



Guidewire Organizer for Endovascular Procedures

BME 200/300

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Abstract

During an endovascular procedure, many guidewires of different styles are used. The guidewire is removed from dispensing tubing and inserted into the patient. The catheter is secured in place and the guidewire is then removed from its casing. After the guidewire is removed, a problem arises. The guidewire can become easily tangled and disorganized. As a result the team has been tasked with creating a device that allows for better organization, storage, and dispensing of guidewires during endovascular procedures. The team came up with four designs: Magnetic Wheel, Clamped Wheel, Wheel of Magic, and Guidewire Hoop. Ultimately, the team chose the Guidewire Hoop as the final design. The proposed design is a ring-like device with a magnetic inner surface in order to keep the guidewire secure at all times and a small hole to thread the guidewire through. The team plans on testing the prototype through timed testing trials of efficiency of storing and removing the guidewire from the Guidewire Hoop.

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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 device will decrease the amount of the 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 a less hazardous setting in the OR. The endovascular treatment device market is currently over \$2.0 billion and is projected to reach \$2.2 billion by 2022 [3]. We hope 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 designs for the guidewire organizer: Angio Assist Docking System and Teirstein Edge Device Organizer, both of which were designed by Teleflex. The Angio Assist Docking System is designed to hold up to one guidewire and one catheter at a time. The product contains slots to facilitate the alignment and introduction of 0.014” guidewires into the catheters [4]. The Teirstein Device Organizer is designed to hold up to six catheters and six guidewires. The guidewires are held by six friction slits which allow for controlled, micro movements of the guidewire. Both designs use easy-to-pinch clips for securing to drapes in the operating room [5].

There are key differences between what these designs offer and what our client is looking for within the guidewire organizer. The device our client suggested should be designed so that each guidewire is coiled up and organized separately and alone. This is so each guidewire will not get tangled with the others.

1.3 Problem Statement

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 wires. Thus, we will engineer a device to organize multiple guidewires and solve this issue. The device will consist of two parts: (1) a divided crate to store (2) 4 wheels in which the guidewires will be placed. The guidewire must stay organized and unknotted when removed from the wheel; to do this there will be a lip on the grate for the guidewire to sit on. It must be easy to remove the wire while in the operating room. The wheels must also be easily placed and removed from the crate.

2. Background

2.1 Relevant Physiology and Biology

As stated previously, our device will assist in the ease of organization of guidewires in endovascular catheter related surgeries. The baseline procedure is called Cardiac Catheterization, which is used to evaluate or confirm the presence of coronary artery disease, valve disease, or disease of the aorta. Cardiac Catheterizations are also used to evaluate heart muscle function as well as determine the need for further treatment (such as an interventional procedure or coronary artery bypass graft, or CABG, surgery) [6].

A Cardiac Catheterization is performed in a standard hospital operation room. A guidewire will be inserted into a vein, and snaked to the region of interest for the surgery [7]. Following this, a long, narrow metal tube, called a catheter, is inserted through a plastic introducer sheath (a short, hollow tube that is inserted into a blood vessel in your leg or arm) and over the guidewire. Then, the surgeon will guide the catheter through the blood vessel to the coronary arteries with the aid of a special x-ray machine as an assisting person unwinds the excess catheter [8].

The next step is a Coronary Angiogram, where *contrast material* is injected through the catheter and x-ray movies are created as the *contrast material* moves through the heart's chambers, valves and major vessels. Finally, the coronary artery is opened, increasing blood flow to the heart and digital photographs of the *contrast material* are used to identify the site of the narrowing or blockage in the coronary artery [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 Ultimaker S5 has a large build volume (33.0 x 24.0 x 30.0 cm) [9], and since our product is fairly large, this 3D printer is ideal for our product. We will use Ultimaker PLA for the printing filament due to its ease of use, high strength, and high stiffness. It is also cost effective and efficient [10], 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 issue of tangled guidewires [11].

