

REVIEW article

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Guidewire Organizer for Endovascular Procedures

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Abstract

Endovascular procedures require multiple guidewires (GWs) of varying diameters, lengths and stiffnesses depending on the blood vessel they are inserted into. Currently, when GWs are inserted into the body, there is no dispensing mechanism and the full length of the GW is exposed. Additionally, when the GWs are removed from the body, they are often stored under a wet towel for possible later use. However, due to the GWs spring-like nature, they are easily tangled and deformed; which in turn, can increase the time spent in the operating room, as well as divert the attention of the medical professionals from performing necessary tasks. Also, storing the GW underneath a wet towel poses a risk for contamination as the lint from the towel may enter the patient's body. The aim of this study is to develop a device to optimize the organization and storage of GWs of varying lengths, diameters and stiffnesses in a sterile, isolated environment. Overall, this device aims to decrease the time it takes for surgeons to organize the wires, increase procedure efficiency, and increase patient safety. The device consists of two injection moldable parts, (1) a GW wheel that securely holds a GW in place and (2) a stand that holds three separate wheels. The device was tested to ensure all design requirements were met. It was concluded the device was compatible with GWs of varying diameters, lengths and stiffnesses and was more efficient in preventing entanglements during loading, storage, and dispensing GWs compared to competing designs. Therefore, the current design was proven to optimize the storage and organization of GWs.

**The format for this journal was based on "Steerable Guidewire for Magnetic Resonance Guided Endovascular Interventions" from the Journal of Medical Devices [11].*

A. Introduction

A.i. Guidewires in Endovascular Procedures

An endovascular procedure is a minimally invasive technique used to diagnose and treat vascular diseases. Unlike traditional surgery, catheter-based intervention is becoming increasingly popular due to advancements in medical technology, and is capable of reaching a larger group of patients. This is especially important for patients who are not suitable candidates for open surgery, such as the growing elderly population. By the year 2030, statistics show that approximately 1 in 6 people around the globe will be over the age of 60 [1], further highlighting the necessity for minimally invasive procedures. These technologies rely on guidewires (GWs) and catheters to travel the vascular system and access the desired position. The use of GWs spans a variety of different surgical sectors including, but not limited to: angioplasty, stenting, pacemaker insertion, electrophysiology studies, atherectomy, thrombolysis, and endourology and therapeutic endoscopy of the gastrointestinal system [1].

In a single endovascular procedure, up to four GWs can be used [2]. Each of these GWs can vary, as they have different purposes in the procedure. For example, during a coronary angioplasty, a flexible GW is used in angled vessels whereas a high support GW is used to provide more support in cases of tortuous anatomy and distal lesions [3]. A GW is inserted into the patient and then directed to the area of interest. From there, the catheter is fed along the GW to the correct area. Once the catheter is in the correct position, the GW is removed. To use GWs more than once during a procedure, GWs must remain uncontaminated and within the sterile field if intended for later use. Since each minute in an operating room (OR) costs an average of \$60 [1], GWs management becomes a critical concern. Currently, most doctors store used GWs under a wet towel (Figure 1). However, these towels shed fibers onto the wire and those fibers have the potential to be displaced into the body, putting the patient at risk for lint contamination complications. Lint contamination can cause serious harm to the patient, and lead to complications including: thrombogenesis, infections, amplified inflammation, poor wound healing, granulomas, adhesions and capsule formation [4].



Figure 1: Wet Towel competing design.

Additionally, the excessive length of GWs also poses an issue. There is no form of dispensing mechanism for the GW, thus as it is inserted into the body, the remainder of the GW is fully exposed and poses the risk of entanglement. In a study about endovascular procedure complications, it was found that 13.3% of procedure errors were due to device failure, which could be attributed to GW knotting or tangling [5]. As for commercial GW storage devices, there is the Cath Clip (Figure 2) where GWs are clipped individually then stored *together* in a single bowl of saline. Another commercial device is the Medline Guidewire Bowl, which is a bowl with tabs to hold multiple GWs *together* (Figure 2). Both the Cath Clip and Medline Bowl do not optimize GW storage because GWs do not stay separated and there is no dispensing mechanism, so the full length of the GW is released all at once. The lack of a true storage and dispensing option for GWs causes entanglement and sterilization concerns, requiring a new GW to be used, raising procedure costs and time spent in the OR.

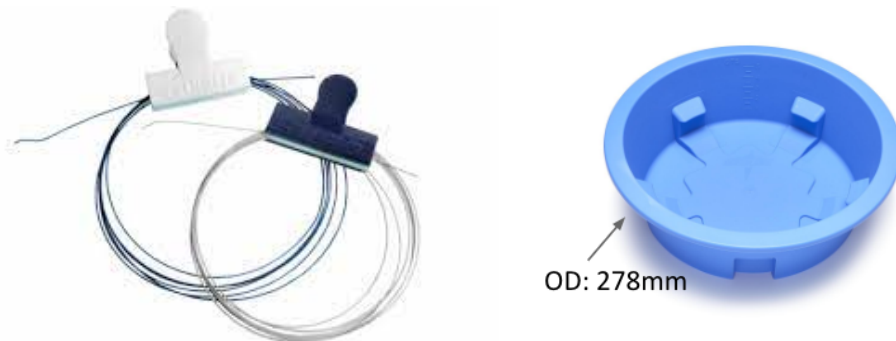


Figure 2: Cath Clip (left) and Medline Bowl (right)

To better understand the opinions and experiences of medical residents regarding GW storage devices, a survey questionnaire was developed. The survey inquired about the previously mentioned GW storage devices like the wet towel method, the CathClip, and the Medline Bowl. These questions assessed each device's ability to prevent disorganization of GWs in the OR, risk of contamination, and cost effectiveness. The full preliminary survey and device comparison can be found in **Appendix D.3**. From the preliminary survey given to medical residents, 75% of the participants claimed the wet towel method caused disorganization in the OR about half the time. 75% of residents also said they would prefer a new GW organizer and dispensing device. These results indicate there is a demand for a device that will allow for better organization of GWs and function as a dispensing mechanism, overall decreasing the time spent to manage GWs and reducing contamination risk. All survey results can be found in **Appendix D.4**.

To address the need for an adequate storage and dispensing mechanism for GWs, the team developed the GWDisc (Figure 3): a *single-use* system that stores GWs *separately* and *dispenses* GWs. The device consists of two components: (1) a wheel to hold a single GW and (2) a stand to hold up to three wheels. To use the device, a GW is wound into a circle by the user, then placed in the cavity of the wheel. The GW can be dispensed from the wheel while on the stand or with the wheel in hand by pulling at the exposed GW tip. GWDisc aims to increase procedure efficiency by having an organized system that alleviates the potential risks current storage techniques pose. The wheel and stand are a safe and efficient storage and

dispensing solution for the fast-paced environment of endovascular procedures, and commercialization of the device will advance the way healthcare professionals operate in endovascular procedures.

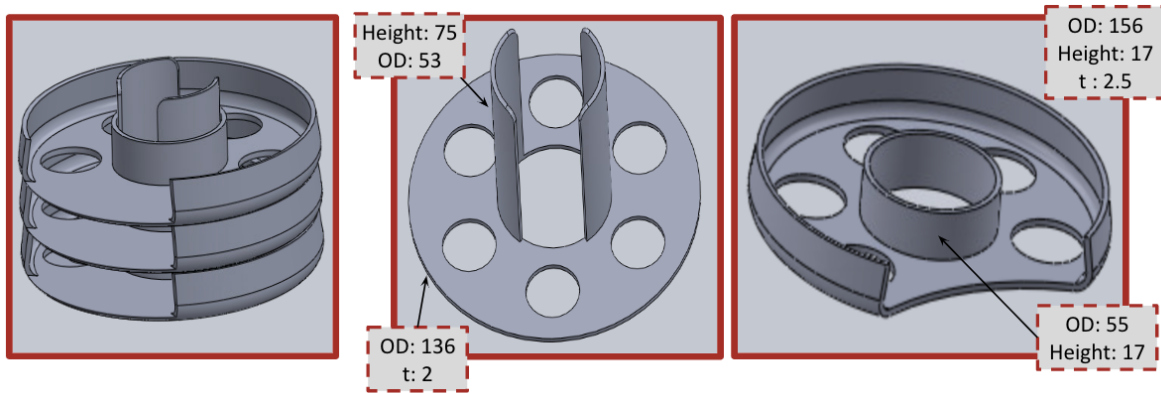


Figure 3: (left to right). Wheel Assembly, Isometric Views of Stand, GWDisc. Measurements in mm ('thickness' denoted by 't').

B. Design requirements

The device consisted of two components illustrated in Figure 4: (1) a wheel to store a GW (GWDisc) and (2) a stand to hold up to three wheels. This prototype had to satisfy multiple design requirements that are indicated below in Figure 4.

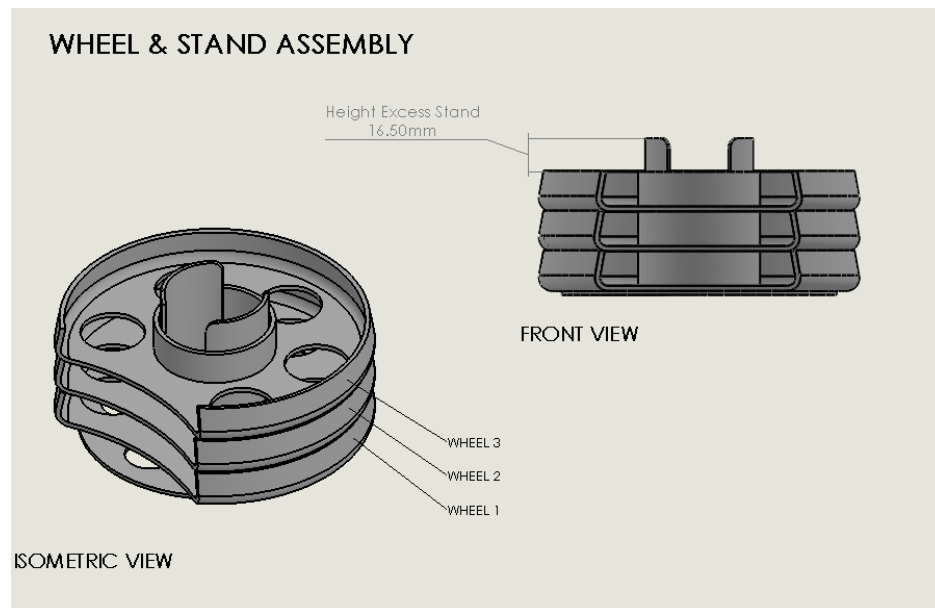


Figure 4: Stand and Wheel Assembly.

Compatibility With GWs. The device needed to be compatible with GWs with diameter sizes of 0.014 to 0.038 inches and varying stiffnesses. It was essential the GWs stay organized and unknotted when removed from the wheel while on the stand.

Req 1.1: The device must dispense the GW without tangling

Req 1.2: The device must load and store the GW without tangling

Wheel. The wheel was designed to be easily gripped by the operator (most likely a surgeon) to ensure maximum control, minimizing excessive movement. The wheel must also be able to function independently from the stand (while dispensing). A surgeon's hand needed to be able to easily slide into the wheel to load the GW. The average male surgeon's hand circumference is 213.5 mm (68 mm width) and female is 189.5 (60 mm width) [6]. The wheel needed to maximize storage and organization efficiency compared to current designs.

Req 2.1: the diameter of the wheel must be 140.0-160.0 mm with a loading opening larger than 68.0 mm to be suitable for various hand sizes

Req 2.2: the wheel must be intuitive and comfortable for use

Req 2.3: the wheel must efficiently load GWs when compared to competing designs

Req 2.4 The wheel must efficiently dispense GWs

Stand. A stand was needed to store the wheels in the operating room. The stand was designed to be compatible with the size of the GW wheels, stack up to three wheels, and allow the GW to be unloaded while the wheel is on the stand. The stand allowed for easy access to the GW at any point during a procedure. The stand device was non-slip on operating room surfaces.

Req 3.1: the height of the stand has to allow for up to three wheels to be placed on top of each other

Req 3.2: the stand allows for dispensing of GWs from any wheel while the wheel remains on the stand

Req 3.3: the stand has to be self-explanatory and comfortable to use

Biocompatibility. The materials used for manufacturing the wheel and stand were biocompatible to limit complications while in use.

Req 4.1: materials used for injection molding of wheel and stand are biocompatible and compliant with operating room standards

C. Methods

C.i. Design

The GWDisc and Stand designs were prototyped in SolidWorks, the iterations made throughout the design process are outlined in **Appendix B**.

Wheel Design. The important components of the wheel (GWDisc) included the following features: the wheel outer diameter, the loading opening, a chimney, the draft angle, and bottom faced holes (Figure. 5). The GWDisc is circular in shape with an outer diameter of 156 mm. The outer diameter had an inward radial force that kept the GW within the cavity. In order to load and dispense the GW, there was a 100 mm opening at one end of the wheel. The chimney in the middle of the wheel had an outer diameter of 55 mm. The chimney acted as a spool and prevented the GW from popping out. The draft angle was 1°, which is the angle measurement between the bottom surface and the walls of the wheel. In order for the wheel design to be

manufactured through injection molding for mass production, the draft angle must be greater than 1°. The holes on the bottom face of the wheel allowed saline to flow through the wheel for sterilization of the GWs during use. These holes were 32 mm in diameter.

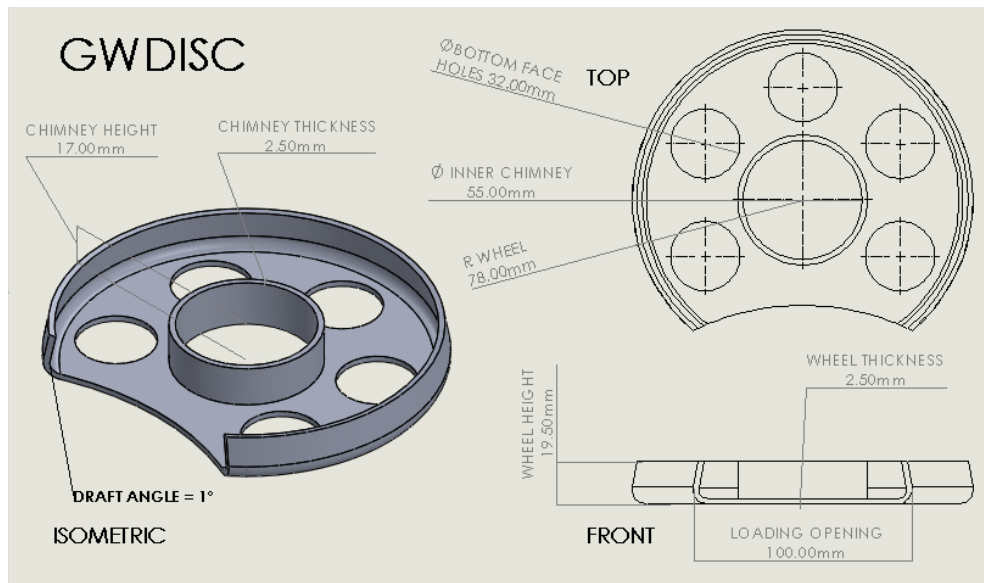


Figure 5. Annotated dimensions of the isometric, front and top view of the GWDisc design.

