BME Design-Fall 2024 - SARA MOREHOUSE
Spring Semester

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Apr 30, 2025 @10:38 PM CDT

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Team contact Information

NOAH HAMRIN - Feb 12, 2025, 2:40 PM CST

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Project description

NOAH HAMRIN - Apr 28, 2025, 4:10 PM CDT

Course Number: BME 402

Project Name: Stabilizer device for intra-cardiac echocardiography (ICE) to assist structural heart interventional procedures

Short Name: ICE Stabilizer

Project description/problem statement:

Intracardiac echocardiography (ICE) is a technique commonly used during catheter-based interventional procedures to treat congenital heart disease, valvular heart disease and myocardial disease. Typically, the ICE catheter is advanced into the right atrial from a femoral vein, where it is positioned for imaging purposes. A separate catheter to perform the interventional procedure such as a transseptal needle or Watchman left atrial appendage occluder delivery system is then introduced. Many times, the ICE catheter drifts out of place, the imaging perspective is lost and the ICE catheter needs to be readjusted. Therefore, there exists a need for a simple re-sterilizable device to stabilize a variety of commercially available ICE catheters during interventional procedures. The device must prevent movement of the ICE catheter so that it does not migrate out of place when in use.

About the client:

Dr. Amish Raval is a faculty member in the Division of Cardiovascular Medicine within the Department of Medicine and holds an affiliate appointment with the Department of Biomedical Engineering in the College of Engineering. He is the recipient of many awards, including NIH R01 and U01 grants and the Wisconsin Alumni Research Foundation Innovation Award for “Best Inventor”. Dr. Raval is board certified in internal medicine and cardiovascular diseases. He also holds certification of Added Qualification in Interventional Cardiology. He is a member of numerous professional societies including the Society for Cardiac Angiography and Intervention, American College of Cardiology and the American Heart Association. Dr. Raval specializes in interventional cardiology, working to minimize the effects of coronary artery disease and valvular heart disease. He performs heart catheterizations to correct valvular and congenital defects and cardiomyopathies, coronary angiography, coronary revascularization and related coronary and pulmonary procedures. He is the Medical Director of the UW Health STEMI program.

2/3/2025 - Initial Client Meeting

NOAH HAMRIN - Feb 12, 2025, 2:51 PM CST

Title: Initial Client Meeting

Date: 2/3/2025

Content by: Noah

Present: Noah, Sara, Max

Goals: Update client on last semester, receive feedback, and ask questions

Content:

- Client was pleased with the product overall and mentioned a desire to patent it through WARF

- Proposed two options for journals to publish to: "Biomedical Materials and Devices" (preferred), or "Medical Devices"

- Introduced modular height saddle idea: produce multiple saddle (top part) parts of varying heights so that after the height is initially set via the pole clamp under the sterile drape, the height can be slightly adjusted without altering anything under the sterile drape.

- Discussed semester timeline and plans for final prototype production and testing, including types of testing (force, magnetic interference, qualitative feedback, etc)

Conclusions/action items:

Discuss with team and implement modular saddle height idea

4/7/25 - Client Meeting in Cath Lab

SARA MOREHOUSE - Apr 30, 2025, 1:23 PM CDT

Title: Client Meeting in Cath Lab

Date: 4/7/25

Content by: Sara Morehouse, Noah Hamrin, Max Aziz, Kaden Kafar

Present: all

Goals: To show Dr. Raval the prototype as is, get feedback on any changes necessary, and to evaluate the device via the user feedback survey.

Content:

In this meeting, we showed Dr. Raval the device and he helped us to set it up in the cath lab to get photos of the device in use. Images attached below.

Dr. Raval also gave us feedback on a number of things to modify about the device before the end of the semester as well as things to think about long-term. These included:

- Cut down the base plate by 3-4 in to offset the pole more
- Cut down middle piece 1in-1.5in
- Angular adjustment in the top pieces
- White paint
- Catheter has a tendency to rotate in its own, make sure it's held in place.
- Sand down corners of bottom plate, single use foam sheet on top of bottom plate, or rubber edge to the bottom plate.
- Velcro strap or some kind of improved strap similar to a yeti cooler strap
- Need to be able to move the base forward and backward for patient variability.(fine adjustments)
- Trident, or longer top piece for various positions forward and backward.

Lastly, Dr. Raval completed the User Feedback Survey for us, with results listed in the "Testing and Results" section of the notebook.

Conclusions/action items:

Looking forward, we will make the adjustments that Dr. Raval suggested. We will cut down the base plate and middle part, update the top pieces, paint the device white, sand down the corners and edges, and improve the strap. Other adjustments or larger modifications will be included in future work.

SARA MOREHOUSE - Apr 30, 2025, 1:24 PM CDT

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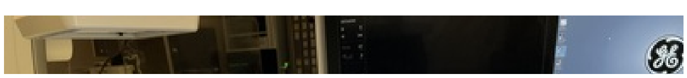
SARA MOREHOUSE - Apr 30, 2025, 1:24 PM CDT



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SARA MOREHOUSE - Apr 30, 2025, 1:24 PM CDT

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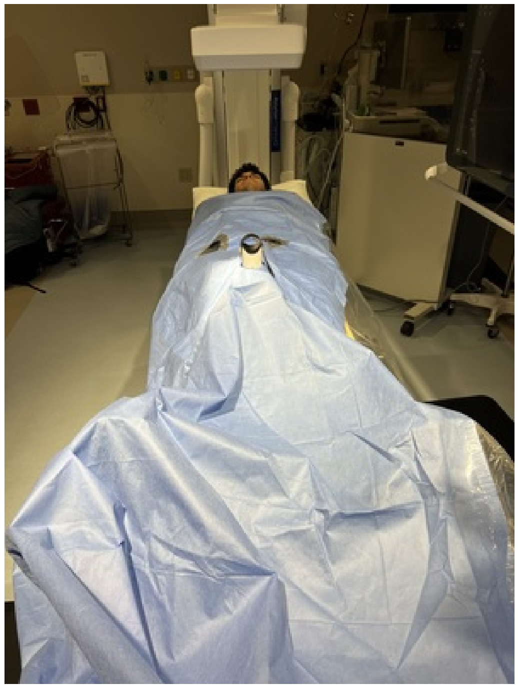
SARA MOREHOUSE - Apr 30, 2025, 1:24 PM CDT



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SARA MOREHOUSE - Apr 30, 2025, 1:24 PM CDT

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SARA MOREHOUSE - Apr 30, 2025, 1:24 PM CDT

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SARA MOREHOUSE - Apr 30, 2025, 1:24 PM CDT

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SARA MOREHOUSE - Apr 30, 2025, 1:24 PM CDT

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SARA MOREHOUSE - Apr 30, 2025, 1:24 PM CDT

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SARA MOREHOUSE - Apr 30, 2025, 1:24 PM CDT

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1/24/2025 - Initial Advisor Meeting

NOAH HAMRIN - Feb 12, 2025, 3:59 PM CST

Title: Initial Advisor Meeting

Date: 1/24/2025

Content by: Noah

Present: Noah, Max, Kaden

Goals: Semester preview and discuss project direction

Content:

- Team shared our plan and timeline for the semester

- Discussed the preliminary presentation and requirements

Conclusions/action items:

Work on preliminary presentation

2/7/2025 - Preliminary Presentation

NOAH HAMRIN - Feb 12, 2025, 4:04 PM CST

Title: Preliminary Presentation

Date: 2/7/2025

Content by: Noah

Present: All

Goals: Share current project status with advisor in a presentation format

Content:

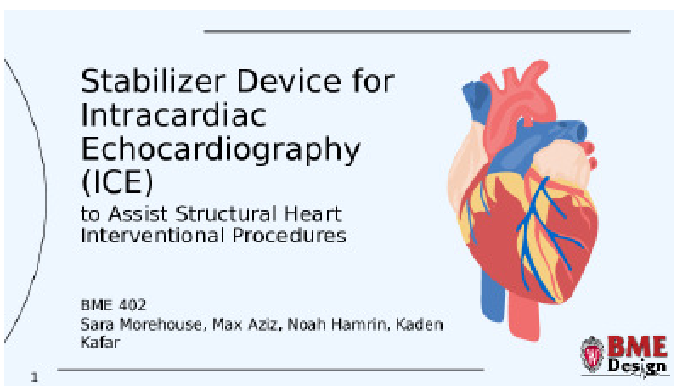
- Presentation attached below

- Dr. Suarez proposed fabricating the top piece out of plastic via injection molding and selling them as pre-sterilized while the rest of the device, which does not have to be sterile under the sterile drape, is constructed out of steel for mechanical properties. This allows the top parts to be more easily produced as different heights, accommodating the client's suggestion to make saddles of varying heights for fine tuning the height above the sterile drape.

Conclusions/action items:

Discuss with team and make necessary changes to solidworks files.

NOAH HAMRIN - Feb 12, 2025, 3:58 PM CST



Download

Preliminary_Presentation_Spring_.pptx (9.19 MB)

4/18/2025 - Discussion of Final prototype and poster

MAX AZIZ (mmaziz@wisc.edu) - Apr 30, 2025, 10:24 PM CDT

Title: Discussion of final prototype and poster

Date: 4/18/2025

Content by: Max Aziz

Present: Max, Noah, Sara, and Dr. Suarez

Goals: To ask for more inputs about testing, device, and poster

Content:

- Our testing plan will suffice

- Matlab graphs should be more condensed

- Device needs to be more polished via metal epoxy

- Device could be spray painted to looks better

- Discussed how poster presentation will look

Conclusions/action items: The team got valuable feedback on testing, device, and how the poster should look for a smooth final presentation.

3/13/2025 - Strap Discussion

MAX AZIZ (mmaziz@wisc.edu) - Apr 30, 2025, 10:30 PM CDT

Title: Strap Discussion

Date: 3/13/2025

Content by: Max Aziz

Present: Max, Kaden, Dr. Suarez

Goals: To discuss the top part of the device and the current strap mechanism

Content:

- Dr. Suarez and the team agreed that the current strap method is too difficult as she could not use the strap

- Kids velcro shoe method was proposed for a locking mechanism of the device

- Kaden said he needs to work on welding and what his future plans on how to weld

Conclusions/action items: The team discovered that the locking mechanism needs to be worked on as the current strap does not work, and Kaden will weld soon.

4/29/25 - Final PDS

SARA MOREHOUSE - Apr 30, 2025, 9:28 PM CDT

Title: Product Design Specifications

Date: 4/29/25

Content by: Team

Present: n/a

Goals: To establish product design specifications for the device.

Content:

Function

This device will be used for the stabilization of intracardiac echocardiography (ICE) equipment during structural heart intervention procedures. In order to clearly visualize a patient's cardiac structure, the ICE catheter and handle must remain still. According to the client, Dr. Amish Raval, even 3-4 mm of movement at the handle of the catheter can significantly affect the visualization of the ICE. Therefore, this device must function as an adjustable support fixture for the handle of the ICE catheter. This device will replace the current stabilization method used by the client, which typically consists of either a technician holding the handle of the catheter in place or wet towels laid on top of the catheter handle. Implementation of this stabilization device will enable the ICE catheter to remain in place while also allowing the physician to make adjustments to the catheter position throughout the procedure.

