Guidewire Organizer for Endovascular Procedures

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Abstract

During an endovascular procedure, many guidewires of various sizes and stiffnesses are used, as each procedure is different. The guidewire is removed from the dispensing tubing and inserted into the patient. A catheter is then directed over the guidewire and secured in place. The guidewire is removed from the patient and stored for possible later use. After the guidewire is removed, a problem arises. The guidewire can become easily tangled and disorganized when operating technicians store the guidewire. As a result, the team was tasked with creating a device that allows for better organization, storage, and dispensing of guidewires during endovascular procedures. The device consists of two parts (1) a guidewire wheel which securely holds a guidewire in place and (2) a stand in which the guidewire wheels will be placed. The team is continuing to move forward with the current stand design. For the wheel, the team is moving forward with the VHold, the control wheel design. From the control, three design modifications were developed to determine which will be best for manufacturing through injection molding. These design variations are the XSHold, XtraHold, and LHold. Each variation has slightly different dimensional changes, but all are a similar design consisting of a circular wheel with an inner cavity to store the guidewire in place. The design variation that will be best suited for injection molding will be chosen for manufacturing. Following all prototyping of the device, it will be tested. Testing will be carried out by physicians and data will be collected using the timing and grade scale. Once testing is completed, the team will work with the client to make the device marketable to the industry.

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1. Introduction

1.1 Motivation

Each lost minute in a hospital operating room costs an average of $60 [1]. Operating rooms are expensive to run, and the main goal of every hospital is efficiency [2]. All of this additional work does not simply throw away money, but also diverts residents, surgeons, physicians, and nurses from performing other necessary tasks and taking care of patients.

This guidewire wheel and stand will decrease the amount of time a surgeon spends in the operating room; therefore, the amount of wasted time and money in the operating room (OR) will be decreased. Additionally, this device will allow for better organization and storage, creating a less hazardous setting in the OR. The endovascular device market is currently over $2.0 billion and is projected to reach $2.2 billion by 2022 [3]. The growing market suggests a need for innovation to ensure well-done and efficient procedures. The team hopes to bring this device to market, making it a popular device that surgeons choose over the current guidewire dispensing tubing and other competing devices.

1.2 Current Competing Systems

There are two main competing systems that exist in the guidewire organization market. The first is the Cath Clip, shown below in **Figure 1**. This single-use device reduces the time spent operating the device by an average of 80%, allowing surgeons to focus on the patient rather than device management [4]. The Cath Clip is lint-free, reducing contamination from potential cotton fibers of towels and other garments [4]. To use the Cath Clip, the operating technician must wind the guidewire into a neat circle and clip it together. The Cath Clip is not the best option since it can lead to disorganization, as the guidewires do not stay separated when placed on the table. Since there is no additional storage unit included for the device, the device can fall onto the floor if bumped or not secured.

Figure 1. *Cath Clip with wound-up guidewire [4].*

The second device is a Guidewire Storage Bowl that is manufactured and distributed by Medline Industries. The five interior tabs shown in **Figure 2** allow the guidewires to be held securely in the bowl, but they can still tangle while inside the bowl. The open top allows the device to be filled with fluid, such as saline, to sterilize the individual guidewires. This device is

marketed as a single bowl or a set with various diameters. The smallest bowl is 8.5” in diameter with an internal volume of 2,500 mL [5]. The largest bowl is 11” in diameter with an internal volume of 5,000 mL [5]. This device comes sterilized [5].

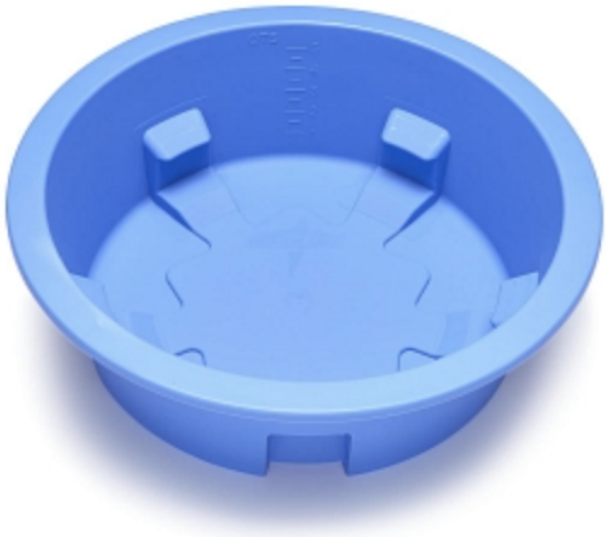


Figure 2. *Medline Guidewire Storage Bowl [5].*

1.3 Problem Statement

In many endovascular surgeries, surgeons must use multiple guidewires during a single procedure. Currently, most doctors store used guidewires under a wet towel for later use. These guidewires are hard to manage as they can get tangled and disorderly. This product aims to decrease the time it takes for surgeons to organize the wires and increase procedure efficiency and safety. Thus, the team will engineer a device to organize and store multiple guidewires and solve this issue. The device will consist of two parts: (1) a stand to store guidewire wheels and (2) three wheels in which the guidewires will be placed. The guidewire must stay organized and untangled when inserted and removed from the wheel. It must be easy to remove the wire from the wheel while stored on the stand or in the operating technician's hand. The wheels must also be easily placed and removed from the stand. The learning curve for the loading and unloading of the guidewire from the wheel should be small. The device will be able to be mass produced. The team will aim to manufacture the device in the most cost effective way possible.