Stand Design. The stand featured a base plate with similar bottom facing holes that allowed for easy flow of saline around the GW (Figure. 6). The baseplate was 135 mm in diameter. There was also a long chimney, 75 mm in height, in the center of the base plate which allowed three wheels to be stacked at one time. The diameter of the chimney was 55 mm, matching the inner diameter of the wheel design. The hollow chimney allowed for minimal material to be used, minimizing manufacturing costs.

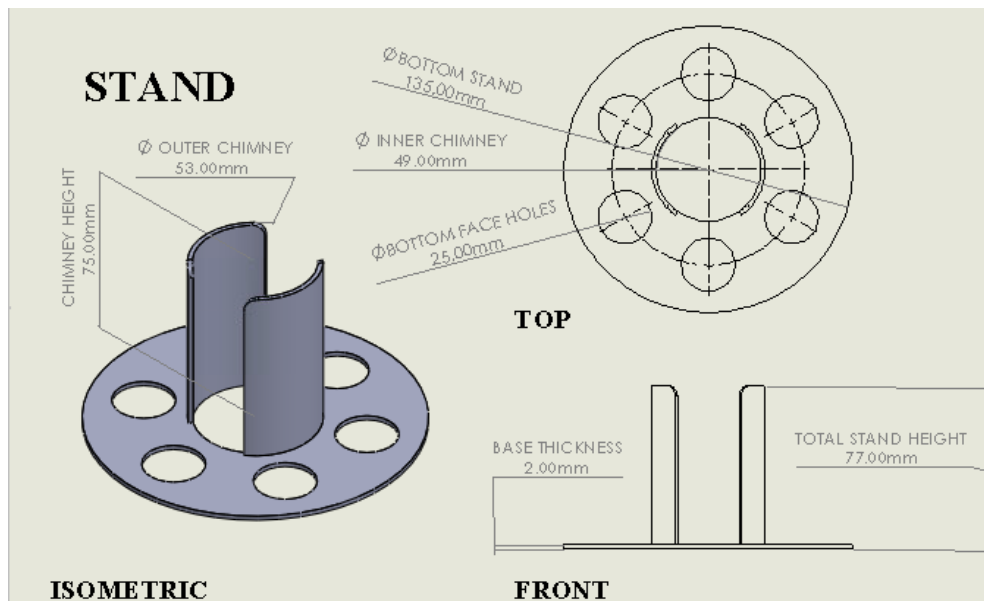


Figure 6. Annotated dimensions of the isometric, front and top view of the stand design.

Stand and Wheel Assembly. When the stand and wheel are assembled, the stand holds up to three separate wheels (Figure 1). There is 16.5 mm of excess space left between the last wheel and the top of the stand to ensure the wheels did not fall off.

C.ii. Manufacturing

The final wheel and stand prototypes were 3D-printed with the Ultimaker S5 printer at the MakerSpace. PLA was chosen as 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. PVA was used for the inner support material as it is able to be dissolved in a warm water bath.

The ultimate goal is for the final market device to be fabricated with a biocompatible thermoplastic material through injection molding. The injection molding process works by loading thermoplastic, thermosets, or elastomer pellets into the cylindrical cavity of the machine where the material is heated and pressurized to a molten state. Once the material is liquified, it is forced through a channel in the mold, cooled to solidify, and ejected within minutes. Most molds used for injection molding consist of two pieces, the core and the cavity [9]. The geometry of the core creates the interior form of the part and contains the ejection mechanism to push out the completed piece [9]. The cavity is the void inside the mold that the plastic fills and it typically forms the exterior side of the part [9].

Wheel Manufacturing. Due to the complex geometry and essential functionality of the overhang, the wheel design will be fabricated with a higher-cost tooling mold with collapsible core technology. A manufacturing analysis provided by ProtoLabs, illustrated in Figure 7, highlights the problematic overhang feature in red. The overhang is unable to be manufactured with the standard, low-cost tooling mold. As the overhang functions to keep the guidewire within the wheel, the walls of the wheel are angled inwards which makes the diameter of the inner cavity larger than the top dimension of the wheel. As standard injection molding only uses two pieces, the device is unable to be ejected from the mold without cracking. In previous semesters, prototyping and testing was conducted to optimize the overhang geometry of the wheel design. However, the design changes proved to drastically decrease the overall functionality of the device. For this reason, the final market device, GWDisc will be injection molded with a collapsible core tooling mold. A collapsible core mold is engineered to match the largest diameter of the mold when being filled. Then when the part is solidified and ready to be ejected, the core collapses radially inward to match the smallest diameter. Collapsible cores eliminate secondary manufacturing operations while providing dramatic cycle-time reductions [10].

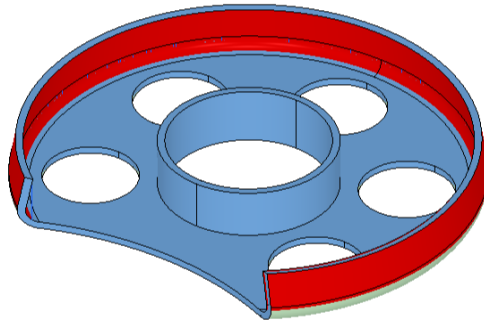


Figure 7. Protolabs injection molding analysis of GWDisc. Area in red is the overhang that is problematic for standard, low-cost injection molding.

Stand Manufacturing. As the stand design does not have any complex features or overhangs, it will be fabricated using the standard injection molding tooling mold and process. A manufacturing analysis provided by ProtoLabs, illustrated in Figure 8, highlighted a simple modification to be made before the tooling mold can be created. The stand design features in red needs to be adjusted to have a 1° draft angle.

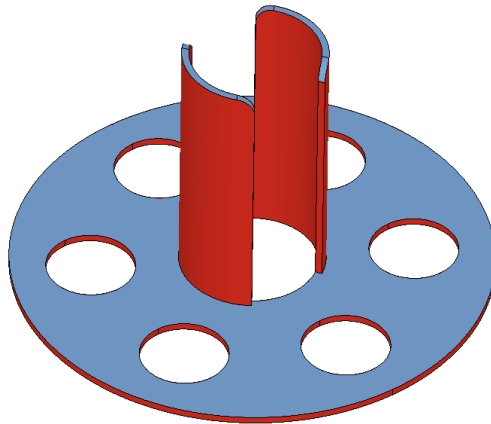


Figure 8. Protolabs injection molding analysis of stand. Areas in red need a simple draft added to be fully injection moldable.

C.iii. Testing

To compare the organization efficiency and trial success of the GWDisc to competing designs on the market such as the wet towel method, the Cath Clip, and the Medline Bowl, the team completed GW loading testing of all four devices. Each device was tested under the same protocols, which can be found in **Appendix A**.

Loading and Dispensing the GWs. Loading and dispensing GWs into the GWDisc was completed to test the wheel's function independently from the stand. The wheel was held by the user in one hand while the other hand was used to hold and load/dispense the GW. The diameter of the wheel was 156 mm, and the loading opening was 100 mm (Req. 2.1) [3]. This provided the most feasible design that maximized comfort and efficiency. The time taken to load and dispense the GWs into and out of the wheel was measured during each of the three testing trials as modeled in **Appendix A.1.1 and A.2.1**. Competing designs were also tested under similar protocols based on each device's unique loading technique to determine if the wheel was efficient (faster and/or equal times) compared to other designs (Req. 2.3).

As part of ongoing testing to evaluate GW dispensability while the wheel is on the stand, the user will remove the GWs from the wheels while they are on the stand. Because the height of each wheel was 19.5 mm, and the chimney of the stand was 75 mm tall, the stand can hold up to three wheels at a time (Req. 3.1). The users will complete three tests, one with the top wheel, one with the middle wheel, and one with the bottom wheel as modeled in **Appendix A.3.1** (Req. 3.2). These tests will be timed during each test.

The competing designs do not have dispensing mechanisms, so recording the time to remove the GWs from the devices were not tested.

Grading and Comfortability of the Trial. The device was designed to function with GWs of varying stiffnesses, lengths and diameters to prevent entanglement during loading, dispensing and storing of GWs. Due to the limited availability of having access to GWs of varying properties, a GW with a diameter of 0.018in was used for all testing. As the GWs were loaded into the wheel independent of the stand, the wheel comfort was evaluated based on a user-to-user basis. The user was asked to complete a verbal evaluation of the wheel comfort for loading and dispensing (Req. 2.2). The user comfort ratings were based on a scale of 1-3 defined in **Appendix A.1.3 and A.2.3**. Each user was asked to rate the wheel after each run in order to determine the average user comfort level. As the GWs were loaded into the wheel, the test administrator was required to rate how the loading trial went (Req 1.2). These ratings allowed for a qualitative analysis of the device to be run to conclude it was compatible with GWs during testing and that the device has high organization efficiency. The ratings for each test were defined in the test protocols in **Appendix A.1.2 and A.3.2**. The test administrator will also be required to rate the dispensing trial (Req 1.1).

As part of ongoing testing of the stand device, the user will be asked to complete a verbal evaluation of the stand comfort for dispensing (Req. 3.3). The user comfort ratings are based on a scale of 1-3 defined in **Appendix A.3.3**. Each user will be asked to rate each trial in order to determine the average user comfort level while the wheel was on the stand.

The order in which the devices were tested for each user was randomized and noted during testing to ensure that every device was tested equally and to guarantee that there were minimal effects of learning in between trials. Competing designs were also tested under the same protocols to determine if the wheel had similar trial success and comfortability compared to other designs (Req. 2.3).

Results

Compatibility with GWs. After testing the GWDisc and the other competing designs, it was observed that the Cath Clip received the highest quantity of 3 graded loadings, meaning the loading trial was successful without any GW complications or awkwardness. The grade ratings for loading the GW into each device is shown below in Figure 9. All rating data for loading trials for the GWDisc can be found in **Appendix A.1.4**. All rating data for loading trials for competing designs can be found in **Appendix A.4.1**.

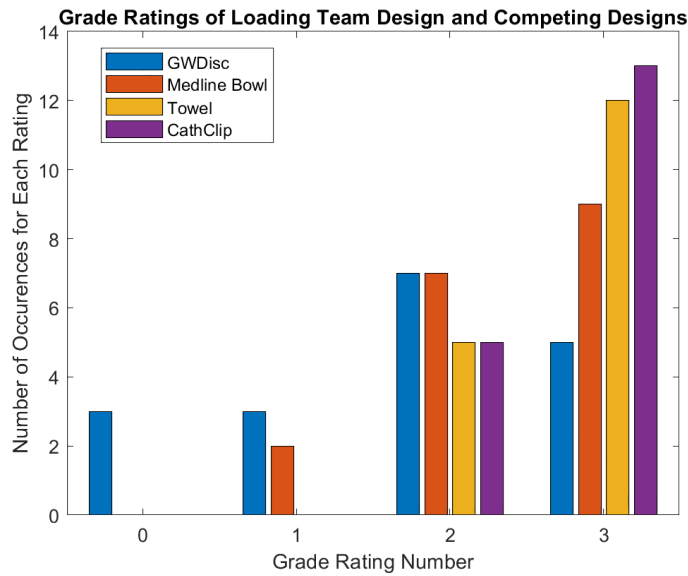


Figure 9. Data distribution of loading times comparing all devices.

Wheel. Based on the loading data for all the devices, it was found that the wet towel method had the fastest average loading time (8.61s +/- 5.51s) while the GWDisc had the slowest loading time (13.37s +/- 3.53s). The averages and standard deviations for loading the GW into each device is shown below in Figure 10. All loading time data for the GWDisc can be found in **Appendix A.1.4**. All loading time data for competing devices can be found in **Appendix A.4.1**.

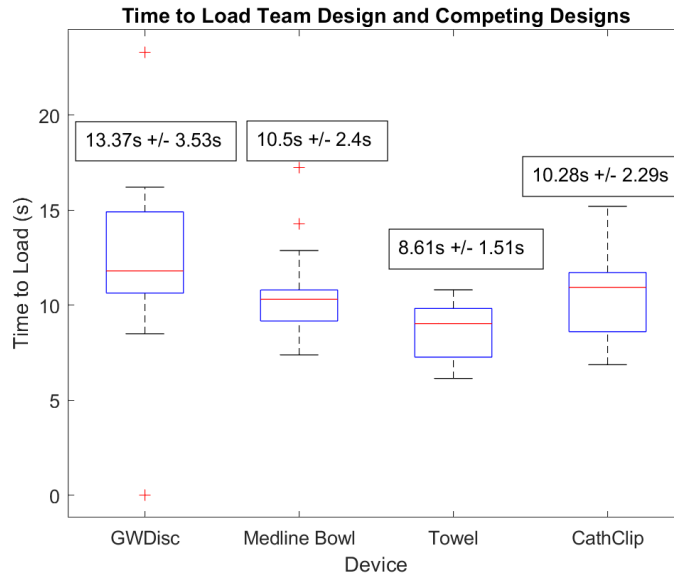


Figure 10. Data distribution of load ratings comparing the GWDisc to competing designs.

Stand. Stand testing is ongoing using the protocols previously described in the methods section to determine if dispensing the GWs from the wheel while on the stand decreases disorganization and contamination risk.

Biocompatibility. The wheel or stand device does not interact directly with the body, however, the wheel makes direct contact with the GW that is inserted into the patient's body. In terms of biocompatibility (Req. 4.1), polypropylene will be used as the final material for the wheel and stand since it is biologically inert.

Discussion

To address the market needs, the team developed the GWDisc system to efficiently store and dispense GWs. The device consists of two components: (1) a wheel to hold a single GW and (2) a stand to hold up to three wheels. To use the device, a wound up GW is placed in the cavity of the wheel, and up to three wheels are placed on the stand. The GW can be dispensed from the wheel while on the stand or with the wheel in hand, increasing procedure efficiency by having an organized system that alleviates the potential risks current storage techniques pose.

After thorough testing of the final design of the GWDisc, the team determined the device to be effective and efficient in storage and dispensing of GWs while fulfilling all of the design requirements. The final design has an outer diameter of 156mm making it smaller than the competing Medline Guidewire Bowl, and more efficient and intuitive to use than the Cath Clip or wet towel method (Req 2.1, 2.2). The GWDisc was tested using various timed loading and unloading tests against these current competing devices in the market. Although there were statistically significant differences in loading times between the GWDisc and all other competing designs ($p < 0.05$ for all comparisons), there is no clinical significance with the extra 2.9-4.8 seconds it takes to load the GWDisc. The GWDisc is able to store the GWs separately, has a

dispensing mechanism, and is less bulky than the Medline bowl, all increasing its organization efficiency and reducing the entanglement of GWs and the risk for contamination (Req 2.3, 2.4).

