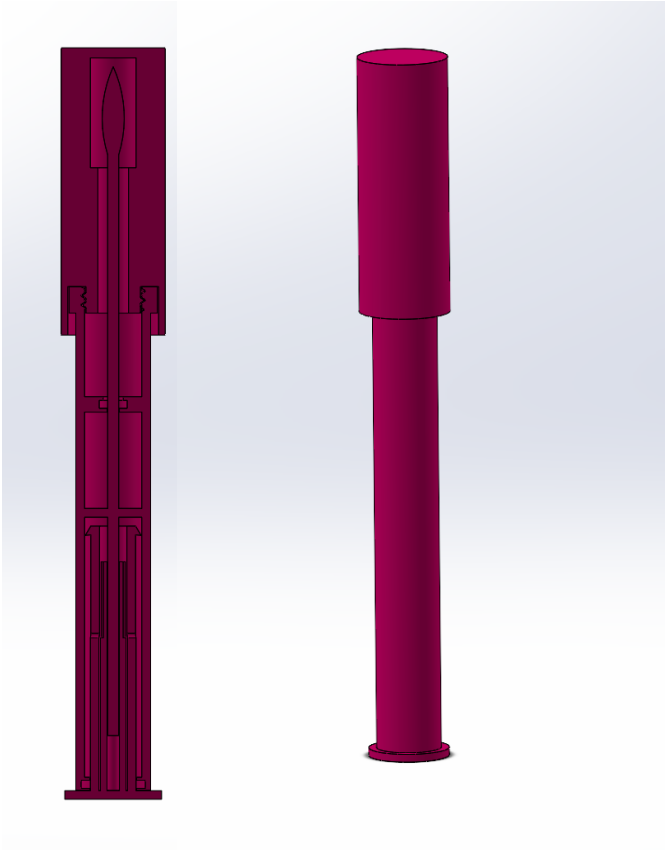
- Small O-ring to be attached in the thin groove shown above

- O-ring site two: AS568-013



- larger O-ring is to be inserted at the base of the device. A slight groove to the plunger may need to be added in order to ensure sealing

- Overall device:



Conclusions/action items:

Share this modified design with the team and add it to the design matrix. Discuss meeting with Jessie from the DesignHub to get help with the O-ring designs or just try to 3D print it to see if it does promote sealing and whether or not it hinders the ease of use.

2/26/24 - Sliding Sheath Design

KATHERINE KAFKIS - Mar 20, 2024, 1:39 PM CDT

Title: Sliding Sheath Design

Date: 2/26/24

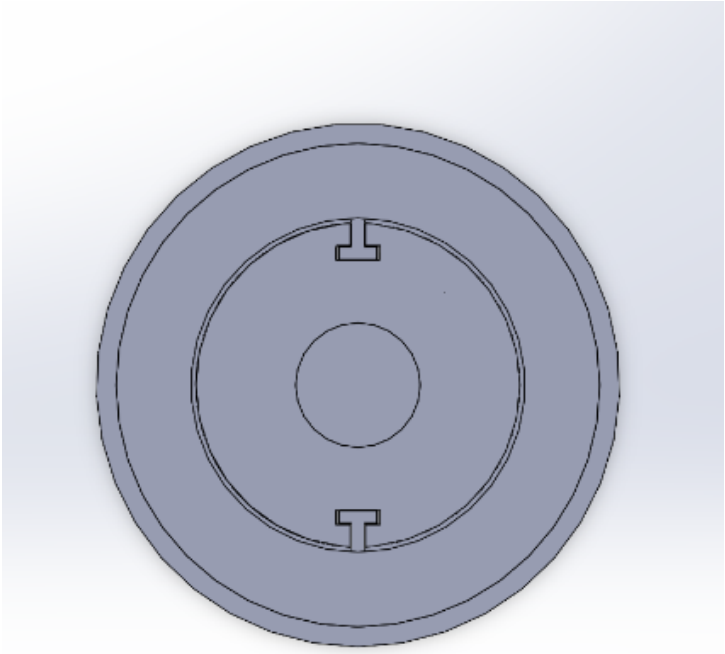
Content by: Katherine Kafkis

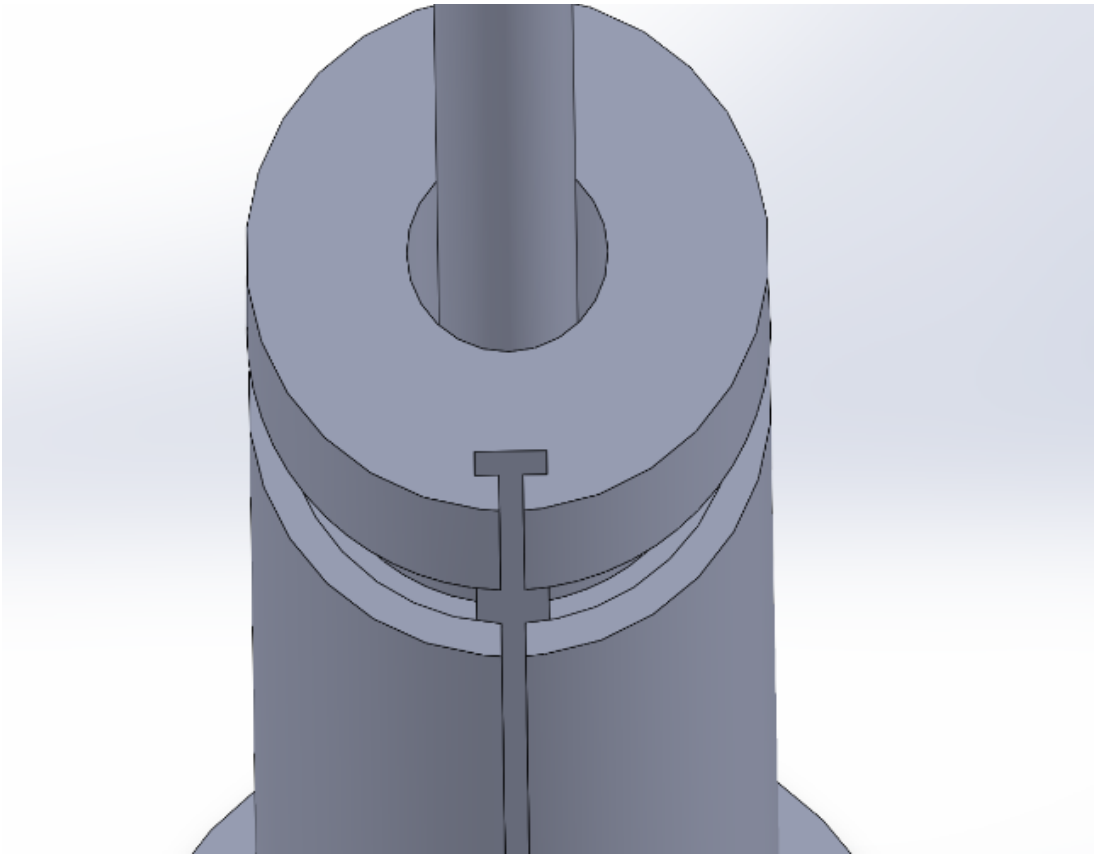
Present: N/A

Goals: To fabricate a device that keeps the swab protected throughout use but also allows for transfer into the Aptima Media Tube.