Client Requirements

The stabilizer device must:

- Have an adjustable height of 22.8 - 34.3 cm
- Allow for the manipulation of the ICE handle controls while it is secured/resting in the stabilizer
- Be able to be used for both the left and right legs
- Not interfere with the therapeutic device
- Not damage the surgical drape used in the procedure in order to maintain a sterile environment
- Be compatible with different brands/models of ICE handles
- Be made of metal and re-sterilizable via ethylene oxide, or be made of plastic, manufactured sterilized and disposable
- Cost less than $300 to manufacture

The research and development budget for the team is $1,000.

Design Requirements

1. **Physical and Operational Characteristics**
    a. *Performance Requirements:* The device must be able to securely hold the ICE handle in place while allowing for the manipulation of the ICE controls. It must also allow for vertical adjustment of the handle from 22.8 to 34.3 cm. In addition, it should be able to withstand common forces it may encounter in a surgical setting, such as bumps of the table.
    b. *Safety:* The stabilizer must be able to hold the catheter autonomously without the catheter being moved or displaced. Such displacements would provide procedural complications such as perforation of an artery or aorta or an atrioesophageal fistula formation (caused by thermal damage from the catheter in the esophagus) [1]. If the aorta is perforated, it causes immediate death in 40% of patients [2]. Additionally, the stabilizer must be properly stabilized between uses. Without proper sterilization, the device could cause serious infection or disease to the patient as the patient's femoral artery is exposed.
    c. *Accuracy and Reliability:* The device must allow complete access to the ICE catheter device's controls. The device must not allow for more than 2 mm of movement of the ICE catheter as even 3 mm of movement can misalign the system. The device should be able to work with any ICE catheter on the market and either be re-sterilizable or sterile and disposable.
    d. *Life in Service:* The life in service of the stabilizer instrument is synonymous with the use duration of the device. The instrument must withstand a use duration of 30 minutes up to 3 hours in accordance with the typical length of cardiac catheterization procedures [3].
    e. *Shelf Life:* The device must either be single-use or reused for numerous procedures. If a reusable instrument is designed, the device must be reusable for at least 500 procedures or 5 years, depending on the waste/device recycling procedures of the hospital or clinic in which it is used. Stainless steel surgical instruments can typically be used for over 20 years and thus the device may have the potential to be used beyond the required lifetime [4].
    f. *Operating Environment:* This device will be utilized in catheterization laboratories (cath labs) which are sterile environments. All parts of the stabilizer above the sterile drape must be sterile, meaning the device must be manufactured and shipped as sterile and be disposable or must be re-sterilizable via ethylene oxide gas [5]. Additionally, the device must not damage or tear the surgical drape in any way as this would result in breaking the sterile field.
    g. *Ergonomics:* The device must be fully functional with no additional human stabilization to the device. It should not interfere with any surgical procedures and must allow access to the ICE handle controls for the user to operate.
    h. *Size:* The device should be as small as possible while maintaining its essential functions so as to not interfere with the other surgical procedures the ICE is supporting. If the route of a table mounted device is chosen, the device should not take up more than a 100 mm x 200 mm x 380 mm. If another design route is chosen, such as an articulating arm, the dimensions may vary as necessitated by the design. It must be able to secure a handle with a diameter of 46.45 mm at the widest and 25.14 mm at the narrowest, with some additional flexibility for adjustment of the device when used with different ICE models. There is limited space in the catheter lab for equipment; therefore, the device should take up a minimal footprint to allow the operator more room to perform the procedure and to leave space for other equipment.

i. *Weight:* As the device is intended to stabilize the ICE by securing its handle, it must have a weight of at least 1 kg to resist bumps and forces that would otherwise knock the ICE out of place. The device must not be overly heavy, however, as it should not be burdensome to set up or move; thus, the device should not weigh more than 6 kg. If alternative methods are used to secure the stabilizer to the table such as a clamp or suction cup, it could be acceptable for the device to weigh less than 1 kg.

j. *Materials:* The device must be made of a material that can withstand ethylene oxide gas sterilization. Specifically, the material must withstand a sterilization cycle of 1-6 hours at 37-63 °C and relative humidity of 40-80% [6]. Such materials could include stainless steel or thermoplastics such as PEEK; however, most commonly-used materials are highly compatible with ethylene oxide. Additionally, the material must be compatible with the chosen method of fabrication, which could potentially include CNC machining or 3D printing.

k. *Aesthetics, Appearance, and Finish:* The geometry and surface finish of the device must be compatible with gas sterilization if a reusable design is chosen; alternatively, the device should be sterile and disposable. The device should not provide a visually distracting appearance to the surgical procedures.

2. Production Characteristics

a. *Quantity:* One functional prototype of the device will be developed in order to gauge if the device integrates with the protocols for the procedure and test if the device meets all requirements.

b. *Target Product Cost:* According to the client, the device must cost under $300.

3. Miscellaneous

a. *Standards and Specifications:* As defined by the FDA in the Code of Federal Regulations, Title 21, Part 880.5210, an intravascular catheter securement device is a Class I (general controls) medical device [7]. While the FDA does not specifically call out an intracardiac catheter stabilization or securement device, a similar stabilization accessory for the MitraClip System is a Class I device [8]. Class I devices must only meet the requirements of the General Controls provisions of the CFR Title 21, Subchapter H in order to prove the device's safety and efficacy [9]. Additionally, ISO 13485, which includes requirements for regulatory purposes of medical devices, states that the design and development process outputs must be documented in a form suitable for verification against the design and development requirements [10].

b. *Customer:* The customer of this device requires that the device improves upon the current method of ICE catheter stabilization. Customers for this product include physicians and hospital or medical clinic staff. The device must streamline the process of performing interventional heart procedures with the goal of improving accuracy and efficiency of the procedures.

c. *Patient-Related Concerns:* The device must be inclusive for use with all patients. Patients undergoing structural heart intervention procedures may be likely to have increased waist circumference or waist to hip ratio as these metrics are predictive of cardiovascular disease [11]; thus, the functionality of the device must be independent of patient size. Additionally, the device must not cause discomfort for the patient during the procedure.

d. *Competition:* There are many ICE catheter stand and clamp systems on the market. The Abbott MitraClip and Triclip are held up by a stand that allows for the attachment of a mitral valve replacement device at an angle to allow for the user to easily access the controls [12]. Furthermore, the Edwards EVOQUE comes on a base plate that has a stabilizer to hold a tricuspid valve replacement device. This also comes with adjustable leg height and clamps [13]. Both the EVOQUE and the MitraClip are similarly sized to ICE catheters.

References

[1] Z. M. Hijazi, K. Shivkumar, and D. J. Sahn, "Intracardiac Echocardiography During Interventional and Electrophysiological Cardiac Catheterization," Circulation, vol. 119, no. 4, pp 587–596, Feb. 2009, doi: https://doi.org/10.1161/circulationaha.107.753046.

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[3] "Everything You Need to Know About Cardiac Catheterization - Penn Medicine," www.pennmedicine.org. https://www.pennmedicine.org/updates/blogs/heart-and-vascular-blog/2020/august/everything-you-need-to-know-about-cardiac-catheterization.

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[12] "MitraClip G4 Features - Tailored. Optimized. Proven.," mitraclip.com. https://mitraclip.com/physician/mitraclip-procedure/mitraclip-features.

[13] "EVOQUE Tricuspid Valve Replacement," Edwards.com, 2014. https://www.edwards.com/healthcare-professionals/products-services/evoque-tricuspid-valve-replacement-system.

Conclusions/action items:

This product design specifications will be used to evaluate our design.

4/30/2025 - Ethical Consideration

MAX AZIZ (mmaziz@wisc.edu) - Apr 30, 2025, 9:37 PM CDT

Title: Ethical Consideration

Date: 4/30/2025

Content by: Max

Present: n/a

Goals: To consider important ethical dilemmas when building this device.

Content:

Although the device needs to be sterilizable, there are serious ethical considerations. One is that the hospital will mainly use ethylene oxide to sterilize the stabilizer. Ethylene oxide is a possible carcinogen that can have serious effects on the reproductive system, skin, and nerves. Another concern is that the stabilizer fails and the catheter perforates the aorta. This can be irrecoverable and the patient could die. Therefore, the device must be tested thoroughly and properly. Lastly another concern could be the disposable use of the top parts could create a lot of undesirable waste, which could be harmful to the environment.

Conclusions/action items: It is important that our device be sterilizable, but it can be sterilizable using other methods besides ethylene oxide. Also, it is important that our device does not move the catheter a considerable amount. Otherwise, there are clear adverse effects. Additionally, the top part could be packaged in recyclable component so that it is less harmful to the environment.

4/30/2025 - Final Design

MAX AZIZ (mmaziz@wisc.edu) - Apr 30, 2025, 10:14 PM CDT

Title: Final Design

Date: 4/30/2025

Content by: Max Aziz

Present: N/A

Goals: To discuss the final design in more depth

Content:

The device consists of three parts: top, middle, and base. The device will rest on the cath lab table. The patient's legs will rest on top of the base of the device with the middle part sticking up between the patient's legs. The middle part can be moved vertically via a quick release clamp to adjust for heights of various patients. Then the sterile drape will be placed above the middle part. On top of the sterile drape, above the middle part of the device, the top part will attach to the middle part via magnets, which are at the top of the middle part and the bottom of the top part of the device, as the sterile drape is strong enough that it will not tear. Then the catheter will be placed on the top part of the device and secured with the rubber strap that is attached to the top part. The bottom and middle parts of the device are made from AISI 4130 stainless steel as it is below the sterile drape and does not have to be sterilized thoroughly. A caddy or Clorox wipe could be used to disinfect these parts between patients. This will require operators to only buy this part of the device once. However, the top part will come in a sterile package as it is above the sterile drape that will be made from polyethylene and will come in multiple sizes such as small, medium, large, and extra large as we have done for the functional prototype. These will be one time use parts and will need to be purchased constantly. The multiple sizes will help with finer adjustments after the sterile drape has been placed on the device. The figures below will guide how the device looks and will be used.