Figure 11 shows the comparisons of GWDisc and its competitors. The longer loading time was also offset by the ability to store three GWs at once on a stand that allows for easy, intuitive dispensing of GWs from any wheel on the stand (Req 3.1, 3.2, 3.3). The device will also be made of polypropylene, making it biocompatible and safe for use (Req 4.1) in endovascular procedures.

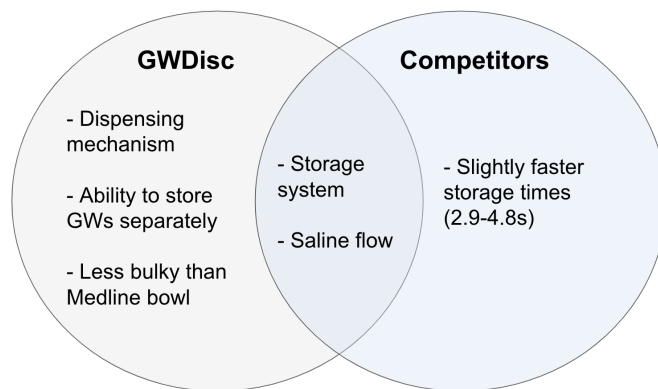


Figure 11. Venn Diagram comparison of GWDisc to the competing designs.

Overall, the GWDisc and stand storage system are a safe and efficient storage and dispensing solution for the fast-paced environment of endovascular procedures, and commercialization of the device will advance the way healthcare professionals operate in endovascular procedures.

Acknowledgements

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Appendix

Appendix A: Testing Protocol

Guidewire Holder Test Method

Loading

A.1.1 Loading

Prepare test subjects by giving them an unwound GW and the wheel and instruct them that they will wind the GW and place it into the wheel. Then test subject starts trial:

Test Subject Trial Instructions:

(Timer is started by test admin)

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

(Timer is stopped by test admin)

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

A.1.2 Test Admin: Grade the Load Trial (0-3)

1. The test admin watches the test subject load GW into the wheel.
2. Based on the table below, the test admin grades the load trial.

Grade	Definition
0	Unable to load GW
1	The GW was placed in the wheel, but there were significant issues (i.e. had to manually maneuver the GW to fit into the wheel), The wheel may be unable to dispense GW after load.
2	GW slid into the wheel with ease, but there were minor issues (i.e. the tip of the GW hung out too far, took longer to load the wheel than usual, etc.), and the wheel was ready to be dispensed.
3	GW slid into wheel without complications

A.1.3 By User: Comfortability (1-3)

1. The user loads the GW from the wheel
2. Based on the table below, the user grades the load trial.

Comfort	Definition
1	Uncomfortable and awkward to load the GW into the wheel

2	GW is loaded with some minor issues/awkwardness and required assistance (ie: Held the wheel device wrong, could not load guidewire, did not know what to do with wheel and guidewire)
3	GW is loaded without complications and no awkwardness, high comfortability and loading with ease (ie: the wheel device was intuitive, did not need any additional assistance)

A.1.4 Data Table

User Number	Trial	Load Time (sec)	Test Admin Grade	User Comfortability
1	1	14.91	2	2
1	2	*	0	1
1	3	16.21	1	1
2	1	12.75	3	3
2	2	11.02	3	3
2	3	*	0	1
3	1	15.14	1	2
3	2	14.23	2	3
3	3	12.35	3	3
4	1	*	0	1
4	2	15.85	2	2
4	3	23.32	1	1
5	1	8.5	2	3
5	2	10.64	2	3
5	3	11.3	2	3
6	1	10.65	3	3
6	2	11.44	2	3
6	3	12.17	3	3

An * indicates a mistrial

Dispensing (Solo Wheel)

A.2.1 Dispensing

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

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

A.2.2 Grade the Dispense (Thread trial) (0-3)

1. The test admin watches the test subject dispense the GW from the wheel.
2. Based on the table below, the test admin grades the load trial.

Grade	Definition
0	Unable to dispense GW.
1	The GW was partially removed from the wheel before tangling and popping out.
2	The GW was removed from the wheel without tangling but partially falls out of wheel during unloading
3	GW was removed from the wheel without complications.

A.2.3 Comfortability by User (1-3)

3. The user dispenses the GW from the wheel
4. Based on the table below, the user grades the dispense trial.

Comfort	Definition
1	Uncomfortable and awkward to dispense the GW from the wheel
2	GW is removed with some minor issues/awkwardness and required assistance (ie: Held the wheel device wrong, could not dispense guidewire, did not know what to do with wheel and guidewire)
3	GW is removed without complications and no awkwardness, high comfortability and dispensing with ease (ie: the wheel device was intuitive, did not need any additional assistance)

A.2.4 Data Table

User Number	Trial	Load Time (sec)	Test Admin Grade	User Comfortability
1	1	4.08	2	3
1	2	4.51	3	3
1	3	4.75	3	3

2	1	4.55	3	3
2	2	6.41	3	2
2	3	7.38	2	1
3	1	6.67	2	1
3	2	6.98	3	3
3	3	4.61	3	3
4	1	3.99	3	3
4	2	4.94	3	3
4	3	4.82	2	2
5	1	2.08	3	3
5	2	2.46	3	3
5	3	2.06	3	3
6	1	4.25	3	2
6	2	5.77	3	3
6	3	4.87	3	3

Dispensing While on Stand

A.3.1 Dispensing On Stand

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

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

A.3.2 Grade the Stand Dispensing (Pull Trial) (0-3)

1. The test admin watches the test subject dispense the GW from the wheel on stand.
2. Based on the table below, the test admin grades the load trial.

Grade	Definition
0	Unable to dispense GW.
1	The GW was removed from the wheel on stand but significant effort was needed (2 hands, extra person utilized).
2	The GW was removed from the wheel on stand but minor issues occurred (i.e. GW caught on middle chimney)
3	GW was removed from the wheel on stand without complications.

A.3.3 Comfortability by User (1-3)

1. The user dispenses the GW from the wheel
2. Based on the table below, the user grades the dispense trial.

Comfort	Definition
1	Uncomfortable and awkward to dispense the GW from the wheel
2	GW is removed with some minor issues/awkwardness and required assistance (ie: Could not dispense guidewire from wheel while on stand, did not know what to do with wheel, guidewire and stand)
3	GW is removed without complications and no awkwardness, high comfortability and dispensing with ease (ie: the wheel device was intuitive, did not need any additional assistance)

A.3.4 Data Table

Trial	Guidewire Specs	Wheel Placement	Dispense on Stand Time	Test Admin Grade	User Comfortability
*	*	*	*	*	*

**Stand testing will be completed in future testing*

A.4.1 Competing Design Loading Data Table

User Number	Trial	Device Number	Load Time (sec)	Test Admin Grade	User Comfortability
6	1	1	7.72	2	2
6	2	1	7.39	3	3
6	3	1	10.16	2	3
6	1	2	6.15	2	2
6	2	2	7.46	2	2
6	3	2	7.54	3	3
6	1	3	10.59	3	3
6	2	3	12.26	3	3
6	3	3	11.35	3	3
4	1	3	8.94	3	3
4	2	3	11.49	3	3
4	3	3	11.64	3	3
4	1	1	11.02	2	2
4	2	1	10.5	3	3

4	3	1	9.17	3	3
4	1	2	7.65	2	2
4	2	2	8.52	3	3
4	3	2	9.55	3	3
3	1	1	14.28	2	3
3	2	1	10.5	3	3
3	3	1	10.23	2	2
3	1	2	10.04	3	2
3	2	2	9.56	3	3
3	3	2	10	3	3
3	1	3	10.22	3	3
3	2	3	11.72	2	3
3	3	3	12.2	2	2
2	1	3	11.83	3	3
2	2	3	8.61	2	3
2	3	3	6.87	3	3
2	1	1	12.88	2	2
2	2	1	10.68	2	3
2	3	1	7.9	3	3
2	1	2	9.76	3	3
2	2	2	7.27	3	3
2	3	2	6.77	3	3
1	1	1	10.8	3	3
1	2	1	9.67	3	3
1	3	1	10.34	3	3
1	1	2	9.58	3	
1	2	2	10.81	3	
1	3	2	10.59		
1	1	3	11.3	3	3
1	2	3	15.2	2	2
1	3	3	9.45	3	3
5	1	1	10.29	1	2
5	2	1	17.25	1	1
5	3	1	8.15	3	3
5	1	2	6.75	3	3

5	2	2	9.83	2	3
5	3	2	7.06	2	3
5	1	3	7.27	3	3
5	2	3	7.03	3	3
5	3	3	6.99	2	3

Device Number Code:

1: *Medline Bowl*

2: *Wet Towel*

3: *CathClip*

Appendix B: Design Process

A. Fall 2021

Fall of 2021 was the team's first semester working on the guidewire organizer. We had decided on moving forward with just one stand design, the Storage Crate (Figure 1), and four initial guidewire designs. The Magnetic Wheel, Clamped Wheel, and the Guidewire Hoop were all compatible with the Storage Crate design that had 4 slots for 4 wheels of each design when placed in an operating room setting. The crate kept guidewires separate when multiple are in use, as it could fit each wheel with a width of 3 cm.

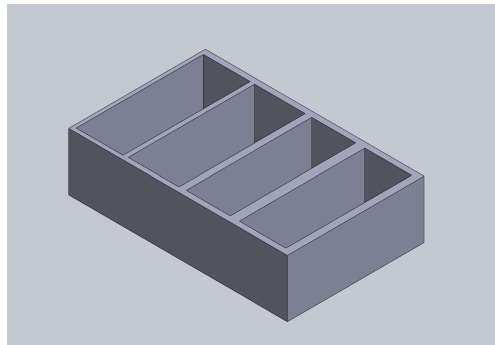


Figure 1. Storage Crate.
Dimensions: 13x30x15cm

The Storage Crate had 4 slots for 4 wheels of each design when placed in an operating room setting. It housed each wheel in a 3 cm wide cavity.

A.1 Magnetic Wheel

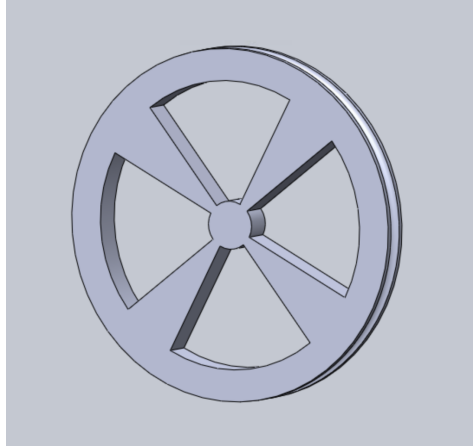


Figure 2. *Magnetic Wheel.*

Dimensions: Outer Diameter: 30cm. Inner Diameter: 28cm.

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 guidewire was spooled around the outside of the wheel.

A.2 Clamped Wheel

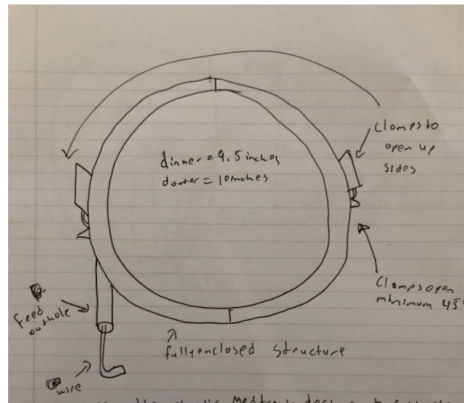


Figure 3. *Clamped Wheel.*

Dimensions: Outer Diameter: 25.4 cm. Inner Diameter: 24.13 cm.

The Clamped Wheel design, Figure 3, utilized a clamp mechanism on the outer surface of the wheel snapped open and closed when the guidewire was placed inside. The hollow circumference of the wheel would contain the guidewire once it is clamped shut. The wheel had a small protruding tube extending from the hollow interior of the perimeter of the wheel, which would contain the very tip of the guidewire for easier access to the wire.

A.3 Wheel of Magic

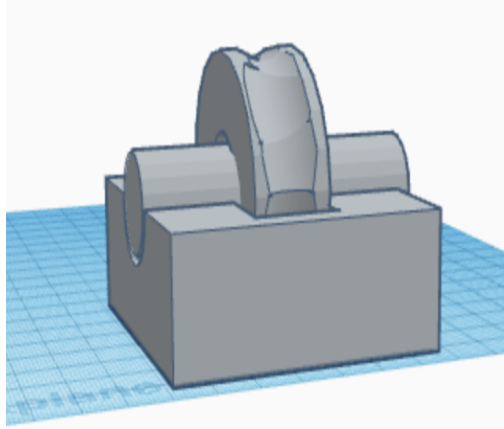


Figure 4. *Wheel of Magic.*

Dimensions: Outer Diameter: 30 cm. Inner Diameter: 15 cm.

The Wheel of Magic had 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 had protruding handles on both sides to have easier access to rotate the wheel. The guidewire was spooled around the wheel within the concave lip and then placed into the lower crate. The crate for this design was different from the crate that is used for the other preliminary designs because it only fit one wheel per crate and had a ‘U’ shaped cut to account for the protruding handles on both sides.

A.4 Guidewire Hoop

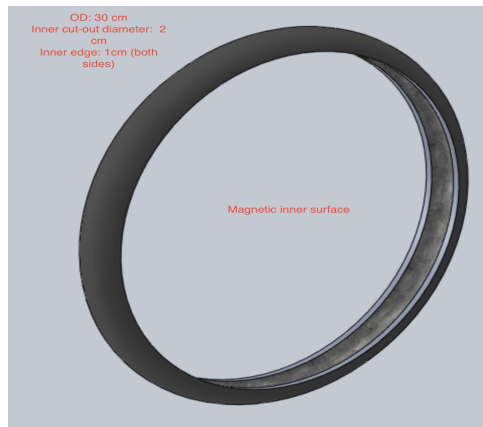


Figure 5. *Guidewire Hoop.*

Dimensions: Outer Diameter: 30cm. Inner Diameter: 29 cm.

The Guidewire Hoop had an internal concave lip that was magnetized. The internal concave lip utilized the radial force of the guidewire when coiled to contain the guidewire within the wheel.

A.4 Fall 2021 Design Matrix

The team moved forward with the Guidewire Hoop design.

Design	Magnetic wheel		Clamped Wheel		Wheel of Magic		Guidewire Hoop	
	Feasibility (30%)	4/5	24	3/5	18	4/5	24	5/5
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	

Table 1. Spring 2022 Design Matrix

B. Spring 2022

In the Spring of 2022, the team focused primarily on the design of the stand. Additionally, the team moved forward by testing 4 designs, all based off of a design provided by the client.