2. Background

2.1 Relevant Physiology and Biology

Guidewires are used in many different endovascular procedures [6]. In each endovascular procedure, up to 4 guidewires can be used [7]. Each of these guidewires can vary in diameter and

stiffness, as they have different purposes in the procedure. A guidewire is inserted into the patient and then directed to the area of interest. From there, the catheter is fed along the guidewire to the correct area, and once the catheter is in the correct position, the guidewire is removed. **Figure 3** shows how a guidewire and catheter interact during an endovascular procedure. The guidewire must be stored in case it is used again during the procedure. Endovascular procedures are minimally invasive, as the guidewire and catheter are inserted through a small incision, lowering health risks that arise during alternative surgeries [6].

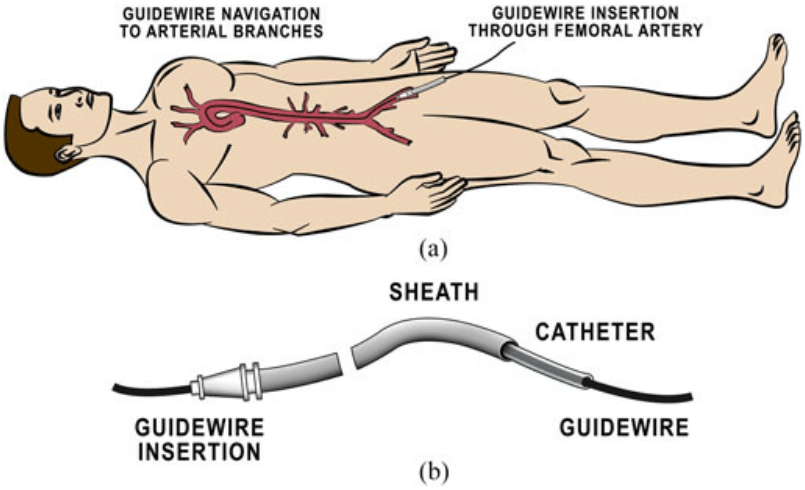


Figure 3. *Guidewire and catheter being inserted into the body [8].*

2.2 Prototyping Materials and Machines

For this project, the prototypes are 3D printed at the MakerSpace. The printer selected is the Ultimaker S5. The team used Ultimaker PLA and PVA inner supports for the printing filament due to its ease of use, high strength, and high stiffness which are all ideal for the large number of test subjects that used the wheel. The PVA supports will be dissolved using a warm water bath. It is also cost-effective and efficient [9], two features that are ideal for prototyping.

2.3 Client Information

Dr. Dai Yamanouchi, MD, PhD, is a surgeon at UW-Health. He specializes in vascular and endovascular-related procedures, as well as research relating to aneurysm post angioplasty including balloon angioplasty and stent placement. He is passionate about creating a device for his operating room to solve the issue of tangled guidewires [10].

2.4 Design Specifications

The wheel must be able to load and unload guidewires of varying stiffnesses with diameters of 0.014, 0.018, and 0.035 inches without the entanglement of the wires [11]. The stand should hold three guidewire wheels as well as allow the guidewires to be removed from the wheel while stored in the stand or with the wheel in hand. Both the wheel and stand are single

use devices (SUDs). The average male surgeon's hand circumference is 21.35 cm and female is 18.95 cm [12]. The wheel should take these dimensions into consideration to optimize the grip of the surgeon on the wheel. For the design to be competitive in the market and meet the client's requirements, production costs of a single wheel should not exceed roughly $2. A complete list of specifications can be found in **Appendix A**.

3. Preliminary Designs

Introduction

3.1 Wheel Function

This section aims to describe to the reader how a wheel is used during a procedure. See **Figure 4** for photographs of the loading process.

A *B* *C*

Figure 4. Insertion of guidewire (GW) into wheel.

1. After a guidewire is removed from a patient during a procedure, the guidewire is handed over to an operator.
2. The wire is wound by the operator by hand.
    a. The operator is then in charge of storing the guidewire safely and promptly.
3. Wound GW is slid into the wheel and expands toward the walls.
    a. It is then placed on the stand.
4. If the guidewire is reused during the procedure, it must be removed from the wheel.
    a. It can be unloaded while on the stand, or
    b. The wheel can be taken off the stand before removing the guidewire.
5. To unload the guidewire, the guidewire is simply threaded out from the opening.

3.2 Control Wheel Design: VHold

VHold (**Figure 5**) is the team's control design. It has a thickness of 1 mm, an outer diameter of 19 cm and overall height of 1.5 cm, a chimney with a 4.5 cm diameter and height of 1.7 cm. There is a hand opening that is 7 cm in length.

