Guidewire Organizer for Endovascular Procedures

BME 301
University of Wisconsin - Madison
Department of Biomedical Engineering
4 May 2022

Client: Dr. Dai Yamanouchi, MD, PhD
University of Wisconsin School of Medicine and Public Health
Department of Surgery

Advisor: Dr. Colleen Witzenberg
University of Wisconsin - Madison
Department of Biomedical Engineering

Team Members:
Tatum Rubald (Team Leader)
Addison Dupies (Communicator)
Victoria Heiligenthal (BPAG)
Rachel Krueger (BWIG)
Alex Pudzisz (BSAC)

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 storage unit 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 came up with three designs for the stand: DYStand, UHold, and Door. The team chose to move forward with UHold design, but moved onto testing and finalizing a wheel design before moving forward with stand testing. The team came up with three modifications for the wheel: the DYWheel, CutChimney, and CurveSpout. All three designs are very similar, and consist of a circular wheel with an inner cavity to store the guidewire in place. The team tested three prototypes, and the DYWheel was determined to be most efficient after testing, but the CutChimney had alternative design advantages. The team will move forward with injection molding of the DYWheel and CutChimney designs. The UHold will be modified to be compatible with these wheels and then tested.

Table of Contents

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. 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.

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.

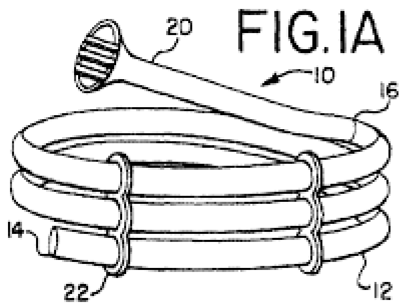


Figure 2. Medical Guidewire Storage and Apparatus Design [5].

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. The learning curve for the loading and unloading of the guidewire from the wheel should be small.

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].

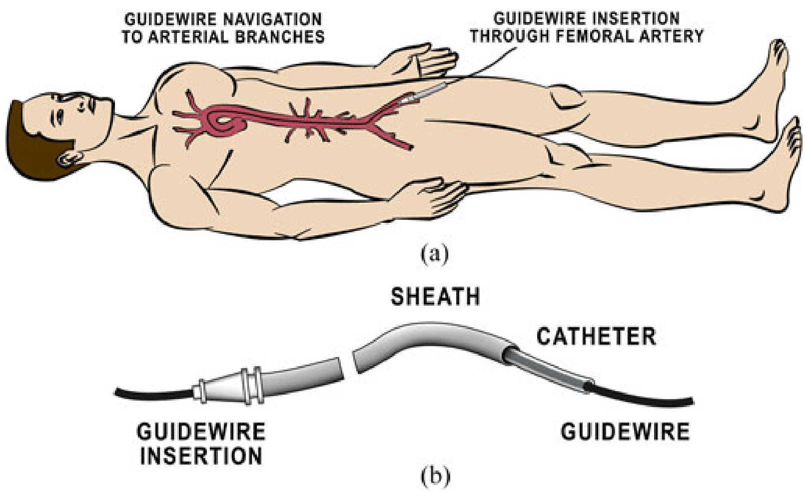


Figure 3. Guidewire and catheter being inserted into the body [8].

2.2 Materials and Machines

For this project, the prototype was 3D printed at the MakerSpace. The printer selected was 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. 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 team aimed to create a stand that is compatible with the current wheel design. The client has requested specific conditions for the device's development. The initial wheel design was provided by the client. The wheel dimensions and basic characteristics were modified and maintained 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 [11]. The stand device holds three guidewire wheels as well as allows the guidewires to be removed from the wheel while stored in the stand or with the wheel in hand. 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 Proposed Wheel Designs

A. DYWheel

The client provided the team with a preliminary wheel design shown in **Figure 4**. The team moved forward with testing on this wheel. Additionally, various dimensions and basic characteristics of this wheel were changed and became their own individual prototypes (see **3.1B** and **3.1C**). The wheel consists of a deep inner cavity, which allows the guidewire to be held securely in place after loading.

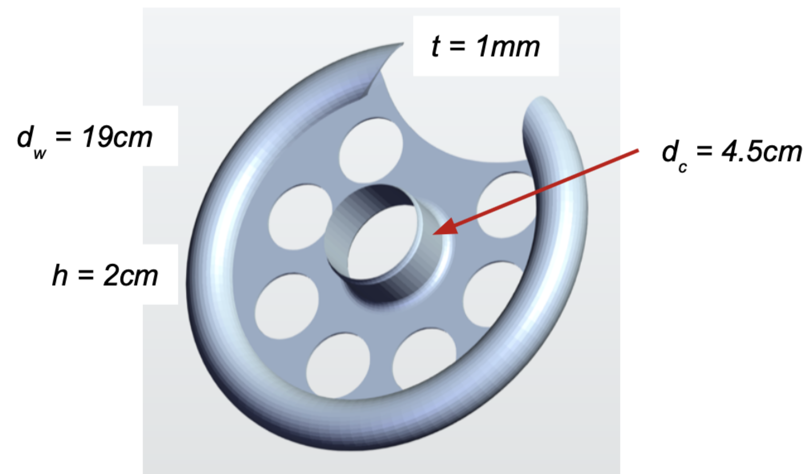


Figure 4. *DYWheel*
Dimensions: Outer Diameter (d_w): 19 cm. Chimney Diameter (d_c): 4.5 cm

B. CutChimney

The CutChimney design is similar in dimensions to the DYWheel. However, the inner chimney is semi-circular to allow it to slide off of the stand after the guidewire is unloaded. After unloading the guidewire, the wheel is able to be removed from any place on the stand.