B.1 Proposed Wheel Designs

B.1.1 DYWheel

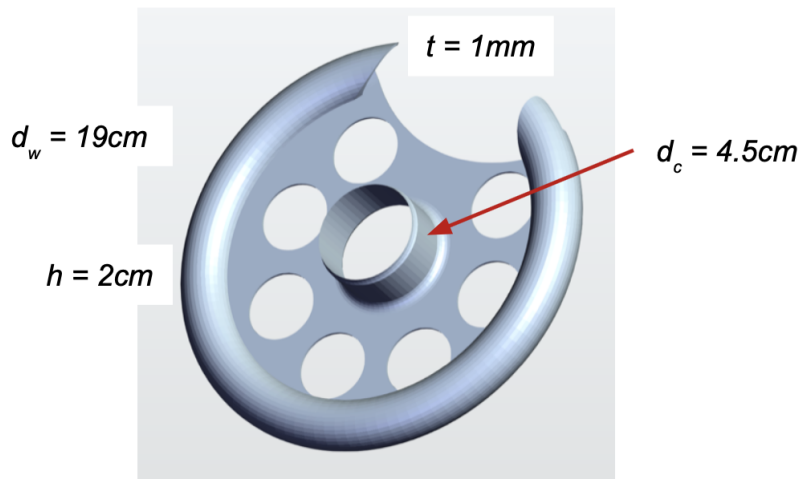


Figure 6. DYWheel

Dimensions: Outer Diameter (d_w): 19 cm. Chimney Diameter (d_c): 4.5 cm

The client provided the team with a preliminary wheel design shown in **Figure 7**. Various dimensions and basic characteristics of this wheel were changed and became their own individual prototypes. The wheel consisted of a deep inner cavity.

B.1.2 CutChimney



Figure 7. *CutChimney*

Dimensions: Outer Diameter (d_w): 19 cm. Chimney Diameter (d_c): 4.5 cm

CutChimney's inner chimney was semi-circular to allow it to slide off of the stand after the guidewire is unloaded. After unloading the guidewire, the wheel was able to be removed from any place on the stand.

B.1.3 CurveSpout

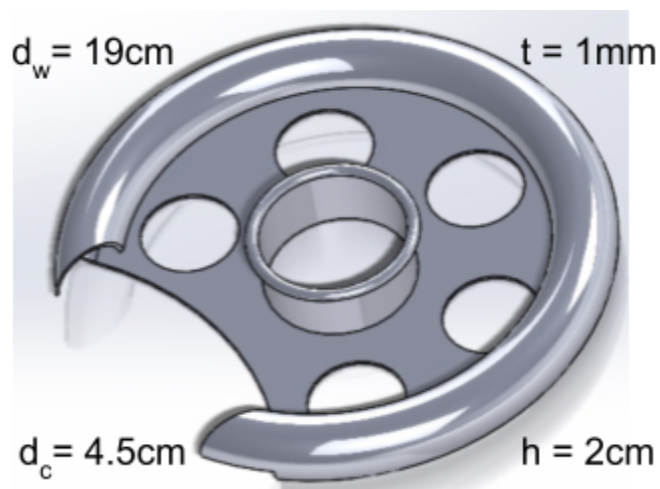


Figure 8. *CurveSpout*

Dimensions: Outer Diameter (d_w): 19 cm. Chimney Diameter (d_c): 4.5 cm

The CurveSpout design has an inner chimney that was curved inward. This modification was meant to ensure that when the wire was unloaded it did not slip up and past the inner chimney.

B.2 Proposed Stand Designs

B.2.1 DYStand

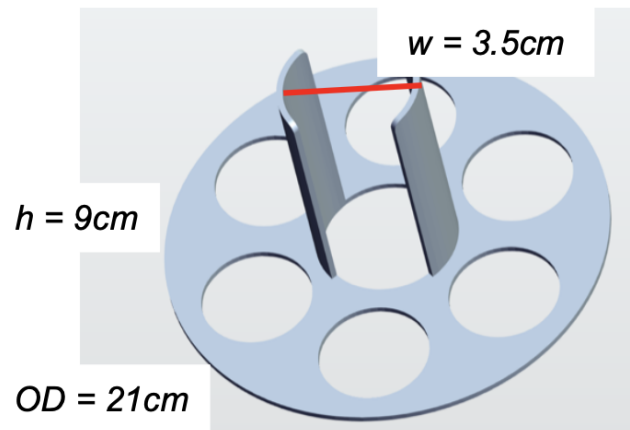


Figure 9. *DYStand.*

Dimensions: Outer Diameter (OD): 21 cm. Inner Diameter (w): 3.5 cm.

The DYStand (**Figure 10**) was 9 cm high and 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.

B.2.2 UHold

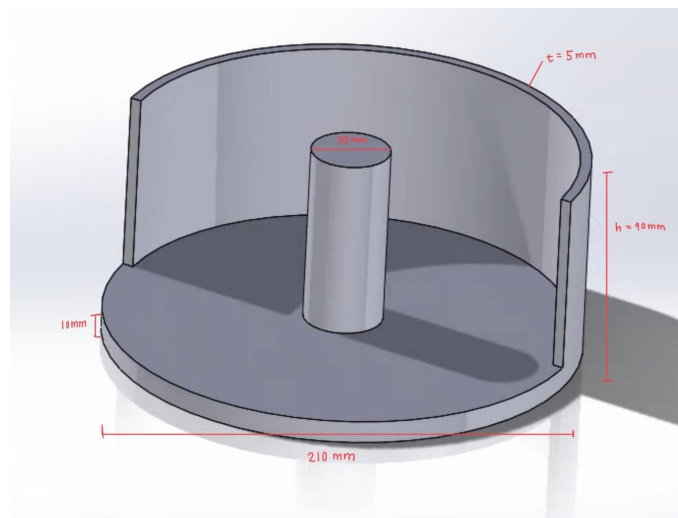


Figure 10: *UHold.*

Dimensions: Outer Diameter: 21 cm. Inner Diameter: 3.5 cm.

UHold had a backplate incorporated into the design to provide additional support to the wheel. This design had a 1 cm thick base plate where weights were added.

B.2.C Door

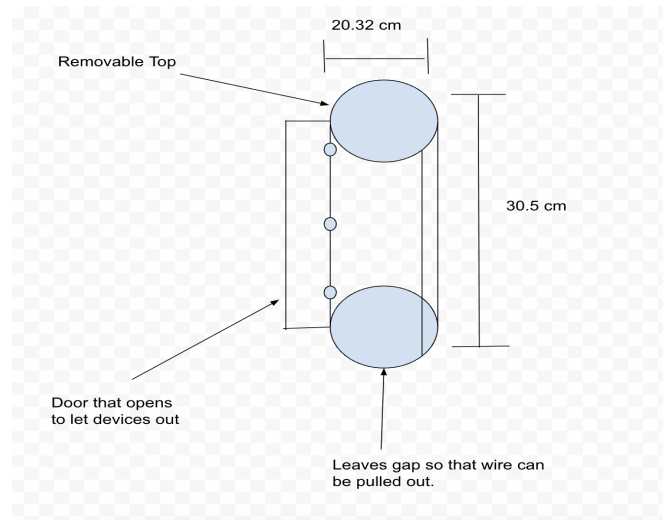


Figure 11. Door.

Dimensions: Outer Diameter: 20.32 cm.

The Door's additional height allowed for more wheels to be stacked inside. The top lid was detachable to allow for wheels to be placed through the top. The door design allowed for the wheels to be taken out in any order (not just top to bottom).

B.3 Spring 2022 Design Matrix

The team moved forward with the UHold design.

Endovascular Catheter Design Matrix

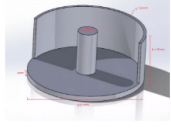
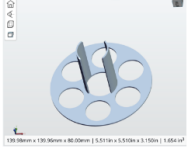
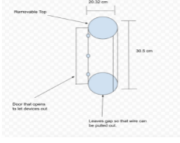
Design	 UHold		 DYStand		 Door	
	Efficiency (30%)	5/5	30	5/5	30	2/5
Learning Curve (25%)	4/5	20	5/5	25	3/5	15
Compatibility (20%)	4/5	16	5/5	20	3/5	12
Durability (15%)	5/5	15	3/5	9	3/5	9
Safety (10%)	5/5	10	3/5	6	3/5	6
Total for each design:	91		90		54	

Table 2. Spring 2022 Stand Design Matrix

C. Fall 2022

In the Fall of 2022 the team focused on the wheel design to make it mass manufacturable from various manufacturing methods. However, it was found that injection molding would be the most feasible method to produce the wheel. The team moved forward testing various designs stemming from the original design provided by the client in *Section B.1.1* that were modified in the focus of being injection moldable.

C.1 Proposed Wheel Designs

C.1.1 XSHold

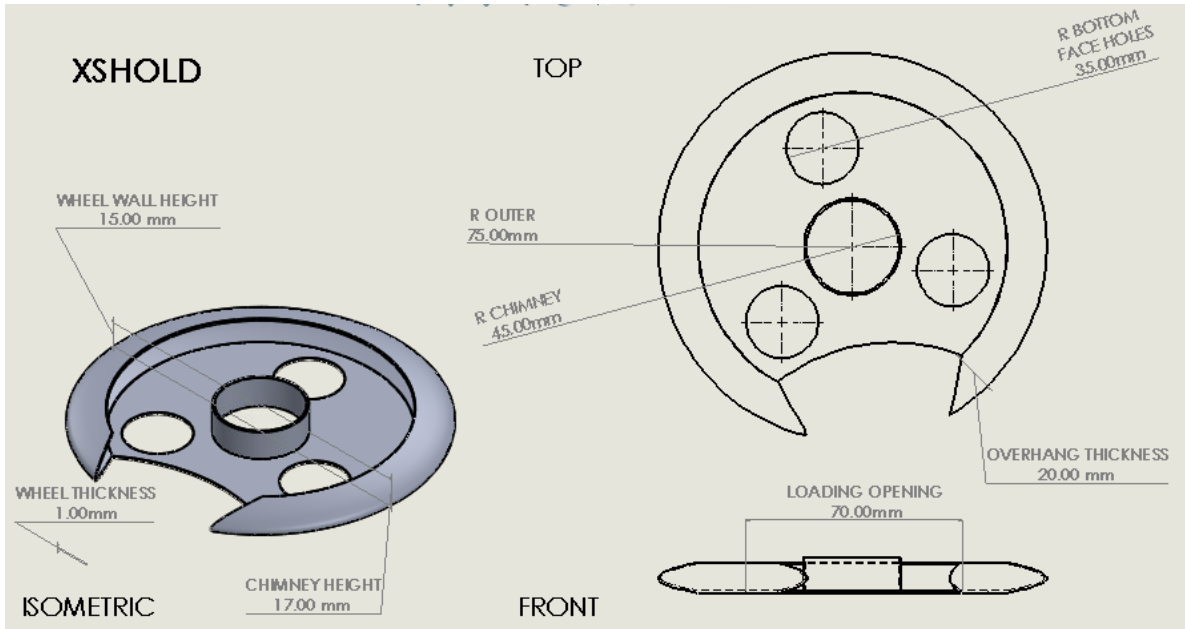


Figure 12. XSHold SolidWorks design.

The design variation seen in **Figure 12** allowed for a tighter hold of the guidewire as there is more force applied to the outer wall of the device. Less material was needed to build this wheel.

C.1.2 XtraHold

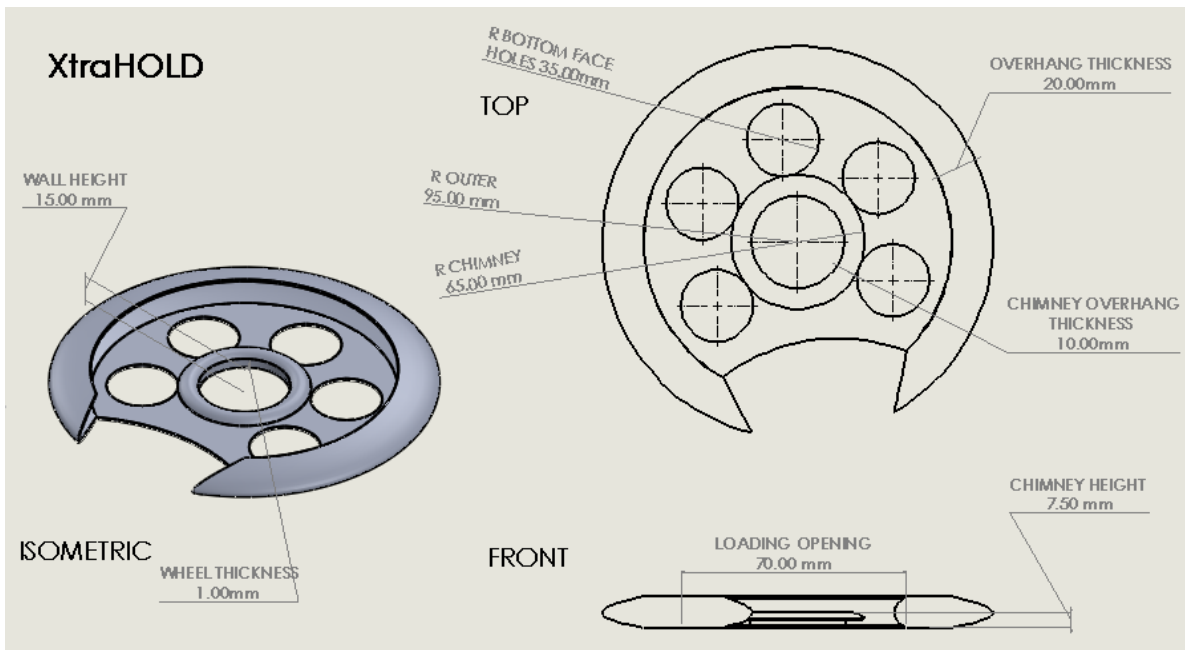


Figure 143 XtraHold SolidWorks design.

The design variation seen in **Figure 13** featured a shorter chimney for easier and more comfortable guidewire loading, and the overhang keeps the guidewire steady in place during guidewire removal.

C.1.3 LHold

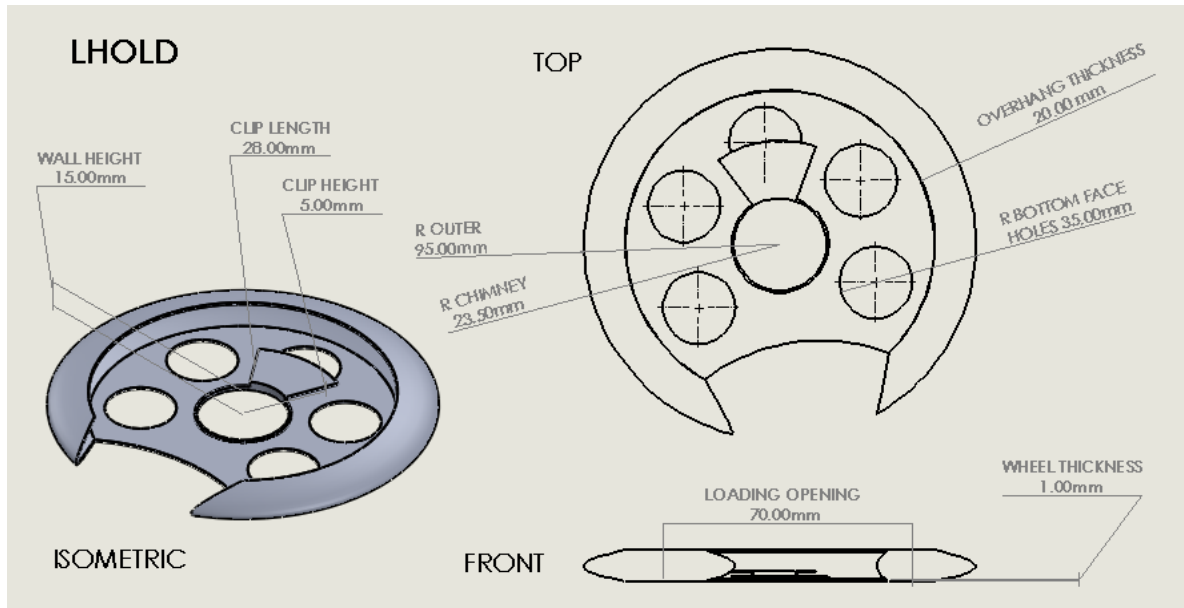


Figure 14. LHold SolidWorks design.

