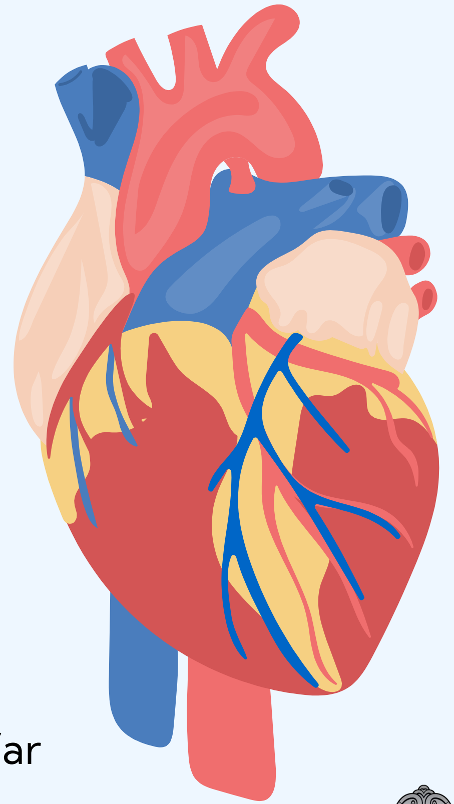
Stabilizer Device for Intracardiac Echocardiography (ICE)

to Assist Structural Heart Interventional Procedures



BME 402
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OUTLINE

- Problem, Background, & Design Constraints
- Broader Impact
- Current Design/Prototype
- Previous Testing
- Fabrication Timeline
- Testing Timeline
- Marketing
- Budget
- Journal
- References
- Acknowledgements & Questions

PROBLEM STATEMENT

- Dr. Amish Raval – client/Interventional Cardiologist
- ICE Catheter instability
- Current method is wet towel or have a tech hold it
- Device must hold all types of ICE catheters and adjust it slightly

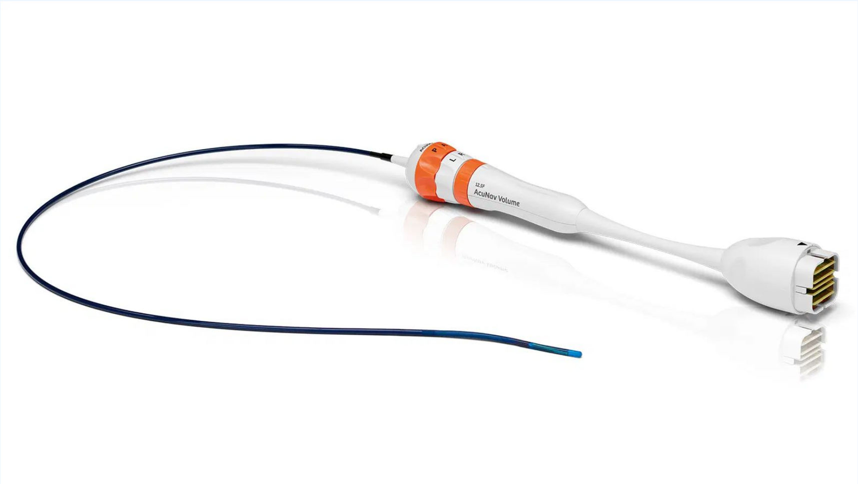


Figure 1: ICE Catheter [1]

BACKGROUND

Figure 2: 4D ICE Catheter insertion [2]

- Imaging Catheter
- Small, precise and clear images
- Femoral vein to inferior vena cava to see either right or left atria or ventricles [3]
- Patient is awake but local anesthesia
- Process efficiency

DESIGN SPECIFICATIONS

- Adjustable support fixture for ICE catheter
- Allow for use of ICE handle controls
- Adjustable height: 22.8 cm to 34.3 cm
- Material must withstand ethylene oxide, gas, or heat sterilization [6]
- Compatible with many models and brands of ICE catheter
- Must be able to keep the catheter secured from load of 2 N
- Manufacturing costs < $300

COMPETING DESIGNS

Figure 3: Abbott MitraClip Catheter with Stabilizer [4]