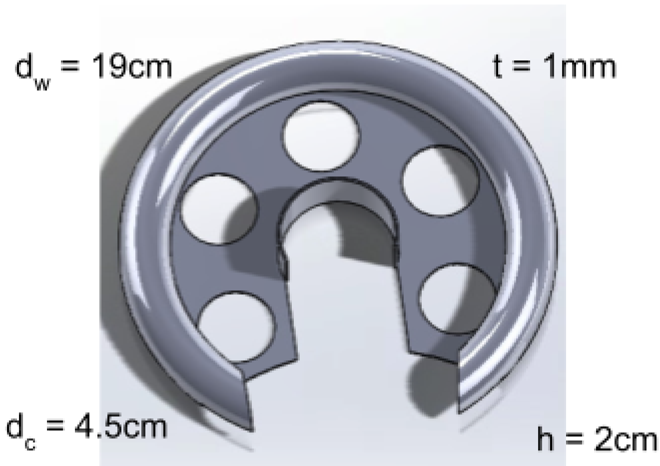


Figure 5. *CutChimney*
Dimensions: Outer Diameter (d_w): 19 cm. Chimney Diameter (d_c): 4.5 cm

C. CurveSpout

The CurveSpout design is another variation of the DYWheel. In this design the inner chimney is curved in. This modification was meant to ensure that when the wire is being unloaded it does not slip up and past the inner chimney.

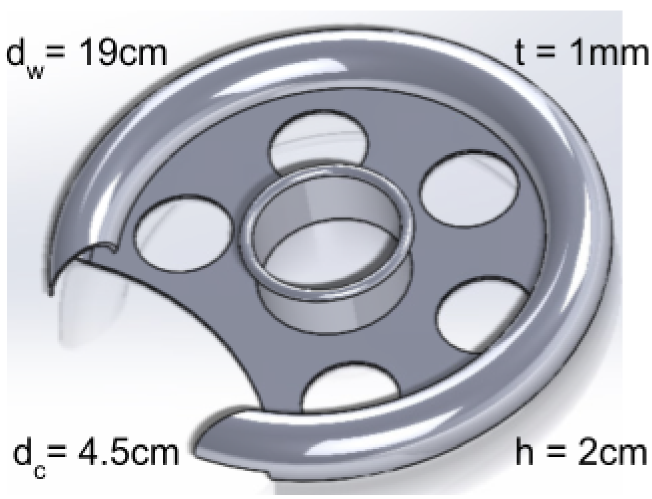


Figure 6. *CurveSpout*
Dimensions: Outer Diameter (d_w): 19 cm. Chimney Diameter (d_c): 4.5 cm

3.2 Proposed Stand Designs

A. 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 7)**. 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**.

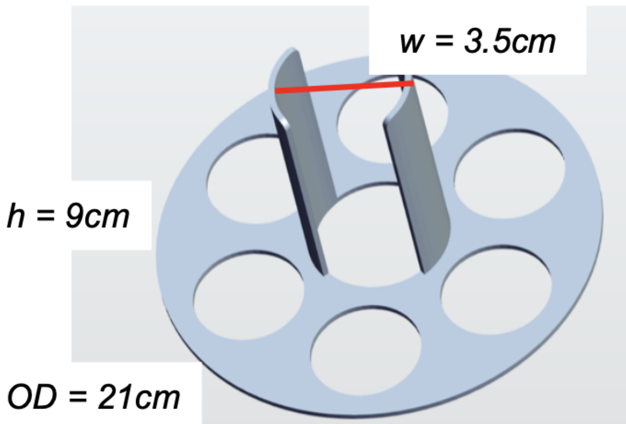


Figure 7. *DYStand.*
Dimensions: Outer Diameter (OD): 21 cm. Inner Diameter (w): 3.5 cm.

B. *UHold*

The second stand design idea is the UHold seen in **Figure 8**. 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.