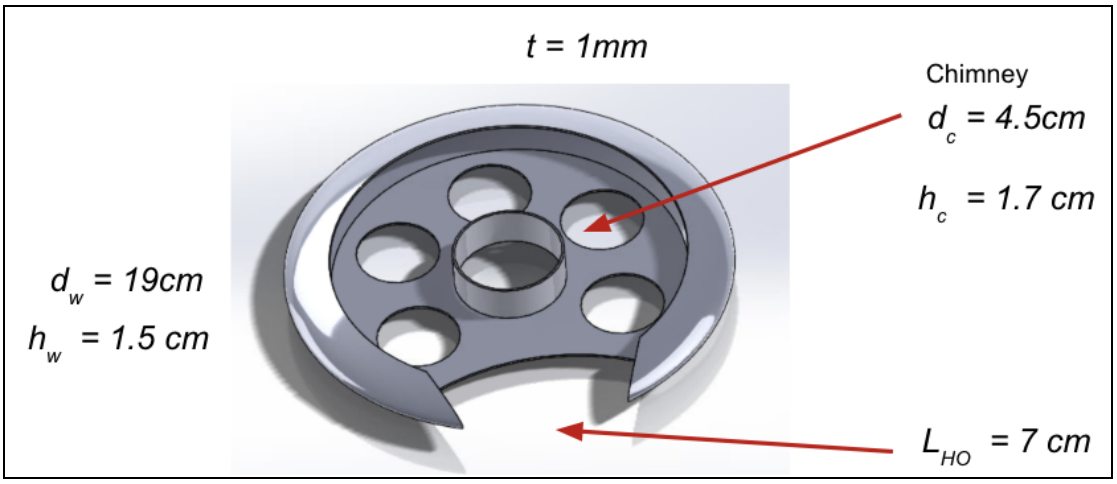


Figure 5. VHold

VHold exemplifies the necessary features for the device to work correctly. These important features are described in **Table 1**. All the design variations discussed in the coming section are based on this control design.

Table 1. Important Design Features

Chimney	- Holds the guidewire in place as it is unloaded by preventing the guidewire from popping out, acting as a spool. - The chimney can in the way of the hand as guidewire is loaded
Bottom Face Holes	- The circular holes on the face of the wheel allow saline to flow through the wheel - Cannot be too large or wires can slip through and get tangled
Wheel Outer Diameter	- Small enough for the guidewire to stay in place and have easy load and unload - Cannot be too large or the guidewire will not have enough radial force to stay in the cavity
Manufactuability	- Aim to be injection moldable with a lower cost mold - If injection molding is not the most efficient method for a low cost mold, device must be easily mass manufacturable using another method

3.3 Wheel Design Variations

A. XSHold

The first design variation seen in **Figure 6** is similar to the control design VHold with a smaller outer diameter of 15 cm. The height and chimney height remain the same as the VHold (1.5 cm and 1.7 cm respectively). The smaller outside diameter of this design allows for a tighter hold of the guidewire as there is more force applied to the outer wall of the device. Less material is also needed to build this wheel, which reduces manufacturing costs.

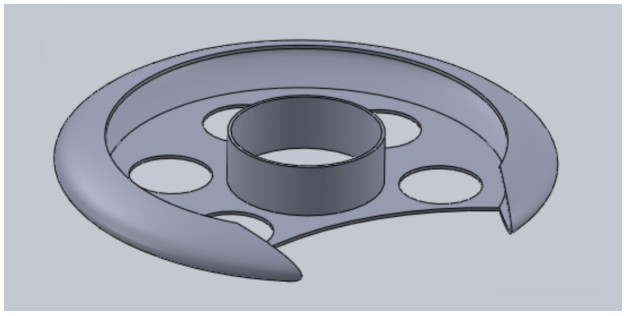


Figure 6. XSHold SolidWorks design.

B. XtraHold

The second design variation seen in **Figure 7** features a redesigned chimney. The outside diameter and height is the same as the VHold (19 cm and 1.5 cm respectively), however the chimney is shorter (0.75 cm) and features an overhanging piece around the top. The shorter chimney allows for easier and more comfortable guidewire loading, and the overhang keeps the guidewire steady in place during guidewire removal. The wall also has a deeper cavity along the outside of the device to ensure tight guidewire storage.

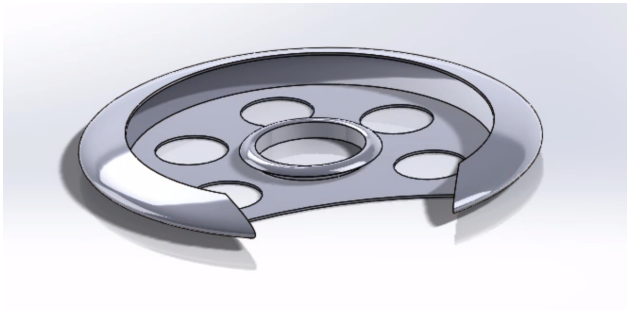


Figure 7. XtraHold SolidWorks design.