The design variation seen in **Figure 14** featured a overhanging clip piece in place of the cylindrical chimney utilized in DYWheel. Removing the chimney eliminates the obstruction that the chimney imposes on the user while loading the guidewire.

C.1.4 LGHold

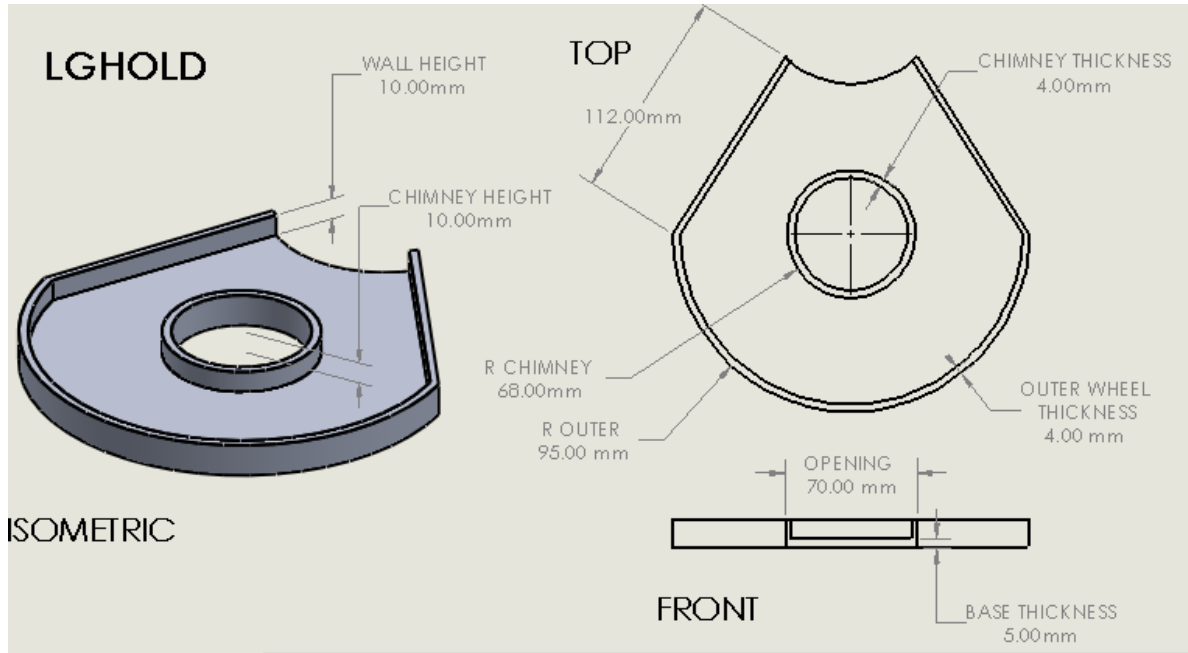


Figure 15. LGHold SolidWorks Drawing.

The design variation seen in **Figure 15** eliminated the overhang. This allowed the device to be injection moldable without any further modifications.

C.1.5 ADHold

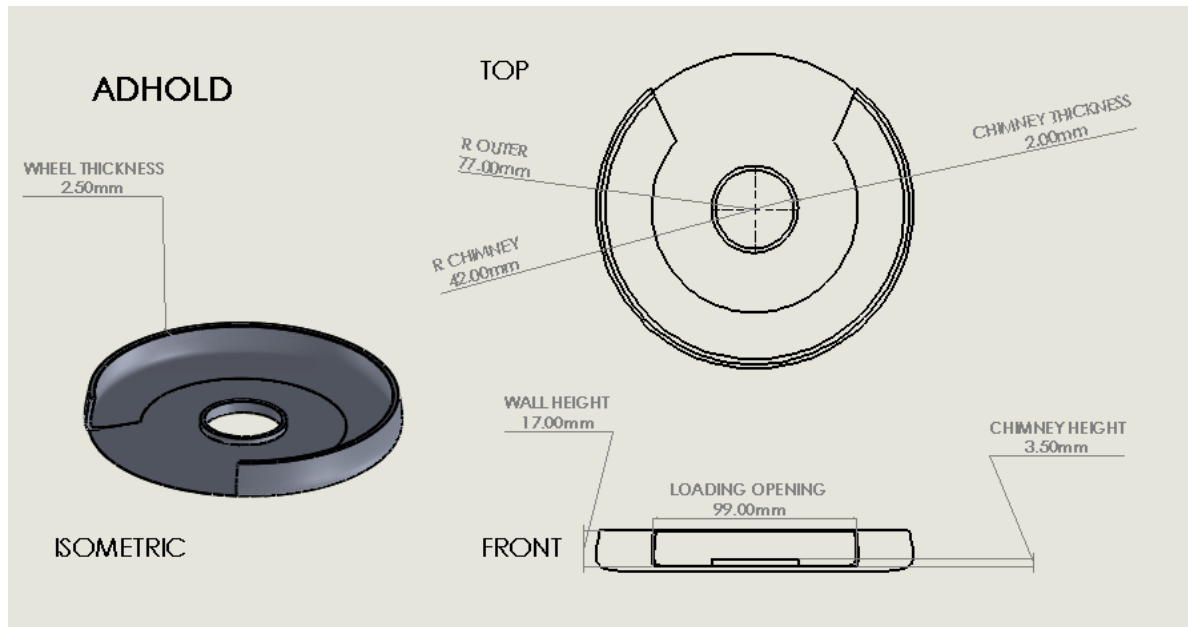


Figure 16. ADHold SolidWorks design.

The design variation seen in **Figure 16** was modeled to the geometry of a frisbee. This device had a slight curvature, which allowed the device to be injection molded.

C.1.6 TRHold

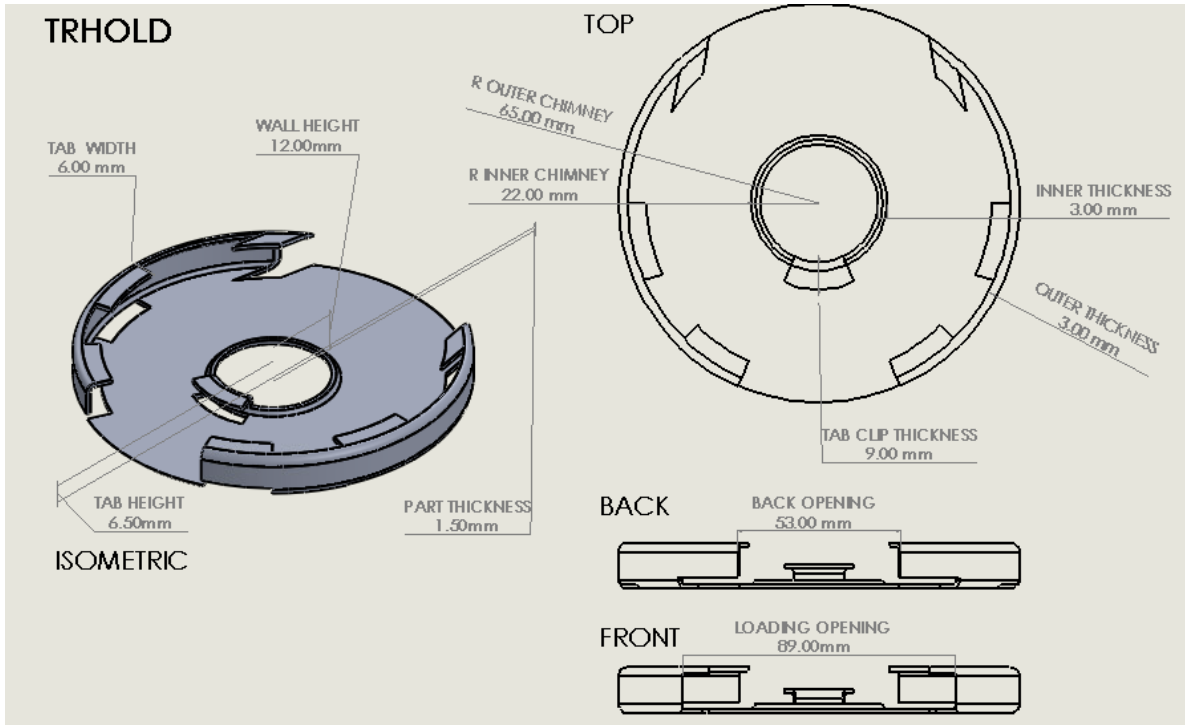


Figure 17. TRHold SolidWorks design.

The design variation seen in **Figure 17** attempted to eliminate overhangs that prevent the device from being injection molded. This device features cutouts below any tab-like extrusions in order to allow the device to be punched out of the injection mold.

C.2 Proposed Stand Design

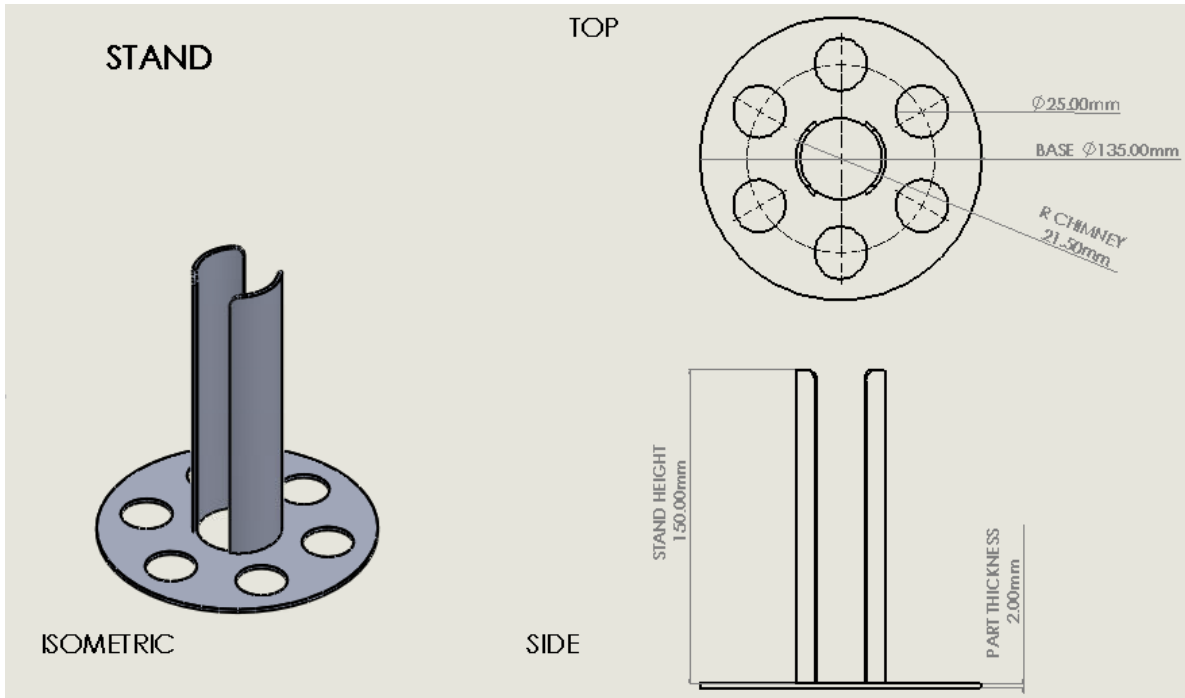
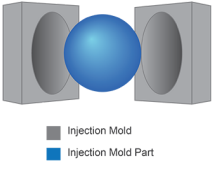

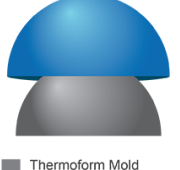


Figure 18. Stand SolidWorks design to hold guidewire organizers.

The stand design seen in **Figure 18** will be used in conjunction with the final wheel design. There was a long chimney in the center of the base plate to stack up to three guidewire wheels at one time.

C.3 Manufacturing Methods Matrix

In order to mass produce the final design, the final manufacturing process must be cost and time efficient. In **Table 3**, the team compared three different manufacturing processes: injection molding, 3D printing, and thermoforming.

Manufacturing Process		 Injection Molding [6]		 3D Printing		 Thermoforming [6]
Production Efficiency (25)	5/5	25	1/5	5	4/5	20
Ease of Manufacturing (20)	3/5	12	5/5	20	4/5	16

Cost Per Part (20)	4/5	16	2/5	8	3/5	12
Material Compatibility (15)	5/5	15	4/5	12	2/5	9
Lead time (10)	2/5	4	5/5	10	3/5	6
Accuracy (10)	5/5	10	2/5	4	2/5	4
Total	82/ 100	82	59/ 100	59	67/ 100	67

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

D. Spring 2023

Throughout the Spring of 2023 the team is focusing on finalizing the wheel dimensions in order to make it injection moldable by eliminating the overhang of the outer edge of the wheel. After our testing results from Fall of 2022, the team is moving forward with the ADHold (C.1.5) and is modifying the wheel to incorporate the diameter of XSHold in Figure C.1.1.

D.1 Proposed Wheel Designs

D.1.1 FrissV1

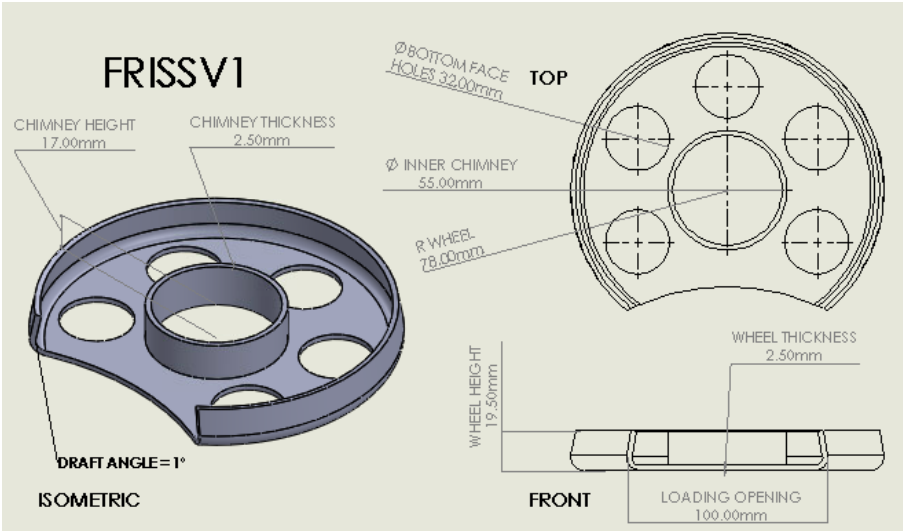


Figure 19. FrissV1

This design variation is identical to FrissV2, however, the top of the wheel where the guidewire is inserted and dispensed is cut down to aid in easier loading of the wheel.

