Guidewire Organizer for Endovascular Procedures

BME 301
University of Wisconsin - Madison
Department of Biomedical Engineering
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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 has been tasked with creating a storage unit that allows for better organization, storage, and dispensing of guidewires during endovascular procedures. Currently, the team has a design for a guidewire wheel (provided by the client). This wheel design will be tested and remodeled until a final design is proven most efficient. A stand must be fabricated to store the wheel. The team came up with three designs for storage: DYStand, UHold, and Door. Ultimately, the team chose the UHold as the final design as it best matched the criteria for the design. The proposed design is a circular stand with an inner support to hold the guidewire wheels in place. The backplate is for added stability, however, with further testing, the backplate may be removed to eliminate the bulkiness of the design. The team plans on testing the prototype through timed testing trials of the efficiency of storing and removing the guidewire wheel from the UHold to verify that the backplate of the UHold is necessary and to improve any additional aspects of the stand design.

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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 almost 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, decreasing the amount of wasted time and money in the operating room (OR). 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 eventually bring this device to market, making it a popular device that surgeons choose over the current guidewire dispensing tubing.

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]. 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. With 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.

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

The second device is a medical guidewire storage method and apparatus, which is patent pending. This flexible tubing holds up to 4 guidewires in each device, and the tube can be unraveled and secured around the exterior of the operating table by an adhesive for easy access to dispense and store the guidewires [5]. The four openings shown in **Figure 2** allow the ends of the guidewires to be separated, but they can still tangle while inside the tubing. The opening allows the device to be filled with fluid, such as saline, to sterilize the device [5]. When feeding the guidewire into the tubing, a resistive force is present. This is not conducive for the fast-paced environment of endovascular procedures.

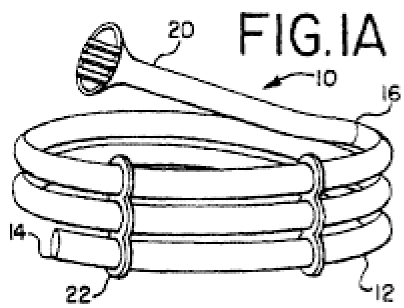


Figure 2. Medical Guidewire Storage and Apparatus Design [5].

1.3 Problem Statement

In many endovascular catheter-related 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 increase procedure efficiency and safety by decreasing the time it takes for surgeons to organize the wires. Thus, the team will engineer a device to organize multiple catheters and solve this issue. The device will consist of two parts: (1) a stand to store guidewire wheels and (2) 3 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 with guidewires within the wheel.

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].

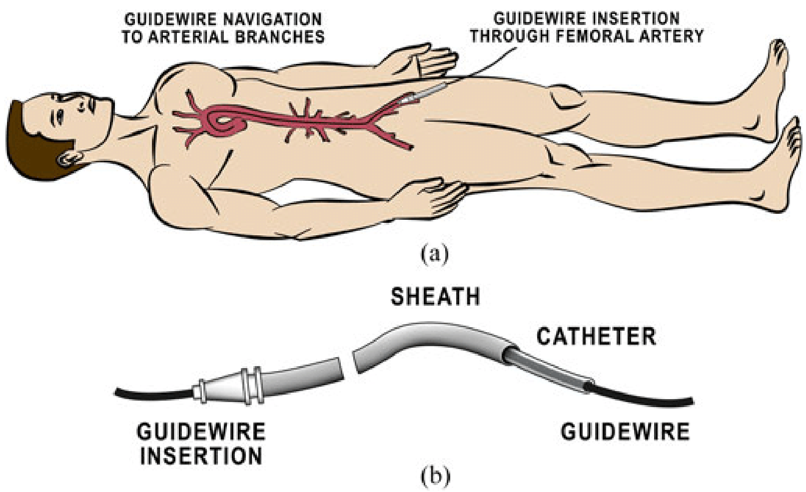


Figure 3. Guidewire and catheter being inserted into the body [8].