2.3 Design Specifications

Some important categories of the product design specification include performance requirements, safety, accuracy and reliability, and overall size. The device will consist of two parts: 4 guidewire hoops (wheel) and a crate to store all the wheels. Each guidewire will be placed within its own individual wheel. The wheel itself will have a 30 cm diameter, and must be

able to hold guidewires with diameter sizes of 0.014 to 0.035 inch. Overall, the guidewire must stay organized and unknotted when inserted and removed from the wheel in the operating room. Lastly, the final device must withstand heavy chemicals needed to sterilize medical devices. Please refer to the full PDS in Appendix 7.1 for more information on design specifications.

3. Preliminary Designs

Introduction

Before introducing our 4 initial guidewire organizer designs, it is important to preface the apparatus used for 3 of the 4 designs. The Magnetic Wheel, Clamped Wheel, and the Guidewire Hoop are all compatible with our crate design that has 4 slots for 4 wheels of each design when placed in an operating room setting. The crate is important for keeping guidewires separate when multiple are in use, as it can fit each wheel with a width of 3 cm.

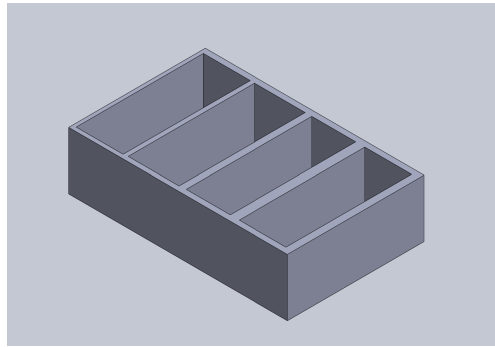


Figure 1: *Storage Crate.* Dimensions: 13x30x15cm

3.1 Magnetic Wheel

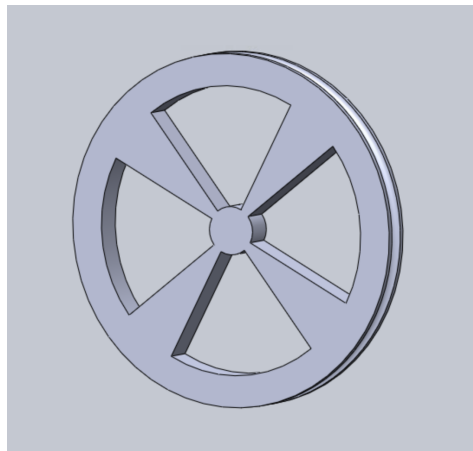


Figure 2: *Magnetic Wheel.* Dimensions OD: 30cm, ID: 28cm.

The Magnetic wheel design shown in Figure 2 was the initial design idea. The goal of the design was to use a magnetized outer ring to keep the metallic guidewire in contact with the wheel while coiled around the magnetized wheel, in order to prevent uncoiling of the guidewire,

and to have easier access to the guidewire. The design has an outer diameter of 30 cm with a concave semicircle cutout around the circumference of the wheel that acts as a lip to contain the guidewire when it is spooled around the wheel. It has an internal diameter of 28 cm. Within the walls of the cutout, there will be a magnetic strip that will attract the metallic guidewire, keeping it in close contact with the wheel at all times, not allowing for the uncoiling of the guidewire when wrapped around the wheel. When the wheel is placed into the crate, the wheel can be accessed through the top of the crate where the wheel is exposed. The wheel can be removed, and the guidewire can be unspooled.