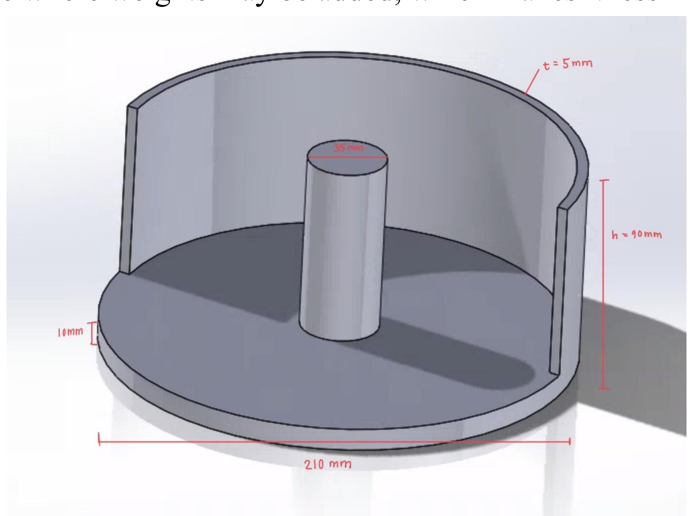


Figure 8: *UHold.*
Dimensions: Outer Diameter: 21 cm. Inner Diameter: 3.5 cm.

C. Door

The third stand design is the Door as shown in **Figure 9**. 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.

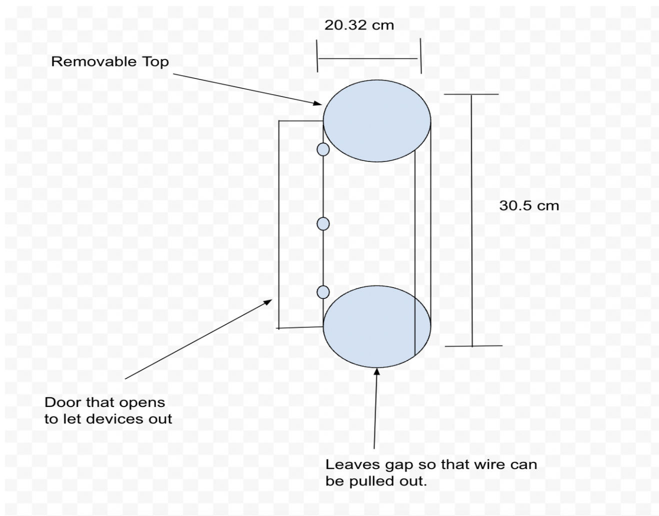


Figure 9. *Door.*
Dimensions: Outer Diameter: 20.32 cm.

4. Preliminary Design Evaluation

4.1 Design Matrix

Endovascular Catheter Design Matrix

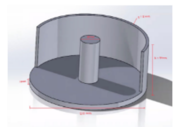
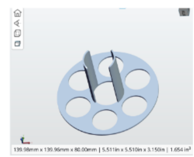
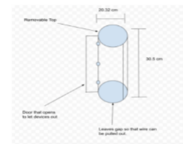
Design	 UHold		 DYStand		 Door	
Efficiency (30%)	5/5	30	5/5	30	2/5	12
Learning Curve (25%)	4/5	20	5/5	25	3/5	15
Compatibility (20%)	4/5	16	5/5	20	3/5	12
Durability (15%)	5/5	15	3/5	9	3/5	9
Safety (10%)	5/5	10	3/5	6	3/5	6
Total for each design:	**91**		**90**		**54**	

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 Stand Design

The UHold design best meets the given requirements as shown by the design matrix evaluation above. The team will move forward with the UHold, but modify and test it *after* a final wheel is decided.

4.3 Proposed Final Wheel Designs

Although the focus of the design matrix is the stand, the team decided that determining a functional wheel design would be the main focus of the semester before moving forward with the stand design. No design matrix was needed for the wheel design because all designs are very similar and the differences in scores for each criteria would be negligible. Thus, to determine the final wheel design, the team moved forward with the testing of all three wheels (DYWheel, CutChimney, and CurveSpout). The results of the testing determined the final wheel, and in-turn the final stand will be created. Thus, the remainder of the paper will focus on the fabrication and testing of the wheels, and the stand will be addressed in **8.2 Future Work**.

5. Fabrication/Development Process

5.1 Materials

The proposed final design of the wheels and stand need a material that provides strength, stability, and slight flexibility. The initial prototypes of all three wheels and UHold stand designs have been 3D printed from the UW MakerSpace using Ultimaker PLA and Ultimaker PVA supports [12]. Ultimaker PLA meets the material requirements for the initial prototypes by having good flexural and impact strengths and high hardness [13]. The team has spent $65.48, and a detailed expense report can be found in **Appendix B**.

5.2 Methods

Initially, one prototype of the UHold stand and one prototype of the CutChimney were 3D printed at the MakerSpace to assess the quality of the print. The first print of the wheel was fully printed with a PLA body and PLA supports. It was unable to be tested due to the cracking of the exterior of the wheel when the supports were removed. The team shifted to printing the two designs, CutChimney and CurveSpout, with a PLA body and PVA supports; after printing the wheels, it was placed in a volume of warm water, which dissolved the PVA supports from the inner cavity of the wheel.

5.3 Final Prototypes

The team printed the CutChimney and CurveSpout wheel using the materials and methods described in sections **5.1** and **5.2** respectively. The team was already given a printed prototype of the DYWheel by the client. The UHold design was also printed, but simply for visualization purposes and future use. The three wheel designs were tested, but the stand did not undergo any testing.