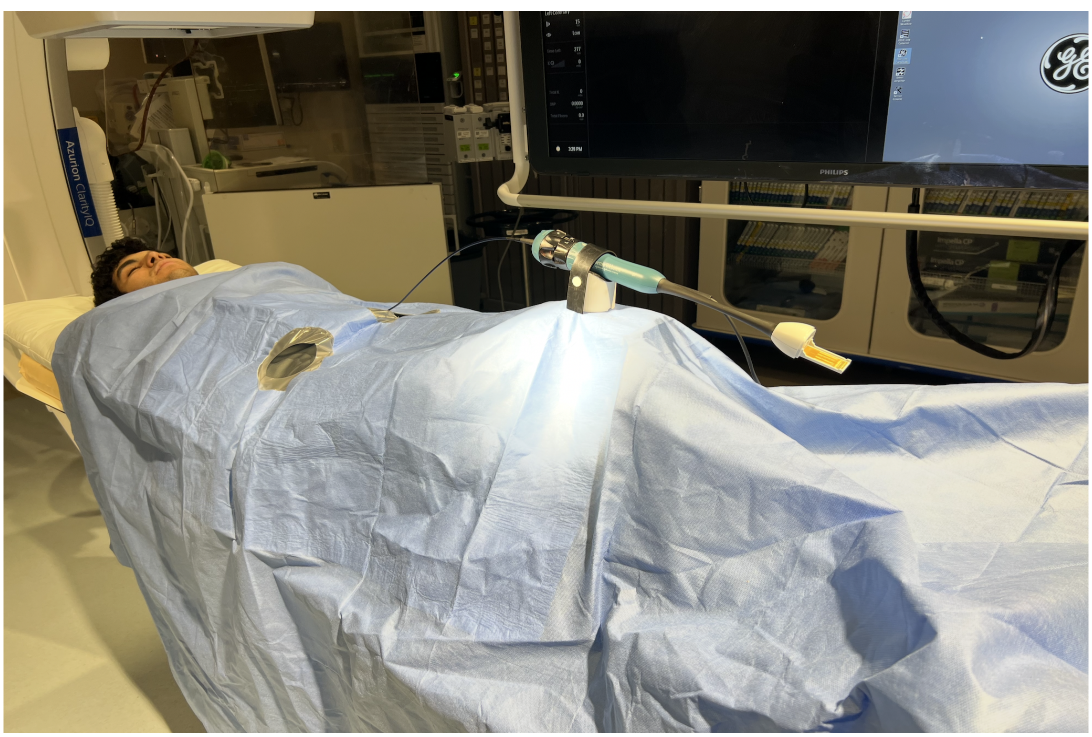

Fig 6: Device in use with catheter and patient.

Conclusions/action items: This device meets the requirements of the PDS and is explained further so that anyone can understand how it is used in its proper setting.

2024/11/8 - Materials List

NOAH HAMRIN - Nov 08, 2024, 2:17 PM CST

Title: Material List

Date: 11/8/2024

Content by: Noah Hamrin

Present: Noah, Sara, and Max

Goals: Create a list of raw materials to order

Content:

- 1 flat metal base plate (355mm x 200mm x 3mm)

- 1 hollow tube (inner diameter: , outer diameter: 34mm)

- 1 hollow tube (inner diameter: , outer diameter:)

- quick release (bike seat) clamp

- rubber strip with adhesive backing

- rubber straps with holes

Conclusions/action items:

Share this design with the team and discuss.

4/30/25 - Expense Spreadsheet

NOAH HAMRIN - Dec 11, 2024, 10:22 PM CST

Title: Expense Spreadsheet - Final

Date: 12/11/24

Content by: Sara Morehouse

Present: N/A

Goals: To list all materials used for the prototype and provide a cost estimate.

Content:

Material	Cost	Price Estimate	Vendor	Part Number
3D printed prototype	$6.97	$6.97	MakerSpace	n/a
Bike seat post clamp (34.9 mm size)	$8.99	$8.99	Amazon	769135257429
¼”x ¼” x ⅛” magnet (2)	$2.57	$5.14	McMaster-Carr	5848K11
¼” x ¾”x ¼” magnet (2)	$6.76	$13.52	McMaster-Carr	5848K83
1" Wide x 1/16" Thick x 10' Long Rubber sheet	$9.99	$0.42	Amazon	B08QZH58KD
2" Wide x 1/16" Thick x 10' Long Rubber sheet with adhesive backing	$12.98	$0.22	Amazon	B0BFHBXCRX
1-⅜” OD 4130 steel shaft - 1ft long	$29.37	$29.37	McMaster-Carr	89955K169
Sheet metal 4130 easy-to-weld steel 6”x36”	$63.80	$63.80	McMaster-Carr	4459T188
4130 steel rod 2”x1ft	$88.65	$88.65	McMaster-Carr	6673T34
Total		$143.21		

Conclusions/action items:

This entry lists all materials that were used/will be used in the final prototype.

SARA MOREHOUSE - Apr 30, 2025, 10:26 PM CDT

Title: Expense Spreadsheet - Final

Date: 4/30/25

Content by: Sara Morehouse

Present: N/A

Goals: To list all materials used for the prototype and provide a cost estimate.

Content:

Item	Cost Per	Total Cost	Vendor	Part #
3D printed prototype	$8.00	$8.00	UW-Design Innovation Lab	N/A
Bike seat post clamp (34.9 mm size)	$8.99	$8.99	Amazon	769135257429
¼”x ¼” x ⅛” magnet (10)	$2.57	$25.70	McMaster-Carr	5848K11
1" Wide x 1/16" Thick x 10' Long Rubber sheet	$9.99	$0.65	Amazon	B08QZH58KD
2" Wide x 1/16" Thick x 10' Long Rubber sheet with adhesive backing	$12.98	$0.22	Amazon	B0BFHBXCRX
1-⅜” OD 4130 steel shaft - 1ft long	$29.37	$20.80	McMaster-Carr	89955K169
Sheet metal 4130 easy-to-weld steel 6”x36”	$63.80	$35.45	McMaster-Carr	4459T188
4130 steel rod 2”x1ft	$88.65	$51.71	McMaster-Carr	6673T34
1-1/8" OD 4130 steel shaft - 1ft long	$25.20	$20.16	McMaster-Carr	89955K959
Total		$171.68		

Conclusion:

This entry lists all materials that were used/will be used in the final prototype.

2/19/2025 - Middle Part CNC Fabrication

NOAH HAMRIN - Apr 28, 2025, 8:48 PM CDT

Title: Middle Part CNC Fabrication

Date: 2/19/2025

Content by: Noah

Present: Noah

Goals: Use toolpaths to fabricate the top of the middle part

Content:

The process went smoothly with the CNC staff finalizing the rough toolpaths prepared. A pair of soft vice clamps were custom made for the cylindrical stock and, once the stock was secured, the ProtoTrak 2op CNC accurately created the design. The next steps are to glue the magnets in the slots and weld the piece to the rod of the middle part.

Conclusions/action items:

Give to Kaden to weld to the rod of the middle part.

NOAH HAMRIN - Apr 28, 2025, 8:42 PM CDT

DATA

Download

pole_top.SLDPRT (220 kB)

NOAH HAMRIN - Apr 28, 2025, 8:42 PM CDT

DATA

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pole_top.emcam (5.24 MB)

4/10/25 and 4/17/25 - Laser Cutting of the Strap

SARA MOREHOUSE - Apr 30, 2025, 1:43 PM CDT

Title: Laser Cutting of Strap, attempt 1

Date: 4/10/25

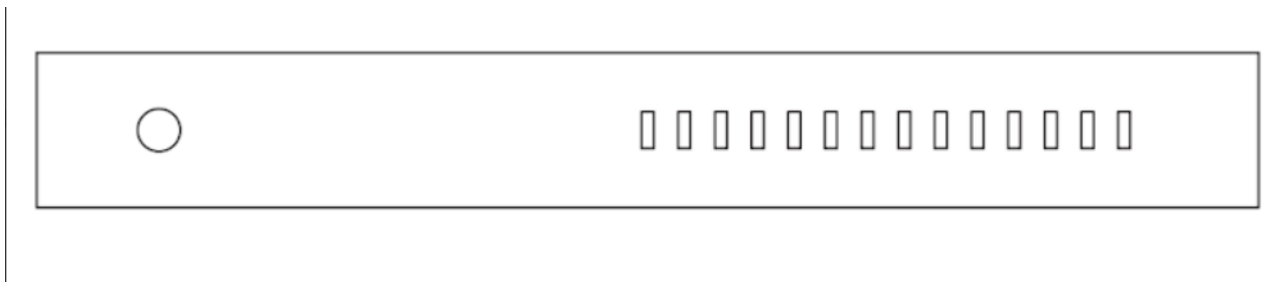
Content by: Sara Morehouse

Present: Sara Morehouse, Noah Hamrin

Goals: To design and laser cut the neoprene rubber straps.

Content:

The strap was first designed in Adobe Illustrator:



The design was updated with input from the team:

- stroke width of 0.001”
- all vector cut components set to RGB Red

Then, the design was uploaded to the Universal Control Panel software for export to the laser cutter. Material settings were adjusted to be neoprene rubber and material thickness was input as measured (0.06"). The Universal Laser Systems model VLS4.75 was used for this process.

The first iteration of the straps was as follows:

However, this strap had a number of issues with the spacing and thickness of the slits/holes. The strap tore very easily, and the design was quickly modified to prevent this.

Conclusions/action items:

This strap was functional, but needs some updates in order to strengthen it, prevent tearing, and clean up the edges slightly. The straps will be re-cut in order to do so.

SARA MOREHOUSE - Apr 30, 2025, 1:45 PM CDT

Title: Laser Cutting of Strap, attempt 2

Date: 4/17/25

Content by: Sara Morehouse, Noah Hamrin

Present: Sara Morehouse

Goals: To design and laser cut the neoprene rubber straps.

Content:

The updated strap was designed in Adobe Illustrator:

- stroke width of 0.001”
- all vector cut components set to RGB Red

Then, the design was uploaded to the Universal Control Panel software for export to the laser cutter. Material settings were adjusted to be neoprene rubber and material thickness was input as measured (0.06"). The Universal Laser Systems model VLS4.75 was used for this process.

Conclusions/action items:

This strap was functional and had minimal issues with tearing. The holes were correctly spaced. 4 copies of this strap were printed for use with each of the top pieces.

4/12/2025 - Top Part 3D printing

MAX AZIZ (mmaziz@wisc.edu) - Apr 30, 2025, 5:06 PM CDT

Title: 3D printing Top Part

Date: April 15, 2025

Content by: Max Aziz

Present: Max Aziz and Noah Hamrin

Goals: To print top part

Content:

- Make solidworks file an STL file (an example has been provided below)

- place download on flashdrive

- use makerspace computers with flashdrive

- choose a bambu 3D printer that is available

- Slice the files appropriately

- Ensure supports are appropriate

- Ensure 15% more fill and stronger walls than normal

- Print device with approval from Makerspace staff

- Gently take off supports

- If the device is not up to par, fix issue in Solidworks and repeat process (this had to be done four times during our design process)

Conclusions/action items: Over the course of a couple weeks, the top parts were successfully printed via the process stated above.

MAX AZIZ (mmaziz@wisc.edu) - Apr 30, 2025, 5:05 PM CDT

Download

saddle_angled_L.STL (152 kB)

4/23/2025 - Spray painting Device

MAX AZIZ (mmaziz@wisc.edu) - Apr 30, 2025, 5:17 PM CDT

Title: Spray painting Device

Date: 4/23/25

Content by: Max Aziz

Present: Max Aziz

Goals: Spray paint the device to make it look more polished and presentable

Content:

- Go outside and find solid ground to begin spray painting device

- Ensure it is dry outside and on ground

- Shake spray paint bottle for 2 minutes straight

- Wear N95 mask

- Stand 9 inches from device

- Press nozzle to begin to spray paint

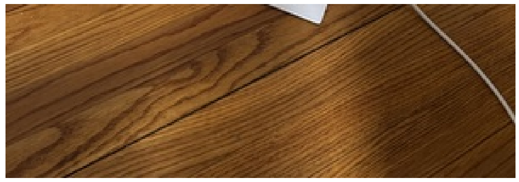
- Spray paint slowly in sweeping motion

- Ensure paint does not drip by not over doing it

- Wait 24 hours for spray paint to dry

Conclusions/action items: The spray paint was successfully completed and the device looks more presentable in white than the steel color it was prior.