Content:

- Sliding sheath will have the swab covered when the patient comes into the testing room
  - need to work on locking the sheath into place - print and test it as is
- Sliding sheath gets pulled back and exposes the swab for testing
  - second locking place keeps the sheath here
- Conduct swab and then snap the swab off into the aptima media tube
  - disadvantage: spilling or splashing of media upon snapping
  - Try to make it so that the upper surface can fit into the aptima media tube for splash protection





- close-ups of sliding track
  - two T-shaped protrusions sliding in two t-shaped tracks
  - secondary cut that are designed around the t-shaped protrusions to allow for twisting and locking the sheath into place

Conclusions/action items:

Send this design idea to the team to get their feedback. If the team likes the idea, add it to the design matrix and preliminary report.

3/18/24 - Three Point Bend + Snap Off Design Ideas

KATHERINE KAFKIS - May 01, 2024, 3:38 PM CDT

Title: 3 Point Bend Design

Date: 3/19/24

Content by: Katherine Kafkis

Present: N/A

Goals: To create a design that allows the collection device to be attached to the aptima media tube with a mechanism of breaking the swab off so that it falls into the media.

Content:

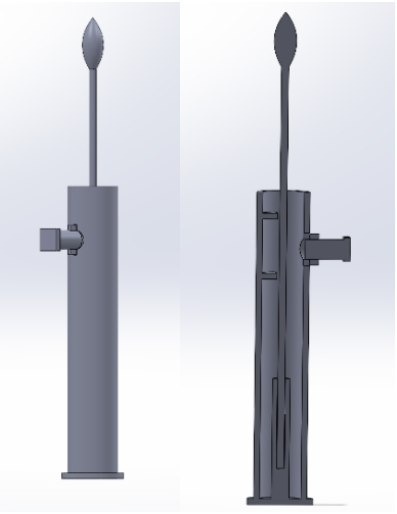
Design Idea 1: Full-length three-point bending design.

- covers the swab shaft and allows patients to hold onto the base of the device

- allows the device to be set down while keeping the swab tip off surfaces

- uses a button that aligns with the perforation point to break the swab

- can be attached to the apitma media tube by a friction fit or maybe threading (discuss with teammates)

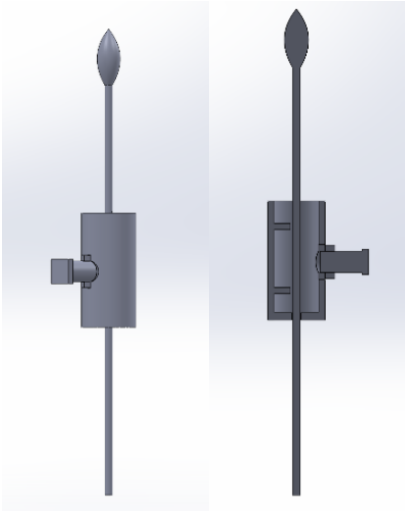


Design Idea 2: Short three-point bending design

- more similar to the current testing method as patients still hold the swab

- possibly less intimidating as there is much less material being used

- can be placed on its external case to keep the swab elevated from surfaces (maybe make one side a flat surface to prevent it from rolling)



Design Idea 3: Snap off with a splash guard

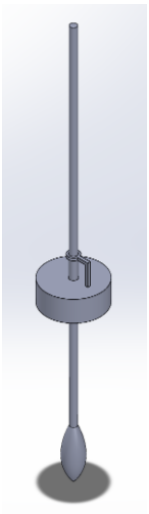
- attachment to the swab that allows it to be set down and elevated off surfaces

- only acts as a splash guard by screwing onto the aptima media tube. perforation point is between the upper protrusion and the splash guard

- upper protrusion holding the swab is firmly attached to the swab, the perforation point lies just below that attachment site

- the hole of the splash guard is loosely fit around the swab so that the patient can snap the swab and it will fall into the tube

- when breaking the swab, the thin support that is attached to the swab is broken as well, then the remaining swab (which is loosely attached) falls into the media tube. the splash guard keeps the process relatively contained as there is only a small hole



Conclusions/action items:

3D print the above design ideas and present them at show and tell. Make sure to print multiple copies of the snap off splash guard design idea with different thicknesses of the support holding the swab above its perforation point as I am unsure if it will be too fragile.

4/14/24 - Snap In Push-Button

KATHERINE KAFKIS - May 01, 2024, 3:49 PM CDT

Title: Three-point bend with a Snap-In Push-Button

Date: 4/14/24

Content by: Katherine Kafkis

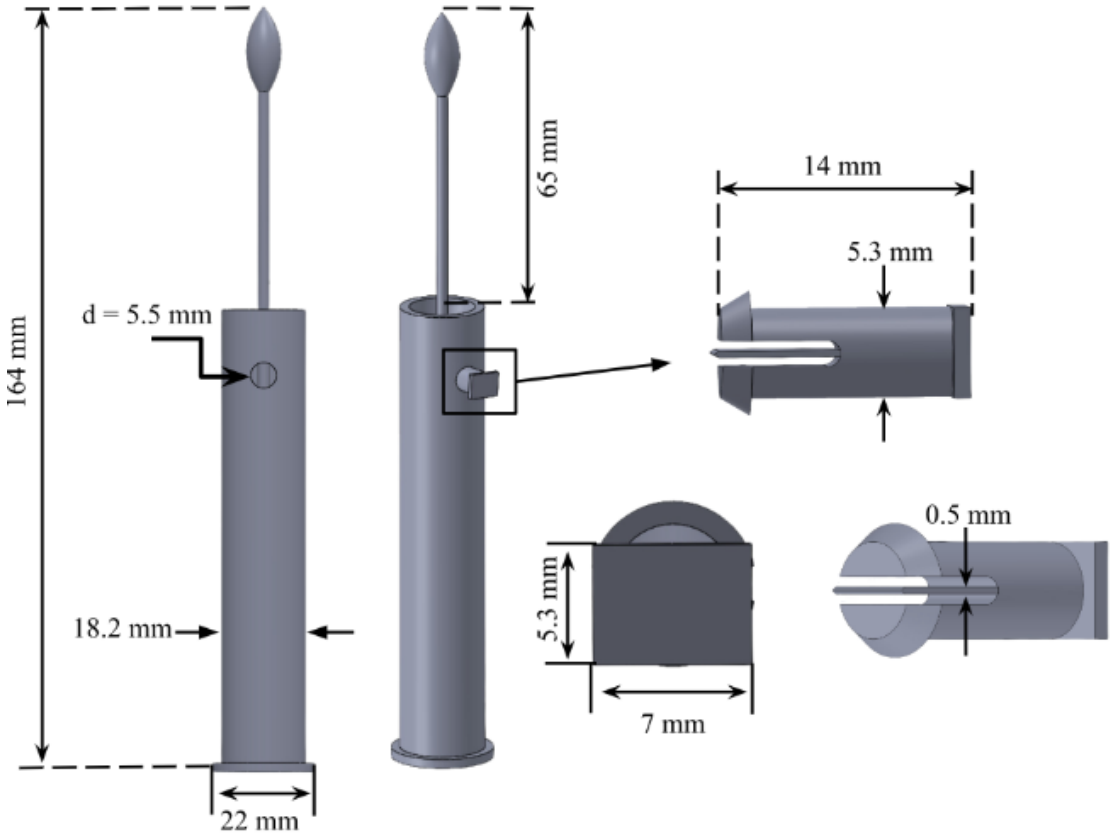
Present: N/A

Goals: To fabricate a push-button that snaps into a hole on the casing of the device rather than a keyed button. This will prevent the removal of the push-button from the device.

Content:

- Modified casing of the device such that there is no longer a key-hole but just a hole

- Redesigned push-button and casing as seen below:



Conclusions/action items:

3D print the above prototype to test the strength of the walls of the snap-in push-button. If they do not snap off, present this idea to the advisors to get feedback.