5.4 Testing

The testing was based on loading and unloading times from the wheels. These timed tests allowed for quantitative analysis of the efficiency of each device, to obtain a definitive result regarding which device was the most efficient. The test administrator was required to rate how the device performed in each run. If there were complications, such as entanglements or the wire coming out of the wheel, then the device was scored according to the defined rankings in the test protocol in **Appendix C**. For this rating scale, a three on the testing scale was the best, meaning a perfect run, and a zero was the worst, showing a mistrial. The order in which the wheels and wires were used in the runs was randomized and noted during testing. The team aimed to ensure that every combination was tested equally in this regard to guarantee that there were minimal effects of learning in between trials. Random, voluntary individuals, both familiar and unfamiliar were tested to eliminate prior knowledge bias of the device. The team had 94 loading trials, and 94 unloading trials.

6. Results

6.1 Statistical Analysis

After testing of all three wheels was done, the team analyzed the data from both the loading and unloading times and the loading and unloading rating scale across all designs. It was found that the DYWheel received 17 perfect scores of 3 for loading and 20 for unloading out of 32 total trials. This was the most out of all the designs, implying the guidewire could be inserted into the wheel most easily without many complications compared to the other two wheel designs. The Cut Chimney wheel design introduced complications for loading and unloading the guidewire as it received the most 1s (the lowest rating given from test subjects) for unloading and tied with the lowest rating score of 0 with the Curve Spout design for loading. From this qualitative data, it can be concluded that the Cut Chimney design is the most inefficient for loading and unloading the guidewires while the DYWheel was the most efficient. **Figure 10** below shows the data distribution of load and unload ratings across all 3 designs.

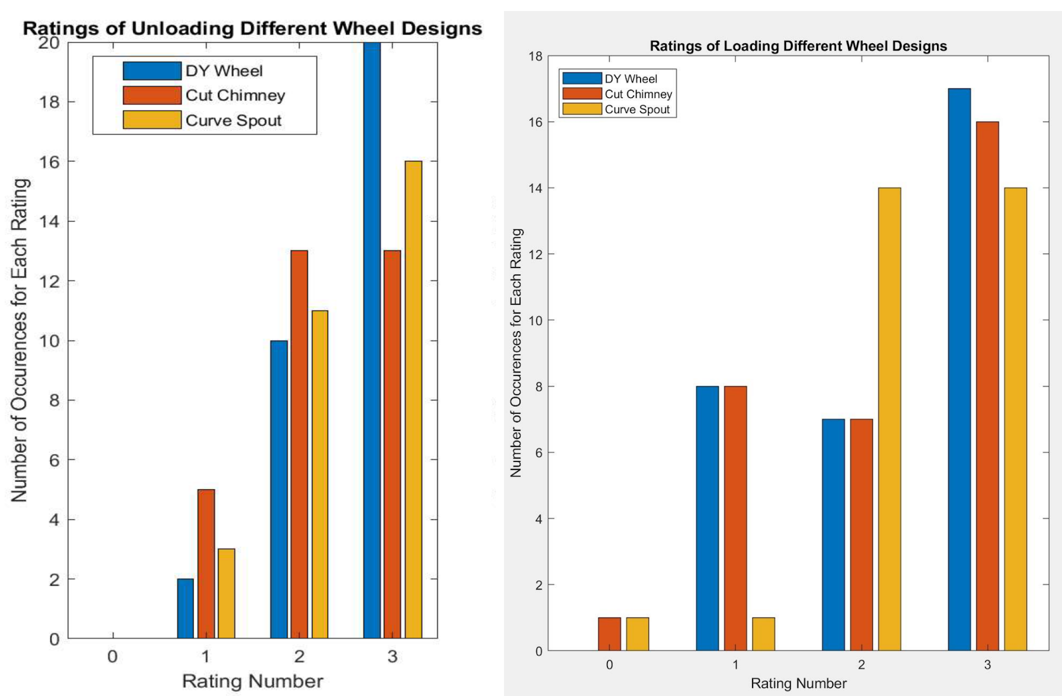


Figure 10: The unloading (left) and loading (right) rating for all designs.

The average loading time for the DYWheel was about 19.61 seconds and an unloading average time of 1.89 seconds. These were the shortest loading and unloading averages across all designs (Cut Chimney loading: 19.78 seconds, Cut Chimney unloading: 2.15 seconds; CurveSpout loading: 20.43 seconds, Curve Spout unloading: 2.51 seconds). The CurveSpout was observed to have the longest loading and unloading times. In **Figure 11** shown below, the data distribution of loading and unloading times across all 3 designs is displayed.

Following testing, a statistical analysis was performed on the data. To determine if there was a statistical difference between the data collected for all designs, an ANOVA test was run. There was no significant difference in loading ($p = 0.96$) and unloading times ($p = 0.23$). This showed that all three designs were relatively similar and functional. The full ANOVA test results can be found in **Appendix D**.