C. LHold

The third design variation seen in **Figure 8** features a unique overhanging piece in the back of the device. The outer diameter and height of this device are the same as the VHold (19 cm and 1.5 cm respectively), and the height of the piece replacing the chimney is 0.5 cm. Removing the chimney allows for easiest loading of the guidewire, and the overhanging piece in the back allows the guidewire to be removed efficiently while staying in place within the device. LHold also contains a deeper cavity along the outer wall, similar to XtraHold.

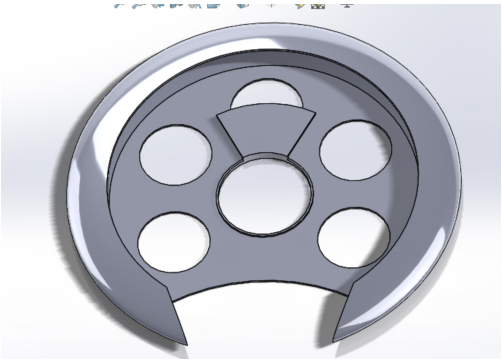


Figure 8. LHold SolidWorks design

3.4 Stand Design

The stand design seen in **Figure 9** will be used in conjunction with the final wheel design. The stand features a base plate with holes to allow for easy flow of saline around the guidewire. There is also a long chimney in the center of the base plate to stack up to three guidewire wheels at one time. The hollow chimney allows for minimal material to be used, minimizing manufacturing costs.

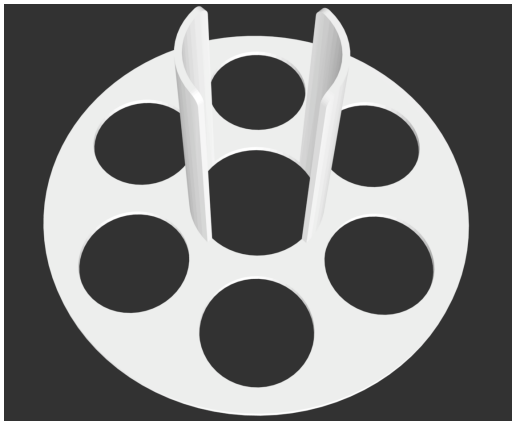


Figure 9. Stand design to hold guidewire organizers.

4. Preliminary Design Evaluation

4.1 Alternative Design Matrix

The team opted out of conducting a formal design matrix for the wheels this semester. This is because all designs would score equally in traditional design matrix criteria since only slight variations are being made to the control design; The criteria are: safety, cost, efficiency, durability, and learning curve. Formal definitions of these criteria are found in **Appendix B.**

This being said, the team will move forward with all four designs: VHold, XSHold, XtraHold and LHold. The main focus this semester will be the manufacturing methods of each design, and the designs will change based on their manufacturability (discussed further in Sections 5.1 and 5.2).

The team's alternative design matrix is a pros, cons, and manufacturing table seen below in **Table 2**. Factors that aren't traditionally evaluated within a design matrix were discussed. **Table 2** will be kept in consideration moving forward with testing and manufacturing.

Table 2. Alternative Design Matrix

Design	Pros	Cons	Manufacturing Method
VHold (control design)	- hand opening optimal for both male and female surgeon hand	N/A	- injection in two pieces (bind using snap clips)
XSHold	- small radius allows for tighter hold on GW - less material	- tall chimney makes loading difficult	- injection in two pieces (bind using snap clips)
XtraHold	- shorter chimney allows for more comfortable GW loading	- overhang of chimney could be hard to manufacture	- 3D print
LHold	- no chimney to get in the way of hand	- "chimney piece" could snap if hit too hard	- injection in two pieces (bind using snap clips)

4.2 Manufacturing Design Matrix

In order to mass produce the final design, the final manufacturing process must be cost and time efficient. In **Table 3**, the team compared three different manufacturing processes: injection molding, 3D printing, and thermoforming. Each manufacturing process was ranked by its ability to fulfill six criteria based on the design specifications outlined in **Appendix A.**

I. *Production Efficiency (25%):* Production efficiency is the time it takes to produce one part. This is weighted as the highest criteria in **Table 3** because the final market device will be mass produced as a single-use product to fulfill the demand of the increasing endovascular device market. It is estimated that 1,020,067 vascular procedures would be done in 2020 [13].

Injection molding scored the highest for production efficiency as it is the most common and time-efficient process used to mass produce parts [14]. Depending on the size of the desired product, the injection molding process can take two seconds to two minutes to produce a part [14]. Thermoforming involves loading a single material sheet into the machine and then heating it to glass transition temperature before each pull. This makes the process take a longer to complete than injection molding [15]. Additionally, due to the geometry of the wheel, the design would need to be cut horizontally, manufactured in two parts and then welded together. 3D printing was ranked ⅕, because the process is extremely inefficient for our design. In Spring 2022, it took three hours to 3D print the device in PVA. Additionally, the inner supports of the overhang had to be dissolved away which took an additional two days.