- Catheter held in place with screws
- Non-adjustable angled placement

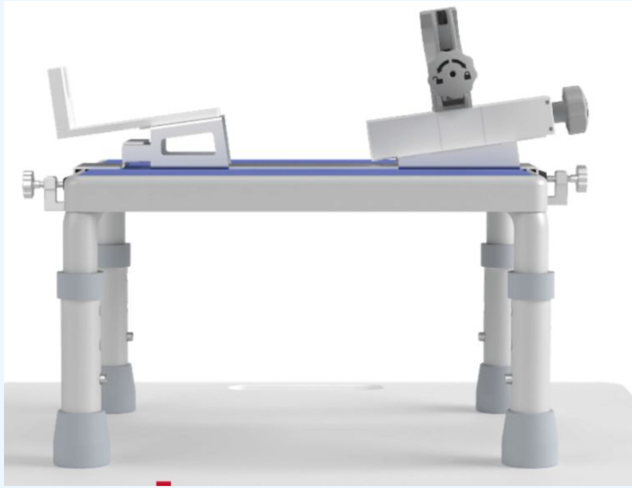


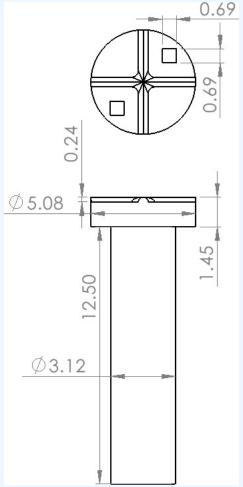
Figure 4: Edwards EVOQUE Stabilizer, base, and plate [5]

- 3 components

Max

CURRENT DESIGN

- Polylactic Acid (PLA) 3D printed prototype
- Height adjustable via pole clamp
- Top part magnetically secures to middle part across sterile drape
- Straps were not included on this prototype



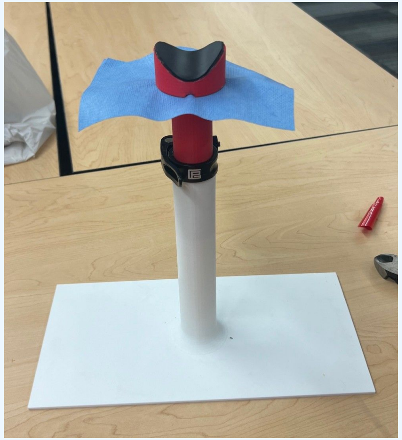
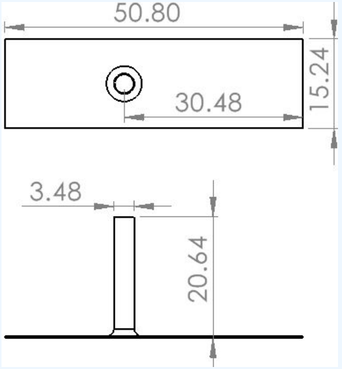


Figure 5: last semester's final prototype



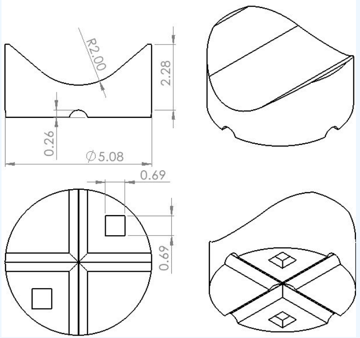


Figure 6: Solidworks drawings of top part (right), middle part (top), and base (left)

PREVIOUS TESTING

Catheter Saddle Dislodging Force Testing:

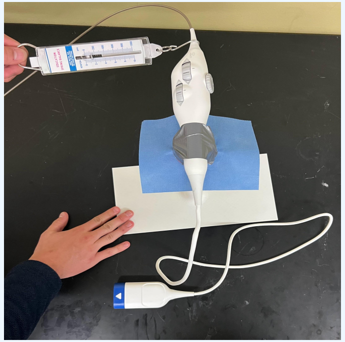
- Bending, torsional, & tensile forces
- Device vs wet towel (current method)
- p-value < 0.001 for torsional & tensile loading