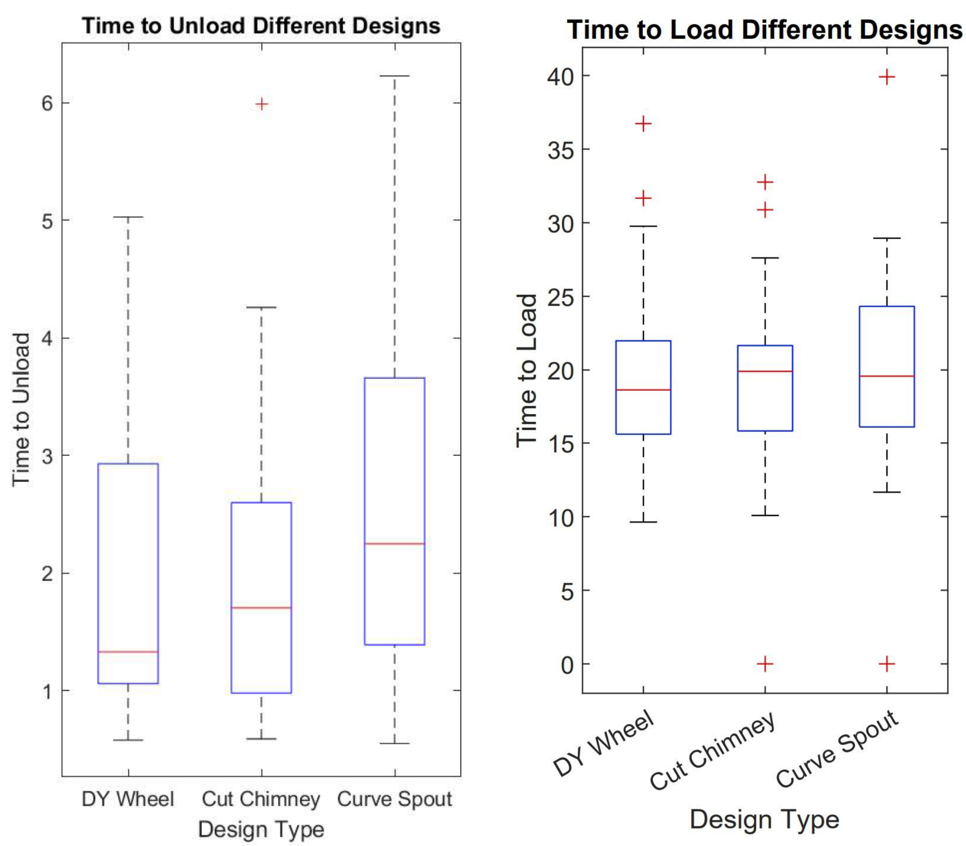


Figure 11: The unloading (left) and loading (right) times for all designs.

7. Discussion

7.1 Implications of Results

The loading and unloading times collected from testing showed that the DYWheel also had the most efficient loading and unloading times. The DYWheel also introduced the fewest complications during loading and unloading. Across all designs, it was found that as the test subjects completed more loading trials, the loading time was decreased. As displayed in **Figure 12** below, this implies that the loading of the guidewires has a small learning curve. A plateau of the curve is expected to be reached by 10 trials and have a loading time of approximately 11s. All collected data can be found in **Appendix D**.

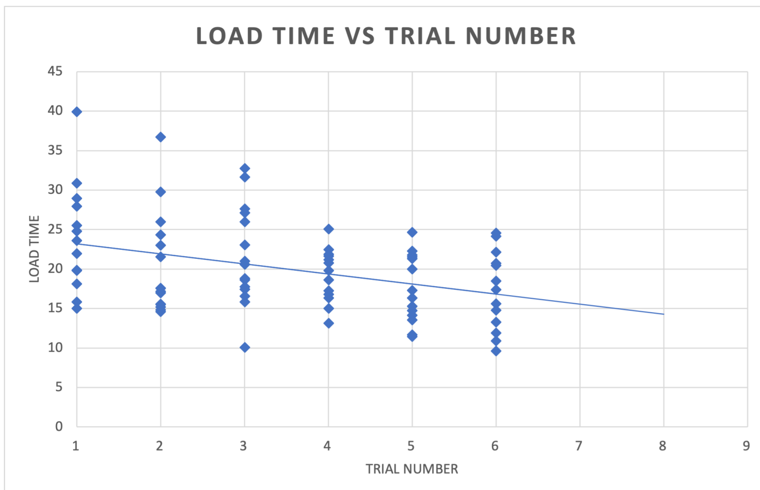


Figure 12: The learning curve distribution. As the number of trials increased, the loading time decreased.

Due to the versatile removal of CutChimney from the stand, the team wanted to move forward with it. It was deemed acceptable because its loading and unloading times were not different enough from the DYWheel to be statistically significant. Furthermore, the CutChimney had a loading time only 0.17s longer than the DYWheel, which was determined to not be of clinical significance between the two.