II. *Ease of Manufacturing (20%):* Ease of manufacturing denotes the amount of additional tooling prototyping and initial costs to begin production of the final market device.

3D printing scored the highest in ease of manufacturing because it does not require additional prototyping or tooling costs. Injection molding and thermoforming are both mold forming processes. There is additional tooling prototyping to create the mold before the device can be mass manufactured. The cost of tooling for injection molding is more expensive than thermoforming because it is made out of a higher grade metal.

III. *Cost Per Part (20%):* The cost of production of the final design should not exceed 2$.

Injection molding scored the highest because it has the lowest cost per part. As seen in **Appendix D**, the team received a quote from Protolabs where the cost of production for one part is $2.88. Thermoforming scored ⅜ because there is excess material from the sheet that is accounted for in the cost per part. 3D printing scored the lowest, in spring 2022, it costs 6$ to print the part.

IV. *Material Compatibility (15%):* Availability of materials compatible for production.

Injection molding is ranked the highest as it is compatible with a wide range of thermoplastic, thermosets, or elastomers [16]. Though 3D printing is also compatible with a wide range of

materials, is ranked ⅘ due to cost of using these materials in 3D printing. Thermoforming is ranked the lowest as it has restrictions on the thickness and temperature characteristics for compatible materials.

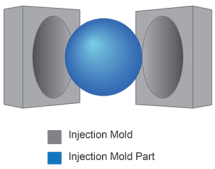
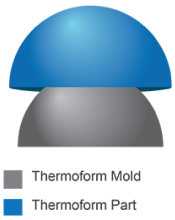
V. *Lead Time (10%): The estimated lead time from now to final market device production.*

3D printing the final market design was ranked the highest because there would be no additional prototyping steps to make our design compatible for 3D printing. The lead time for prototyping the tooling for injection molding is 12-16 weeks, and for thermoforming it is 0-8 weeks [17].

VI. *Accuracy (10%): The degree of precision, or tolerance of the manufacturing process achieves.*

Injection molding scored the highest for accuracy as it is ideal for creating smaller, more intricate and complex parts; it can accommodate tolerances +/- .005 mm [18]. Thermoforming scored ⅖ as it bends a sheet of plastic around the mold, it works best with larger parts with more basic designs[19]. 3D also scored ⅖ because it is difficult to dissolve the supports entirely, creating greater tolerances between parts.

Table 3. Manufacturing Process Design Matrix. Individual criteria were graded on a scale of 1(Low) - 5(High), these scores were then multiplied by the predetermined weight of the criteria to calculate the weighted score. The highest scores for criteria are highlighted in blue and total scores are out of 100.

Manufacturing Process		 **Injection Molding [6]**		 **3D Printing**		 **Thermoforming [6]**
Production Efficiency (25)	**5/5**	**25**	1/5	5	4/5	20
Ease of Manufacturing (20)	3/5	12	**5/5**	**20**	4/5	16
Cost Per Part (20)	**4/5**	**16**	2/5	8	3/5	12
Material Compatibility (15)	**5/5**	**15**	4/5	12	2/5	9
Lead time (10)	2/5	4	**5/5**	**10**	3/5	6

Accuracy (10)	**5/5**	**10**	2/5	4	2/5	4
Total	**82/ 100**	**82**	59/ 100	59	67/ 100	67

4.3 Proposed Final Wheel Designs

To manufacture the final market device with injection molding, a mold of the wheel design needs to be created. Due to the complex geometry of our current prototype, the dimensions of the wheel must be altered and tested.

5. Fabrication/Development Process

5.1 Materials

The final market device will be fabricated with injection molding to be single-use. The proposed final market device will need a material that provides strength, stability, and flexibility. Additionally, the material will be a cost-efficient thermoplastic compatible with injection molding.

5.2 Methods

Injection molding is a forming process using molds [16]. This process works by loading thermoplastic, thermosets, or elastomer pellets into the cylindrical cavity of the machine where the material is heated and pressurized to a molten state. Once the material is liquified, it is forced through the nozzle of the injection unit that feeds into a channel in the mold. As soon as the molten material enters the mold, it begins to cool and the solidified part is ejected. In order to create the tooling mold for the endovascular guidewire organizer the dimensions of the wheel need to be optimized through testing and prototyping. To do so, the team will need to work with an injection molding company. It is crucial that the wheel design has an inner cavity and overhang in order to keep the guidewires secured. Typically, an injection mold consists of two haves that create the hollow area where the melted plastic goes. However, due to the complex geometry of the overhang, our mold will consist of three pieces.

5.3 Testing

The testing will consist of loading and unloading times of the wheel done by surgeons and medical residents. These timed tests allow for quantitative analysis of the efficiency of the device. The test administrator will be required to rate how the device performs in each run. If there are complications, such as entanglements or the wire coming out of the wheel, then the device will be scored according to the defined rankings in the test protocol in **Appendix C**. For this rating scale, a three on the testing scale is the best, meaning a perfect run, and a zero is the worst, showing a mistrial. The order in which GWs are used in the runs are randomized and

noted during testing. The team aims to ensure that every combination is tested equally in this regard to guarantee that there are minimal effects of learning in between trials. Random, voluntary clinicians, both familiar and unfamiliar will be tested to eliminate prior knowledge bias of the device.