2.2 Materials and Machines

For this project, the prototype will be 3D printed at the MakerSpace. The printer selected will be the Ultimaker S5. The team will use Ultimaker PLA for the printing filament due to its ease of use, high strength, and high stiffness which are all ideal when considering the large amount of testing that will transpire. It is also cost-effective and efficient [9], two features that are ideal for prototyping. Additionally, the team will consider outsourcing the device to be 3D printed for a more precise print because the product is specific down to the millimeter. The team has considered using Protolabs. Using selective laser sintering with PA 12 White, the team can print the device with 0.3 mm precision [10]. However, printing would be much more expensive, costing around $170. Using Protlabs to print may be a viable option for the final prototype.

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 [11].

2.4 Design Specifications

Aiming to create a stand that is compatible with the current wheel design, the client has requested specific requirements for the device's development. The current wheel design has been provided by the client. The wheel dimensions and basic characteristics must be finalized and should maintain the ability 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 [12]. The stand device must be able to hold three guidewire wheels as well as allow the guidewires to be removed from the wheel while stored in the stand. Both the final stand and the wheel market designs must be biocompatible and have the ability to be sterilized since they will be used in operating rooms.

For the design to be competitive in the market and meet the client's requirements, the budget of the design should not exceed roughly $200, however, the budget is flexible. A complete list of specifications can be found in **Appendix A**.

3. Preliminary Designs

Introduction

3.1 DYWheel

As mentioned earlier, the client has provided the team with a preliminary wheel design shown in **Figure 4**. The team aims to change various dimensions and some basic characteristics until the most effective design is determined. Effectiveness will be determined by different tests which are introduced below in **Section 5.3**.

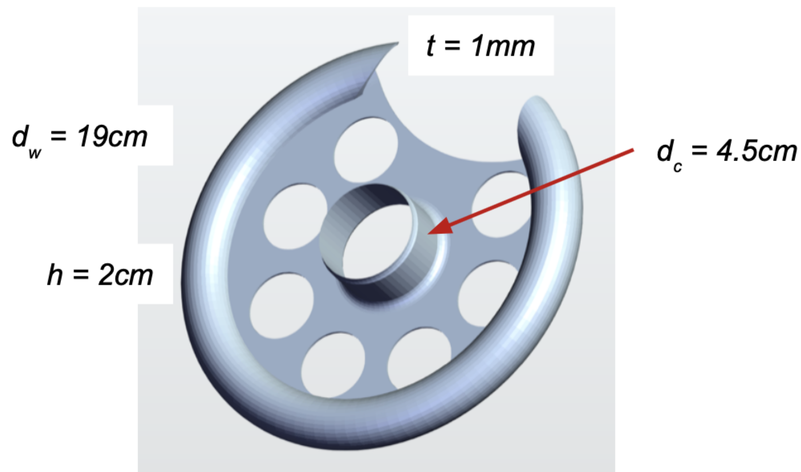


Figure 4. *DYWheel*
Dimensions: Outer Diameter (d_w): 19 cm. Chimney Diameter (d_c): 4.5 cm

3.2 DYStand

The team developed three stand designs. These stands must be compatible with the wheel design, so it is important to note that their dimensions will be constantly changing as the wheel design varies.

The DYStand is shown below **(Figure 5)**. It is 9 cm high and is able to hold 3 wheels. The wheels are simply stacked on top of each other, with the inner support of the stand going through the wheel's chimney. It is a minimal and basic design, which means it will result in little clutter within the OR. The base of the stand is 1 mm thick, thus there are some concerns that the stand may not be stable enough to use within the operating room. Additional dimensions of the stand can be found in **Figure 5**.