MAX AZIZ (mmaziz@wisc.edu) - Apr 30, 2025, 5:13 PM CDT



Download

CAEBE9E7-5C8E-44C6-8E63-62C8E39C56F9_1_105_c.jpeg (299 kB)

4/18/2025 - Grinding Weld

NOAH HAMRIN - Apr 30, 2025, 10:28 PM CDT

Title: Grinding Weld

Date: 4/18/2025

Content by: Max Aziz

Present: Max and Noah

Goals: Weld needs to be ground down to make it smoother so it does not hurt any patients

Content:

- Obtain angle grinder from TeamLab

- Wear heavy gloves

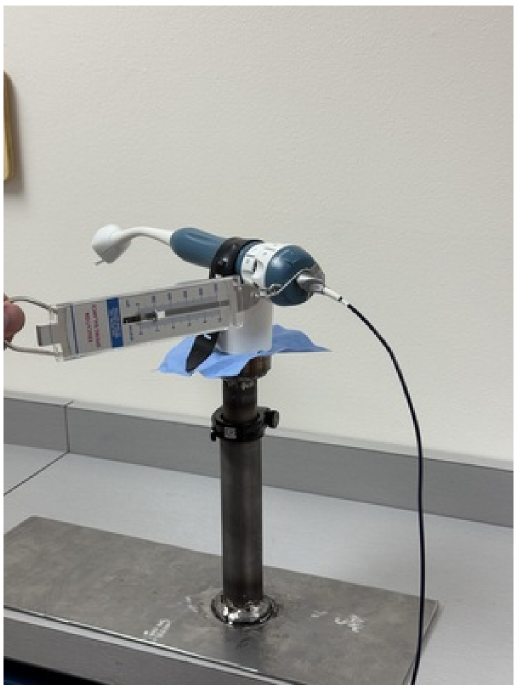
- Have one person hold the device and one person hold the grinder

- Slowly approach weld and fix areas that are protruding outward

- Fix any parts of the device that have metal protruding outward

Conclusions/action items: The device was properly smoothed so that patients will not experience any harm from sharp edges.

MAX AZIZ (mmaziz@wisc.edu) - Apr 30, 2025, 5:28 PM CDT



Download

EDDCC499-E4D2-4F92-AD14-4F1ADBAE726C_1_105_c.jpeg (230 kB)

4/22/2025 - Metal Epoxy Weld

MAX AZIZ (mmaziz@wisc.edu) - Apr 30, 2025, 5:35 PM CDT

Title: Metal epoxy weld

Date: 4/22/2025

Content by: Max Aziz

Present: Max and Sara

Goals: Metal epoxy weld to ensure it is smooth and strong

Content:

- Obtain metal epoxy

- Obtain popsicle sticks and paper towel

- Mix contents from metal epoxy packaging together with popsicle sticks on paper towel

- Apply those contents to weld

- Wait 24 hours for it to dry

Conclusions/action items: The metal epoxy filled in holes of the weld to make it smoother and stronger, which will make the device safer for use to patient and operator.

4/18/2025 - Cutting Sheet of Metal and Sanding

NOAH HAMRIN - Apr 30, 2025, 10:27 PM CDT

Title: Cutting Sheet of Metal and Sanding

Date: 4/18/2025

Content by: Max Aziz

Present: Max and Noah

Goals: The base needs to be shortened, so that the middle and top parts of the device are more off-centered and the whole device fits on the table.

Content:

- Make line on the metal of where it should be cut (3" perpendicular to long way)

- Turn on metal band saw with light

- Slowly feed the device through the band saw until it is complete

- Use the power sand machine to sand all the sides of the device to ensure that are no sharp edges.

Conclusions/action items: The device is now an appropriate length to be fit on the cath lab table, and the edges are smooth to ensure no patient will get injured or harm.

4/16/25 - Force Testing Protocol

MAX AZIZ (mmaziz@wisc.edu) - Apr 30, 2025, 5:21 PM CDT

Title: Force Testing Protocol

Date: 4/16/25

Content by: Sara Morehouse, Noah Hamrin, Max Aziz

Present: Noah Hamrin, Max Aziz

Goals: Protocol for performing force testing on the prototype.

Content:

Materials:

- 4D ICE Catheter
- 3D ICE Catheter
- Prototype
- Duct tape
- Spring force gauge
- Wet towels (2)

Procedure:

1. Place 3D ICE catheter into the saddle of the prototype.
2. Hook the spring gauge onto the front end of the catheter in the vertical direction, perpendicular to the axis of the catheter.
3. Apply a downward force with the spring gauge until the magnets in the prototype become disconnected. Record this force value.
4. Repeat step 3 for a total of 5 trials.
5. Hook the spring gauge onto the front end of the catheter in the transverse horizontal direction, perpendicular to the axis of the catheter.
6. Apply a transverse (twisting) force to the prototype via the spring gauge until the magnetic saddle twists off of the prototype. Record this force value.
7. Repeat steps 5-6 for a total of 5 trials.
8. Tape the hook of the spring gauge to the front end of the catheter in the axial direction.
9. Apply a tensile force with the spring gauge to the catheter until the magnets in the prototype become disconnected. Record this force value.
10. Repeat steps 8-9 for a total of 5 trials.
11. Repeat steps 1-10 with the 4D ICE catheter.
12. Wrap the 3D ICE catheter with one of the wet towels, then drape the second towel over the top of the 1st towel.
13. Repeat steps 5-10 with the 3D catheter in the towels.
14. Repeat step 12 with the 4D ICE catheter.
15. Repeat steps 5-10 with the 4D catheter in the towels.
16. Once all force values have been collected, upload data into MATLAB.
    a. The following code can be used to graph the data:

```
device_4d_bendingXL = [4.2, 4.0, 3.8, 3.8, 4.0];
device_3d_bendingXL = [4.6, 4.4, 4.2, 4.4, 4.4];
device_4d_bendingS = [10.0, 10.0, 10.0, 10.0, 10.0];
device_3d_bendingS = [10.0, 10.0, 9.8, 9.2, 10.0];
towel_bending = [0.8, 0.6, 0.7, 0.6, 0.5, 0.2, 0.4, 0.3, 0.4, 0.3];
mean_device_d4_bendingXL = mean(device_4d_bendingXL);
mean_device_d3_bendingXL = mean(device_3d_bendingXL);
mean_device_d4_bendingS = mean(device_4d_bendingS);
mean_device_d3_bendingS = mean(device_3d_bendingS);
mean_towel_bending = mean(towel_bending);
std_device_d4_bendingXL = std(device_4d_bendingXL);
```

```
std_device_d3_bendingXL = std(device_3d_bendingXL);
std_device_d4_bendingS = std(device_4d_bendingS);
std_device_d3_bendingS = std(device_3d_bendingS);
std_towel_bending = std(towel_bending);
means = [mean_towel_bending, mean_device_d4_bendingS, mean_device_d4_bendingXL,
mean_device_d3_bendingS, mean_device_d3_bendingXL];
stds = [std_towel_bending, std_device_d4_bendingS, std_device_d4_bendingXL,
std_device_d3_bendingS, std_device_d3_bendingXL];
figure(1);
bar(means);
hold on;
errorbar(1:5, means, stds, 'k', 'LineStyle', 'none', 'CapSize', 10);
xticks(1:5);
xticklabels({'Towel', 'Device 4D Small', 'Device 4D XL', 'Device 3D Small', 'Device
3D XL'});
xtickangle(30);
ylabel('Force (Newtons)');
title('Twisting Force Comparison');
set(gca, 'FontSize', 14);
ylim([0 12]);
hold off;
```

b. The following code can be used to obtain p-values for the data:

```
%% Force testing
% Device vs. Towel
[h,p] = ttest2(Tensile4D_t,Tensile_d)
[h,p] = ttest2(Twisting4D_t,Twisting4D_d)
[h,p] = ttest2(Tensile3D_t,Tensile_d)
[h,p] = ttest2(Twisting3D_t,Twisting3D_d)



% 4D vs 3D
[h,p] = ttest2(Bending3D_d,Bending4D_d)
[h,p] = ttest2(Twisting3D_d,Twisting4D_d)
% for tensile, p>0.05



% Mean values
bending4D_d_mean = mean(Bending4D_d)
bending3D_d_mean = mean(Bending3D_d)
twisting4D_d_mean = mean(Twisting4D_d)
twisting3D_d_mean = mean(Twisting3D_d)
tensile4D_t_mean = mean(Tensile4D_t)
tensile3D_t_mean = mean(Tensile3D_t)
twisting4D_t_mean = mean(Twisting4D_t)
twisting3D_t_mean = mean(Twisting3D_t)
```

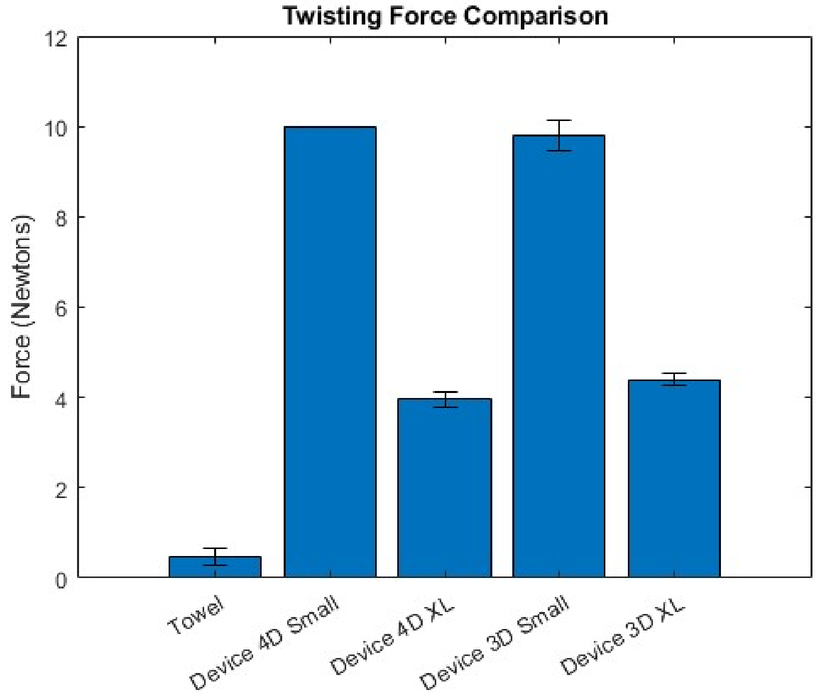


Fig. 1 Average twisting force, which is the force in the perpendicular direction relative to the catheter, to dislodge 3D and 4D ICE catheters comparing the current method with the devices' small and extra large top parts ($p < 0.001$)