6. Discussion

6.1 Ethical Considerations

When testing and implementing new devices into the medical field there are seven main principles of clinical research [20]. There are two principles that are crucial for testing this device: consent and risk-benefit ratio. Although the device itself falls within the engineering field, testing this device on patients in the operating room will occur to ensure its functionality during an endovascular procedure. This is the final step before bringing a device to market. The device must ensure that it is not harmful to the patient nor the surgeon. Additionally, the patient must consent to the use of a new device that is not typically used and is currently in the process of testing. The device must be compatible in the operating room and able to be sterilizable. The device should be tested to ensure it is able to be used on many different guidewires of varying sizes and stiffnesses to be able to accommodate many different operations and patient considerations. Lastly, the risk-benefit ratio presented for this device is positive in terms of benefit, which allows for this device to be tested in the operating room.

7. Conclusion

7.1 Summary of Design

The device consists of the stand and the wheel. The stand will be modified after a final wheel dimension is determined. The stand will store three guidewire wheels. The guidewires are able to be removed from the wheel while on the stand. The team will be moving forward with VHold wheel design, but small dimensional alterations may be made to the design for optimizing injection molding. These variations are the XSHold, XtraHold and LHold. The VHold design has all the design features necessary for the wheel to be successful. These features include the chimney, bottom face holes, wheel outer diameter, and manufacturability. These features are further outlined in **Table 1**. The final design will be best formed through injection molding for mass production and manufacturing as well as future marketability.

7.2 Future Work

After presenting the team's work to the client, the team is ready to take the next steps to bring the device to market. Moving forward, the team will strive to make the device more marketable to the industry by creating a one-time use disposable wheel and stand that is FDA approved. However, during a procedure, the wheel will be used multiple times throughout a single procedure with the same patient. Once the procedure is complete, the wheel will be disposed of.

Rather than 3D printing the final wheel design, the wheel will be made via injection molding. This is the shaping of rubber or plastic particles by injecting heated material into a mold [17]. The material used in the injection molding will polyester. This is because polyester is already used in endovascular procedures. This will decrease the material approval process that would have to take place if the team chose a different material. The source of injection molding the team will work with also needs to be finalized.

The current design of the wheel is the VHold. In order to make the design optimized for injection molding, the team is making slight alterations to the dimension of this design. Due to this, the VHold is a control wheel for the modified designs of the XSHold, XtraHold and LHold. Once the best wheel design is determined for injection molding, the team will move forward with that design. One of the most important dimensions that will be altered for all variations is the diameter of the wheel. The diameter must be an appropriate size for physicians to easily load and unload guidewires into the wheel.

Once both the wheel and stand designs are finalized, the team will continue testing the device with the grade scale and timing with physicians. The physician will practice loading and unloading the device 10 times before the trials begin. This is done to reach the plateau of the learning curve, which will give the most accurate results of how the device would be used in industry. Finally, the team will work closely with the client on the business side to discover the best ways to make this marketable in the industry starting with patenting the device through WARF.

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9. Appendix

9.1 Appendix A: Product Design Specifications

Product Design Specifications

Date of Last Revision: September 22, 2022

Title: Guidewire Organizer for Operation Room
Client: Dr. Dai Yamanouchi
Advisor: Dr. Darilis Suarez-Gonzalez
Team: Tatum Rubald, Addison Dupies, Rachel Krueger, Victoria Heiligenthal, Lily Gallagher, and Benjamin Smith
Section Number: BME 400, Lab 309

Function:
In many endovascular catheter related surgeries, surgeons must use multiple guidewires during a single procedure. These guidewires are hard to manage as they can get tangled and disorderly. This product aims to increase procedure efficiency and safety by decreasing the time it takes for surgeons to organize the guidewires.

Client requirements:

- The project consists of two pieces: a guidewire wheel and wheel stand.
- The team will determine and finalize the dimensions (diameter, wall thickness and hand slot) of the current guidewire wheel design.
- The wheel will sucessfully load guidewires of varying stiffnesses.
- The wheel stand will stack three guidewire wheels.
- Guidewires must be able to be removed from the wheel while the wheel is stored on the stand.
- Single use device (SUD).
- The final market device must be able to be mass produced and released into the market in an FDA approved material at a low cost.