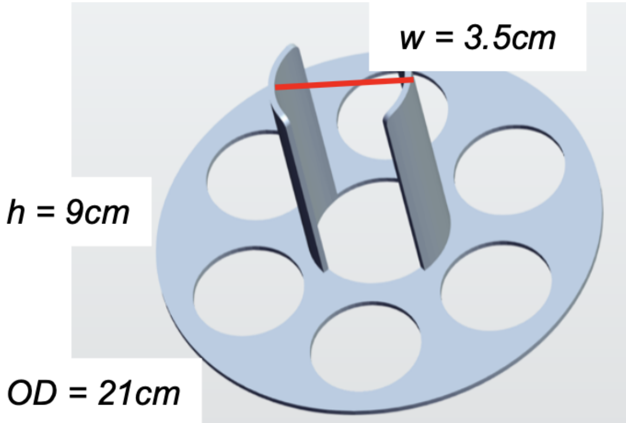


Figure 5. *DYStand.*
Dimensions: Outer Diameter (OD): 21 cm. Inner Diameter (w): 3.5 cm.

3.3 UHold

The second stand design idea is the UHold seen in **Figure 6**. The UHold is similarly dimensioned to the DYStand and has the same wheel loading technique. However, it has a backplate incorporated into the design to provide additional support to the wheel. This design has a 1 cm thick base plate where weights may be added, which makes it less likely to tip.

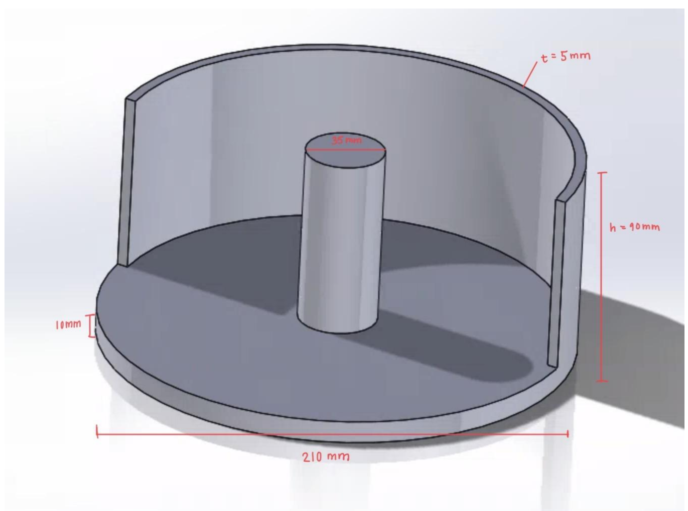


Figure 6: *UHold.*
Dimensions: Outer Diameter: 21 cm. Inner Diameter: 3.5 cm.

3.4 Door

The third stand design is the Door as shown in **Figure 7**. Its outer diameter is 20.32 cm and is 30.5 cm in height. The additional height allows for more wheels to be stacked inside. The top lid is detachable to allow for wheels to be placed through the top. The lid is then replaced once all wheels are inside. The door design allows for the wheels to be taken out in any order (not just top to bottom). The design allows for the guidewires to be taken out even when the door is closed. The door is held to the device with 3 hinges along with a clip that keeps the door shut.

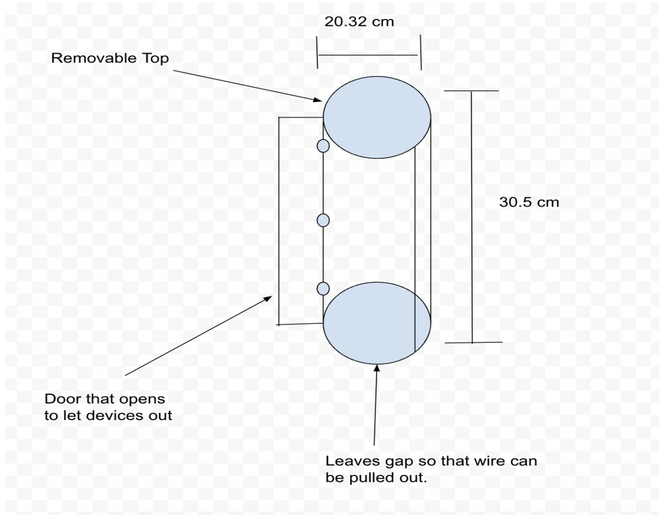


Figure 7. *Door.*
Dimensions: Outer Diameter: 20.32 cm.