3.2 Clamped Wheel

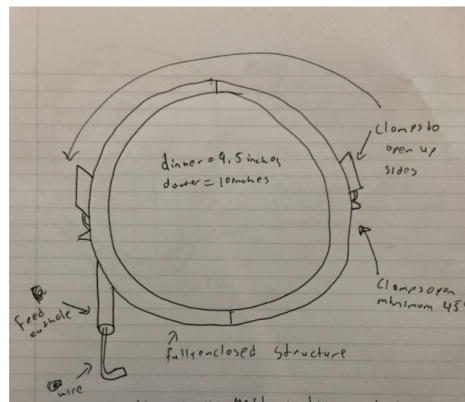


Figure 3: *Clamped Wheel*. Dimensions: OD: 25.4cm ID: 24.13cm

The Clamped Wheel design, Figure 3, utilizes a different mechanism for containing the guidewire when the guidewire is placed inside of the wheel. Instead of the guidewire being spooled around the wheel, there is a clamp on the circumference of the wheel that can snap open and closed once the guidewire is placed inside. The hollow circumference of the wheel will contain the guidewire once it is clamped shut, as the guidewire must be coiled and placed into the wheel prior to shutting the clamp. The wheel also has a small protruding tube extending from the hollow interior of the perimeter of the wheel, which will contain the very tip of the guidewire for easier access to the wire, as the tip of the wire can be pulled to uncoil the wire without having to unclamp the wheel. The outer diameter of the wheel is 25.4 cm, and the inner diameter of the wheel is 24.13 cm, and in between those diameters is the hollow surface that contains the guidewire.

3.3 Wheel of Magic

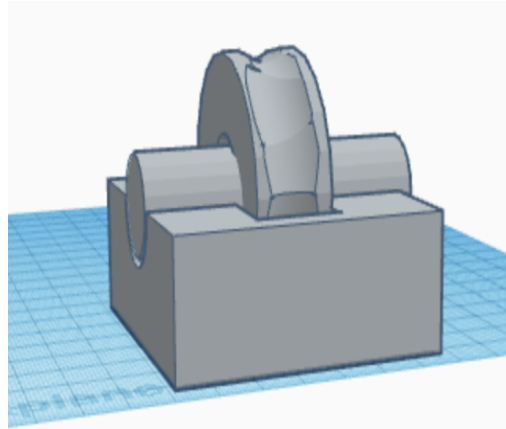


Figure 4: *Wheel of Magic.* Dimensions: OD: 30cm ID: 15cm

The Wheel of Magic, Figure 4, design has a more unique function in comparison to the other preliminary designs. The Wheel of Magic has three structures: the wheel, the middle rotating handles, and the lower crate portion. The wheel portion is used as a guide for the guidewire to be spooled around and has protruding handles on both sides to have easier access to rotate the wheel, allowing for hands-free uncoiling of the guidewire. The Wheel has an outside diameter of 30 cm with a concave lip cut into the width of the wheel that ends with an internal diameter of 15 cm. The guidewire is then spooled around the wheel within the concave lip and then placed into the lower crate. The crate for this design is different from the crate that is used for the other preliminary designs because it only fits one wheel per crate and has a ‘U’ shaped cut to account for the protruding handles on both sides. The purpose of the crate, in addition to keeping the guidewire separate from other guidewires, is to contain the guidewire by using the radial force applied by the guidewire to the crate internally, which does not allow for the uncoiling of the guidewire on the top of the wheel. The guidewire access point is where the top of the crate no longer encloses the wheel, and the handles can be used to slowly uncoil the guidewire from the design.

3.4 Guidewire Hoop

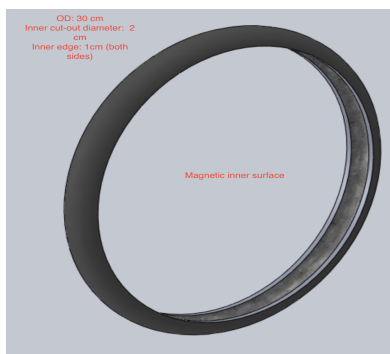


Figure 5: *Guidewire Hoop.* Dimensions: OD: 30cm ID: 29cm

The Guidewire Hoop in Figure 5, and was heavily influenced by the three previous designs. Using the innovative properties of the magnetized wheel in addition to the recognition of the radial force the guidewire exerts when coiled, this design aims to prevent the uncoiling of the guidewire internally. This design, instead of having a concave lip externally cut into the wheel, has an internal concave lip that is magnetized. The internal concave lip utilizes the radial force of the guidewire when coiled to contain the guidewire within the wheel, as the wire presses against the external wall of the wheel. In addition, the internal concavity is magnetized to ensure that the guidewire will remain in contact with the wheel against the lip, keeping the wire as stationary as possible to prevent the incidental uncoiling of the wire.