Design requirements:

1. Physical and Operational Characteristics
    a. *Performance requirements*: The device will consist of two pieces: (1) a stand to store 3 wheels in which the guidewires will be placed. The wheel must be able to hold guidewires with diameter sizes of 0.014 to 0.035 inches and varying stiffnesses. Additionally, the guidewire must stay organized and unknotted when removed from the wheel while on the stand. It must be easy to load and remove the wire into the wheel while in the operating room [1]. The wheels must be easily placed and removed from the stand. The stand must hold the 3 wheels at once. The stand should allow easy access to the guidewire at any point during a procedure.

b. *Safety*: There should be no risk for the user and all edges must be smooth to prevent the risk of cuts through medical gloves [1].
c. *Accuracy and Reliability*: In order for the device to comply with the requirements made by the client, the device must be able to fit 3 catheter guidewires, which ideally fit within the finalized optimized diameter of each wheel, and each wheel must be able to hold various guidewire sizes separately [1]. In addition to the precision it will take to design the device, it also must be able to undergo surgeries and have the ability to keep the multiple guidewires used during surgery organized. This will allow the operating room workers to navigate the guidewires easier than without the device. The stand should not interfere with the performance of the wheel. The stand should keep the wheel firm in place to allow for efficient loading and unloading.
d. *Life in Service*: The final product will be a SUD. It must be able to withstand the loading and unloading of a guidewire 3-5 times during a single procedure.
e. *Shelf Life*: Although the final market device will be discarded after each use, the product must last at least two years on the shelf. To ensure the material of the device will not degrade, the device will be stored in an environment where the humidity and temperature are regulated to the material's specifications.
f. *Operating Environment*: The final market device will be used within an operating room and be fully functional within standard operating room conditions. These include a relative humidity of 20 to 60%, and a temperature between 68°F and 75°F [2].
g. *Ergonomics*: The wheel should be easily gripped by the operator to ensure maximum control which includes minimizing excessive movement. A surgeon's hand should be able to easily slide into the wheel to load the guidewire. The average male surgeon's hand circumference is 21.35 cm and female is 18.95 cm [3]. The hand opening should take these dimensions into consideration. The circular wheel and storage devices should have a minimum learning curve to hasten the use. The stand device should not slip on surfaces.
h. *Size*: The design consists of a circular wheel with a diameter of 15-25cm and an inner diameter cutout of 10-25 cm for maximum control by the operator [3]. The circular wheel will have a thickness of 3-8 mm. The stand will have dimensions that will be determined based on the wheel dimensions
i. *Weight*: The final wheel design will be lightweight and easy to maneuver by the operator. The stand must fit within operating room size requirements and various table setting environments [4]. The stand must be heavier than the wheel design so it does not tip over while holding the wheels.
j. *Materials*: The initial materials for the prototype will be plastic filament (PLA) from the Makerspace [4]. The stand may require weights in the base. The final product will be made out of an FDA approved polymer that can be mass manufactured while

fulfilling weight, size, and shelf life requirements.

k. *Aesthetics*, *Appearance, and Finish:* The final market device should be an FDA approved plastic and should have a smooth, clean finish [5]. The prototype should also have a smooth, clean finish. The color will be consistent throughout.

2. Production Characteristics
    a. *Quantity*: One prototype is needed, yet the prototype needs to be conceptually and physically sound and able to be utilized in real time. The final design will consist of 3 wheels and a stand, which will house the wheels. However, the final manufactured design will be mass produced.
    b. *Target Product Cost*: Taking into consideration the materials and size, the estimated cost of the final product will be approximately $2 per wheel and $5 per stand [1].
3. Miscellaneous
    a. *Standards and Specifications*: This product would likely be considered as a Class I medical device. There is no direct FDA regulation for this device; both the stand and wheel are assumed to be a Class I device and may require premarket approval in the form of a 510(k) [6].
    b. *Customer*: The target market for the guidewire organization device would ideally be cardiothoracic surgeons and medical facilities that perform routine endovascular surgeries. This would be the case due to the highly beneficial organization of the guidewires in endovascular catheter surgeries, as they are often misordered which leads to extended surgery time, making this prototype appeal to those who want to avoid the disorganization of guidewires during surgical procedures. The effect of disorganized guidewires can potentially lead to internal damage based on the insertion of the guidewire and where the wire leads to. Tips of a guidewire can break and the broken guidewire could harm the arterial wall that it is placed in [7].
    c. *Packaging*: The client wants the product to be packaged with guidewires and distributed in conjunction with guidewires [1]. It will be assembled and packaged in a clean room environment. The stand will be purchased separately.
    d. *Patient-related concerns*: Because this device will be used in endovascular procedures, it is important to take into account patient safety. The guidewire wheel and stand should ensure that the wire can be inserted in a safe way so the patient's health is not at risk.
    e. *Competition*: A main competing guidewire organization device is the Cath Clip. To use the Cath Clip, an operating technician winds the guidewire into a neat circle and clips it together using the device. Cath Clip is a single-use and lint-free device device. The Cath Clip can lead to disorganization as the guidewires do not stay separated when placed on the table. Since there is no additional storage unit included for the device, after it is placed on the table it can fall onto the floor if bumped or not secured [8]. Another guidewire organization device produced by Medline Industries is the Guidewire Bowl. This device comes in various sizes ranging from 8.5 inches

to 11 inches in diameter. These bowls have 5 interior tabs that overhang to hold various guidewires within the bowl while submerged in saline. This device is also plastic and single use [9]. A guidewire organization device that currently exists is the Angio Assist™ Docking Station by Teleflex, which facilitates the introduction of guidewires into catheters and atherectomy burrs. This friction-fit guidewire holder is for the use of a single-operator and eliminates the need to touch or hold the stent during guidewire loading. There are two slots that facilitate the alignment of guidewires and catheters on this device. Another product is the Tierstein Edge Device Organizer, by Teleflex which has 6 friction fit slots for guidewires and catheters and is designed to minimize loss of motion control of eternal guidewire as well as increase security of excess wires during procedures [10].

