Femoral Lead Extraction Snaring Tool

Final Report

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Executive Summary

Femoral lead extraction is a technique used for removing old or fractured pacemaker leads from the heart through the femoral vein. This is accomplished by implementing a catheter with a snaring tool into the femoral vein, maneuvering it to the location of the lead near the patient's heart, and grasping and removing the lead using a combination of the snaring tool and fluoroscopy. Phillips currently lacks a snaring tool that can extract leads through the femoral vein. The UCCS team was contracted by Philips to develop an innovative design for Philips' femoral lead extraction portfolio.

The team devised a set of requirements to focus on during the design process. The snare needed to comply with densities that would allow for it to be presented clearly on the fluoroscopy screen used during the femoral lead extraction procedure. The snare had to be atraumatic to tissue to prevent any unnecessary harm to the patient. The design of the tool had to be unique and innovative when compared to other products currently on the market. The sheath portion of the tool had to be deflectable and maneuverable to make the lead extraction process easier. The snare material had to be flexible to ensure the snare was easy to manipulate when attempting to grasp the lead. The design had to be easily modifiable to accommodate for different sized leads and patient heights. The design had to be manufactured in a manner that adhered to all Sterilization and Biocompatibility Standards. The snare had to effectively grasp the lead for removal as well as disengage for repositioning and abandonment if necessary. Finally, the tool had to include simple controls so that the physician could use the snaring tool by themselves.

Multiple designs were considered. From designs that utilized basic Chinese Finger Trap technology to designs that would use pumps and suction to grasp the lead. It was decided that a spring could be utilized to create a snare that would comply with most of the parameter set out in the project's planning stages. The spring design would allow for deflection, maneuverability, flexibility, and grasping and release of the lead, all while allowing the physician to control the lead with ease and great visibility on the fluoroscopy screen.

The final design for the tool includes a spring snare, which is composed of a compression wire, compression plate, and spring. The design also includes a handle with a plunger on the bottom end to compress the compression wire/plate, a side-mounted knob that is used for moving the spring snare in and out of the outer sheath, as well as knobs to deflect the outer sheath. Finally, the design includes inner and outer sheaths which are used for maneuvering the snare through the human body.

Throughout the testing process, the spring rate, maximum load (load to full compression), and other spring specifications were analyzed to determine how they would interact with the grasping force, or in other words, the force that caused the lead to slip out from the coils of the spring. The tests concluded that a maximum load of the spring between 5 to 10 lbs was necessary to ensure the grasping force of the snare was greater than 5 lbs.

Based on the test results, an ideal, final spring design was devised, and a prototype was created. The prototype was used to exemplify the capabilities of the spring snare, with controls that would retract and release the spring snare from the outer sheath, to deflect the outer sheath, and to compress the spring around the lead. The custom order spring used in the prototype, that was supposed to be the ideal spring for the femoral lead extraction procedure, did not have the desired max load (force to full compression) and did not grasp the lead as well as intended. The prototype did suffice for the project, as it met nearly all the project requirements, but did not perform ideally in testing. The ideal spring for this snare would be a spring 1" in length, have an outer diameter of .21", have a coil displacement of 0.09", be made of stainless steel, and have a maximum load between 5-10 lbs. Additional custom springs could be purchased and tested to ensure they suffice for removing leads with the femoral approach.

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Introduction

Philips is a technology company that strives to make the world healthier and more sustainable with innovative solutions to some of the world's most difficult problems. Philips serves both professional and consumer markets all over the world in the health systems and personal health areas.

Electronic Implantable Devices* (EID) are utilized for patients that have irregular heart rhythms. Leads* are implanted inside the body through veins and connect the EID's to different chambers of the heart, allowing for electric current to be effective in treating the irregular rhythms. The leads are accessible through the chest pocket that is implemented with the EID.

The leads can become problematic as degradation or tissue growth occurs. The latter can be solved by utilizing mechanical or laser cutting sheaths* that separate the tissue from the lead. Degradation can cause the lead to fall apart and prohibits access through the chest pocket. When this happens, the femoral approach for lead extraction must be utilized. With that, one of the projects that Philips is working on in these areas is their own product in the field of femoral lead extraction.

The leads can be difficult to extract during femoral lead extraction. This procedure is only utilized when the leads are completely separated from the pacemaker at the chest pocket, rendering it inaccessible unless the femoral vein is utilized. The femoral* extraction process begins in the femoral vein where the snare apparatus is inserted and pushed through the vessel* to the Inferior Vena Cava* (IVC) near the right atrium* of the heart. Once the snare is in position near the lead(s), the electrophysiologist* operating the snare uses fluoroscopy* to position the snare more directly over the lead(s). The operating physician then attempts to grasp the lead with the snare, and once it is secure in the snare the lead is pulled out through the entry hole in the upper thigh.