4. Preliminary Design Evaluation

4.1 Design Matrix

The Design Matrix Criteria:

Feasibility (30%):

Feasibility is the team's ability to produce the design as a working prototype in the next two months. This takes into account the team's time, equipment, and assembly constraints. The goal of the project is to create a working proof of concept, or prototype, that can then be mass produced in order to start a company. This criteria describes that goal exactly, and is given the highest percentage contribution of 30%.

Efficiency (25%):

Efficiency is determined by how fast the wire can be stored and accessed. This criteria is the other major section of the goal of the project. The prototype must work and must be proven to be faster and more convenient to the client. This gives it a purpose and a method to market it as a company in the future.

Durability (20%):

Durability is another important aspect to this project. The product will be used in a location and situation where lives can be lost. The device must not break or malfunction during this time. The device must be able to withstand multiple surgeries, cleanings, and accidents. These accidents can involve things such as being dropped. In addition to the importance during surgery, the durability is also important for the lifetime of the product. This will give the product another aspect to market.

Safety (10%):

The safety criteria measures the threat to the doctor's and the patient's safety. The products will be in the surgery room and must not interfere with any of the procedures and the equipment surrounding the doctors. The criteria is worth a lower percentage as the products should be safe. The prototypes do not include electronics or other parts that can malfunction.

Learning Curve (10%):

The learning curve is determined by the time needed to become accustomed to the new device. The devices should not have a long time to learn their functions and should be quick to pick up. The devices are meant to be intuitive and to save the doctors time, not to give them something else to think about during surgery. The lower percentage for this criteria is because the devices are all relatively uncomplex.

Cost (5%):

The cost is the final criteria. It was given the lowest percentage as the client has decided that the current project will be purely a proof of concept. This means that the cost of the device does not have to represent the final cost of the product. The client has also determined that the cost of prototyping is not an issue. The cost is further lowered as the process of prototyping is done by 3D printing with cheap plastics.

Design Matrix Evaluation:

In the feasibility criteria, the winner was the Guidewire Hoop. This design was evaluated to be the most likely to have a working prototype by the end of the semester. This design consists of a 3D print, followed by a magnetic strip on the inside of the ring. By comparison, the other designs have a part of them that would make it more complicated to construct. The Clamped Wheel would require the team to find a compatible clamp, and then find a method of combining it with a plastic shell in a way that ensures zero error. The Magnetic Wheel would require an appropriate strength magnet to counteract the wire's tendency to straighten and to find a method to ensure that the magnets would not fall off over time. The Wheel of Magic would require three prints with a low margin of error to ensure that the product works properly.

Efficiency was also evaluated. The Guidewire Hoop was the winner as it was estimated to be the fastest design to insert and remove the wire from. The quick wire storage comes from the ability of tension and magnets to hold the wire in place. This means after releasing the wire on the inside cavity, tension and magnets would hold it in place. The Wheel of Magic and Magnetic Wheel scored lower as they require manually coiling the wire around the device, and uncoiling it afterward. This makes the devices only slightly better than the original method. Finally, the Clamped Wheel made access very simple as it only requires opening a clamp. The issue with this design would be that both clamps must be opened simultaneously in order to keep the guidewire from springing out and unwinding hazardously.