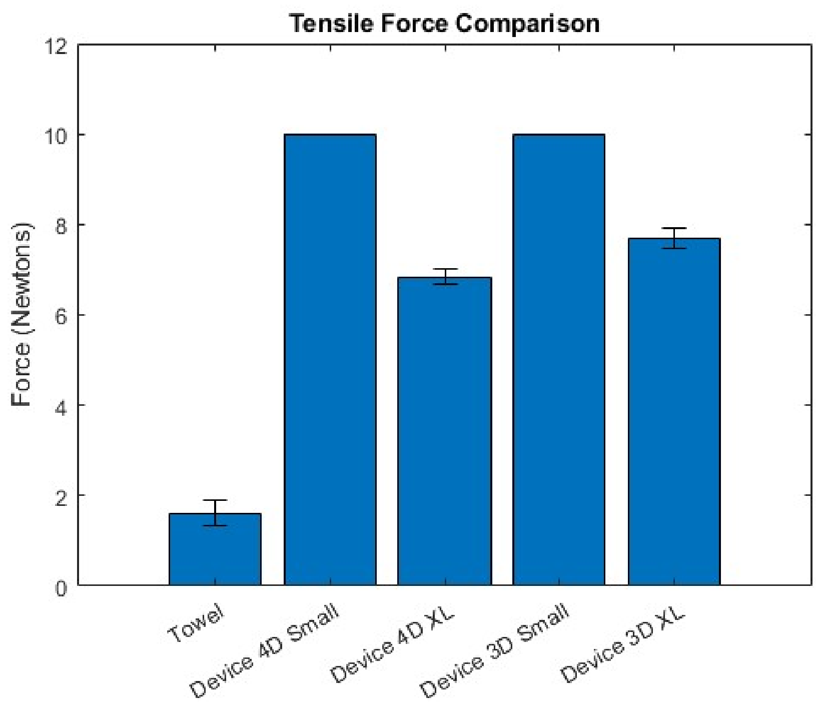


Fig. 2 Average tensile force, which is the force in the outward direction relative to the catheter, to dislodge the 3D and 4D ICE catheters comparing the current method with the devices' small and extra large top pieces ($p < 0.001$)

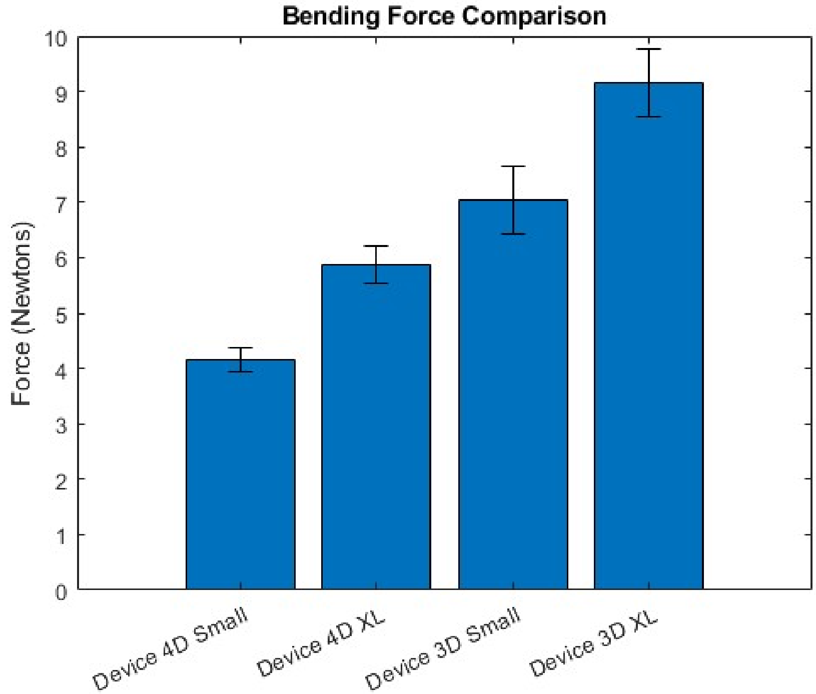


Fig. 3 Average bending force, which is the force in the downward direction relative to the catheter, to dislodge the 3D and 4D ICE catheters from the devices' small and extra large top parts ($p < 0.001$)

Conclusions/action items:

This test is used to verify that the prototype is capable of keeping the catheter secured better than the previous method that was used (wet towels). The data will be analyzed with a T-test to check whether significantly more force is required to displace the catheters from the prototype than from the towels.

4/7/25 - User Feedback Survey

SARA MOREHOUSE - Apr 30, 2025, 1:35 PM CDT

Title: User Feedback Survey

Date: 4/7/25

Content by: Sara Morehouse, Max Aziz

Present: all

Goals: To evaluate the device on qualitative aspects including ease of use based on the client's feedback.

Content:

In each category, 5 refers to the positive score and 1 is the most negative score possible.

Survey:

How easy is it to use the device on a scale of 1-5, 5 being very easy to use?

1 2 3 **4** 5

On a scale of 1-5, rate the ease of adjusting the height of the device via the bicycle clamp, with 5 being very easy and 1 being very difficult.

1 2 3 4 **5**

On a scale of 1-5, rate the ease of swapping out the top piece of the device, including removing a top piece and placing a new one in the correct position. 5 refers to very easy and 1 refers to very difficult.

1 2 3 4 **5**

On a scale of 1-5, rate the ease of securing the catheter into the top piece via the rubber strap, with 5 being very easy and 1 being very difficult.

1 2 **3** 4 5

On a scale of 1-5, rate the level of security of the catheter in the top piece. Consider if the catheter slides forward/backward, rotates, or moves transversely. 5 refers to very secure and 1 refers to not secure at all.

1 2 3 4 **5**

On a scale of 1-5, rate the ease of placing the device on the table underneath the patient's legs, with 5 being very easy and 1 being very difficult.

1 2 3 **4** 5

On a scale of 1-5, rate the overall aesthetics and appearance of the device, with 5 being very aesthetically pleasing and 1 being not aesthetically pleasing at all.

1 2 3 **4** 5

On a scale of 1-5, how much does the device interfere in any way with the procedure, 5 being no interference and 1 being significant interference?

1 2 3 4 **5**

If the device cost under $500, would you purchase it and use it? **Yes** No

Conclusions/action items:

Based on this feedback, it is clear that Dr. Raval and his coworkers find the device overall easy to use and thinks it would integrate well into procedures. In the categories that the prototype did not score as well, such as the strap, Dr. Raval provided ideas for how to improve the device that the team will implement moving forward.

2/12/2025 - Magnetic Interference with Echocardiography

NOAH HAMRIN - Feb 12, 2025, 4:25 PM CST

Title: Magnetic Interference with Echocardiography

Date: 2/12/2025

Content by: Noah

Present: Noah

Goals: Research potential interference between magnets and echocardiography

Content:

Patent Watch: Ultrasound Guide Probe Device | Scientific American

- unlike MRI, ultrasound is unaffected by magnetic fields

Understanding the design of electromagnetic navigation technology

- properly shielded wires prevent signals from being distorted by magnetic fields

Conclusions/action items:

While there is reason to believe the catheter images will be unaffected by the small magnets we are using, testing will need to be conducted to confirm this. Regardless, because it is unlikely given the sources and known information, the development process can continue without design changes.

2/12/2025 - Applicable Standards

NOAH HAMRIN - Feb 12, 2025, 4:40 PM CST

Title: Applicable Standards

Date: 2/12/2025

Content by: Noah

Present: Noah

Goals: Identify which standards the device must adhere to

Content:

ISO 13485 – Quality Management Systems for medical devices

ISO 14971 – Risk Management for Medical Devices

ISO 10993 – Biological evaluation of medical devices

ISO 10993-5 – Cytotoxicity testing

Conclusions/action items:

Keep these standards and their requirements in mind as development continues

2/12/2025 - Cath Lab Accessories

NOAH HAMRIN - Feb 12, 2025, 4:35 PM CST

Title: Cath Lab Accessories

Date: 2/12/2025

Content by: Noah

Present: Noah

Goals: Find other competing designs

Content:

Beyond the similar catheter stands identified last semester, there appear to be very few devices on the market addressing this need.

Cardiac Cath Lab Accessories | InnerSpace Healthcare

- Some carts, stands, and accessories used in catheter labs

- no product listed that is moderately comparable to this project

Conclusions/action items:

Discuss with team and if in agreement, move forward with WARF patent process.

2/12/2025 - Top Part with Strap Clips

NOAH HAMRIN - Feb 12, 2025, 5:22 PM CST

Title: Top Part with Strap Clips

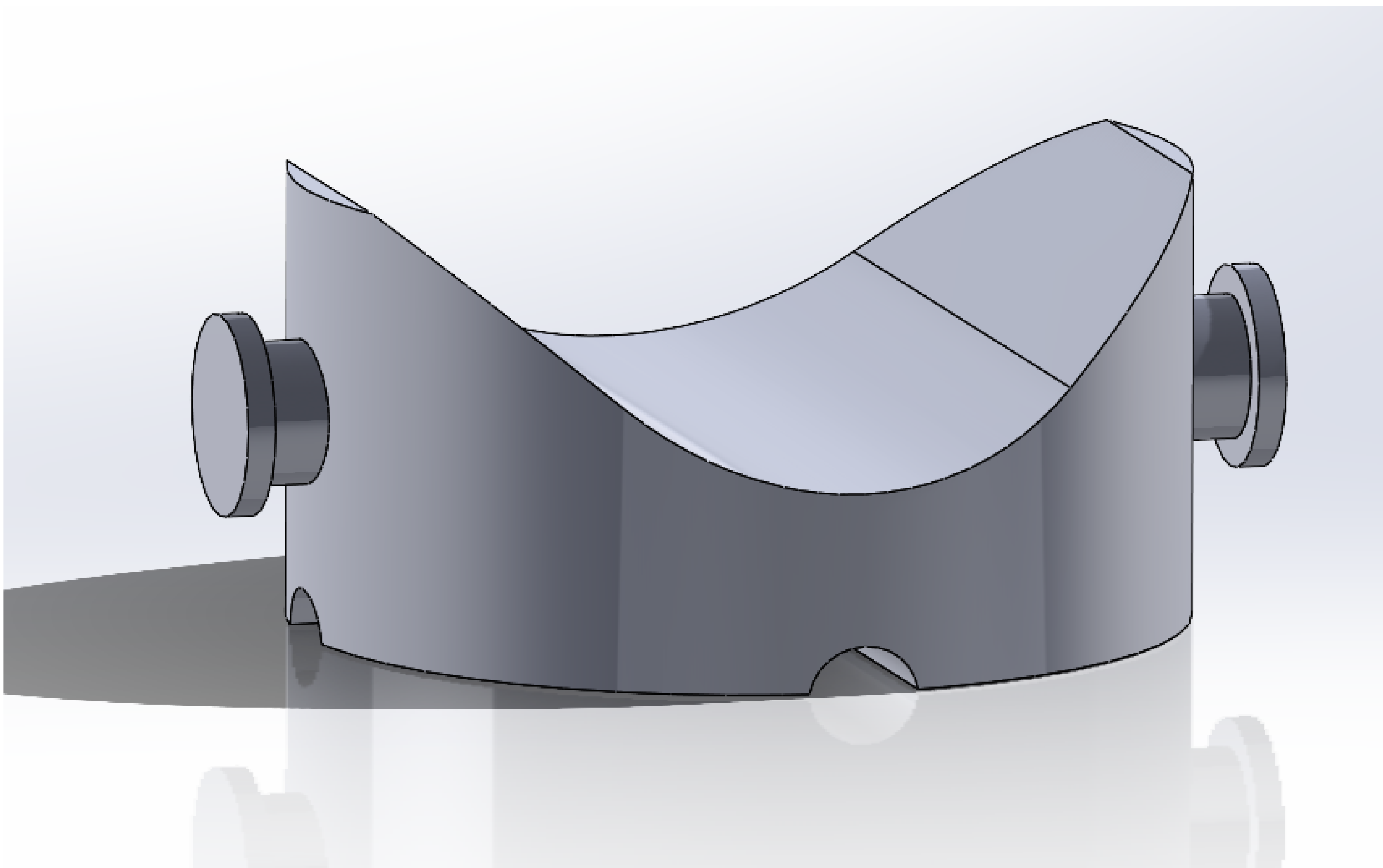
Date: 2/12/2025

Content by: Noah

Present: Noah

Goals: Add clips for the rubber straps to the Solidworks file for the top saddle part