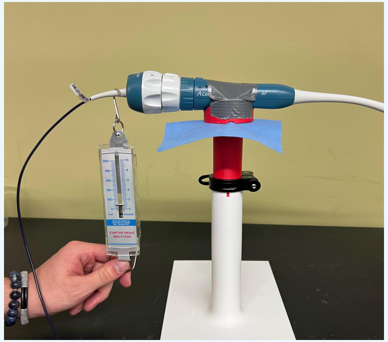
Weld Stress Concentration Analysis:

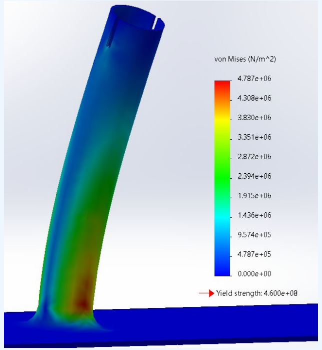
- Transverse 38 N load applied to top of shaft
- ASTM 4130 Steel (annealed) [S_Y = 460 MPa, S_U = 560 MPa]
- Highest stress: 4.8 MPa
- FOS: 96.3

Surgical Drape Tensile Testing:

- Load required to tear drape: 100.23 N







	Young's Modulus (MPa)	Max Load (N)	Max Strain
Average	7.65 ± 0.95	100.23 ± 8.33	0.55 ± 0.07

BME Design

FABRICATION TIMELINE

1

2

3

Design
- Straps
- Magnetic modules for various heights

Plan
- Updated 3D model
- CNC & welding protocol

Fabricate
- CNC & welding
- Stainless steel

TESTING TIMELINE

1

2

3

Magnet Validation

- Ensure compatibility between magnets and echocardiography

Revised Force Testing

- Updated prototype

User Feedback

- Direct assessment of design criteria
- Physician & cath lab personnel

Sara

MARKETING & PACKAGING

- Corrugated box
- PE closed foam inserts
- Individually wrapped components
- Labeled and Documented
- Top component sterile

Figure 7: Medical Device Packaging

BUDGET

- Budget: $1000
- Manufacturing Budget: $300
- Product Cost: $143.21

Item	*Total Cost*	*Fraction*	*Cost*
Quick release clamp	$8.99	100.00%	$8.99
(2) 1/4x1/4x1/4 magnets	$5.14	100.00%	$5.14
(2) 1/4x3/4x1/4 magnets	$13.52	100.00%	$13.52
Rubber straps	$9.99	4.17%	$0.42
Adhesive rubber	$12.98	1.67%	$0.22
1-⅜” OD shaft - 1ft long	$29.37	70.83%	$20.80
Sheet metal 4130 easy-to-weld steel 6”x36”	$63.80	55.56%	$35.45
4130 steel rod 2”x1ft	$88.65	58.33%	$51.71
3D print	$6.97	100.00%	$6.97
Total			**$143.21**

Table 1: Costs Spreadsheet

JOURNAL

- *Biomedical Materials and Devices*
    - Published by Springer
    - Sections
        - Abstract
        - Introduction
        - Methods
        - Results
        - Discussion
- Manufacturing innovations and clinical translations of devices
- Recommended by Dr. Raval

REFERENCES

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[3] J. Garg et al., "Intracardiac echocardiography from coronary sinus," Journal of cardiovascular electrophysiology, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9828028/#:~:text=2%20%2C%203-,Standard%20ICE%20imaging%20includes%20placing%20the%20catheter%20in%20the%20right,%2C%20via%20the%20transseptal%20approach). (Accessed Oct. 1, 2024).

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[6] Z. B. Jildeh, P. H. Wagner, and M. J. Schöning, "Sterilization of Objects, Products, and Packaging Surfaces and Their Characterization in Different Fields of Industry: The Status in 2020," physica status solidi (a), vol. 218, no. 13, p. 2000732, Mar. 2021, doi: https://doi.org/10.1002/pssa.202000732. (Accessed Oct. 1, 2024).