Durability is a very significant criterion. The designs needed to ensure that, in a high-stakes setting, they do not break. The Guidewire Hoop, again, was the winner. The design is one continuous piece, meaning that there are no moving parts to break. The Clamped Wheel's clamps have a possibility of breaking, giving it a lower score. The Magnetic Wheel has magnets on the outside and has spokes on the center that are also more likely to break. Finally, the Wheel of Magic has three parts that are separated and if chipped may not slide as easily as before.

Safety is an important issue, especially in a place where lives are saved. The devices all scored a perfect score as they did not directly affect the patient's or doctor's safety. The devices would have the wire taken out prior to using it in surgery, so it would not be used, as a surgery device, during the operation. The devices may lie inside the room, but they do not have any toxic material or anything else that could affect the health of those nearby.

The learning curve is the estimated time to become accustomed to the device. The winner for this criteria was the guidewire hoop. This design took what doctors were already accustomed to doing,

wrapping the wire in a loop around their hands, and only required them to release that loop into the device. The Wheel of Magic and Magnetic Wheel were only slightly lower as instead of looping it around their hand, they would be required to loop it around the new devices. This may feel foreign at first, but given that the devices are not complex is estimated to take little time. The Clamped Wheel was rated the lowest as operating both clamps would be required in order to open the device. This is a more difficult task, and is not something the doctors are familiar with doing.

Finally, the cost is a small issue as the device is a proof of concept, and not representative of the true device in material. The Guidewire Hoop and the Magnetic Wheel were rated the lowest. This is due to the additional cost of magnets. The other two devices only required the cost of the print or other cheap materials, giving them a higher rating. The full design matrix with the numerical scores can be found in Appendix 7.2.

4.2 Proposed Final Design: Guidewire Hoop

The proposed final design was chosen from the preliminary Guidewire Hoop design, seen in Figure 5. The Guidewire Hoop was the best design, using minimal material and the innovative idea of using the radial force of the guidewire to secure it within the wheel. The magnetized interior, in addition to the utilization of the radial symmetry, made it clear that this design would be the most secure organizer for the guidewire, while still being able to uncoil/remove the wire efficiently.

In the preliminary design, there are a few missing aspects to the design that need to be added in order to make the Guidewire Hoop the most innovative and useful guidewire organizer. The new design will have a hole of 0.13 cm diameter cut through the hoop where the guidewire tip can be accessed. This will make it easier to uncoil the guidewire slowly from the hoop instead of having to take the entire wire out to insert into the patient. Additionally, the outer and inner diameters of the hoop will each be decreased by 2 cm each in order to hold the guidewire more tightly, as the more coiled the guidewire is, the more radial force it will apply to the internal concavity, making the guidewire more secure. These new dimensions will make the outer diameter to be 28 cm and the inner diameter to be 27 cm. The hoop will also have a thickness of 3 cm, with a 0.5 cm edge on both sides of the inner surface and an internal semi-circle concavity. The semi-circle inner concavity, where the coiled guidewire is placed, will have a diameter of 2 cm. The hoop will then be placed into the crate structure with 4 slots that can hold 4 hoops. The crate has a height of 15 cm, a width of 30 cm, and a length of 13 cm, as it is a rectangular prism. Each opening in the container is 3 cm wide and 29 cm long, as they are just the right size to contain each wheel.

5. Fabrication/Development Process

5.1 Materials

The proposed final design, the Guidewire Hoop, has a simple composition. However, there are specific requirements that the materials must meet in order for them to be viable options. This material must be able to withstand any force, within reason, either by the operator or guidewire itself. In addition, the final material must be biologically inert. The prototype of both the crate and the hoop will be 3D printed and made of Ultimaker PLA. This is the most cost effective material that fulfills the criteria. A magnetic strip will also be glued onto the inner surface of the hoop using superglue.