KATHERINE KAFKIS - May 01, 2024, 3:51 PM CDT

Update: 4/20/24

- Walls of the snap-in push-button broke off

- Discussed with the team and decided to continue with the keyed push-button as the final design

4/21/24-Modification of Keyed Push-Button

KATHERINE KAFKIS - May 01, 2024, 6:11 PM CDT

Title: Modification of Keyed Push-Button

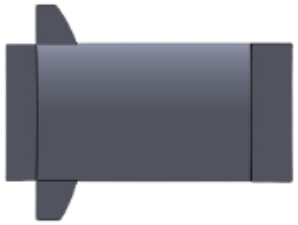
Date: 4/21/24

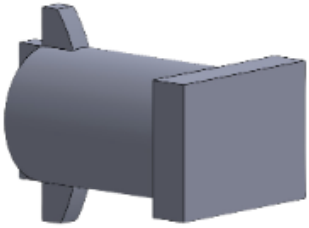
Content by: Katherine Kafkis

Present: N/A

Goals: To modify the flanges of the keyed push-button such that it lays flush with the interior surface of the casing. To modify the "button" part such that it is rectangular and the correct orientation of the long edge can be described in the instructions for three-point bending.

Content:





- Flanges are chamfered with the same radius (r = 6.8 mm) as the interior surface of the casing

- "Button" is now rectangular so the patient should orient it with the long edge facing upward to ensure the rectangular protrusion is perpendicular to the perforation point of the swab.

Conclusions/action items:

3D print two of these new push buttons for the final presentation. Make a dimensioned sketch of the keyed push-button and external casing for the poster presentation and final report. Modify the instruction manual to include a step instructing patients to ensure that the long edge is facing upward (with a visual) before breaking the swab.

2024/31/01 - Plastics

CHERRY QIU - Jan 31, 2024, 12:26 PM CST

Title: Plastics

Date: 2024/31/01

Content by: Cherry Qiu

Present: Cherry Qiu

Goals: To identify and consider alternative materials for our device.

Content:

Last semester, the previous team decided to polylactic acid (PLA) as the material for their final design. PLA is a biopolymer that is both biocompatible and nontoxic. PLA is produced using microbial fermentation, which also limits some of the waste that is produced during traditional plastic manufacturing. One downside to PLA is that it is not able to withstand the temperature of steam autoclaving. While these devices are meant to be single use, the team would still prefer the devices to be sterilized before use. Another downside to PLA is that it is not easily recyclable. While it is technically possible to, the actual process of recycling PLA is tedious and sometimes does not work.

One alternate to PLA is polypropylene. Polypropylene is medical safe, lightweight, and able to handle temperatures high enough to be autoclaved. Polypropylene is also easier to recycle than PLA, but does lose some strength after the recycling process.

https://bmpmedical.com/what-plastics-are-used-in-medical-devices/

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9228835/

Conclusions/action items:

Look into Polypropylene as alternate final prototype material.

2024/02/02 - O ring

CHERRY QIU - Feb 02, 2024, 9:03 AM CST

Title: O-Ring Mechanics

Date: 2024/02/02

Content by: Cherry Qiu

Present:

Goals: Learn more about O rings and their mechanisms.

Content:

An O Ring is a doughnut-shaped closed circle made out of rubber. The main purpose of an O ring is to prevent leakage. The three primary ways to install an O Ring, Flange seal, Piston seal, and Rod Seal.

O Ring compression force depends on the hardness of the O ring, cross section, and compression percentage.

https://engineeringproductdesign.com/knowledge-base/o-ring-compression-force/

Conclusions/action items:

In order to create a tight seal, we have to consider the o ring's compression force.

2024/31/01 - STI Demographics

CHERRY QIU - Jan 31, 2024, 1:44 PM CST

Title: STI Demographic Prediction using Machine Learning

Date: 2024/31/01

Content by: Cherry Qiu

Present: Cherry Qiu

Goals: To understand STI demographic more and apply them to our design process

Content:

This entry was created during 301's lecture. The article was found using Scopus, a database from the Library page.

The machine learning was successful in predicting STI diagnosis in both the male and female populations.

By identifying high risk populations, we can also better market our device so people have access to better testing.

https://bmcmedinformdecismak.biomedcentral.com/articles/10.1186/s12911-024-02426-1

Conclusions/action items:

apply this within the scope/reach of our project

2024/02/02 - Sustainability

CHERRY QIU - Feb 02, 2024, 10:32 AM CST

Title: Sustainability

Date: 2024/02/02

Content by: Cherry Qiu

Present:

Goals: Learn more about sustainability with medical devices.

Content:

- Try to use more sustainable material
- increase shelf life
- think about packaging of product as well

https://www.johner-institute.com/articles/health-care/and-more/medical-device-sustainability/

Conclusions/action items:

Apply this to our final design

2024/16/02 - Design Matrix Drafting

CHERRY QIU - Feb 16, 2024, 11:12 AM CST

Title: Design Matrix Drafting

Date: 2024/16/02

Content by: Cherry Qiu

Present:

Goals: Ramify design criteria we chose for design matrix.

Content:

Cost:

- Cost is important due to our device's end goal of being mass produced.
- This means we want to maintain a relatively low manufacturing cost
- 5/5 for the report means that we can stay within the budget of 500 and it can be manufactured at a low cost.

Safety:

- Safety is really important especially for devices that require insertion.
- the device itself should not be inserted into the vagina, but there could be user error.
- To promote safety, the material the design is made out of has to be bio-compatible and non abrasive.

Conclusions/action items:

2024/01/28-General Vagina Anatomy

ADAM BERDUSCO - Jan 28, 2024, 5:54 PM CST

Title: General Vagina Anatomy

Date: 2024/01/28

Content by: Adam Berdusco

Present: N/A

Goals: Gain a better understanding of the anatomy of the vagina so that I can better understand the function and short falls of the current device.

Citation:

C. C. medical professional, “Vagina: Anatomy, function, conditions & what’s normal,” Cleveland Clinic, https://my.clevelandclinic.org/health/body/22469-vagina (accessed Jan. 28, 2024).

Content:

This article outlines several key aspects of the female reproductive system. There are two main categories within the female anatomy, external and internal. There are seven external components that this article outlines: clitoris, urethral opening, labia majora, labia minora, hymen, and the vaginal opening. Additionally, the article goes into detail about five internal elements: fallopian tube, ovary, uterus, cervix, and vagina. Below is further detail into each of the anatomical elements.

External:

The external structures serve to protect the genitals from infection and facilitate reproduction. As a whole, the external structures are referred to as the vulva.

Clitoris: located where the labia minora meet, it is a sensitive protrusion that is normally covered by a fold of skin called the prepuce.

Urethral Opening: The opening to the urethra allows for females to urinate

Labia Majora: Latin for large lips, they enclose and protect the other external structures.

Labia Minora: Latin for small lips, they are found just beneath the surface of the labia majora. They surround the vagina and the urethra.

Hymen: The Hymen is a section of connective tissue that covers and surrounds part of the vaginal opening

Vaginal Opening: This opening is where babies and menstrual blood exit the body.

Internal:

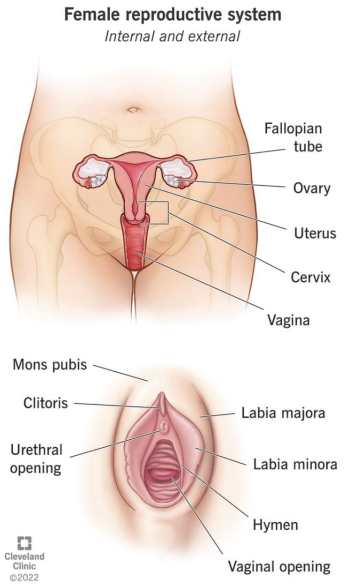
Ovary: The ovaries are small glands that produce eggs and hormones . They are located on either side of the uterus.