4. Preliminary Design Evaluation

4.1 Design Matrix

Endovascular Catheter Design Matrix

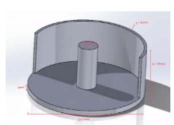
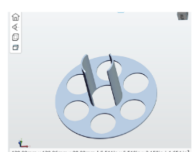
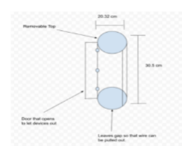
Design	 UHold		 DYStand		 Door	
Efficiency (30%)	5/5	30	5/5	30	2/5	12
Learning Curve (25%)	4/5	20	5/5	25	3/5	15
Compatibility (20%)	4/5	16	5/5	20	3/5	12
Durability (15%)	5/5	15	3/5	9	3/5	9
Safety (10%)	5/5	10	3/5	6	3/5	6
Total for each design:	**91**		**90**		**54**	

Table 1: The team's design matrix.

The Design Matrix (Table 1) Criteria and Evaluation:

Efficiency (30%): *The device should be more efficient than the current options that are available. With no external device, the wires are more likely to be tangled and disorganized. Disorganization is a main cause of decreased efficiency. The device should be able to efficiently load and unload the guidewire wheels. This is weighted very heavily due to the fact that efficiency is the purpose of the device/project.*

The majority of doctors do not use any device, resulting in disorganization and potential tanglement; all three designs from **Section 3** aim to decrease this. In this category, the DYstand and Uhold are tied. Both devices have a similar method of loading from the top that can be done very quickly. On the other hand, the Door device requires opening the top lid to load the guidewires, making it less efficient. All three designs keep the wires organized and separated.

Learning Curve (25%): *Learning to use the device must be a quick and simple process. The operator of the device should not have to spend a significant amount of time to understand how to properly use and operate the device. This is a high priority because the device will not be successful in the market if doctors have to spend any significant amount of time learning how to use it.*

The DYstand has a low learning curve as it can be loaded and the wire can be pulled from any side of the device. The UHold was scored lower because the guidewire tip must be opposite the back plate in order to be removed, thus it can not be removed from all directions. Finally, the Door device was scored lowest because it requires more loading/unloading steps than both previous designs.

Compatibility (20%): *The stand must be able to be stored in small spaces and be utilized on any surface in the operating room. This device must be able to unload guidewires of varying stiffness and sizes as well.*

Given this definition, the DYstand scored highest. It can be placed in many locations in the operating room because of its smaller size. It is also the most accessible, allowing it to face any direction. The UHold is more bulky due to the thick backplate that may not fit in all places, and this backplate reduces the accessibility to the guidewire within the wheel. The door device scored the worst as it is tall and requires space to open the door, taking away from both parts of compatibility.

Durability (15%): *The criteria was included to assess the ability of the design to withstand stress upon operation and testing. This category was given a weight of 15% due to the durability of the device being an important and key feature for multiple testing cycles.*

The UHold scored highest in durability because it is the thickest design, allowing it to withstand impact without chipping or breaking. The DYstand is thinner, making it more likely to snap in half. The door design can be damaged easily because the hinges can break.

Safety (10%): *The device must be safe to use in an operating room and safe to use by a doctor. With safety, the stand must not tip over in the process of unloading or loading the guidewire wheels. Safety is important; however, all three designs have similar safety features, which is why safety is weighted at 10%.*

The UHold stand is the heaviest and has the biggest base, making it the least likely to fall over. The DYstand is lighter in weight, thus any significant force applied will cause the stand to tip. The Door design is the most tall and narrow making it less stable. All three designs are safe to use by doctors during a patient procedure.