D.1.2 FrissV2

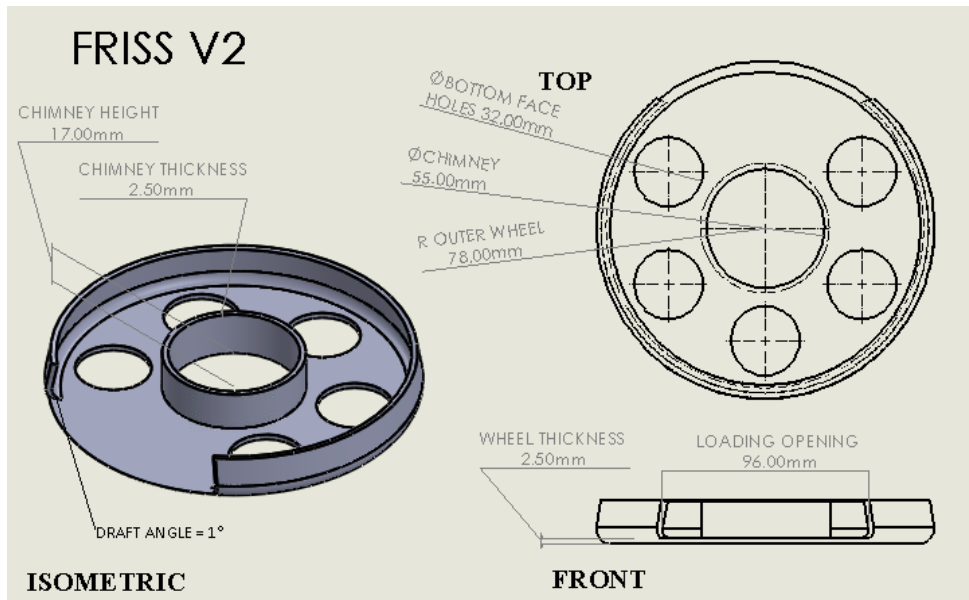


Figure 20. FrissV2

This design variation incorporates the holes for saline flow, chimney, and smaller diameter from the XSHold (C.1.1) into the ADHold (C.1.5). The wheel aims to be injection moldable by modifying the extreme overhang into a slight overhang.

D.1.3 DiscGolf

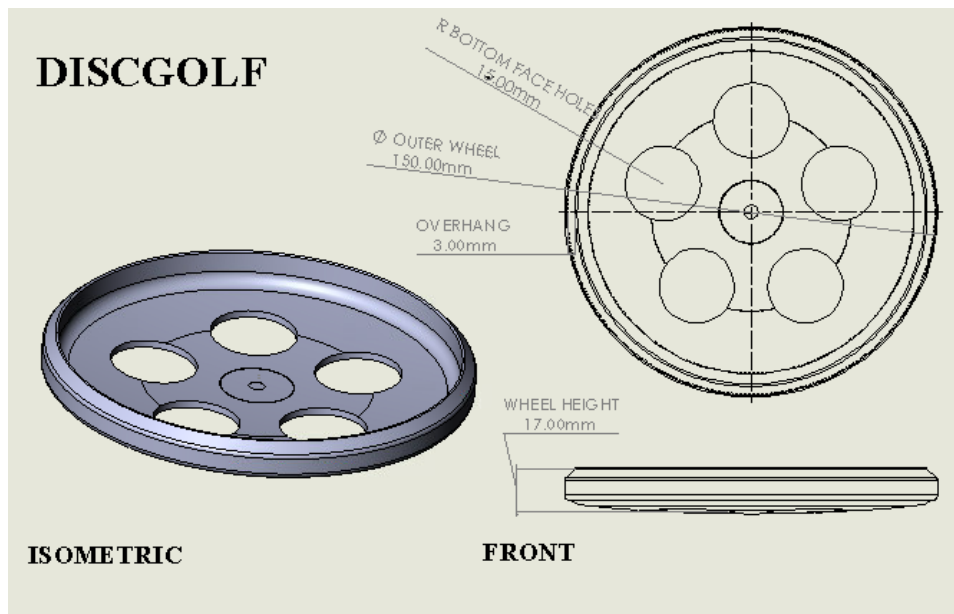


Figure 21. DiscGolf

This design variation was made from a CAD model of a discgolf frisbee. The holes for saline flow were added to the top surface and the diameter was changed to 150.00mm to match the target size of our wheel design.

D.2 Proposed Stand Design

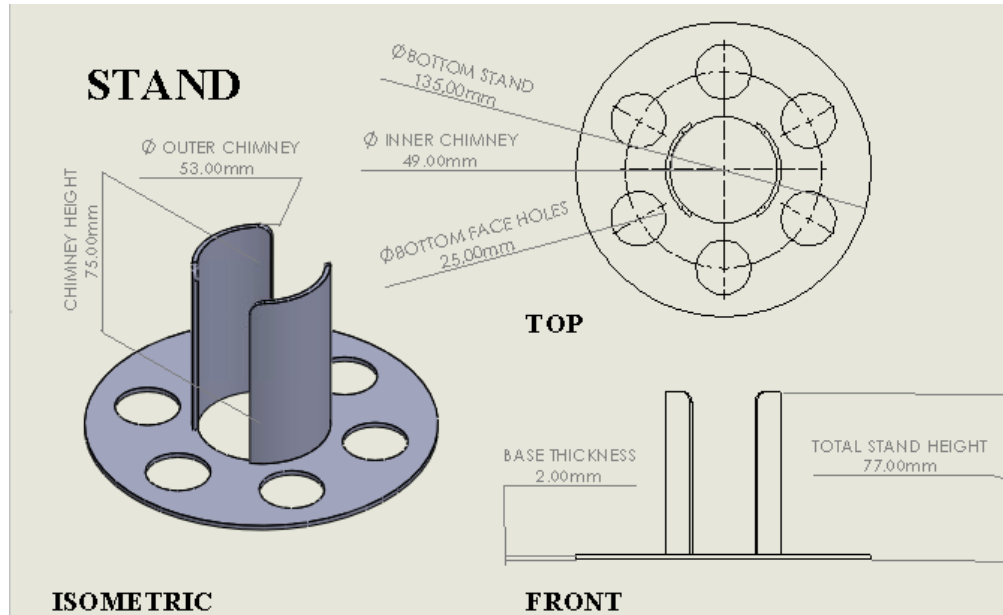


Figure 22. Stand 2023

The stand design was slightly modified from Fall of 2022 (C.2) by shortening the height of the stand and enlarging the diameter of the middle shaft to better secure the wheels.

D.3 Survey Questionnaire

1. Using the current method of storing guidewires under a wet towel while in the operating room, how many issues does this cause in terms of contamination resulting in the need for a new wire? Please rank on a scale of 1-5:
 1. This method never causes contamination
 2. This method has caused contamination very few times in my experience
 3. This method causes contamination about half of the time
 4. This method causes contamination more often than not
 5. This method causes contamination every or nearly every time
 6. (N/A) I have never used this method
2. Using the current method of storing guidewires under a wet towel while in the operating room, how often does this cause the guidewire to kink, tangle, or become disorderly? Please rank on a scale of 1-5:
 1. This method never causes these issues
 2. This method very rarely causes these issues

3. This method causes these issues about half of the time
 4. This method causes these issues more often than not
 5. This method causes these issues every or nearly every time
 6. (N/A) I have never used this method
3. Using the method of storing guidewires under a wet towel while in the operating room, do you feel this method is the most efficient and cost effective method?
 1. Yes, this method causes little disruption in the operating room and is inexpensive
 2. Maybe, this method is inexpensive but often results in complications in terms of contamination and function of the wire
 3. No, this method often results in complications in terms of contamination and function of the wire and does not outweigh the cost benefit
 4. (N/A) I have never used this method
 4. Given your experience with guidewire use and storage, what do you rank your desire for a new storage method of guidewires on a scale of 1-5?
 1. I have no desire for a new storage method
 2. I have given very little thought for a new storage method but am not opposed
 3. I am indifferent to a new storage method
 4. I would prefer a new storage method if it is more efficient and less likely to have issues in the operating room than the current method
 5. I absolutely would prefer a new storage method
 6. (N/A) I have never used this method
 5. Using the method of storing guidewires with a cath clip, how often does this result in contamination? Please rank on a scale of 1-5:
 1. This method never causes contamination
 2. This method very rarely causes contamination
 3. This method causes contamination about half the time
 4. This method causes contamination more often than not
 5. This method causes contamination every or nearly every time
 6. (N/A) I have never used this method
 6. Using the method of storing guidewires with a cath clip, how often does this method result in disorderly, kinked, or tangled wires? Please rank on a scale of 1-5:
 1. This method never causes these issues
 2. This method rarely causes these issues
 3. This method causes these issues about half the time
 4. This method causes these issues more often than not
 5. This method causes these issues every or nearly every time
 6. (N/A) I have never used this method
 7. Using the method of storing guidewires in the Medline bowl, how often does this result in contamination of the wire, which then requires a new wire? Please rank on a scale of 1-5:
 1. This method never causes contamination

2. This method very rarely causes contamination
 3. This method causes contamination about half the time
 4. This method causes contamination more often than not
 5. This method causes contamination every or nearly every time
 6. (N/A) I have never used this method
8. Of the three storage methods discussed, please select the method you most prefer: wet towel, cath clip, medline bowl.
1. Wet towel method
 2. Cath Clip method
 3. Medline bowl method

D.4 Survey Questionnaire Results

1. Using the current method of storing guidewires under a wet towel while in the operating room, how many issues does this cause in terms of contamination resulting in the need for a new wire? Please rank on a scale of 1-5:
 1. This method never causes contamination **(1 answer)**
 2. This method has caused contamination very few times in my experience **(5 answers)**
 3. This method causes contamination about half of the time **(1 answer)**
 4. This method causes contamination more often than not
 5. This method causes contamination every or nearly every time
 6. (N/A) I have never used this method **(1 answer)**
2. Using the current method of storing guidewires under a wet towel while in the operating room, how often does this cause the guidewire to kink, tangle, or become disorderly? Please rank on a scale of 1-5:
 1. This method never causes these issues **(1 answer)**
 2. This method very rarely causes these issues
 3. This method causes these issues about half of the time **(6 answers)**
 4. This method causes these issues more often than not
 5. This method causes these issues every or nearly every time
 6. (N/A) I have never used this method **(1 answer)**
3. Using the method of storing guidewires under a wet towel while in the operating room, do you feel this method is the most efficient and cost effective method?

1. Yes, this method causes little disruption in the operating room and is inexpensive **(3 answers)**
2. Maybe, this method is inexpensive but often results in complications in terms of contamination and function of the wire **(3 answers)**
3. No, this method often results in complications in terms of contamination and function of the wire and does not outweigh the cost benefit **(1 answer)**
4. (N/A) I have never used this method **(1 answer)**
4. Given your experience with guidewire use and storage, what do you rank your desire for a new storage method of guidewires on a scale of 1-5?
 1. I have no desire for a new storage method
 2. I have given very little thought for a new storage method but am not opposed
 3. I am indifferent to a new storage method **(1 answer)**
 4. I would prefer a new storage method if it is more efficient and less likely to have issues in the operating room than the current method **(6 answers)**
 5. I absolutely would prefer a new storage method
 6. (N/A) I have never used this method **(1 answer)**
5. Using the method of storing guidewires with a cath clip, how often does this result in contamination? Please rank on a scale of 1-5:
 1. This method never causes contamination **(4 answers)**
 2. This method very rarely causes contamination **(4 answers)**
 3. This method causes contamination about half the time
 4. This method causes contamination more often than not
 5. This method causes contamination every or nearly every time
 6. (N/A) I have never used this method
6. Using the method of storing guidewires with a cath clip, how often does this method result in disorderly, kinked, or tangled wires? Please rank on a scale of 1-5:
 1. This method never causes these issues **(4 answers)**
 2. This method rarely causes these issues **(4 answers)**
 3. This method causes these issues about half the time
 4. This method causes these issues more often than not
 5. This method causes these issues every or nearly every time
 6. (N/A) I have never used this method

7. Using the method of storing guidewires in the Medline bowl, how often does this result in contamination of the wire, which then requires a new wire? Please rank on a scale of 1-5:
 1. This method never causes contamination (**3 answers**)
 2. This method very rarely causes contamination (**1 answer**)
 3. This method causes contamination about half the time (**3 answers**)
 4. This method causes contamination more often than not
 5. This method causes contamination every or nearly every time
 6. (N/A) I have never used this method (**1 answer**)
8. Of the three storage methods discussed, please select the method you most prefer: wet towel, cath clip, medline bowl.
 1. Wet towel method
 2. Cath Clip method (**8 answers**)
 3. Medline bowl method

Appendix C: Reference Journal

Steerable Guidewire for Magnetic Resonance Guided Endovascular Interventions

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In endovascular interventions, thin, flexible instruments are inserted through the skin into the blood vessels to diagnose and treat various diseases of the vascular system. One drawback is that the instruments are difficult to maneuver in the desired direction due to limitations in shape and flexibility. Another disadvantage is that the interventions are performed under intermittent fluoroscopy/angiography imaging. Magnetic resonance imaging (MRI) may offer advantages over X-ray guidance. It presents a good soft tissue contrast without the use of nephrotoxic media or ionizing radiation. The aim of this study is to develop a guidewire that is compatible with MRI and includes a steerable segment at the tip. This added degree-of-freedom may improve the maneuverability of the devices thereby the efficiency and safety of the navigation. A 1.6 m (5 ft, 3 in.) long and 0.035 in. diameter guidewire that consists of MR compatible materials and has a flexible tip was designed. The only metallic part was a nitinol rod that was implemented at the distal flexible tip. To limit the risk of heating in the MRI, this rod was kept shorter than 30 mm. The tip could be deflected in one direction by pulling on a Dyneema wire that was placed in the lumen of the shaft of the guidewire. To drive the steerable tip, a handle that could be easily attached/detached from the instrument was designed and implemented. Using the handle, the tip of the 1.60 m long guidewire prototype could be actuated to reach angles from 30 deg to 250 deg. The handle could easily be placed on and removed from the guidewire, so conventional 0.035 in.-compatible catheters could slide over from the proximal end. However, in order to make the guidewire more efficient to enter a bifurcation, the stiffness of the tip should progressively increase from its proximal to its distal end. The guidewire was imaged in a 1.5T MRI using real-time imaging without producing artifacts that would have shaded the anatomy. It was possible to assemble a guidewire with a steerable segment in the required size, using MR compatible materials. Therefore, the current design is a promising proof of concept and allowed us to clearly identify the features that need to be improved in order to come to a clinically applicable instrument. [DOI: 10.1115/1.4026560]

Keywords: interventional radiology, navigation, steerability, magnetic resonance imaging

Introduction

Endovascular intervention is a minimally invasive technique used to treat various diseases of the vascular system using X-ray guidance. Compared to open surgery, the technique offers many advantages for the patients, such as less pain and faster recovery. However, these interventions are more complex to execute and require longer training.