Fallopian Tube: These are small tubes that connect the ovary glands to the uterus. Fertilization of eggs by sperm typically happens in the fallopian tubes. The fertilized egg then moves to the uterus for the fetal growth process

Uterus: The Uterus contains, and grows the baby during pregnancy. The uterus can be divided into two categories, cervix and corpus. The corpus is the upper, larger section that will drastically expand during pregnancy.

Cervix: The cervix is the most internal part of the vaginal canal. A hole in the middle allows for menstrual blood to exit and sperm to enter. The cervix will dilate during childbirth.

Vagina: The vagina is a muscular canal that connects the external body to the cervix. It is lined with a mucous membrane that helps keep it moist and healthy. This is the location that the swab will need to collect the sample for the STD testing within the prototype.



Conclusions/action items: A solid base of female reproductive anatomy was built. I would like to shift the biological research to better understand the intricacies of testing for Sexually transmitted diseases

ADAM BERDUSCO - Jan 28, 2024, 3:35 PM CST

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Your vagina is an important part of both your internal and external reproductive anatomy. It's a powerful passage that plays a role in sex, menstruation, pregnancy and childbirth. Regular pelvic exams and Pap smears, and safer sex practices can help keep your vagina healthy and infection-free.

ContentsOverviewFunctionAnatomyConditions and DisordersCare

Function

ContentsOverviewFunctionAnatomyConditions and DisordersCare

Overview

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Vagina__Anatomy_Function_Conditions_What_s_Normal.html (218 kB)

2024/01/28-Aptima® Multitest Swab Specimen Collection Kit - Copy

Title: Aptima® Multitest Swab Specimen Collection Kit

Date: 2024/01/28

Content by: Adam Berdusco

Present: N/A

Goals: Better understand the advantages and drawbacks to one of the most popular self swab kits on the market.

Citation:

"APTIMA® Multitest Swab Specimen Collection Kit," Women's Health Products, https://www.hologic.com/hologic-products/collection-devices/aptima-multite utm_source=google&utm_medium=cpc&utm_term=vaginal+swab&utm_campaign=2023_Multitest&gclid=CjwKCAiAk9itBhASEiwA1my_65x6Br0K4J2 qxoCjb4QAvD_BwE (accessed Jan. 28, 2024).

Content:

The Aptima multitest swab kit is a self administered diagnostic test that tests for seven different infections. The Aptima is manufactured and sold by the com diagnostic tests.

Procedure for using the Amtima:
The swab and the test tube are the two major components within the Amptia. The consumer starts by carefully removing the swab from the package. It is cr contact with any other surface than the vaginal canal. If during the process of inserting the swab and gathering the sample the swab does touch another su test is to be purchased. After the sample is gathered the consumer must carefully put the swab into the media inside the test tube. The consumer is to send be analyzed.

Throughout this procedure there are several instances where the test could potentially become invalidated. Two of the most likely scenarios are that either t or that the test tube is split or contaminated. Any invalidation of the test would cause the consumer to need to purchase another test kit.

Conclusions/action items: The information gained through learning about this product was beneficial, however, It would be of value to find a research arti swab devices

ADAM BERDUSCO - Jan 30, 2024, 4:02 PM CST

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2024/02/02-A Review Of At-Home Specimen Self-Collection Kits

ADAM BERDUSCO - Feb 02, 2024, 12:39 PM CST

Title: A Review Of At-Home Specimen Self-Collection Kits

Date:2024/02/02

Content by: Adam Berdusco

Present: N/A

Search terms: Category: review article, " Self administered STD collection kets" on google scholor

Citation:

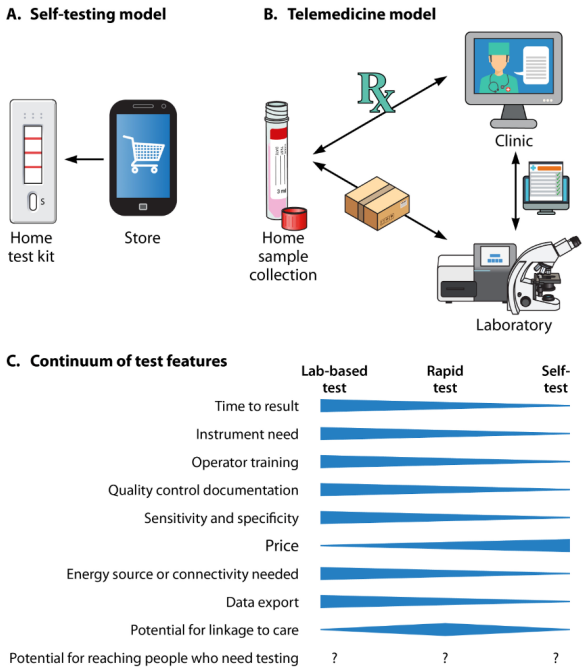
E. N. Kersh, “At-Home Specimen Self-Collection and Self-Testing for Sexually Transmitted Infection Screening Demand Accelerated by the COVID-19 Pandemic: a Review of Laboratory Implementation Issues,” Journal of Clinical Microbiology, https://journals.asm.org/doi/epub/10.1128/jcm.01741-07 (accessed Feb. 2, 2024).

Goals: Gain a broad understanding of the current methods of self collection kits available on the market

Content:

During the COVID-19 pandemic, the volume of clinically administered STD tests went up significantly, while take-home tests grew. At a minimum, 19 million diagnostic tests are performed each year. This article will discuss technical and regulatory aspects of current methods currently available form healthcare providers.

The article establishes a need for these devices: “More than 2.4 million U.S. cases of syphilis, gonorrhea, and chlamydia were reported to the Centers for Disease Control and Prevention (CDC) in 2018”. At the time of the study the rates were continuing to rise year on year. It is hard to know how many tests are done each year as the CDC only reports when there is a positive result.



The article reviews two main types of take-home test options.

- In the self-testing model, The consumer decides what test they would like to buy. the product is purchased commercially over the counter or online. They perform the test, as well as reading and interpreting the results. The clinic is only informed of the result if the consumer chooses to contact them. At the time of the article there is no way of testing for GC, C. trachomatis, or syphilis. The article suggests that this method is best for patients who have definite symptoms, so that they can accurately guess what test they will need. The average cost of these tests are often around $100.

- The telemedicine model is similar to the previous except that the clinic accepts self-collected specimens. The clinic then tests and analyzes the results for the consumer. A drawback from this method is that in some states only medical providers can order diagnostic STI tests.

Conclusions/action items:

This review article analyzed two of the most common methods for take-home STD testing. The article found concerns for the high costs, possible error rates and limited availability within the products it reviewed. Further research should be done to understand the cost breakdown of the diagnostic tests.