4.2 Proposed Final Design

The UHold design best meets the given requirements. The learning curve, while not the lowest, is almost negligible and should allow doctors to pick up and use the device with ease. The device is small enough to fit into most spaces in the operating room. Finally, because of its base size and thick walls, it is the least likely to fall over, and therefore the most durable and safe. This device is what the team will move forwards with. In the future, if it is decided that the bulkiness of the device impedes its functionality too greatly, then it is possible that the DYstand may be reconsidered.

5. Fabrication/Development Process

5.1 Materials

For the final proposed design of the wheel and the stand to meet the needs of the client. To be successful, materials that provide strength, stability, and slight flexibility are required. The initial prototypes of both the current wheel and UHold stand designs have been 3D printed from the UW MakerSpace using Ultimaker PLA [13]. Ultimaker PLA meets the material requirements for the initial prototypes by having good flexural and impact strengths and high hardness [14]. The team is considering outsourcing for a final prototype stage. The team has spent $33.28, and a detailed expense report can be found in **Appendix B**. However, the final market device should be made out of stainless steel so it can be sterilized and reused. The stand may also require weights to be added to the base to prevent falling over in the operating room.

5.2 Methods

Initially, one prototype of both the UHold stand and current wheel design will be 3D printed at the MakerSpace using CAD files developed by the team and the client. Both designs will be altered and reprinted throughout the semester when design or material changes need to be made. Testing on the stand and wheel will be conducted to finalize the dimensions of the wheel and determine the most efficient wheel design. Additionally, testing will be completed to ensure the device meets the client's requirements and could be successful in the market.

5.3 Testing

The testing will consist of testing both the wheel and the stand. For the wheel, the testing will consist of timed loading and unloading tests. This will provide a definitive answer regarding if the device is faster than the original method. It will also allow testing of consistency and other complications. The stand will be tested at timed loading and unloading speeds. In addition to this, a test will be conducted to ensure that the wire can be unloaded without issue. Many different individuals, both familiar and unfamiliar with the device, will perform these tests which allows for the learning curve to be quantized. The number of test runs each individual completes will be recorded to assess the effect of becoming familiar with the device. A formal testing protocol will be developed in the future.

6. Discussion

6.1 Ethical Considerations

When testing and implementing new devices into the medical field there are seven main principles of clinical research [15]. 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 and Future Work

Incorporating all innovative properties of designs created thus far in the semester, the design for the guidewire wheel and stand has been presented and effectively organizes and holds guidewires for easier access. The proposed final design, explained in **Section 4.2**, has a diameter of 19 cm, a chimney of 4.5 cm, a height of 2 cm, and a thickness of 1 mm. The stand will store 3 guidewire wheels. The stand has an outer diameter of 21 cm, a height of 9 cm, and a wall thickness of 5 mm. The guidewires will be able to be removed from the wheel while on the stand. The proposed final stand design will be tested and evaluated throughout the rest of the semester in order to create the most effective device possible. The current wheel design dimensions and characteristics will be finalized through a variety of prototyping phases and tests to determine the most efficient and organized device. The stand design's dimensions will be altered to hold the modified wheel. Finally, the team will quantitatively assess and analyze the results to prove the effectiveness of the device.

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9. Appendix

Appendix A: Product Design Specifications

Product Design Specifications

Date of Last Revision: Feb 9, 2022

Title: Guidewire Organizer for Operation Room
Client: Dr. Dai Yamanouchi
Advisor: Colleen Witzenburg
Team: Tatum Rubald, Addison Dupies, Alex Pudzisz, Rachel Krueger, Victoria Heiligenthal
Section Number: BME 301

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 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 wheel while wheel is stored on the stand
- The final market device must ultimately have biocompatible properties**
- The final market device must be sterilizable by autoclave or other alternatives**

*Client provided the basic concept of the wheel design, requires testing and alteration of dimensions