5.2 Methods

Five wheels will be printed along with the crate, with the dimensions specified in section 4.2 “Proposed Final Design: Guidewire Hoop”. After the wheels are printed, a 2 cm wide magnetic strip will be glued to the inner surface of the wheel. Prior to gluing the assembly, a small hole with a diameter of 0.13 cm will be drilled through the magnetic strip. This hole will align with the 0.13 cm hole through the 3D printed wheel. These wheels will be placed in the crate once sufficiently dried.

5.3 Testing

The prototype will test the amount of time it takes to organize the wires using the prototype. The device will be tested on the time required to store the wire within the wheel, and then again on the time required to access and remove the wire. The participants involved in this experiment will involve the team members, and potentially doctors at UW Hospital. The participants will follow the test method found in Appendix 7.3. The doctor will also perform the same test with the current organization method in order to have baseline data. The participant list may also extend to random participants, to get rid of any discrepancies in the data due to familiarity with the guidewire wheel device. Statistical analysis will be run to find any significant changes in efficiency, defined by time. There will also be separate notation and observations for complications in the new device. One possible issue that will be observed is entanglement.

6. References

- [1] Strate, C., 2020. *The Cost Of A Lost Minute In The OR*. [online] Accesefm.com. Available: <<https://www.accesefm.com/blog/the-cost-of-a-lost-minute-in-the-or>> [Accessed 07-Oct-2021].
- [2] James G. Wright, A., 2020. *Improving On-Time Surgical Starts In An Operating Room*. [online] PubMed Central (PMC). Available: <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2878988/>> [Accessed 07-Oct-2021].
- [3] D. R. T. Dangi, “Endovascular treatment devices: EVAR and tevar emphasis,” *Endovascular Treatment Devices (EVAR & TEVAR) Market Report*. [Online]. Available: <https://www.bccresearch.com/market-research/healthcare/endovascular-treatment-devices-evar-and-tevar-emphasis.html>. [Accessed: 19-Oct-2021].
- [4] B. I. B. A. Publishing, “Vascular solutions launches the Angio Assist Docking Station and the Teirstein Edge device organizer,” *Vascular News*, 09-Nov-2010. [Online]. Available: <https://vascularnews.com/vascular-solutions-launches-the-angio-assist-docking-station-and-the-teirstein-edge-device-organizer/>. [Accessed: 19-Oct-2021].
- [5] “Interventional accessories: US,” *Teleflex*. [Online]. Available: <https://teleflex.com/usa/en/product-areas/interventional/coronary-interventions/interventional-accessories/index.html>. [Accessed: 19-Oct-2021].
- [6] “Dai Yamanouchi, MD, Phd,” *Department of Surgery*, 01-Jan-2000. [Online]. Available: <https://www.surgery.wisc.edu/staff/dai-yamanouchi/>. [Accessed: 19-Oct-2021].
- [7] “Ultrasound Guided Central Access - Compliance Within Practice,” *Section 9: Tips when working with guidewires*, 2011. [Online]. Available: <https://www.teleflex.com/en/usa/arrowUniversity/vascular/cvc/section9/1.html>. [Accessed: 19-Oct-2021].
- [8] “Cardiac catheterization: Procedure, preparation, Duration & Risks,” *Cleveland Clinic*. [Online]. Available: <https://my.clevelandclinic.org/health/diagnostics/16832-cardiac-catheterization>. [Accessed: 19-Oct-2021].
- [9] “The ultimaker S5 is here,” *ultimaker.com*. [Online]. Available: <https://ultimaker.com/learn/the-ultimaker-s5-is-here>. [Accessed: 19-Oct-2021].
- [10] “3D printers,” *UW Makerspace*. [Online]. Available: <https://making.engr.wisc.edu/3d-printers-2/>. [Accessed: 19-Oct-2021].
- [11] Yamanouchi, Dai, MD, Phd. “Client Meeting,” Conference. [Accessed: 17-Sept-2021].