ADAM BERDUSCO - Feb 02, 2024, 12:14 PM CST

Journal of Clinical Microbiology

MINIREVIEW

At-Home Specimen Self-Collection and Self-Testing for Sexually Transmitted Infection Screening Demand Accelerated by the COVID-19 Pandemic: a Review of Laboratory Implementation Issues

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kersh-et-al-2021-at-home-specimen-self-collection-and-self-testing-for-sexually-transmitted-infection-screening-demand.pdf (557 kB)

2024/02/01-The Chemical Recycling of PLA

ADAM BERDUSCO - Feb 01, 2024, 6:19 PM CST

Title: The Chemical Recycling of PLA

Date: 2024/02/01

Content by: Adam Berdusco

Present: N/A

Search terms: PLA plastic AND environmental impact on google scholar

Citation:

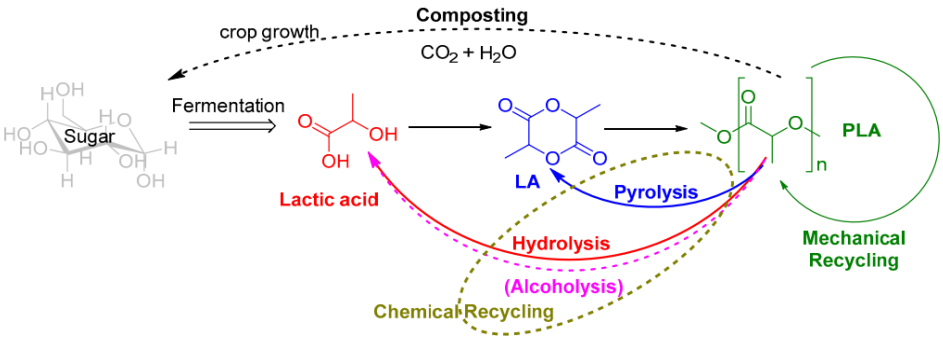
[1] P. McKeown and M. Jones, “The Chemical Recycling of PLA,” Sustainable Chemistry,

Goals: Gain a better understanding of the environmental impact of PLA plastic being used as a material to manufacture the device

Content:

The goal of this article is to assess the current practices for recycling poly lactic acid (PLA) plastics. This article focuses on chemical recycling processes as the are able to preserve many of the monomers maintaining the usefulness of the plastic compared to other methods. Only approximately 1% of the 380 metric tons of plastic consumed in 2015 were produced with a bio-based source. This is of particular concern for marine environments where plastics tend to accumulate.

PLA is a bio-based plastic as it is fabricated through the fermentation of food crops. However, this leads to an increased price of plastic compared to petroleum based plastics. Even though the material is biodegradable, it requires relatively high temperatures and a long time to begin the degradation process.



This article provides a review of several different means to accomplish a more effective recycling process. As seen in the figure, if left to decompose the sugar would then need to undergo fermentation again, while the other methods preserve the molecules.

The first process that is analyzed is the PLA hydrolysis. Due to the solubility of PLA in an aqueous media, effective bulk hydrolysis would require temperatures ranging from 180°C - 350°C rendering this process infeasible for the team.

Additionally, another process that this study looked at is alcoholysis to alkyl lactates.This process involves using methanol which then creates methyl lactate. Turning PlA into a lactate is beneficial for synthesizing lactic acid. The article goes into great depth about different procedures for that syntheses.

Conclusions/action items:

This article reviews potential modalities of recycling PLA plastic. Given PLA plastic is the martial of choice for the prototype, it is important to understand the environmental impact. Even though there are some methods of recycling PLA, most require a complex processes with high temperatures. Further research should be done to determine potential materials that are more easily recycled.

ADAM BERDUSCO - Feb 01, 2024, 5:42 PM CST

sustainable chemistry

Review

The Chemical Recycling of PLA: A Review

Paul McKeown * and Matthew D. Jones *

Department of Chemistry, University of Bath, Claverton Down BA2 7AY, UK
* Correspondence: pm642@bath.ac.uk (P.M.); mj2054@bath.ac.uk (M.D.J.); Tel.: +44-1225-384008 (M.D.J.)

Received: 16 April 2020; Accepted: 28 April 2020; Published: 2 May 2020

Abstract: Plastics are an indispensable material with numerous benefits and advantages compared to traditional materials, such as glass and paper. However, their widespread use has caused significant environmental pollution and most plastics are currently non-renewable. Bio-based polymers represent an important step for tackling these issues, however, the end-of-life disposal of such materials need to be critically considered to allow for a transition to a circular economy for plastics. Poly(lactic acid) (PLA) is an important example of a bio-based polymer, which is also biodegradable. However, industrial composting of PLA affords water and carbon dioxide only and in the natural environment, PLA has a slow biodegradation rate. Therefore, recycling processes are important for PLA, particularly chemical recycling, which affords monomers and useful platform chemicals, maintaining the usefulness and value of the material. This review covers the different methods of PLA chemical recycling, highlighting recent trends and advances in the area.

Keywords: polylactic acid; plastic recycling; chemical recycling; circular economy

1. Introduction

The majority of plastics, that as a society we rely on, are sourced from petroleum-based resources, with only a fraction currently being derived from renewable feedstocks. In 2015, 380 million metric tons of plastic was produced globally, with less than 1% of this production being derived from a bio-based source [1]. This is of particular concern as the use of petroleum resources is associated with global pollution and climate change, as well as being a finite resource [2]. To mitigate these issues, a transition towards bio-based plastics is needed, especially considering the increasing demand for such materials. Based on the present rate of growth, plastic production is predicted to double within the next 20 years [3]. A further issue currently associated with plastic usage is the pollution that is caused by end-of-life mismanagement. Plastic pollution is particularly a problem in marine environments, where it has a tendency to accumulate and persist [4–6]. The application of plastics in everyday life has undeniable advantages and societal benefits [7–9], however, their concerns need to be urgently addressed to make plastic usage sustainable. Therefore, as well as a shift towards bio-based materials, there is a necessity to consider the end-of-life treatment of these materials and ensure there are efficient routes of disposal available. The current use of plastics follows a linear model, whereby plastics are prepared, used, and disposed, and this is especially true, as well as problematic, for single-use plastics [10,11]. The future of plastic use needs to be based on a circular model, whereby the value of the material is retained after its useful lifetime [10,12,13].

Poly(lactic acid) (PLA) is a bio-based polymer, which has received extensive attention, both in academia and industrially in the last 20 years. The main constituent, lactic acid, is derived, through fermentation, from renewable feedstocks such as food crops (corn) as well as waste sugars (cellulosic material) [14,15]. Compared to petroleum-based plastics, PLA is currently more expensive due to increased production costs associated with the fermentation and purification of LA, which accounts for approximately 50% of the total cost [16,17]. The polymerisation to PLA

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2024/02/01-Quantitative Leak Test

ADAM BERDUSCO - Feb 01, 2024, 10:58 PM CST

Title: Quantitative Leak Test

Date: 2024/02/01

Content by: Adam Berdusco

Present: N/A

Search terms: quantitate and leak test on google scholar

Citation:

Author links open overlay panelAirek Mathews et al., “Quantitative leak test for microholes and microtears in whole gloves and glove pieces,” Polymer Testing, https://www.sciencedirect.com/science/article/abs/pii/S014294181630383X?casa_token=gZPJ53ORugcAAAAA%3A3uTo01QWB-KBnIaSrQeANencEEOalFQDPzzadMVWZDWaAKxLMrOm-kXIarskdHar8nn_2lAqdA (accessed Feb. 1, 2024).