Content:



Conclusions/action items:

Share with team and 3D print

NOAH HAMRIN - Feb 12, 2025, 5:22 PM CST

Download

top_mount.SLDPRT (193 kB)

2/19/2025 - Top Part Different Sizes

NOAH HAMRIN - Apr 28, 2025, 2:44 PM CDT

Title: Top Part Different Sizes

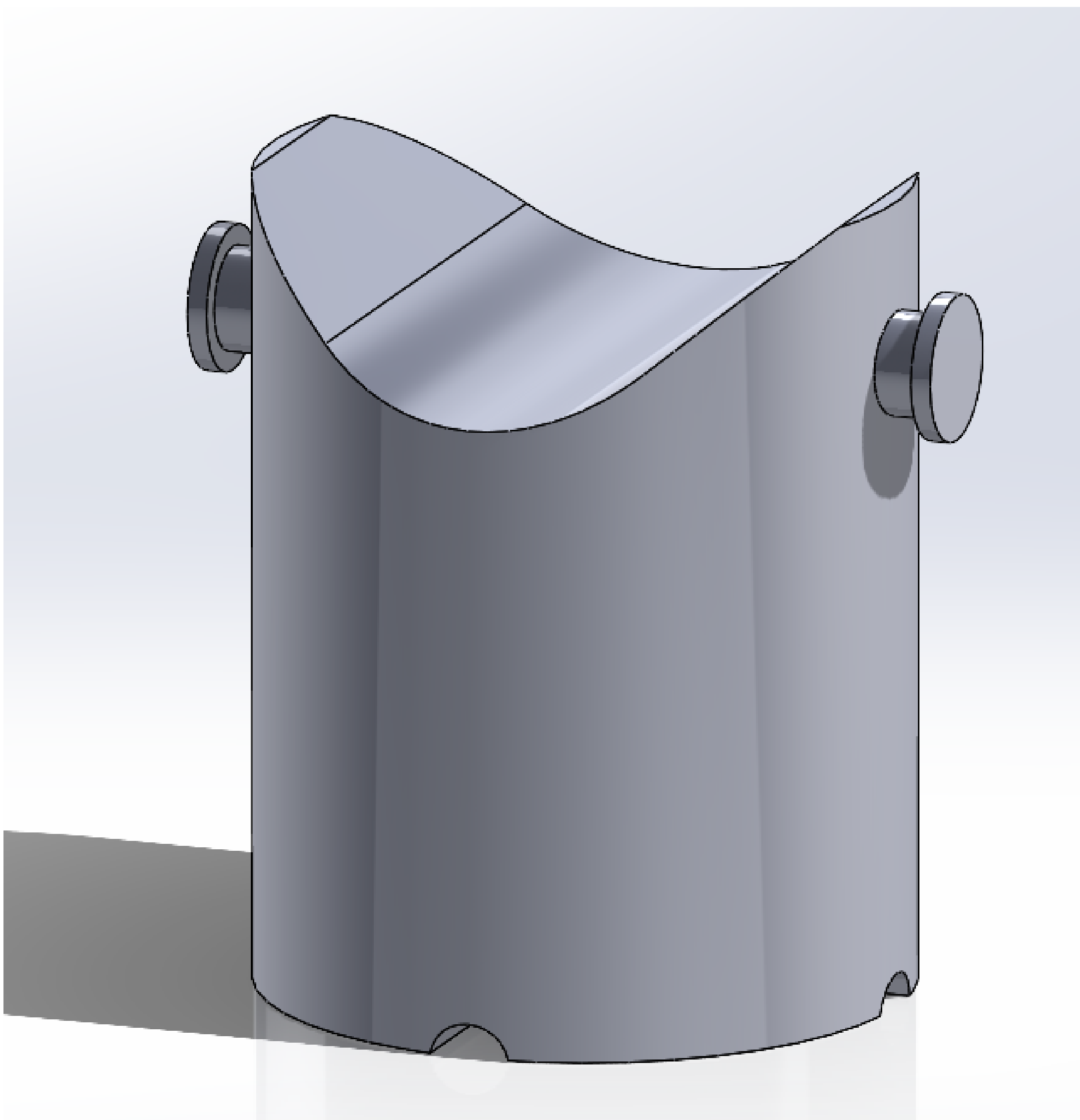
Date: 2/19/2025

Content by: Noah

Present: Noah

Goals: Create different sized top pieces

Content:



Created small (S), medium (M), large (L), and extra large (XL) sizes. Extra large is pictured above

Conclusions/action items:

Share with team and 3D print to test

NOAH HAMRIN - Apr 28, 2025, 2:50 PM CDT

Download

saddle_L.SLDPRT (170 kB)

NOAH HAMRIN - Apr 28, 2025, 2:50 PM CDT

Download

saddle_M.SLDPRT (171 kB)

NOAH HAMRIN - Apr 28, 2025, 2:50 PM CDT

Download

saddle_S.SLDPRT (189 kB)

NOAH HAMRIN - Apr 28, 2025, 2:50 PM CDT

Download

saddle_XL.SLDPRT (167 kB)

4/16/2025 - Updated Base Plate

NOAH HAMRIN - Apr 28, 2025, 2:57 PM CDT

Title: Updated Base Plate

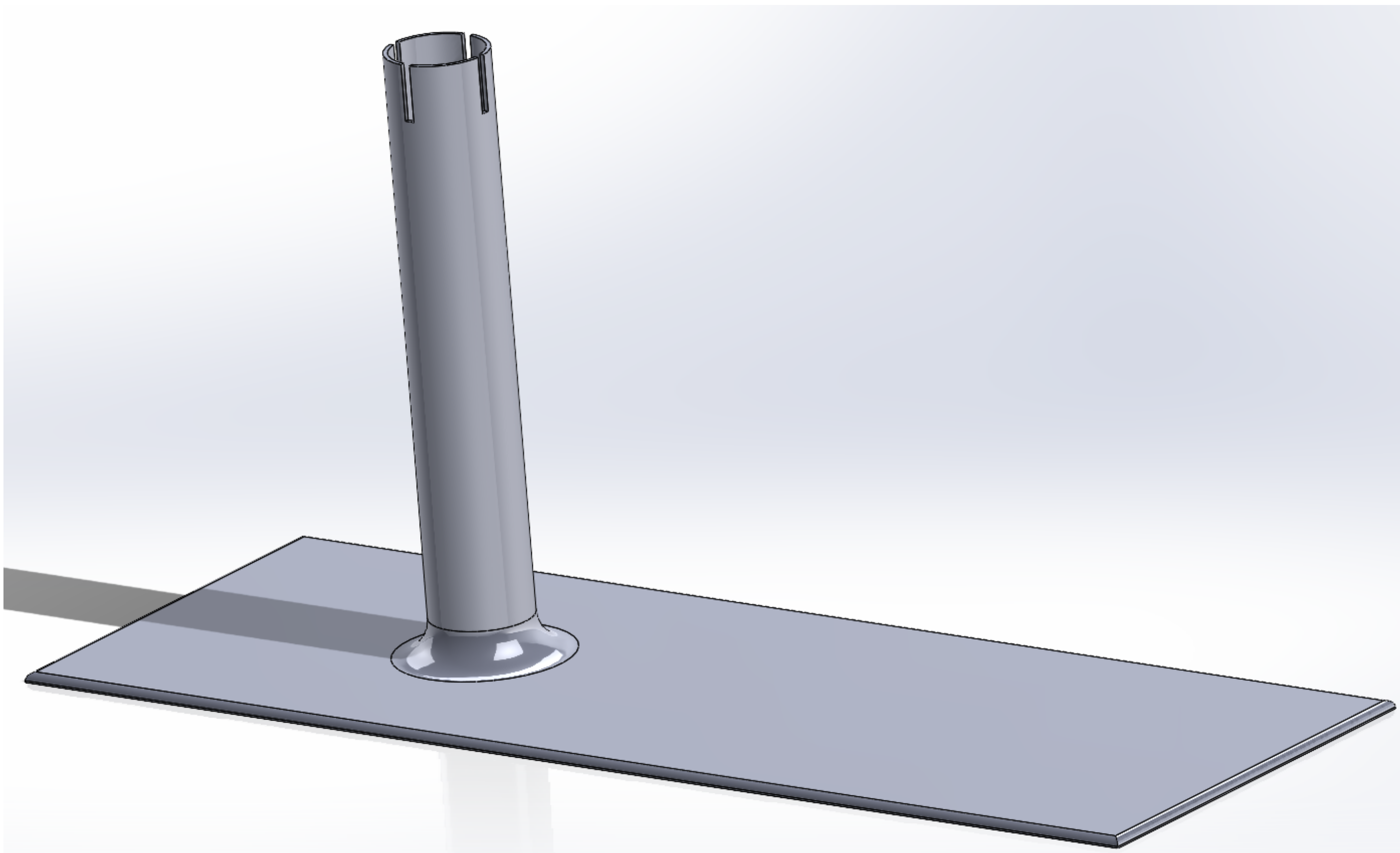
Date: 4/16/2025

Content by: Noah

Present: Noah

Goals: Tweak the base plate solidworks to match the actual prototype

Content:



Conclusions/action items:

Include on poster

NOAH HAMRIN - Apr 28, 2025, 2:58 PM CDT

Download

base.SLDPRT (140 kB)