7. Appendix

7.1 Product Design Specification

Product Design Specifications

Date of Last Revision: 09/21/2021

Title: Guidewire Organizer for Operation Room

Client: Dr. Dai Yamanouchi

Advisor: Dr. Kip Ludwig

Team: Tatum Rubald, Addison Dupies, Serena Raval, Scottie Waterfield, Alex Pudzisz, Soniya Patel

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 and decrease the time it takes for surgeons to organize the wires.

Client requirements:

- The device must be easy to use and increase organization in the operating room
- The device must consist of a main storing unit (the crate) to house 4-5 guidewire wheels
- The final device must ultimately have biocompatible properties*
- The final device must be sterilizable by autoclave or other alternatives*

*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 parts: (1) a divided crate to store (2) 4-5 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. Additionally, the guidewire must stay organized and unknotted when removed from the wheel; to do this there will be a lip on the edge of the crate for the guidewire to sit on. It must be easy to load and remove the wire into the wheel while in the operating room [1]. The wheels must also be easily placed and removed from the crate.
 - b. *Safety:* The 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 4-5 catheter guidewires, which ideally fit within the 11.8 inch diameter of each wheel, and each wheel must be able to hold a 0.035, 0.018, 0.014 inch guidewire [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.

- d. *Life in Service*: This product is a prototype. The life of service should be long enough to confirm that it works and present to possible investors and to provide proof of concept. This could be up to a year, but the minimum time under little stress should be a month. If the product is eventually made to be sold, and made out of medical grade stainless steel, it should last for at least a lifetime, or 100 years [3].
- e. *Shelf Life*: In order for our device to be practical for surgical use, and last at least 5 years, between uses the 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 [4].
- f. *Operating Environment*:
This 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 and 75 °F [5]. It should be stored in a designated sterile storage room.
- g. *Ergonomics*: The device should be easily gripped by the operator to ensure maximum control which includes minimizing excessive movement. Post operation, this device should be easily inserted into an autoclave for sterilization. When not in use, the device should be easily stored away in a storage room.
- h. *Size*: The design consists of a circular wheel with a diameter of 11.8 inches. The crate for storing the wheels will be 12x7x6 in. The lip on the crate will be a semicircle with a diameter of .15 inches [1].
- i. *Weight*: The prototype will be lightweight and under two pounds and easy to maneuver but able to withstand operating room size requirements and various table setting environments [6]. The final product will be heavier as it will be made of stainless steel.
- j. *Materials*: The initial materials for the prototype will be plastic filament (PLA) from the Makerspace [6]. Beyond the prototyping phase the material should be medical grade stainless steel to make it possible to sterilize and reuse.
- k. *Aesthetics, Appearance, and Finish*: The client addresses the device may be 3D printed [1]. The final device should be FDA medical grade steel and should have a smooth, clean finish [7]. 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 main focus will be producing a single prototype to ensure proof of concept. In the future, this prototype will ideally be mass produced, so the ability to have steady organization of guidewires and catheters is available in all operating rooms, which leads to the production of many devices.
 - b. *Target Product Cost*: Taking into consideration the materials and size, we estimate that the approximate cost of the 3D printed Guidewire Organizer prototype to be around 200 USD.
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 [8, 9]. 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 [10].
 - b. *Customer*: The target market for the guidewire organization device would ideally be cardiothoracic surgeons and medical facilities that perform routine 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 [11].
 - c. *Patient-related concerns*: Because this device will be used in endovascular procedures, it is important to take into account patient safety. The guidewire holder 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 external guidewire as well as increase security of excess wires during procedures [12].