Interventional cardiologists and radiologists need to learn to manipulate long, thin, and flexible catheters, guidewires, and sheaths that are inserted through the skin into the blood vessels. The instruments typically have a fixed shape and a limited range of flexibility, which makes it difficult to maneuver in the desired direction [1–3]. As the instruments pass through lesions or turns, the control of its tip progressively decreases [4] so that the instrument may be more likely to deviate from the desired path into side branches. Consequently, some locations cannot be reached or can only be reached with a low success rate [2]. Moreover, the instruments need to be exchanged frequently to replace tip shape or size. It was estimated that physicians perform on average 20

extractions and insertions of catheters, guidewires, and sheaths, per procedure [5]. This repeated extraction and insertion increases the risk of infection, embolization, procedure time, radiation dose, waste consumables, and it easily causes interventionalists to feel fatigued [2,6].

Another drawback of the technique is that the interventions are performed under intermittent two-dimensional projection fluoroscopy/angiography image guidance. Operators have to rely on mental images of the anatomy, based on two-dimensional angiographic images previously taken during the procedure, while manipulating the instruments in three dimensions [7]. Since fluoroscopy images present a poor soft-tissue contrast, these angiographic images require the administration of a large volume of nephrotoxic and iodine-containing contrast media in order to visualize the anatomy. However, it is known that the use of contrast presents a risk of precipitate contrast-induced nephropathy or potentially life threatening anaphylactic reaction [8].

Magnetic resonance imaging (MRI) may offer several advantages over fluoroscopy/angiography guidance. No ionizing radiation is used and MR guidance for endovascular interventions is performed without the use of iodine-based contrast agents [9], but with a more biocompatible contrast medium [10]. This is an important advantage for patients with impairment of renal function

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or presenting allergies to iodine. Moreover, since vascular structures can be visualized, MRI can perform images comparable to an angiograph, and may even allow some endovascular interventions without the use of any contrast media [11,12]. However, to become part of the clinical routine, MRI-guided interventions still require MR compatible instruments [13,14], which are not widely available at the moment.

The aim of this study is to develop a guidewire that is compatible with the MRI environment and can be used with conventional endovascular instruments for peripheral interventions. To further support the navigation process, the design also includes a steerable segment at the tip of the guidewire. This added degree-of-freedom might improve the maneuverability of the devices, reduce the number of instrument exchanges, and may therefore make the procedure safer and faster.

The paper first specifies the main requirements and parameters of the developed guidewire with improved maneuverability, and secondly, describes the prototype that has been realized.

Design Requirements

The prototype was to consist of two main components: the guidewire itself, composed of a shaft and a steerable tip, and a detachable handle. This prototype had to satisfy a number of significant design requirements that are specified below.

Compatibility With Conventional Catheters. The guidewire needed to be compatible with conventional endovascular instruments, meaning that it should be possible to slide the guidewire inside the lumen of catheters. Catheters have an inner lumen with a diameter, ranging from 0.014 in. to 0.038 in. (0.35 mm to 0.97 mm) and are used in combination with a guidewire that has a specific diameter. In the case of peripheral interventions, procedures are usually performed with guidewires that are 0.035 in. in diameter, and from 145 cm to 300 cm (4.7 ft to 9.8 ft) in length [4]. Finally, the stiffness, pushability, and torque control of the design should enable the user to slide catheters over the prototype and to perform simple navigation tasks. This gave us the following requirements:

- Req. 1.1: the diameter of the steerable guidewire has to be less than 0.89 mm (0.035 in.)
- Req. 1.2: the length of the steerable guidewire has to be more than 150 cm (4.9 ft)
- Req. 1.3: it should be possible to exchange selective catheters by sliding them over the guidewire

Steerable Tip. According to personal communication with IRs, only angles from 30 deg to 120 deg are useful for navigation. In fact, they indicated that sharper angles might not be helpful, since it is difficult to advance wires in the opposite direction of the push. Also, the required length of the steerable segment depends on the way the steerable guidewire is used. Finally, it is known that the control of the tip decreases as the guidewires pass lesions or turns [4]. However, the deflectable tip should be controllable even if several turns were encountered to reach the area of interest.

- Req. 2.1: the steering angle of the steerable tip has to be in the range (30 deg; 120 deg) (1DOF)
- Req. 2.2: the length of the steerable part has to be defined in relation with the target vessel
- Req. 2.3: control of the tip has to be possible even when the shaft of the guidewire is looped at least once

Handle. A handle was needed to actuate the tip of the guidewire from the proximal side. As it was desirable to have the ability to exchange catheters at the proximal side, it must be possible to easily remove the handle and to reattach it several times during one intervention without damaging the guidewire. Further, it seemed best to keep the workload for the user to a minimum when

driving the tip. Therefore, it was decided that only one hand should be required to actuate the deflectable segment.

- Req. 3.1: the handle has to be easy to detach (no tool needed)
- Req. 3.2: the handle has to be fast to attach/detach (less than 1 min)
- Req. 3.3: no damage is induced on the steerable guidewire by the handle
- Req. 3.4: tip of the guidewire driven with one hand only
- Req. 3.5: a holding mechanism maintain the tip in position

Biocompatibility. In order to prevent future limitations, all materials included in the design of the guidewire shaft and steerable tip should be biocompatible.

Req. 4: all the materials used in the design of the steerable guidewire are biocompatible

MRI Compatibility and Visibility. The prototype will be manipulated in a model under real time MR images. Therefore, no magnetic metals can be included in the design. Furthermore, it has to be safe for the user. The major safety issue with MRI guidance of catheters/guide-wire is potential pickup of radio frequency energy, with heating of the catheter/guidewire, especially at the tip [15]. This can be observed even with the use of nonmagnetic metals [15], but this effect is limited when metallic parts of short length are used [16]. In addition, the guidewire has to be visible on the images without producing artifacts that would shade the anatomy of interest. Compatibility with the MRI field at the entrance of the bore was the only requirement for the materials of the handle, as it was not designed to be imaged by the scanner but to be kept at the entrance of the magnet.

- Req. 5.1: the materials of the guidewire have to be nonmagnetic
- Req. 5.2: the materials of the guidewire should not produce artifacts that obscure the anatomy that needs to be visualized
- Req. 5.3: the length of thin and long metallic structures should be less than 13 cm (5.1 in.)
- Req. 5.4: the materials of the handle have to be nonmagnetic

Design

Guidewire Design. The guidewire itself was composed of a flexible shaft, a deflectable tip, and an actuation wire (Fig. 1).

The shaft of the guidewire, 0.8 mm outside diameter (0.031 in. OD), 0.2 mm inside diameter (0.0078 in. ID), consisted of a 150 cm (4.9 ft) long tube of polyether ether ketone (PEEK). This polymer can be used for medical applications, as it is a biocompatible material and can be autoclaved or sterilized by ethylene oxide. PEEK also has mechanical properties that are suitable for the current application as it is one of the stiffest polymer material [17], with high tensile strength, torquability, and pushability. A shrinking tube that was made of polyethylene (PE), which is also a biocompatible material, covered the PEEK tube.

The shaft was connected to the deflectable tip that was composed of a flexible tube, 0.79 mm diameter (0.031 in.), cut from a *Progreat* microcatheter (2.4Fr, Terumo Corporation, Tokyo, Japan). While the design of the shaft of the steerable guidewire stemmed from the dimensions of conventional instruments, the design of the tip was based on the way endovascular instruments with a prebent tip are used to navigate in the vascular tree and cannulate branches; conventional catheters or guidewires need

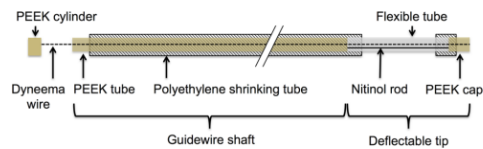


Fig. 1 Design of the steerable guidewire

support from the vessel walls. Their shaft and the distal part of the tip have to be supported from both sides of the vessel wall. Typically, in case of a catheter, the tip of the instrument is placed above a branch, and is then slowly pulled back until the tip of the instrument enters the vessel. In other words, it is difficult to direct the tip of the instrument into a target vessel when its shape is smaller than the vessel diameter. Assuming the deflectable tip of the current steerable guidewire adopts a perfect semicircle when actuated, a direct relationship, Eq. (1), can be found between the length of the tip (ℓ), the bend angle (α), and the vessel diameter (D_v).

$$D_v(\text{mm}) = \frac{180\ell(\text{mm})}{\pi\alpha(\text{deg})} (1 - \cos(\alpha(\text{deg}))) \quad (1)$$

D_v , ℓ , and α had to be defined for the current design. Interventional radiologists indicated that only angles from 30 deg to 120 deg would be helpful for navigation tasks, thereby explicitly defining the span of the angles of interest. Given a chosen maximum target vessel, max D_v , of 20 mm (0.79 in.) and the fact that function Eq. (1) is monotonically increasing for this span of angles of interest (30 deg; 120 deg), we calculated that the required tip length was 28 mm (1.1 in.) (Req.2.2).

The 28 mm long flexible tube contained a flattened nitinol rod. This rod had two functions: its elastic properties helped to straighten the tip and constrained bending to one plane. The connection between the shaft and the flexible tube was secured with the same PE shrinking tube that covered the shaft. This shrinking tube was also used to connect the flexible tube to a PEEK cap, placed at the very distal end of the instrument. A 0.1 mm (0.0039 in.) diameter Dyneema® wire was fixed on the cap and ran through the lumen of the flexible tube and of the shaft. Pulling on this wire results in bending the deflectable tip.

Handle Design. In order to easily actuate and control the steerable segment, a handle was designed so that it could be intermittently connected to the shaft (Fig. 2). This handle was composed of two clamps and one friction-based slider. The first clamp, located at the distal part of the handle held the shaft of the instrument via two metallic jaws (Fig. 3). The jaws were opened or closed via a screw that could be easily tightened or loosened by hand. When tightened, the jaws hold the shaft. To avoid damages to the shaft, a safety mechanism was integrated to prevent the manipulator from overtightening the jaws. Then, the second clamp was placed below the slider, in the middle of the handle (Fig. 2). Since Dyneema is a very slippery material, it was difficult to find

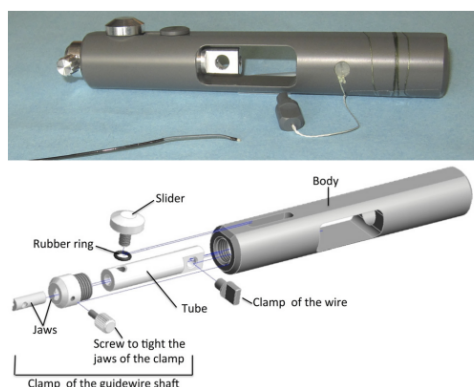


Fig. 2 Handle and tip of the steerable guidewire (top) and exploded view of the handle (bottom)

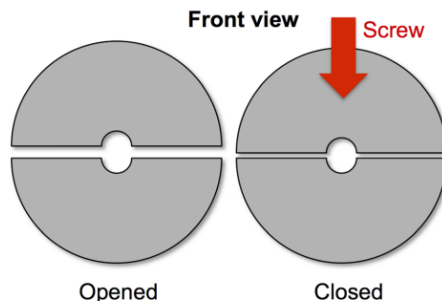


Fig. 3 Front view of the clamp of the guidewire shaft in the opened and closed position. The shaft of the guidewire is placed and held inside the lumen of the clamp.

a clamping mechanism that would grasp the wire without damaging it. Therefore, the proximal part of the wire was connected to a 2.3 mm (0.91 in.) long and 0.6 mm (0.024 in.) diameter PEEK tube (Fig. 1). Rather than the wire, the second clamp seized this PEEK cylinder (Fig. 4). Together the two clamps enabled the user to apply the needed translation on the wire and to orient the tip in any preferred angle. If released by the manipulator, the friction induced by a rubber ring helps to hold the slider, and therefore the tip, in position.

Results

Compatible With Conventional Catheters. The prototype measured 1.60 m (5.2 ft) long with an average diameter of 0.83 mm (0.032 in.), matching the dimensions of a conventional guidewire (Req.1.1 and 1.2). Even though the diameter of the connection between the flexible segments and its cap was slightly larger, 0.94 mm (0.037 in.), no problems were observed when the instrument was used in combination with several conventional catheters of the 0.035 in. system. Therefore, the prototype was judged to be compatible with conventional catheters. It was possible to slide catheters over the guidewire (Req.1.3) from both the distal and proximal end. The prototype enabled users to straighten the shape of selective catheters, allowing their use in the vascular tree. The prototype could successfully be used in guiding the catheters but the support was limited when several bifurcations were passed, or in the case bifurcation with an acute angle was encountered.

In order to compare the support of conventional guidewires and our PEEK-based instruments, measurements of the flexural rigidity were performed. A 0.035 in. Glidewire from Terumo (Tokyo, Japan) was selected since it is one of the most used guidewires for navigation in the peripheral anatomy. The bending stiffness of the shaft was measured with a dual-cantilever setup and the average

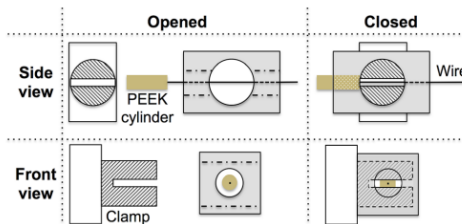


Fig. 4 Side and front view of the clamp of the wire: when placed, the clamp restrains the PEEK cylinder that is connected to the pulling wire

value was equal to $8.75 \times 10^{-4} \text{ N m}^2$. This value was compared to the theoretical flexural rigidity of the PEEK tube used in the design that was calculated by multiplying the material's modulus of elasticity, E (Pa) (or Young's modulus) by the second moment of area relative to the neutral plane of bending, I (m⁴). For a tube, the second moment of area is defined by Eq. (2), where d_o is the outer diameter and d_i is the inside diameter (both in m),

$$I = \pi(d_o^4 - d_i^4)/64 \quad (2)$$

In the case of our PEEK tube, $d_o = 0.78 \text{ mm}$ (0.031 in.) and $d_i = 0.2 \text{ mm}$ (0.0078 in.), and $E = 3.5 \text{ GPa}$. This gives a flexural rigidity of $6.33 \times 10^{-5} \text{ N m}^2$, which is more than ten times lower than the Terumo guidewire of the 0.035 in. system. Therefore, it is assumed that even with the PE shrinking tube, the guidewire described in this article presents a flexural rigidity that is significantly lower than conventional guidewires.