Goals: Learn about current quantitative methods of testing for leaks

Content:

The aim of this article was to develop a method of quantitatively measuring the extent to which latex gloves were leaking. The current methodology involves a qualitative analysis to determine if there was a leak. The developed method is capable of detecting tears in the gloves that are as small as 0.13 mm and flow rates as low as 2.5 mL/min

Procedure:

- The glove was filled with compressed air until a resistance of 2mL/min flow rate
- Maintaining the inflation, a tight rubber band was wrapped around the glove
- Needle nips of a variety gauges were used to puncture the gloves
- The glove was deflated then a 5.1 cm ring was cut around the whole
- This section of glove was fit around a pvc bushing and connected to the test dome
- A vacuum of 18-20 cm water gauge was created
- 50 mL of water was placed onto the glove
- The glove was set to rest there for 90 seconds
- The water that leaked through was collected inside the testing chamber
- The water was then measured to determine how much the glove leaked

Conclusions/action items:

This article outlines a procedure of quality testing how much water leaked out of latex gloves. This procedure can be adapted to fit the needs of the project so that a successful leak test can be performed

ADAM BERDUSCO - Feb 01, 2024, 10:29 PM CST

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S014294181630383X.html (279 kB)

2024/02/03-Mechanics of Snap Fits

ADAM BERDUSCO - Feb 15, 2024, 10:01 PM CST

Title: Mechanics of Snap Fits

Date: 2024/02/03

Content by: Adam Berdusco

Present: N/A

Goals: Gain a better understanding of how snap fits work and the physics behind them

Search Terms: "physics of snap on cap" on Google Scholar

Citation:

K. Yoshida and H. Wada, “Mechanics of a snap fit,” Physical Review Letters, https://journals.aps.org/prl/abstract/10.1103/PhysRevLett.125.194301 (accessed Feb. 15, 2024).

Content:

This article goes into detail about the importance and utility of snap on fits. Snap on fits are used commonly throughout manufacturing, they are seen in pen caps to legos. The design is made so that it is easier to put the cap on, but then requires more force to take the cap off. This article investigates the physical behavior of the snap on fits. The aim is to determine the optimal ratio of larger diameter to smaller diameter so that the material does not buckle, if it is too small, or provide no resistance, if it is too large.

$$\frac{F_D R_s^2}{B} = 2\alpha K(\Phi)\frac{\sin(\Phi/\alpha) - \alpha^{-1}\sin\Phi}{\tan(\Phi/\alpha)}.$$

The article develops several equations such as the one above. Although interesting in theory, they would be hard to put into practice as many of the constants would be unknown such as the friction coefficient of the PLA that will be used to 3D print the design. However, a rough approximation could be used to determine a starting point to begin testing and iterating about.

Conclusions/action items: I will use what I have learned to properly evaluate the snap on design

PHYSICAL REVIEW LETTERS 125, 194301 (2020)

Mechanics of a Snap Fit

Kiriaki Yoshida and Hirofumi Wada

Department of Physical Sciences, Ritsumeikan University, Kusatsu, Shiga 525-8577, Japan

(Received 19 March 2020; accepted 28 September 2020; published 2 November 2020)

Snap fits are versatile mechanical designs in industrial products that enable the repeated assembling and disassembling of two solid parts. This important property is attributed to a fine balance between geometry, friction, and bending elasticity. In this Letter, we combine theory, simulation, and experiment to reveal the fundamental physical principles of snap-fit functions in the simplest possible setup consisting of a rigid cylinder and a thin elastic shell. We construct a phase diagram using geometric parameters and identify four distinct mechanical phases. We develop analytical predictions based on the linear elasticity theory combined with the law of static friction and rationalize the numerical and experimental results. The study reveals how an operational asymmetry of snap fits (i.e., easy to assemble but difficult to disassemble) emerges from an exquisite combination of geometry, elasticity, and friction and suggests optimization of the notable functionalities for a range of mechanical designs.

DOI: 10.1103/PhysRevLett.125.194301

Assembling and disassembling two solid components is a fundamental process for functional structures in natural and manmade systems. Examples encompass different length scales ranging from ligand-receptor interactions in biochemistry [1] and plastic shell covers in industrial products [2] to the docking of free-flying space vehicles [3]. In manufacturing industries, snap fits are typically used to join two plastic parts without gluing, constituting a simple design with necessary resilience to allow for repeated assembly and disassembly [4]. Today, snap fits are found everywhere, including the cap of a marker pen, plastic zipper bags, and toys such as Lego® blocks. The "click" sound is a familiar snap-fit characteristic present in our daily lives. In most snap-fit designs, assembling requires relatively little effort whereas disassembling is more difficult. Mechanical asymmetry is a central property of snap fits for industrial use and emerges from an interplay between flexibility, frictional interactions, and the geometric structure of the snap-fit parts. However, despite its familiarity and prevalent use in daily life, fundamental aspects of snap-fit mechanics are highly unexplored, at least from the perspective of physics.

In this Letter, we propose a model experimental system that can illustrate snap-fit behavior. We investigate its physical properties by combining force measurements, numerical simulations, and theoretical analysis. We consider a semicylindrical shell of radius R, and thickness t [Fig. 1(a)], which is pushed onto a surface of a rigid cylinder with radius R [Fig. 1(b)–(c)]. The shell either clutches the cylinder via a snap fit or buckles on the cylindrical surface depending on the geometric parameters of the shell and the cylinder. We integrate experimental and numerical data to construct a phase diagram in terms of the geometric parameters and rationalize the observed phase boundaries with an analysis based on linear elasticity theory combined with a dry friction law [5–12]. The proposed

FIG. 1. Schematics of a model snap-fit system. (a) Definition of geometric parameters of the shell, i.e., radius R, and opening angle Φ in its natural configuration. (b),(c) Sequence of snapshots of a thin plastic shell undergoing the Type I snap-fit (b), and Type II snap-fit (c), process. (d) Schematic photographic view of our experimental system for force measurements during assembling and disassembling processes.

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2024/02/15-Ball Valve Idea

ADAM BERDUSCO - Feb 15, 2024, 10:27 PM CST

Title: Ball Valve

Date: 2024/02/15

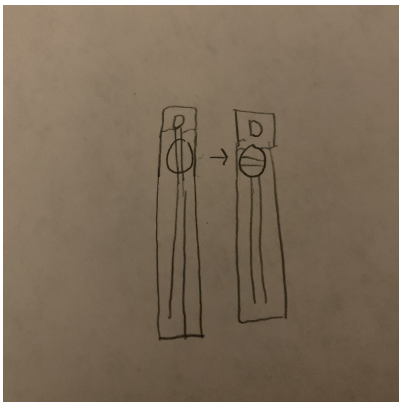
Content by: Adam Berdusco

Present: N/A

Goals: Document a possible design solution

Content:

This proposed solution is very similar to the current design. It would use the same plunger mechanism to house and deploy the swab. The only modification would be made to the cap to help leakage. There would be a ball valve put into the cap that the swab would pass through when initially inserted, the swab would then break the seal containing the liquid and the valve would be turned close. The valve would break the swab shaft, which is acceptable and stop any liquid from flowing down into the shaft.



Possible draw backs from this design include an increased manufacturing difficulty.