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9.2 Appendix B: Design Matrix Definitions

Safety, cost, efficiency, durability, and learning curve.

Safety: The device must be safe to use on patients in a hospital operating room and should be safe to use by a doctor. With safety, the wheel must not break in the process of unloading or loading the guidewire wheels.

Cost: The cost of each design; the client did not give us a set budget. However, the production of a single wheel in the final stages should not be more than $2.

Efficiency: The device should be more efficient than the current options that are available; most doctors do the process of organizing manually, and without the aid of any external device. The device should be able to efficiently load and unload the guidewire wheels.

Durability: The ability of the design to withstand stress upon operation. The final market device must be able to withstand a single procedure.

Learning Curve: Because a priority of this device is to increase efficiency, learning to use the device must be a quick and simple process. The operator of the device should not have to dedicate a significant amount of time to understand how to properly use the device. The device will not be successful in the market if doctors have to spend any significant amount of time learning how to use it.

9.3 Appendix C: Testing Protocol

Guidewire Holder Test Method

Loading

1. Start timer
2. Wind guidewire by hand
3. Pick up wheel from table
4. Use one hand to hold wheel, one to hold wire-loop
5. Slide wire-loop into wheel
6. When guidewire is fully secured within the wheel, place wheel in one hand
7. Stop timer

*If the guidewire is not able to load properly, record load time as MT (mistrial)

Grade the Load Trial (0-3)

0 - Unable to load guidewire
1 - The wire slid into the wheel, but there were some issues (i.e. the tip of the wire hangs out too far, had to manually maneuver the wire to fit into the wheel, e.g.)
2 - Wire slid into the wheel with ease, but the wheel itself made the sliding motion uncomfortable/less time efficient
3 - Wire slid into wheel without complications

Unloading

1. Start timer
2. Use one hand to hold wheel, and one hand to thread guidewire out of loop
3. When wire is fully out of wheel, stop timer

DO NOT STICK FINGERS THROUGH CENTER OF WHEEL TO AID IN REMOVAL. MUST REMOVE WIRE WITHOUT TOUCHING
*If the guidewire is not able to unload properly, record load time as MT (mistrial)

Grade the Unload (Thread trial) (0-3)
0 - Unable to unload the guidewire
1 - The guidewire was partially removed from the wheel before tangling and popping out
2 - The guidewire was removed from the wheel without tangling but partially falls out of wheel during unloading
3 - The guidewire was removed without complications

Unloading Pull

1. Use one hand to hold wheel, and one hand to remove guidewire out of loop
2. When wire is fully out of wheel rate the difficulty of removing the guidewire

Grade the Unload Trial (Pull Trial)(0-3)
0 - Unable to unload the guidewire
1 - The guidewire was removed from the wheel but significant effort was needed (2 hands, extra person utilized)
2 - The guidewire was removed from the wheel but was caught on middle chimney
3 - The guidewire was removed without complications

Record the following values for each trial:

- Member or Participant Number
- Design Used
- Guidewire Used
- Load time
- Unload time
- Grade

9.4 Appendix D: Protolabs Injection Molding Quote

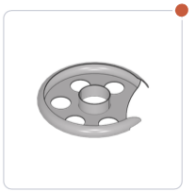
PROTOLABS
Manufacturing. Accelerated.

Quote Date: October 4, 2022

Quote 2276-240

Prepared for UW Madison

Injection Molding *(1 Part)* ITAR (No)



ShortSpout.SLDPRT
1995-4114-001
Current Revision: 1
Mold Life: Unlimited (On-demand Manufact...
1 Cavity
ABS : Lustran 433 (Black)
Black (Original Material Color)
Cosmetic: PM-F0
Non-Cosmetic: PM-F0
X: 169.65mm Y: 20.00mm Z: 168.60mm
Machining Tolerance: +/- 0.003 in. (0.076 mm)
Material Tolerance: +/- 0.002 in./in. (0.002 ...

⚠ This part needs your attention:

Sample Quantity
25

See volume pricing as low as $1.57

25 Parts @ $2.88	$72.00
Mold	$8,850.00
Total	**$8,922.00**

Order by:
Wed 4:00 PM
Receive by:
Thu, Oct 27

Thu, Oct 13	Mon, Oct 17	Thu, Oct 20	Mon, Oct 24	Thu, Oct 27
+ $4,425.00	+ $3,717.00	+ $2,212.00	+ $1,504.00	