Fluoroscopy is the only source that the physician can utilize to visual the lead once it enters the patient's body and becomes situated inside the blood vessel. This technique utilizes low-dose x-ray imaging to get visuals of the upper right atrium. The x-rays are pulsed, intermittently, through the patient to limit the patient's exposure to radiation. Fluoroscopy creates a 2-D image due to contrasting densities. Since the image is 2-D, it creates significant challenges when trying to remove a lead from the body. It is often difficult for a physician to know where the snare is relative to the lead, as it is impossible to tell if it is behind, in front, or right on top of the lead.

The figure below shows an image of fluoroscopy taken during a femoral extraction procedure that utilized the Needle's Eye Snare, a snare design currently on the market. In this picture, the Needle's Eye Snare, the Atrial Lead, the Ventricular Lead and the patient's spine are distinguishable.

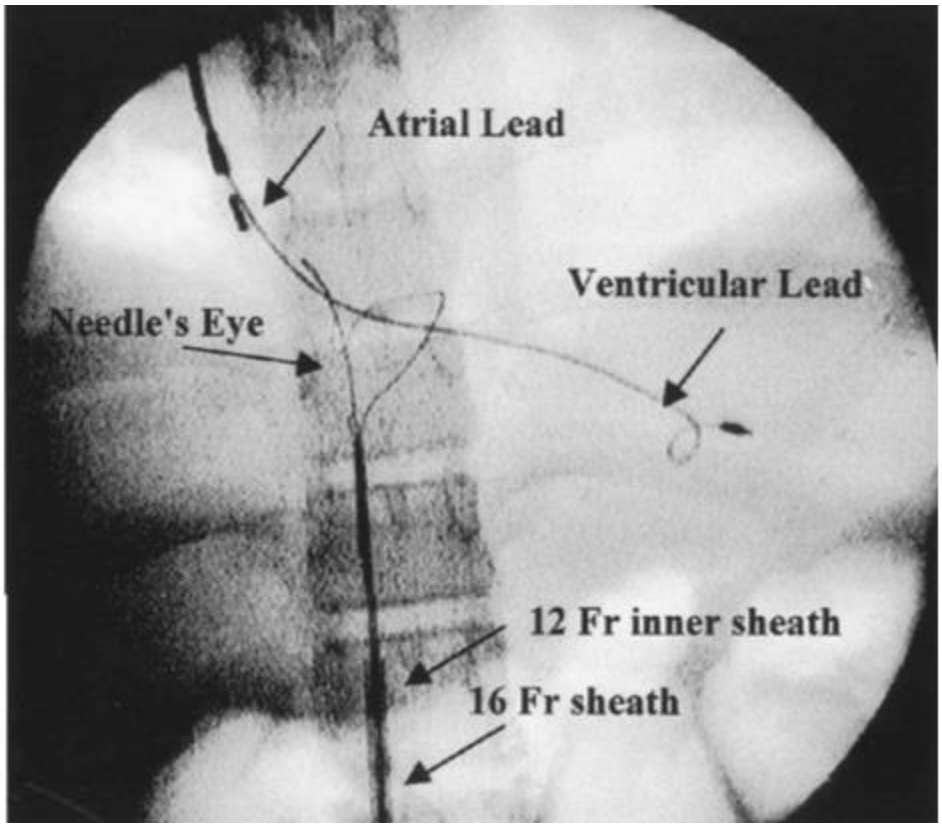


Figure 1: Example of a Snare and Lead in a Human Body Under Fluoroscopy.

All current designs, that are atraumatic to tissue, utilize 90-degree and multiple loops to eliminate sharp and blunted edges in the snare. Some of these designs are highlighted in the figure below. The figure below clearly shows that none of these snares would lead to any traumatic issues in the heart. To keep these designs from having rough surfaces, they are often polished or smoothed in the manufacturing process.

Figure 2: Industry Leading Snares Currently on the Market that are Atraumatic to Tissue.

Although the products currently on the market are all atraumatic to tissue, there are several downfalls to them. Since the most widely used snares utilize a circular loop design, it is difficult to visualize under fluoroscopy, as it is not easy to tell if the loops are around the lead. The loops may become tangled when trying to snare the lead, rendering the snare ineffective at grasping the lead. Furthermore, the simple designs, such as the Amplatz Gooseneck Snare, require additional tools to grasp the lead, as it cannot grasp it without another wire to wrap around the lead. Many products do not have a flexible sheath, which helps for maneuvering the snare around the lead. These drawbacks create a frustrating environment for the physician, as the process becomes a guess and check approach to lead extraction, making for a long and costly procedure.