References:

- [1] Dr. D. Yamanouchi, “Client Meeting One,” 17-Sep-2021.
- [2] H. Gül, “Occupational health and safety in operating rooms,” *IntechOpen*, 26-May-2021. [Online]. Available: <https://www.intechopen.com/online-first/76118>. [Accessed: 23-Sep-2021].
- [3] “Durability and life expectancy for stainless steels in external environments,” *British Stainless Steel Association*. [Online]. Available: https://bssa.org.uk/bssa_articles/11-technical-library-pitting-corrosion-pre-numbers/. [Accessed: 24-Sep-2021].
- [4] “Steam sterilization,” *Centers for Disease Control and Prevention*, 18-Sep-2016. [Online]. Available: <https://www.cdc.gov/infectioncontrol/guidelines/disinfection/sterilization/steam.html#:~:text=Specific%20temperatures%20must%20be%20obtained,minimal%20time%20to%20kill%20microorganisms>. [Accessed: 24-Sep-2021].
- [5] Weigel, B., 2020. Controlling Operating Room Temperature And Humidity, And Managing Expectations. [online] [Buildingenergy.cx-associates.com](https://buildingenergy.cx-associates.com). Available at: <https://buildingenergy.cx-associates.com/2014/12/controlling-operating-room-temperature-and-humidity-and-managing-expectations/> [Accessed 16 September 2020].
- [6] U. W. Makerspace, “3D printer cost calculator,” *UW Makerspace*. [Online]. Available: <https://making.engr.wisc.edu/3d-printers/3dprint-cost/>. [Accessed: 24-Sep-2021].
- [7] Center for Devices and Radiological Health, “Safety of metals and other materials used in medical devices,” *U.S. Food and Drug Administration*. [Online]. Available: <https://www.fda.gov/medical-devices/products-and-medical-procedures/safety-metals-and-other-materials-used-medical-devices>. [Accessed: 23-Sep-2021].
- [8] “Product classification,” *accessdata.fda.gov*. [Online]. Available: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/classification.cfm?id=997>. [Accessed: 23-Sep-2021].
- [9] “Product classification,” *accessdata.fda.gov*. [Online]. Available: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/classification.cfm?id=953>. [Accessed: 23-Sep-2021].
- [10] Center for Devices and Radiological Health, “Convenience Kits Interim Regulatory guidance,” *U.S. Food and Drug Administration*. [Online]. Available: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/convenience-kits-interim-regulatory-guidance>. [Accessed: 23-Sep-2021].
- [11] S. Arora, V. Aggarwal, L. Maini, and A. Dhal, “Broken guidewire protruding into the hip joint: A bone endoscopic-assisted retrieval method,” *Indian Journal of Orthopaedics*, vol. 46, no. 1, pp. 109–112, 2012.
- [12] “Interventional Accessories: US.” *Teleflex*, Apr. 2018, teleflex.com/usa/en/product-areas/interventional/coronary-interventions/interventional-accessories/index.html.

7.2 Design Matrix

Design								
	Magnetic wheel		Clamped Wheel		Wheel of Magic		Guidewire Hoop	
Feasibility (30%)	4/5	24	3/5	18	4/5	24	5/5	30
Efficiency (25%)	3/5	15	4/5	20	2/5	10	5/5	25
Durability (20%)	3/5	12	3/5	12	3/5	12	4/5	16
Safety (10%)	5/5	10	5/5	10	5/5	10	5/5	10
Learning Curve (10%)	4/5	8	3/5	6	4/5	8	5/5	10
Cost (5%)	3/5	3	5/5	5	5/5	5	4/5	4
Total for each design:	72		71		69		95	

7.3 Device Testing Instructions

Preliminary Test Method Document:

Instructions

1. Give prototype and guidewire to tester
2. Instruct participant on method of wire insertion into device
3. Start timer when participant is ready
4. Stop timer as the participant finishes putting wire into device
 - a. Record time in notebook entry
5. Instruct participant to take wire out of the device
6. Start timer when participant is ready
7. Stop timer as the participant finishes taking wire out of the device
 - a. Record time in notebook entry
8. Observe wire for any tangles or entwinements
 - a. If obstructions exist record in notebook entry
9. Fill in table below as experiment is ran

Results Table

Trial Number	Loading Duration	Removing Duration	Total Duration of Process	Complications?