7.2 Sources of Error During Testing

There are multiple potential sources of error that could have occurred during testing. The main source of error is the timing system of the testing. The team used an iPhone stopwatch to record the time for loading and unloading trials. This is due to human error, as there is no precise technique to record time. Another source of error was the uniformity of teaching the test subjects how to load and unload the guidewires into the wheels. If the procedure was understood differently by each subject, they easily could have made mistakes during testing, which could have increased loading and unloading times or biased the ratings. Lastly, the guidewires could have been a potential source of error during testing. The guidewires are easily deformable, sometimes making loading and unloading more difficult. As more trials were carried out across test subjects with each design, the wheels could have been bent or changed shape near the end of testing, making it more challenging for the final test subjects. This could have increased loading and unloading times as well as skewed the subjects perception of difficulty or ease for loading and unloading the wires and changing the ranking results across the designs.

7.3 Ethical Considerations

When testing and implementing new devices into the medical field there are seven main principles of clinical research [14]. 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.

8. Conclusion

8.1 Summary of Design

The design consists of the stand and the wheels. The UHold stand will be moving forward in the next stages of the prototyping process. This stand design will be altered from the current dimensions to decrease the bulkiness and increase dimensional accuracy. The alterations of the design will be further discussed in **Section 8.2**.

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 two designs: the DYWheel and the CutChimney design. The CutChimney is different from the DYWheel because it has a semicircular chimney, rather than a circular chimney. This allows for the wheel to be removed from the stand at any place after the guidewire is removed from the wheel.

8.2 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. The stand will be multi-use and autoclavable, with the material determination coming in the future. This wheel will be made of a disposable material. 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 [15]. The material used in the injection molding will be a nylon or polyester. This is because these materials are 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.

After finalizing the wheel portion, the team will redesign the stand; the stand is currently too bulky, which is not ideal for the operating room environment and is expensive. The inner chimney of the stand will therefore be made hollow and increased in diameter to better secure the wheels on the stand. The back board and base of the stand will be less bulky by decreasing the thickness of the material. To offset the decrease in weight of the stand, the team will investigate possible ways to secure the stand to the table. Once both the wheel and stand designs are finalized, the team will continue testing the device with the grade scale and timing, but 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.

8. References

[1] Strate, C., 2020. The Cost Of A Lost Minute In The OR. [online] Accessefm.com. Available: <https://www.accessefm.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] "Cathclip Value Analysis Information," *CathClip*. [Online]. Available: https://www.cathclip.com/value-analysis-information.html. [Accessed: 28-Feb-2022].

[5] "EP1145730A1 - Medical Guidewire Storage Method and apparatus," *Google Patents*. [Online]. Available: https://patents.google.com/patent/EP1145730A1/en. [Accessed: 22-Feb-2022].

[6] "Vascular and endovascular procedures," *Vascular and Endovascular Procedures - Brigham and Women's Hospital*. [Online]. Available: https://www.brighamandwomens.org/surgery/vascular-and-endovascular-surgery/procedures. [Accessed: 28-Feb-2022].

[7] Yamanouchi, Dai, MD, Phd. "Client Meeting," Conference. [Accessed: 17-Sept-2021].

[8] "Endovascular procedure basics." [Online]. Available: https://www.researchgate.net/figure/Endovascular-procedure-basics-a-Insert-guidewire-into-femoral-artery-navigate-to_fig1_301719931. [Accessed: 02-Mar-2022].

[9] "3D printers," *UW Makerspace*. [Online]. Available: https://making.engr.wisc.edu/3d-printers-2/. [Accessed: 28-Feb-2022].

[10] Yamanouchi, Dai, MD, Phd. "Client Meeting," Conference. [Accessed: 17-Sept-2021].

[11] Dr. D. Yamanouchi, "Client Meeting One - 301," 9-Feb-2022.

[12] "3D Printers," *UW Makerspace*. https://making.engr.wisc.edu/3d-printers/ (accessed Feb. 28, 2022).

[13] “Ultimaker PLA material: Highly versatile, easy to print,” *ultimaker.com*.

[14] “Ethics in Clinical Research | Clinical Center Home Page.” https://clinicalcenter.nih.gov/recruit/ethics.html (accessed Oct. 19, 2021). https://ultimaker.com/materials/pla (accessed Feb. 28, 2022).

[15] “Definitions, meanings, & Spanish translations,” *Lexico Dictionaries | English*. [Online]. Available: https://www.lexico.com/. [Accessed: 02-May-2022].

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].

References:

[1] Dr. D. Yamanouchi, “Client Meeting One - 301,” 9-Feb-2022.

[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] “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].

[4] Weigel, B., 2020. Controlling Operating Room Temperature And Humidity, And Managing Expectations. [online] 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].

[5] U. W. Makerspace, “3D printer cost calculator,” *UW Makerspace*. [Online]. Available: https://making.engr.wisc.edu/3d-printers/3dprint-cost/. [Accessed: 24-Sep-2021].

[6]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].

[7] “Product classification,” *accessdata.fda.gov*. [Online]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?id=997. [Accessed: 23-Sep-2021].