4/17/2025 - Updated Top Parts with Angles

NOAH HAMRIN - Apr 28, 2025, 3:16 PM CDT

Title: Updated Top Parts with Angles

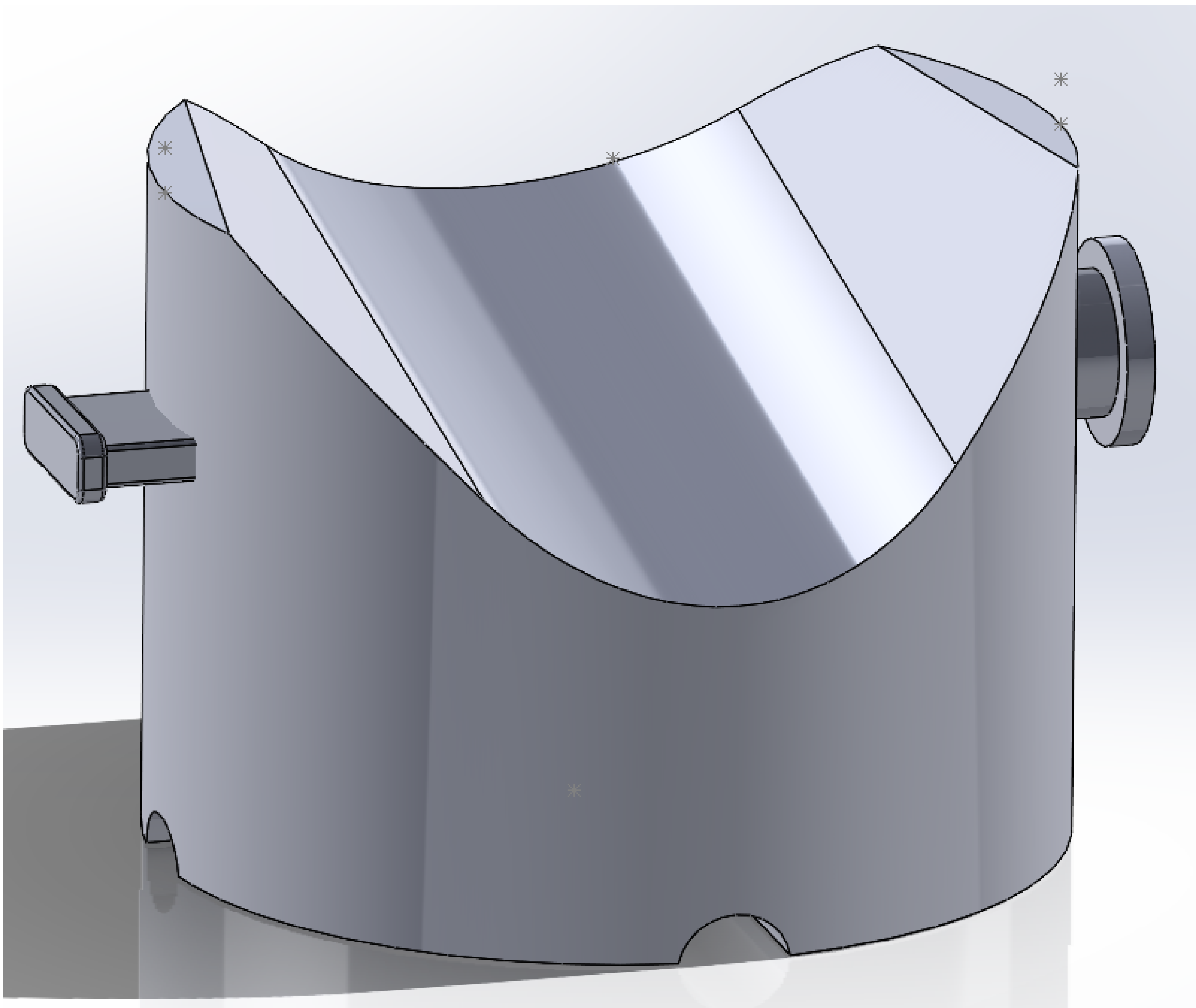
Date: 4/17/2025

Content by: Noah

Present: Noah

Goals: Add an angle to the saddle along with an updated strap button

Content:



Conclusions/action items:

3D print and use for testing

NOAH HAMRIN - Apr 28, 2025, 3:17 PM CDT

NOAH HAMRIN - Apr 28, 2025, 3:17 PM CDT

Download

saddle_angled_L.SLDPRT (256 kB)

NOAH HAMRIN - Apr 28, 2025, 3:17 PM CDT

Download

saddle_angled_M.SLDPRT (257 kB)

NOAH HAMRIN - Apr 28, 2025, 3:17 PM CDT

Download

saddle_angled_S.SLDPRT (261 kB)

NOAH HAMRIN - Apr 28, 2025, 3:17 PM CDT

Download

saddle_angled_XL.SLDPRT (256 kB)

2/19/2025 - Middle Part Prep for CNC

NOAH HAMRIN - Apr 28, 2025, 3:56 PM CDT

Title: Middle Part Prep for CNC

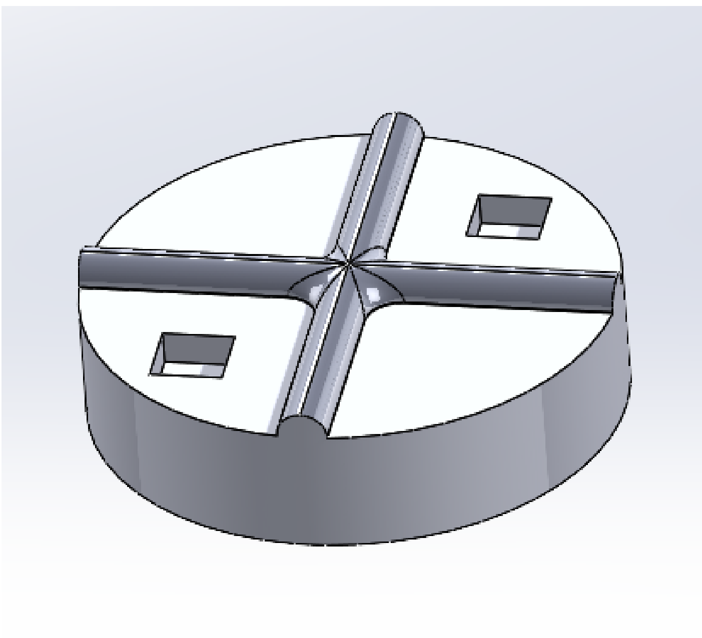
Date: 2/19/2025

Content by: Noah

Present: Noah

Goals: Isolate the top of the middle part for CNC, and create toolpaths

Content:



Conclusions/action items:

Complete CNC fabrication of middle part

NOAH HAMRIN - Apr 28, 2025, 3:56 PM CDT

Download

pole_top.SLDPRT (220 kB)

NOAH HAMRIN - Apr 28, 2025, 3:57 PM CDT

Download

pole_top.emcam (5.24 MB)

4/18/2025 - Strap .ai File

NOAH HAMRIN - Apr 28, 2025, 4:02 PM CDT

Title: Strap .ai File

Date: 4/18/2025

Content by: Noah

Present: Noah

Goals: Create an Adobe Illustrator file to laser cut rubber straps

Content:

Conclusions/action items:

Laser cut straps

NOAH HAMRIN - Apr 28, 2025, 4:01 PM CDT

Download

ICE_strap.ai (335 kB)

2024/11/7 - CNC Training Upgrades

NOAH HAMRIN - Nov 14, 2024, 10:13 AM CST

Title: CNC Taining Upgrades

Date: 11/7/2024

Content by: Noah Hamrin

Present: Noah Hamrin

Goals: Complete CNC training at least through Mill II Upgrade

Content:

Membership Type	Start Date	Expiry Date	Renew	Card Info
CNC Mill II	Mon, Nov 4 2024	Permanent	Not Renewable	N/A
CNC Mill I	Tue, Aug 20 2024	Permanent	Not Renewable	N/A
CNC Mill I - Training Eligible	Tue, Aug 20 2024	Wed, Dec 31 3000	Not Renewable	N/A
Access Fee	Mon, May 22 2023	Sun, Dec 31 2023	Not Renewable	N/A
Machining	Sun, Jan 1 2023	Tue, Dec 30 3000	Not Renewable	N/A
Lab Orientation	Sun, Jan 1 2023	Tue, Dec 30 3000	Not Renewable	N/A
Laser Cutter	Sun, Jan 1 2023	Tue, Dec 30 3000	Not Renewable	N/A
Shop Tools	Sun, Jan 1 2023	Tue, Dec 30 3000	Not Renewable	N/A

Conclusions/action items:

Determine if CNC III Upgrade is needed and use to fabricate prototype.

2/27/25 - PLA Sterilization

SARA MOREHOUSE - Feb 27, 2025, 11:54 AM CST

Title: How to Sterilize Polylactic Acid Based Medical Devices?

Date: 2/27/25

Content by: Sara Morehouse

Present: n/a

Goals: To understand how PLA can be sterilized and to determine if we need to select an alternate thermoplastic for the final version of our device top part.

Content:

[1] S. Pérez Davila, L. González Rodríguez, S. Chiussi, J. Serra, and P. González, "How to Sterilize Polylactic Acid Based Medical Devices?," *Polymers*, vol. 13, no. 13, p. 2115, Jun. 2021, doi: https://doi.org/10.3390/polym13132115.

- Gamma irradiation can deteriorate polymers resulting in decreased molecular weight and increased biodegradation rates.
- Ethylene oxide is a polymer softener and plasticizer
    - Being progressively prohibited by several hospitals in the EU and USA because toxic, flammable, and explosive gas, has carcinogenic and allergenic effects

However, according to :[Plastics Compatibility with Sterilization Methods from ISM and IS Med Specialties](), PLA exhibits good compatibility with ethylene oxide and gamma irradiation sterilization.

Conclusions/action items:

The compatibility of PLA, or other thermoplastics that are considered, with various sterilization methods should be tested.

2/13/25 - Rubber strap design

SARA MOREHOUSE - Feb 14, 2025, 10:09 AM CST

Title: Rubber strap design

Date: 2/13/25

Content by: Sara Morehouse

Present: N/A

Goals: Learn more about rubber straps, how they are designed, and important considerations for this.

Content:

Source: [1] "Designing Rubber Components - Product Development Guide | MN Rubber," *Minnesota Rubber & Plastics*, 2020. https://www.mnrubber.com/tools-resources/design-guide/designing-rubber-components/ (accessed Feb. 14, 2025).

- The only harsh environment that the straps will be exposed to is sterilization, whether that is heat/gas/radiation, so the material must be able to withstand this environment
  - beyond this, material properties such as elasticity and friction are important
- The material chosen for the straps should be thermoplastic so it can be molded
- for medical applications, silicone rubber is a good choice
- rubber parts should not have sharp corners
- When adding holes to a rubber part, the height should not be more than 2x the diameter
- If you are molding rubber to another molded part, special adhesives can be used to make a strong chemical bonds

Conclusions/action items:

This source was helpful to learn more about some design considerations for rubber parts and how rubber parts are manufactured, but did not provide much information on strap mechanisms.