Philips does not currently have an extraction tool to utilize the femoral approach for lead extraction, and Philips is wanting a competitive product to compete against other products in the market for this procedure. Philips wants a unique and innovative design that capitalizes on the positive aspects of the current products, while changing the design so that the shortcomings of the current products are eliminated. Philips has contracted UCCS to design their tool for femoral lead extraction. Team Phyllis has chosen to solve this problem by utilizing a spring type snare* apparatus with the ability to compress around the lead.

Problem Description

To begin the design process, project requirements were devised based on sponsor, physician, and patient feedback, as well as scholarly articles and competitive analysis related to femoral lead extraction. The following section was used to justify the requirements devised for the design process. Furthermore, engineering parameters were created to allow for a quantitative measure of success in satisfying all the project requirements. The parameters were also justified with their corresponding project requirements.

Requirements

Easily Distinguishable Under Fluoroscopy*:

Requirement Justification:

When the physician can easily distinguish the snare under fluoroscopy, the procedure will be completed in a shorter amount of time. This is overall better for the patient since their exposure to radiation is limited and the snare apparatus has a lower chance of being traumatic to tissue.

For the snare to be easily distinguishable, it would not mimic the shape of leads, or other natural body parts as it could lead to confusion for the physician. To prohibit the chosen snare design from being confused with the patient's spine or leads, densities and certain geometric parameters should be considered.

The density* of the material used for the manufacturing of the snare must be 6,000 to 20,000 kilograms per cubic meter (kg/m^3). These number were chosen because they would allow for the metal to be much denser than bone and other material found in the upper right atrium. Fluoroscopy generates a clearer and darker visual of metal when it is denser. A density of 6,000 kg/m^3 will generate the lowest amount of visibility that a physician is comfortable with. While there shouldn't be a limit of 20,000 kg/m^3 for visualization purposes, the density also affects the flexibility of the snare. Any metal over 20,000 kg/m^3 would result in a snare that lacks the flexibility to maneuver the upper right atrium and grasp the lead.

The density of the material used for the catheter must comply with a range of 2,000 to 2,500 kg/m^3) to allow for the deflection capability to be built in to the snare apparatus and to allow for the physician to have a contrast in materials from the snare. The high range of the density would be the densest material that would be visually different from the snare material.

Radiopaque bands are used to be visualize the end of the catheter with fluoroscopy imaging. It is important, in selecting the materials for the radiopaque bands, to have densities that are clearly different than blood and internal organs when using fluoroscopy imaging. The interval for the densities of the radiopaque material were defined by platinum and similar materials.

Corresponding Engineering Parameters:

- The density* of the material used for the manufacturing of the snare must be within the range 6,000-20,000 kilograms per cubic meter (kg/m^3).
- The density of the material used for the catheter must be within the range 2,000-2,500 kg/m^3.
- The density of the material used for radiopaque band on the outer catheter must be within the range 20,000-25,000 kg/m^3.

Atraumatic*:

Requirement Justification:

This is the most crucial part of this design. If the snare becomes traumatic at any point in the procedure, it will become inferior to all other designs. A physician's concern is the health and safety of their patient. If an apparatus does anything to interfere with this, they will not use it.

As a precaution, if the walls of the heart are impacted from a lead extraction procedure, open heart surgery could be required. There have been cases where permanent injury or death have been a result of traumatic tissue damage in the upper right atrium of the heart. To prohibit the snare design from being traumatic to tissue, blunt and sharps edges and rough surfaces must not be incorporated.

The Root Mean Square* (RMS) of the surface roughness of the snare material should be less than 2.00 nanometers (nm). Complying with 2.00 nm would prohibit the design from having any abrasions or scratches with the type venous walls. The value for RMS of surface roughness was determined by looking at current materials used in the femoral lead extraction process such as stainless steel, titanium, and nitinol (all used in medical devices), which had an RMS value that ranged from 1.5 to 2 nm. The snare material can't be too smooth, so the surface roughness just needs to be less than 2 nm.

Little is known about quantifying the traumatic effects of a snare apparatus. After conducting a competitive analysis, it was concluded that most snare apparatuses for the femoral approach to lead extraction comply with the range of 80-420 GPa regarding the modulus of elasticity. This range promotes flexibility within the snare, minimizing traumatic properties within the snare.

Corresponding Engineering Parameters:

- The Young's Modulus of the material used for the snare must be within the range 80-420 Gigapascals (GPa).
- The RMS of the material used for the snare must be less than 2.00 nanometers (nm).

Unique Design:

Requirement Justification:

Philips wants their own, unique design for femoral lead extraction that sets them apart from the competition currently in the field. It would not be possible to be competitive in the field if the design was like a product already on the market. Therefore, it is necessary to create a completely new, unique, and innovative design for the process of femoral lead

extraction. It was difficult to define a quantitative property of uniqueness and innovativeness, so the single parameter that was set for this requirement was that the design was unique enough to be patentable by Philips. By obtaining a patent, the snare design could be used to compete against other products, as well as stand out from the other products on the market, which are all like each other in some manner.