[8] “Product classification,” *accessdata.fda.gov*. [Online]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?id=953. [Accessed: 23-Sep-2021].

[9] 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].

[10] 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.

[11] “Interventional Accessories: US.” *Teleflex*, Apr. 2018, teleflex.com/usa/en/product-areas/interventional/coronary-interventions/interventional-accessories/index.html.

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	$11.28	$11.28	See above
Component 4								
ShortSpout		UW MakerSpace	N/A	2/23/22	1	$3.36	$3.36	See above
Component 5								
CutChimney	Modification of current design	UW MakerSpace	N/A	3/29/22	1	$15.24	$15.24	See above
Component 6								
CurveSpout	Modification of current design	UW MakerSpace	N/A	4/6/22	1	$7.60	$7.60	See above
TOTAL:	**$65.48**							

Table 1: Expenses Table

Appendix C: Testing Protocol

Guidewire Holder Test Method
(UPDATED 31 MAR 2022)

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 UWHEEL 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 with out 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

Appendix D: ANOVA Results

ANOVA Table

Source	SS	df	MS	F	Prob>F
Columns	3.8	2	1.9016	0.05	0.9551
Error	3602.22	87	41.4049		
Total	3606.03	89			

Figure 1: ANOVA results table from loading times

ANOVA Table

Source	SS	df	MS	F	Prob>F
Columns	5.937	2	2.96872	1.48	0.2332
Error	174.452	87	2.00519		
Total	180.389	89			