Conclusions/action items: This design will be presented to the team. More design ideas should be made

2024/02/14-SnapON

Title: SnapOn Design

Date: 2024/02/14

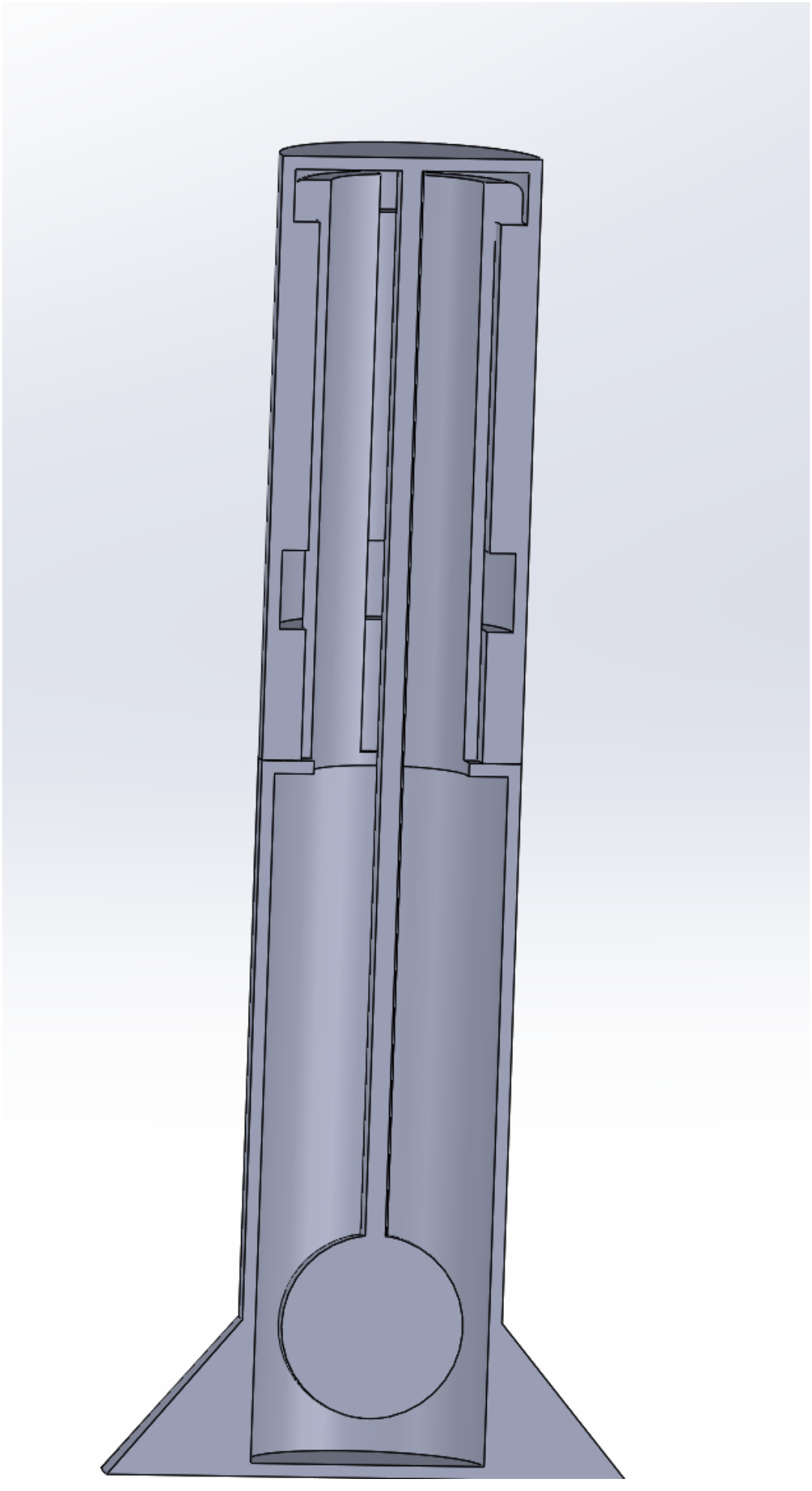
Content by: Adam Berdusco

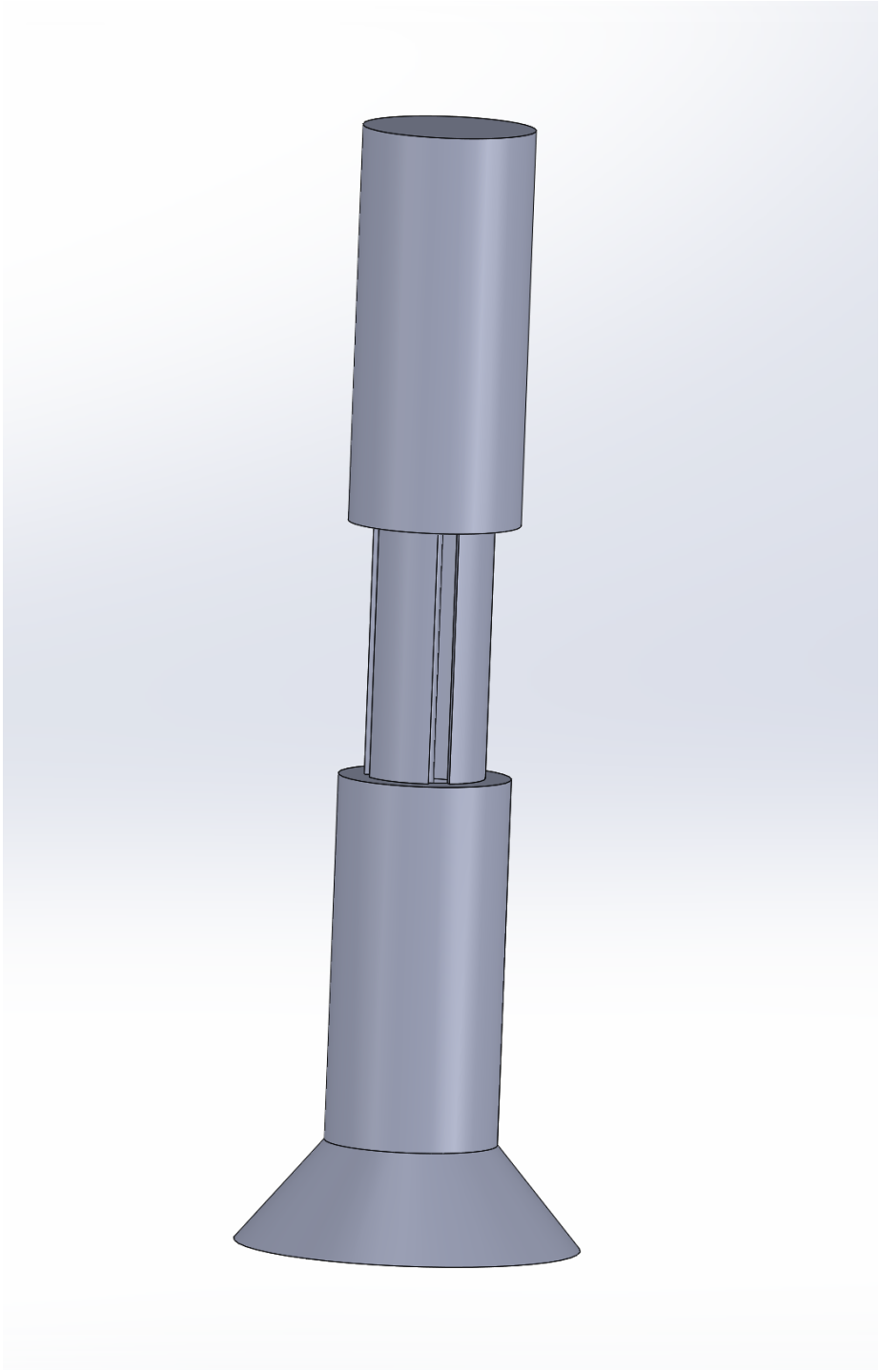
Present: N/A

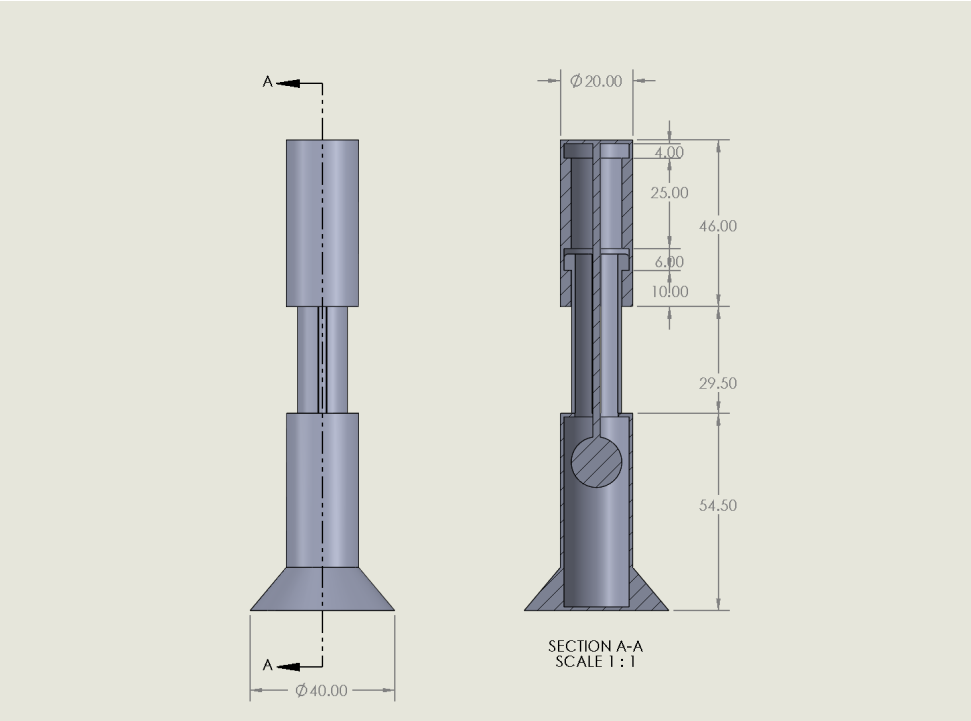
Goals: Document a design idea

Content:

This design incudes two parts, the base and cap. The base will house the swab and contain two different notches within it. The cap will slide into the base and rest at one of the two notches in the base. The design would be given to the customer in the up position, they would remove the cap by pushing the flexible parts in. Once the swab has been taken, the cap would be placed back into the base and this time pushed all the way down to the lowest notch. This would submerge the tip of the swab into the media







A potential draw back to this design is that it could be hard to prevent leaking if the device is tipped upside-down

Conclusions/action items: This design will be presented to the team and potentially evaluated in a design matrix

2024/04/05-Template - Cigar Cutter Design

Title: Cigar Cutter Design

Date: 2024/04/05

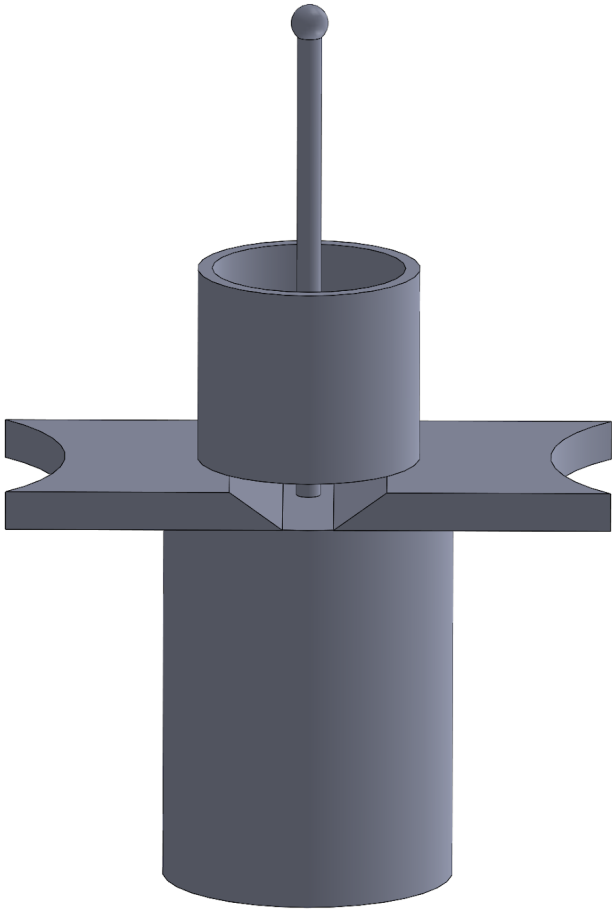
Content by: Adam Berdusco

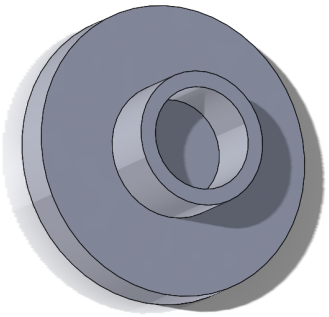
Present: N/A

Goals: Brainstorm a new idea so that the self swab device incorporates Hologic tube.

Content:

The team recently learned that the lab tests the swab sample by putting them into a machine that is made specifically for the Hologic tube. This means the device will need to be reworked so that it incorporates that tube.





The current design idea accomplishes this by approaching the problem from a different perspective than the last design. This design is centered around the swab. The user would receive the swab and device as one object as shown in the first picture. The patient would perform the swab procedure, then insert the swab into the Hologic tube. Next, the patient would push the two plates together, this process would cut the swab leaving it in the Hologic tube. The second image shows a base for the tube which would help hold it as the swab is being performed.

Conclusions/action items:

This design idea is a new take on the previously proposed designs. It will help mitigate contamination by limiting the number of objects in the patient's hands, and by providing stability to the tube. The next steps will be to discuss this idea with the team, iterate it and bring it to our client.

2014/11/03-Entry guidelines

John Puccinelli - Sep 05, 2016, 1:18 PM CDT

Use this as a guide for every entry

- Every text entry of your notebook should have the **bold titles** below.
- Every page/entry should be **named starting with the date** of the entry's first creation/activity. subsequent material from future dates can be added later.

You can create a copy of the blank template by first opening the desired folder, clicking on "New", selecting "Copy Existing Page...", and then select "2014/11/03-Template")

Title: Descriptive title (i.e. Client Meeting)

Date: 9/5/2016

Content by: The one person who wrote the content

Present: Names of those present if more than just you (not necessary for individual work)

Goals: Establish clear goals for all text entries (meetings, individual work, etc.).

Content:

Contains clear and organized notes (also includes any references used)

Conclusions/action items:

Recap only the most significant findings and/or action items resulting from the entry.

2024/02/03-Template

John Puccinelli - Nov 03, 2014, 3:20 PM CST

Title:

Date:

Content by:

Present:

Goals:

Content:

Conclusions/action items:

Fall 23 Notebook

KATHERINE KAFKIS - Jan 26, 2024, 12:36 PM CST

BME Design-Fall 2023 - KATHERINE KAFKIS
Complete Notebook

PDF Version generated by
KATHERINE KAFKIS
on
Jan 26, 2024 @ 12:14 PM CST

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Final Report Fall 23

KATHERINE KAFKIS - Jan 26, 2024, 12:51 PM CST

DEPARTMENT OF
Biomedical Engineering
UNIVERSITY OF WISCONSIN-MADISON

Self-Swab STI Test for Limiting Contamination

BME 200/300 Final Report

December 13th, 2022

Client:
Dr. Jean Ripenhoff

Advisor:
Dr. Pamela Keeger

Team Members:
Team Leader: Jenna Sorenson
Team Leader: Katherine Kafkis
BWIG: Mia LoRicco
BPAG: Morgan Kopidlansky
Communicator: Sara Morehouse
BSAC: Kaiya Merritt

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KATHERINE KAFKIS - Jan 26, 2024, 12:52 PM CST

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