Steerable Tip. The dimensions of the steerable tip were defined following Eq. (1), in relation to the target vessel (Req.2.2) under the assumption that the tip would adopt a round shape when actuated. After assembly, measurements were performed in order to validate the model. The extremity of the tip to shaft dimension, equivalent to D_v , was measured for all possible angles (α). The tip was bent from 30 deg to 120 deg (Req.2.1) but it was observed that the tip was so flexible that it was also possible to steer it further. With the span of the slider of the handle as limiting factor, the maximum bend that could be reached was 253 deg. The force that needed to be applied on the wire to obtain this angle was 1.7 N.

It was possible to actuate and control the tip when the shaft of the instrument was looped one or even two times (Req.2.3) with a radius of about 6 cm (2.4 in.). It was also observed that the tip was not reaching its absolute straight position, but remained in a bent position with an angle of 30 deg when the wire actuating the tip was released. This effect was not limited by the length of the wire, but due to the mechanical properties of the material of the tip.

The position of the extremity of the tip was measured in two series for the whole range of actuation (30 deg; 253 deg): The distal extremity of the shaft was taped to a board, just below the connection with the flexible tube (Fig. 5). The handle was used to actuate the tip for angles between 30 deg and 253 deg. Special care was taken to assure that the bending plane of the deflectable tip was parallel to the board so that the movements of the tip were not restricted. The position of the extremity of the tip was marked by a point on the board for the entire range of angles that was tested. The board was then scanned and the angle of actuation and tip to shaft position, equivalent to the vessel diameter D_v , was measured for each point using Solidwork2010 (Dassault Systèmes, Vélizy-Villacoublay, France). Thirty-six points were measured for the first measurement series, and 29 for the second. The measured

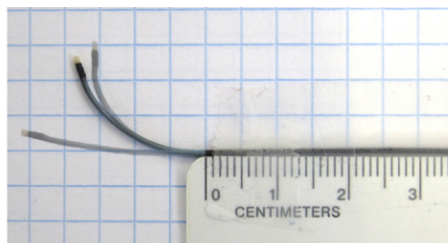


Fig. 5 Measurements setup: the base of the deflectable segment was taped to the board and the tip was actuated; each position of the tip was measured (overlay of three pictures with three distinct positions of the steerable tip)

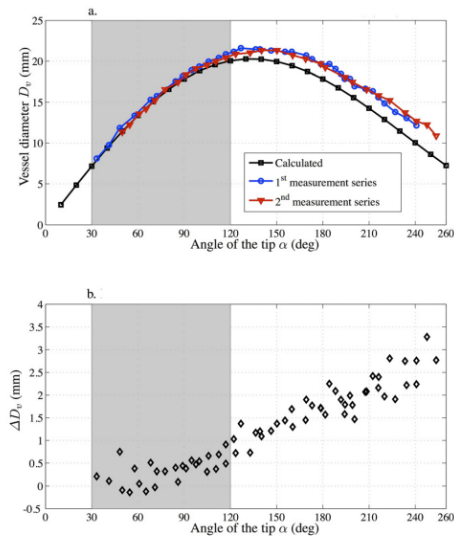


Fig. 6 Shape of the steerable guidewire tip compared to the calculated results for a 28 mm (1.1 in.) long tip. (a) Measured and calculated vessel diameter D_v . (b) Difference between the calculated and measured results ΔD_v .

data were compared with the values calculated with Eq. (1) (Fig. 6(a)). The calculated and measured curves progressively differed from each other with the angle (α) and the distance between these points (ΔD_v) were calculated (Fig. 6(b)).

In Fig. 6, it is shown that there is a systematic difference ΔD_v between the calculated and measured vessel diameter. Presumably, this is due to the fact that the shape of the tip did not adopt a perfect circular shape when actuated. Furthermore, the base of the flexible tube had the tendency to bend more than the rest of the tip. This was most likely caused by the nitinol rod that was not fixed to the shaft. Furthermore, the proximal part of the tip presented a bend with a smaller radius than the distal part (Fig. 7). The bigger the angle α , the more both effects were observed. Other parameters, such as the measuring method ($\pm 0.5 \text{ mm}$ (0.02 in.)) and the fact that the tip did not exactly bend in the plane had only minor influences on the results. Nevertheless, the experimental results were close to the calculated ones, with a maximum measured deviation of 3.3 mm (0.13 in.) for an angle of 248 deg. In the range of interest, from 30 deg to 120 deg the mean deviation was 0.3 mm (0.011 in.), and the maximum deviation 1 mm (0.039 in.) for 117 deg (20.9 mm (0.82 in.) measured versus



Fig. 7 Inhomogeneous bending of the tip for a 180 deg angle. A sharp bend was observed at its base (red circle), and the proximal and distal part of the tip presented two radii of curvatures (white arcs of circle drawn over the tip).

19.9 mm (0.78 in.) calculated). The observed deviations were small, considering the limitations of the measurement method.

Handle. One slider and two clamping mechanisms were used in the design of this handle. No damage was observed on the guidewire, wire, and shaft, even after multiple uses and tests (Req.3.3). No tool was needed to assemble and detach the guidewire from the handle (Req.3.1), and only one hand was required to drive the tip (Req.3.4). After a few attempts and while wearing standard latex gloves, less than 30 s were required to connect the handle and about 15 s were needed to detach it (Req.3.2). To assemble the guidewire on the handle, the steps described in Fig. 8 were followed. Detachment requires the release of the Dyneema wire and the shaft from their clamp, and to remove the shaft of the lumen of the handle.

When the handle was connected, the steerable tip was driven via a simple and efficient friction-based slider. Dry or wet, this slider held any position of the tip (Req.3.5). Neither the handle, nor its parts were broken or lost. With its fast and easy way to connect/disconnect and to use, the handle met all the predefined requirements. However, special care was taken not to kink or break the shaft of the prototype, as it was particularly vulnerable to such damage at the exit of the handle.

Biocompatibility. In our case *biocompatibility* (Req.4) corresponds to *biocompatibility of short-term implantable devices* as the prototype was designed to be placed within the vascular system only for the short period of time needed to perform diagnostic or treatment [18]. PEEK, PE, Dyneema, nitinol, and flexible tube, as part of the shaft and steerable tip, will be in contact with blood.

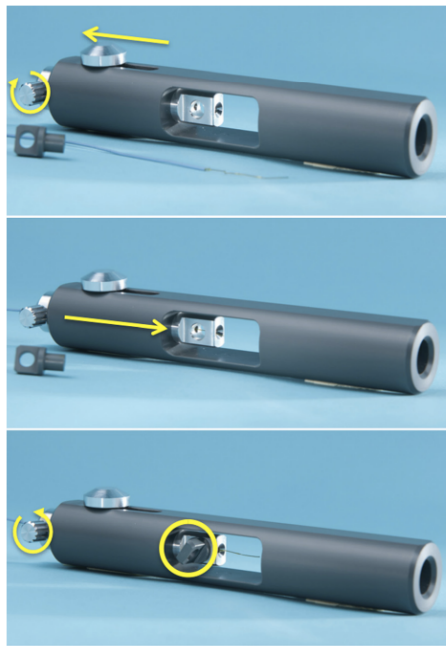


Fig. 8 Assembly of the guidewire on the handle: place the slider in front position and open the front clamp (top), align the PEEK cylinder with the shaft and place the distal part of the guidewire inside the lumen of the handle (middle), and place the Dyneema wire and the PEEK cylinder into the clamp, fasten the shaft (bottom)

In order to prevent future limitations, all materials were chosen from a list of possible biomaterials that are widely used for various short-term and/or long-term implanted devices, which are in contact with blood (i.e., catheters and guidewires, or sutures, stents, and stent-graft). Unfortunately, the materials that the tube of the flexible tip consisted of, were not specified by the manufacturer. However, this tube was part of a commercially available and widely used biocompatible microcatheter. We therefore assume that the material is suitable for endovascular interventions.

MRI Compatibility and Visibility. Only polymers and non-magnetic metals were selected for the steerable guidewire. Polymers, as nonmetallic materials, are neither conductive nor magnetic (Req.5.1). A 25 mm (0.98 in.) long nitinol rod was the only metal part of the design (Req.5.3). Nitinol is a nonferromagnetic metal that is known to cause minor artifacts [13,19]. However, even with the presence of this rod, the tip of the prototype was not visible on real-time MR images (Signa HDxt, 1.5T, GE Medical System, Waukesha, WI, US). Therefore, a few FeO particles (1–6 μm diameters) were glued to the tip, and placed above and below the steering part. These particles produced small artifacts that did not shade the anatomy (Req.5.2). They were used as passive markers during real time MR scans (Fig. 9). The diameter of the markers was 0.7 mm (0.027 in.) for the proximal and 1.2 mm (0.047 in.) for the distal one (FSPGR sequence, slice thickness 5 mm (0.19 in.), 1fps). The handle was made of nonferromagnetic materials, polymers, aluminum, and nonferromagnetic stainless steel (Req.5.4). It could therefore be safely used in the MR room and outside of the bore during scans.

Discussion

In the current study, we designed and evaluated a 1.60 m (5.3 ft) long PEEK-based prototype with a steerable tip that could be bent from 30 deg to 250 deg. This first proof of concept met the main requirements that were defined. The steerable guidewire was tested in combination with conventional catheters for simple navigation tasks in a vascular model. When needed, the handle could easily be attached/detached from the guidewire without inducing any damage to the shaft and it was visible on real-time MR images without producing large artifacts. The current design is therefore a promising proof of concept that, in addition to meeting the requirements, presented several favorable features.

It was still possible to actuate and to accurately control the tip even when the core of the prototype was looped one or two times. This shows that the friction between the wire and the lumen of the PEEK tube was low enough and did not limit the translations of



Fig. 9 MRI scan (fGRE RT, slice thickness 12 mm (0.047 in.), 1 fps) of the steerable guidewire in a vascular model (transcatheter valve simulator heart model, Elastrat, Geneva Switzerland) with pulsatile flow. The two passive markers (white arrows) indicated the localization of the steerable tip that was lying in the thoracic artery, above the celiac trunk.

the wire. The control of the tip was also not restricted by the bends that resulted from the turns taken in the vascular model. Consequently, it seems possible to make even longer functional prototypes, close to the length of the longest conventional guidewires of 300 cm (9.8 ft) [4]. Another promising feature was that the shaft of the steerable guidewire was presenting no buckling when it was steered.

The tip could be bent far beyond the required angle of 120 deg with a maximum of 250 deg. Such extreme angles are usually not used during endovascular procedures and are probably not of interest for navigating a task since it is difficult to advance wires in the opposite direction of the push. However, the possibility to adopt this shape is interesting from another point of view as it is a shape that is similar to the tip of conventional “atraumatic J-tip” guidewires. According to literature [4], such J-tip guidewires can be used for difficult situations, such as for passage through an occlusion or a previously stented arterial segment. Presumably, J-tip guidewires are less likely to pass under the mesh of a stent or create a false passage. The J-tip guidewire can also be used to recross a lesion when the guidewire is no longer across it and more endovascular interventions are required. The particular shape of the tip would avoid entering a newly created dissection plane. Indeed, it seems reasonable to think that such a tip would present less risk of damaging a vessel wall (e.g., dissection, perforation), detaching calcification than a straight or curved tip configuration. This is especially of interest for our prototype that has, for the time being, a hard PEEK cap at the distal part of the tip. Even though the tip may buckle when resistance is encountered, a soft tip should be implemented in the near future to reduce the possibility of inflicting damage to the vessel.

The length of the tip was chosen as 28 mm (1.1 in.) but, in principle, one could optimize it according to Eq. (1) with a specific max D_v and range of angles. This offers the possibility to investigate the use of various tip lengths in relation to different target interventions or different vessel diameters of the peripheral anatomy. In case no optimized length could be found for a wide use, a set of steerable instruments could be created, with each designed for a specific intervention or target. Furthermore, in order to make the tip more efficient to enter a bifurcation, the stiffness of the tip should progressively increase from the proximal part until the distal end of the tip. Conventional selective guidewires are usually designed in this way.

With the choices of material for both the guidewire and handle, the current prototype was safe to be manipulated in vitro, in an MR environment, showing promising results. However, we cannot classify this prototype MR-safe or MR-compatible yet; the tip contained a nitinol rod, an electrical conductor, so that the risk of radio frequency heating due to pickup of radio frequency energy in an MRI applies. It is known that this effect is more important with long wires [9,10,13] and it was observed that heating at the tip could be minimized by using wires of less than 13 cm (5.1 in.) long in aqueous soft tissues at 1.5 T [16]. Therefore, our prototype with a flattened nitinol rod of 25 mm (0.98 in.) in length should present minimum heating. However, we plan to run all the required tests and simulations in order to evaluate possible heating effects, as well as the MR compatibility of a final device and classify it as MR-safe, MR-conditional, or MR-unsafe.

We are aware that a number of additional requirements will have to be met in order to guarantee clinical applicability of the prototype. A PEEK-based prototype may not meet all requirements, but this material has several mechanical properties that are satisfactory in terms of stiffness, pushability, and torquability for a first prototype and proof of concept. Furthermore, PEEK had already been used to overcome the safety problems associated with regular guidewires in an MRI. A PEEK-based guidewire was developed and tested by Meke et al. [10] to replace the metallic core in a 0.035 in. MR-compatible guidewire. The torque of this prototype was described as meeting clinical requirements, and the guidewire could be used with any 0.035 in. compatible catheter, and was well-suited for clinical application due to an absence of

the risk of core fracture. However, one of the limitations of this PEEK-based prototype was its lack of support for catheter guidance [14]. Similarly, catheters could only be guided on the shaft of our prototype after the PE shrinking tube was placed on the PEEK. This thin layer of PE made the guidewire shaft stiffer so that catheters could slide over it and the shape of the catheter was straightened.

Another issue is with the shaft of the prototype. This part, primarily constituted of PEEK, was not completely straight, thereby impairing in some cases the manipulation during the navigation task. This effect had also been observed by Kos et al. [14]. PEEK tubes are often stored and delivered rolled up. It is possible to apply a heating treatment on the PEEK tube to straighten it. However, this treatment would be of short effect if one would store the instrument rolled up again, as is done with most guidewires.

In order to overcome some of the mentioned issues, a fiber reinforced material is most likely a suitable alternative for the core of the prototype. Such composite materials give the possibility of having a final product with characteristics different from the individual components. The use of fiber-reinforced material in an MRI-compatible guidewire prototype, among which are the ones developed by Bakker et al. [20] or Peeters et al. [21], have been described as promising [17]. Kos et al. [14] developed in 2009 an MRI-compatible guidewire composed of fiberglass fibers in PEEK.

An MRI-compatible steerable guidewire has to match many requirements to be clinically applicable. The key features are safety, visibility, pushability, device support, and torque control. This study aimed at the development and evaluation of a first design that targeted all these requirements. As such, the proposed design is a successful proof of concept that opens the way toward the design of an MRI-safe guidewire with improved maneuverability at the tip.

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