2/14/25 - Design idea for straps

SARA MOREHOUSE - Feb 14, 2025, 10:25 AM CST

Title: strap design idea

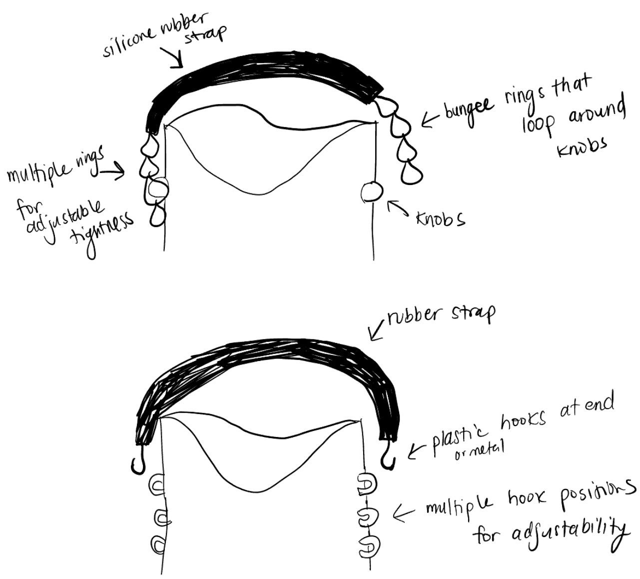
Date: 2/14/25

Content by: Sara Morehouse

Present: n/a

Goals: To lay out a couple basic concepts for the strap design.

Content:



The first idea is to have a strap will multiple rings or holes that can hook onto a knob on either side of the stabilizer. This puts the adjustability on the straps, rather than the stabilizer.

The second idea is to have a single strap length with hooks at either end, and then have multiple knobs or loops for the hooks to attach to. This ensures that the strap will be stretched when it is attached, which will create more force on the catheter and therefore more friction to prevent it from sliding out or rotating.

Conclusions/action items:

Share with team and discuss other options.

12Nov24 - CNC Training Documentation

SARA MOREHOUSE - Nov 13, 2024, 11:10 PM CST

Title: CNC 1 Training Documentation

Date: 11/12/24

Content by: Sara Morehouse

Present: n/a

Goals: To provide a record of my completed CNC training.

Content:

Sara Morehouse

ID Number: 9083120205

Eligibility: CoE Students

Profile

My Memberships

Membership Type	Start Date	Expiry Date	Renew	Card Info
CNC Mill I	Tue, Aug 20 2024	Permanent	Not Renewable	N/A
Access Fee	Mon, May 22 2023	Sun, Dec 31 2023	Not Renewable	N/A
Machining	Sun, Jan 1 2023	Tue, Dec 30 3000	Not Renewable	N/A
Lab Orientation	Sun, Jan 1 2023	Tue, Dec 30 3000	Not Renewable	N/A
Laser Cutter	Sun, Jan 1 2023	Tue, Dec 30 3000	Not Renewable	N/A
Shop Tools	Sun, Jan 1 2023	Tue, Dec 30 3000	Not Renewable	N/A

Conclusions/action items:

Complete the CNC 2 upgrade.

2/13/25 - Injection Modeling

MAX AZIZ (mmaziz@wisc.edu) - Feb 14, 2025, 9:25 AM CST

Title: Injection molding and materials

Date: 2/13/25

Content by: Max Aziz

Present: n/a

Goals: To learn more about what kinds of materials are used for injection molding and how sterilization works for this process. This information will be used for designing our top piece.

Content:

[1] L. Jmerson, “The Ingenious Process Behind Medical Grade Components,” *First Mold*, Nov. 18, 2024. https://firstmold.com/tips/medical-injection-molding/ (accessed Feb. 14, 2025).

- Medical grade polymers are heated and injected with high pressure into a mold
- This creates precise and intricate parts
- Disposable medical items/equipment can be made with injection molding - this allows you to make high volumes of the product
    - syringes, catheters, vials
- Reusable medical items can also be injection molded but they must be sterilizable
- There are a few types of injection molding:
    - conventional - heat plastic pellets and inject them into the mold
    - Thin-walled - used when the part has very thin walls <1mm thick. This is good for lightweight parts
    - Over molding - mold a component onto a preexisting structure
    - Insert molding - Plastic can be injected around metal inserts, magnets, or electrical components
    - Liquid silicone rubber molding - liquid silicone rubber is injected into a mold and then cured, the resulting material is flexible and can withstand extreme temperatures and chemicals
- The most commonly used materials are:
    - Polyethylene (PE) - comes in various levels of rigidity and durability
    - polypropylene (PP) - tough, flexible, resistant to chemicals and electrical currents
    - Polystyrene (PS) - hard, almost no flexibility but can be machined
    - Polycarbonate (PC) - transparent, strong mechanical properties, can withstand high temperature and UV
    - PEEK - very strong mechanical properties and durability, can withstand high heat and radiation
    - silicone - similar to rubber, good mechanical properties and biocompatibility

Conclusions/action items: This source helped me to learn about injection molding and how it works. With this information in mind, injection molding should be a good option to manufacture the top piece of our device as it will allow us to make it out of rubber and plastic and incorporate the magnets in a cheap and fast way.

2/13/25 - Sterilizing single use devices

MAX AZIZ (mmaziz@wisc.edu) - Feb 14, 2025, 9:30 AM CST

Title: Sterilization Trends for Single-Use Consumables

Date: 2/13/25

Content by: Max Aziz

Present: n/a

Goals: To learn more about how single use devices are sterilized

Content:

[1] C. A. Challener, "Sterilization Trends for Single-Use Consumables," *BioPharm International*, vol. 37, pp. 22–2722–27, Aug. 2024, Accessed: Feb. 14, 2025. [Online]. Available: https://www.biopharminternational.com/view/sterilization-trends-for-single-use-consumables

- The main techniques for single-use sterilization are:
    - ionizing radiation (gamma-, electron-beam [e-beam]-, X-ray), gas exposure (ethylene oxide [EtO], vaporous hydrogen peroxide [VHP]), and heat/steam
    - Most common are gamma radiation and EtO
- It is essential to choose the right method for the device or component
- There are requirements for sterilizing with ionizing radiation in ISO 11137
- Gamma radiation can sterilize multiple materials in the same cycle
- With EtO, it can be hard to ensure all surfaces are exposed

Conclusions/action items: This source gave me information about how single use devices are sterilized. Gamma radiation is one of the most common methods and should work for sterilizing the top piece of our device.

2/14/25 - Testing friction

MAX AZIZ (mmaziz@wisc.edu) - Feb 14, 2025, 10:39 AM CST

Title: Testing Idea - Friction

Date: 2/14/25

Content by: Max Aziz

Present: n/a

Goals: The goal of this entry is to come up with an idea for how to test the friction of the straps to make sure they will keep the catheter secure.

Content:

According to this source: Guide to Coefficient of Friction Testing - Industrial Physics, a common way to test COF is to measure how much force it takes to move a sled placed on that surface. The amount of force needed is then divided by the weight of the sled, to give a calculation and rating.

- We can adapt this idea for the catheter and measure the amount of force it takes to move the catheter when strapped in and surrounded by rubber in the stabilizer

This source: Ultimate Guide to Coefficient of Friction Testing: ASTM D1894 Explained - Goldsupplier gives more information about the ASTM standard that describes the requirements for testing friction.

- We will need to test the static coefficient of friction (we want to know the amount of force required to start moving the catheter)
- For testing static friction, you place the material on a flat surface and secure it in place. Then, place an object or "sled" of a known weight on the material and make sure there is uniform contact between the surfaces. Slowly start sliding the sled over the surface and record the force applied over time. The initial peak force will give the static friction coefficient after calculations are performed.
- For this testing, it is important to choose the right testing speed - the standard suggests 150 mm/ min
- Control the testing conditions like temperature and humidity during this test
- For this testing, COF testing machines are usually used and involve a force sensor or gauge
    - However, this setup can probably be recreated by the team

Conclusions/action items:

These sources were very helpful to learn about numerical ways to test friction of materials. This test is something that the team can perform on the stabilizer with the ICE catheters.

4/30/2025 - Impact of Device

MAX AZIZ (mmaziz@wisc.edu) - Apr 30, 2025, 9:46 PM CDT

Title: Impact of Device

Date: 4/30/2025

Content by: Max Aziz

Present: N/A

Goals: To figure out how impactful the device will be in the setting that it is used.

Reference:

[1]“Milestones in Intracardiac Echocardiography,” Siemens-healthineers.com, 2017. https://www.siemens-healthineers.com/en-us/ultrasound/news-innovations/ice-history (accessed April 30, 2025).

Content:

According to Siemens, their ICE catheter has been in use for 20 years with over 2 million procedures performed; this is just one brand of ICE catheter with many more out in the market. While the device was conceived and designed for ICE catheters during mitral valve procedures, the device has many other potential applications. Any procedure using a catheter with a cylindrical handle that is inserted into a femoral vein has potential compatibility with this product.

Conclusions/action items: Our device will clearly be used frequently if it is strictly for ICE catheters. However, as it is made right now, it will be ubiquitous and will have an even bigger impact that stated above.

10/28/24 - MIG Welding Permit

MAX AZIZ (mmaziz@wisc.edu) - Nov 13, 2024, 11:12 PM CST

Title: MIG Welding Permit

Date: 10/28/2024

Content by: Max Aziz

Present: n/a

Goals: To get my welding permit in order to weld for our design.

Content:

- I did the online training to get my MIG welding
- I went in person to complete the in person portion of my training.

Membership Type	Start Date	Expiry Date	Renew	Card Info
MIG Welding	Mon, Oct 28 2024	Permanent	Not Renewable	N/A
MIG Welding - Training Eligible	Tue, Aug 20 2024	Wed, Dec 31 3000	Not Renewable	N/A
Access Fee	Mon, May 22 2023	Sun, Dec 31 2023	Not Renewable	N/A
Lab Orientation	Sun, Jan 1 2023	Tue, Dec 30 3000	Not Renewable	N/A
Machining	Sun, Jan 1 2023	Tue, Dec 30 3000	Not Renewable	N/A
Shop Tools	Sun, Jan 1 2023	Tue, Dec 30 3000	Not Renewable	N/A

Conclusions/action items: Now I can help the team with welding parts of the projects. This will be crucial as we are designing parts that use metal.

Sterilized packaging

KADEN KAFAR - Feb 14, 2025, 1:15 PM CST

Title: Sterile Packaging

Date: 2/14/2025

Content by: Kaden Kafar

Present: N/A

Goals: Discover how we would package out tops sterilized.

Content:

https://medpak.com/sterile-packaging/

First step is to sterilize through ethylene oxide gas sterilization.

Can monitor the sterilization process through chemical and biological monitoring.

Needs clear labeling as well.

Needs barcode

Tamper evident seals

Conclusions/action items:

Decide on material that can provide safe packaging for the top part of the device.

Strap mechanics

KADEN KAFAR - Feb 14, 2025, 1:28 PM CST

Title: Straps

Date: 2/14/2025

Content by: Kaden kafar

Present: N/A

Goals: Find ideas for the strap mechanism

Content:

https://www.strapcode.com/blogs/all-about-watch-bands/12-watch-clasp-and-watch-band-fastening-mechanisms-you-should-know?srsltid=AfmBOor03O4Tkihs-9-ml2hETbyEuzDoZXocePR8KJdNp6IlWFEN5tbc

This website lists many strap mechanisms used for watches which follow a similar system as our straps.

Many non extrusive ideas to clasp the strap shut.

Also includes velcro.

Sliding buckle design.

Conclusions/action items:

Finalize a design idea for the straps.

2/12/2025 - Template

NOAH HAMRIN - Sep 16, 2024, 2:04 PM CDT

Title:

Date:

Content by:

Present:

Goals:

Content:

Conclusions/action items:

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.