Figure 2: ANOVA results table from unloading times

Appendix E: Raw Collected Data

1		Guidwire number:	Trial Number:	Loading Time:	Loading Grade (0-3):	Unloading time (not on stand):	Unloading Grade (0-3)	Design Number:	Guidwire numbe	Trial Number:	Loading Time:	Loading Grade (	Unloading time (	Unloading Grade (0-3)
2	0- DYWheel	0-Stiff	5	15.3	3	5.03	3	0- DYWheel	1-Soft	6	24.13	1	4.18	2
3	0- DYWheel	0-Stiff	4	21.88	3	1.79	3	0- DYWheel	1-Soft	2	36.73	1	3.05	2
4	0- DYWheel	0-Stiff	3	31.67	1	3.56	3	0- DYWheel	1-Soft	1	25.53	3	4.37	2
5	0- DYWheel	0-Stiff	1	19.84	3	0.92	3	0- DYWheel	1-Soft	3	17.41	2	1.16	3
6	0- DYWheel	0-Stiff	3	26	3	0.79	3	0- DYWheel	1-Soft	2	29.76	2	1.22	3
7	0- DYWheel	0-Stiff	2	17.55	3	1.64	3	0- DYWheel	1-Soft	3	18.81	2	1.13	2
8	0- DYWheel	0-Stiff	4	13.13	3	1.58	2	0- DYWheel	1-Soft	1	18.1	1	1.12	3
9	0- DYWheel	0-Stiff	1	21.98	2	2	3	0- DYWheel	1-Soft	4	19.8	2	1.99	3
10	0- DYWheel	0-Stiff	6	10.9	3	1.06	3	0- DYWheel	1-Soft	5	14.13	3	0.58	3
11	0- DYWheel	0-Stiff	6	18.48	3	1.32	3	0- DYWheel	1-Soft	5	21.33	3	1.34	3
12	0- DYWheel	0-Stiff	6	9.63	3	1.25	3	0- DYWheel	1-Soft	5	11.46	3	0.81	3
13	0- DYWheel	0-Stiff	1	15.83	3	2.93	3	0- DYWheel	1-Soft	6	20.73	1	0.91	2
14	0- DYWheel	0-Stiff	5	17.31	1	1.18	1	0- DYWheel	1-Soft	6	14.77	1	1.82	2
15	0- DYWheel	0-Stiff	4	17.23	3	0.69	3	0- DYWheel	1-Soft	3	27.12	3	0.73	3
16	0- DYWheel	0-Stiff	6	15.6	3	2.95	2	0- DYWheel	1-Soft	5	19.3	2	4.99	2
17	0- DYWheel	0-Stiff	3	18.63	2	1.23	1	0- DYWheel	1-Soft	4	17.41	1	1.13	2
18	0- DYWheel	0-Stiff						0- DYWheel	1-Soft					
19	0- DYWheel	0-Stiff						0- DYWheel	1-Soft					
20	Design Number:	Guidwire number:	Trial Number:	Loading Time:	Loading Grade (0-3):	Unloading time (not on stand):	Unloading Grade (0-3)	Design Number:	Guidwire numbe	Trial Number:	Loading Time:	Loading Grade (	Unloading time (	Unloading Grade (0-3)
21	1- CutChimney	0-Stiff	4	22.46	3	3.41	2	1- CutChimney	1-Soft	3	32.76	2	3.95	2
22	1- CutChimney	0-Stiff	1	23.59	3	3.26	3	1- CutChimney	1-Soft	3	27.61	2	3.77	2
23	1- CutChimney	0-Stiff	2	21.54	3	1.73	3	1- CutChimney	1-Soft	4	Mistrial	0	2.46	2
24	1- CutChimney	0-Stiff	2	15.52	3	2.49	3	1- CutChimney	1-Soft	4	14.99	2	0.96	3
25	1- CutChimney	0-Stiff	4	20.76	3	0.8	3	1- CutChimney	1-Soft	1	30.88	3	1.58	2
26	1- CutChimney	0-Stiff	1	19.8	3	3.53	3	1- CutChimney	1-Soft	4	25.06	1	1.2	2
27	1- CutChimney	0-Stiff	3	10.08	3	0.9	3	1- CutChimney	1-Soft	2	15.54	3	0.89	3
28	1- CutChimney	0-Stiff	2	16.99	3	1.5	2	1- CutChimney	1-Soft	3	20.58	1	2.33	1
29	1- CutChimney	0-Stiff	3	23.06	1	0.83	3	1- CutChimney	1-Soft	4	21.66	2	0.88	3
30	1- CutChimney	0-Stiff	3	16.55	3	1.68	3	1- CutChimney	1-Soft	3	20.99	1	1.22	3
31	1- CutChimney	0-Stiff	4	16.35	2	1.09	2	1- CutChimney	1-Soft	4	21.19	2	2.6	1
32	1- CutChimney	0-Stiff	2	15.18	1	2.14	2	1- CutChimney	1-Soft	5	20.01	2	2.6	2
33	1- CutChimney	0-Stiff	4	16.79	1	1.23	1	1- CutChimney	1-Soft	3	18.65	1	2.12	1
34	1- CutChimney	0-Stiff	5	14.73	3	0.98	3	1- CutChimney	1-Soft	6	20.49	1	0.59	2
35	1- CutChimney	0-Stiff	3	15.82	3	4.26	2	1- CutChimney	1-Soft	4	19.29	3	5.99	1
36	1- CutChimney	0-Stiff	2	14.81	3	1.93	2	1- CutChimney	1-Soft	1	19.35	3	3.93	2
37	1- CutChimney	0-Stiff						1- CutChimney	1-Soft					
38	1- CutChimney	0-Stiff						1- CutChimney	1-Soft					
39	Design Number:	Guidwire number:	Trial Number:	Loading Time:	Loading Grade (0-3):	Unloading time (not on stand):	Unloading Grade (0-3)	Design Number:	Guidwire numbe	Trial Number:	Loading Time:	Loading Grade (	Unloading time (	Unloading Grade (0-3)
40	2- CurveSpout	0-Stiff	1	24.8	2	6.13	1	2- CurveSpout	1-Soft	2	25.99	2	6.23	2
41	2- CurveSpout	0-Stiff	5	24.67	3	1.4	3	2- CurveSpout	1-Soft	6	24.55	2	1.71	2
42	2- CurveSpout	0-Stiff	5	22.29	2	2.66	2	2- CurveSpout	1-Soft	6	MISTRIAL	0	1.5	1
43	2- CurveSpout	0-Stiff	6	17.39	3	1.16	2	2- CurveSpout	1-Soft	5	21.56	2	0.67	3
44	2- CurveSpout	0-Stiff	6	20.45	3	0.81	2	2- CurveSpout	1-Soft	5	21.78	3	1.65	3
45	2- CurveSpout	0-Stiff	5	11.66	2	3.03	3	2- CurveSpout	1-Soft	6	11.88	3	2.6	3
46	2- CurveSpout	0-Stiff	5	13.56	2	2.49	3	2- CurveSpout	1-Soft	6	13.28	1	1.05	2
47	2- CurveSpout	0-Stiff	6	22.12	2	4.19	2	2- CurveSpout	1-Soft	5	16.32	2	5.37	1
48	2- CurveSpout	0-Stiff	2	17.16	3	0.55	3	2- CurveSpout	1-Soft	1	39.91	2	1.39	3
49	2- CurveSpout	0-Stiff	2	14.6	3	3.66	3	2- CurveSpout	1-Soft	1	28.95	3	1.39	3
50	2- CurveSpout	0-Stiff	2	17.56	3	0.78	3	2- CurveSpout	1-Soft	1	15.03	3	3.19	2
51	2- CurveSpout	0-Stiff	3	17.73	2	3.98	2	2- CurveSpout	1-Soft	4	18.62	3	1.12	3
52	2- CurveSpout	0-Stiff	1	20.6	3	2.38	3	2- CurveSpout	1-Soft	2	24.32	2	2.45	2
53	2- CurveSpout	0-Stiff	1	18.71	3	1.06	3	2- CurveSpout	1-Soft	2	22.99	2	1.99	3
54	2- CurveSpout	0-Stiff	2	16.09	3	3.93	3	2- CurveSpout	1-Soft	1	27.93	2	4.8	2
55	2- CurveSpout	0-Stiff						2- CurveSpout	1-Soft					
56	2- CurveSpout	0-Stiff						2- CurveSpout	1-Soft					
57	2- CurveSpout	0-Stiff						2- CurveSpout	1-Soft					

Table 2. Raw data.