**Clients main goal is a successful prototype and proof of concept

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 3 wheels at once. The stand should allow easy access to the guidewire at any point during a procedure.

b. *Safety*: The final market device should be able to withstand heavy chemicals such as, glutaraldehyde, formaldehyde, ethylene oxide that are needed to sterilize medical tools in the operating room [2]. Additionally, 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, it must be able to fit 3 catheter guidewires, which ideally fit within the 188 mm diameter of each wheel, and each wheel must be able to hold a 0.035, 0.018, 0.014 inch guidewire 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 so the operating room workers can 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*: This product is a prototype. The life of service for the prototype should be long enough to confirm that it works and present to possible investors and to provide proof of concept. A large amount of prototype testing will be conducted over the next six months, so the prototype must be able to withstand multiple loading/unloading tests during this time to show it operates properly and efficiently.

e. *Shelf Life*: In order for the final market device to be practical for surgical use, and last at least 5 years, between uses the final market device will need to be autoclavable or some other form of sterilizable. With this in mind, the material used to design this device should be able to withstand sterilizable temperatures (121-132 °C) in order to maintain its shelf life after being used for the first time [3].

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 [4]. It should be stored in a designated sterile storage room.

g. *Ergonomics*: The should be easily gripped by the operator to ensure maximum control which includes minimizing excessive movement. Ensure that the circular and storage devices 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 188 mm, and an inner diameter cutout of 45 mm. The circular wheel will have a thickness of 45 mm. The stand will have dimensions of 210 mm outer diameter, with a 35 mm inner diameter pole. The stand will have a 90 mm tall wall and a 5 mm thick wall around half of the device.

i. *Weight*: The prototype will be lightweight, under two pounds, and easy to maneuver but able to withstand operating room size requirements and various table setting environments [5]. The stand must be heavy enough to not tip over while using the wheels. This is approximately 5 pounds.

j. *Materials*: The initial materials for the prototype will be plastic filament (PLA) from the Makerspace [5]. The stand may require weights in the base. After the prototyping phase, the final market device material should be medical grade stainless steel to make it possible to sterilize and reuse.

k. *Aesthetics*, *Appearance, and Finish:* The client requests that the prototype be 3D printed to allow for easy replication of the device that remains cost efficient [1]. The final market device should be FDA medical grade steel and should have a smooth, clean finish [6]. 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. In the initial prototyping phase, many wheels will be produced and modified to allow for ample testing until the final prototype is produced. The final prototype will consist of 3 wheels and a stand, which will house the wheels.

b. *Target Product Cost*: Taking into consideration the materials and size, we estimate that the approximate cost of the 3D printed stand and wheels prototype to be around 200 USD, but the client's budget is flexible.

3. Miscellaneous

a. *Standards and Specifications*: This product would likely be considered as a Class II medical device. There is no direct FDA regulation for this device, so it will be assumed to follow the same rules as a guide wire kit and guidewire torque device [7, 8]. Both of these are Class II and require premarket approval in the form of a 510k. There may be a way to prove that it does not require premarket approval, but the team would need further guidance to determine if it is possible [9].

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 [10].

c. *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.

d. *Competition*: 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 [11].

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Appendix B: Expenses Table

Item	Description	Manufacturer	Part Number	Date	QTY	Cost Each	Total	Link
Component 1								
UHold Stand	Stand for wheels with a back wall for stability	UW MakerSpace	N/A	2/22/22	1	$22	$22	UW-MakerSpace
Component 2								
DYWheel		UW MakerSpace	N/A	2/23/22	1	$6.00	$6.00	See above
Component 3								
DYSpool		UW MakerSpace	N/A	2/23/22	1	$1.92	$1.92	See above
Component 4								
ShortSpout		UW MakerSpace	N/A	2/23/22	1	$3.36	$3.36	See above
TOTAL:	**$33.28**							

Table 1: Expenses Table