Corresponding Engineering Parameters:

- The design of the snare/sheath must be patentable.

Deflectable* and Maneuverable*:

Requirement Justification:

Deflection in the sheath would allow for the snare to move so that the physician could access awkwardly placed leads. This would be beneficial for patients since their extraction procedures could potentially be shortened since the physician should be able to grasp the lead quicker. The physicians would also benefit since they would only have to control a single apparatus, rather than having to use separate deflection and snare apparatuses.

Based on current flexible sheaths, the Young's Modulus of the material used for the sheath must adhere to a range of .4-.6 GPa. This would allow for the sheath to be flexible enough to be able to deflect and maneuver, while maintaining enough strength to prevent buckling under the forces associated with the procedure.

Corresponding Engineering Parameters:

- The Young's Modulus of the material used for the sheath must be within the range .4-.6 GPa.

Flexible* Snare Material:

Requirement Justification:

One reason why the snare material is flexible is to eliminate any traumatic risks. Flexible materials are less likely to cause damage to the walls of the heart or the veins.

The snare must be able to function properly after being released from a sheath, where it will be deformed slightly due to the tight fit between the sheath and snare. Therefore, the snare must be flexible enough to avoid plastic deformation when inside the sheath.

To ensure that the snare is easy to manipulate to compete with current products, the Young's Modulus of the snare material must be between 80-420 GPa, as this is the range present in current products.

Corresponding Engineering Parameters:

- The Young's Modulus of the material used for the snare must be within the range 80-420 Gigapascals (GPa).
- Snare must fit through and function after being retracted in a sheath with an outer diameter within the range of 11-12 French (Fr) or approximately 4 millimeters (mm) without plastically deforming.

Easily Modifiable to Accommodate Different Snare Lengths and Diameters:

Requirement Justification:

The length between the entrance of the femoral vein in the thigh and the upper right atrium differs from person to person, since the snare is used for patients of different heights and ages, from children to adults. To accommodate for this, the length of the sheath/snare system must have varying lengths, between 90-120 cm.

The femoral vein is the smallest vessel that the snare/sheath will be going through in the lead extraction process. To comply with the diameter of the femoral vein, the guiding catheter must not exceed 16 Fr in diameter.

There are different sized leads in different patients, meaning they have different sized diameters. To ensure that all lead sizes can be grasped by the snare, the snare must have the capability to grasp all lead diameters. To quantify this, the snare must have a grasping diameter of between 15-20 mm.

Corresponding Engineering Parameters:

- The length of the sheath/snare system must be within the range 90-120 cm.
- The guiding catheter must be no larger than 15-16 Fr (5 mm) in diameter.
- The snare must have a grasping diameter of between 15-20 mm.

Manufacturable*:

Requirement Justification:

The snare needs to be manufacturable. If something can't be manufactured, there is no way for it to be produced and applied in a competitive application. Furthermore, since the procedure is an invasive medical procedure, the materials used in manufacturing must adhere to Sterilization and Biocompatibility Standards, which means the manufacturing process must ensure that the materials are sterile when they are shipped out for use.

Corresponding Engineering Parameters:

- Material used for snare/sheath must adhere to Sterilization and Biocompatibility Standards.

Snare Effectively Grasp Leads for Removal:

Requirement Justification:

The main use of the snare apparatus is to remove the lead. There is no need to put a patient under stress with an intravenous procedure and risk open heart surgery if the medical device doesn't work properly.

To ensure all diameter leads can be easily grasped, the snare must have a variable grasping diameter between 15-20 mm. Furthermore, in order to ensure the snare is flexible enough to successfully grasp a lead, the Young's Modulus of the snare material must be within the range of 80-420 GPa.

To ensure that the snare is resilient enough for clinical usage, the snare must fit through and function after being retracted in a catheter with an outer diameter of 16 Fr without plastically deforming. Furthermore, to ensure that snare does not break with the lead grasped, the snare must be able to withstand a pulling force of at least 5 lbs, which is the approximate amount of force experienced in clinical applications.

Corresponding Engineering Parameters:

- The snare must have a grasping diameter of between 15-20 mm.
- The Young's Modulus of the material used for the snare must be within the range 80-420 Gigapascals (GPa).
- Snare must fit through and function after being retracted in a catheter with OD between 16 Fr without plastically deforming.
- The snare must be able to withstand a pulling force of at least 5 lbs.

Simple Controls:

Requirement Justification:

The controls are the interface between the snare and the physician. The simpler the controls, the easier it is for physicians to use and the more competitive the design will be in market. The main goal for the controls to integrate the deflection capability into the same interface as the compression apparatus. This hasn't been done with any design currently on the market and it would revolutionize the controls for the femoral approach for lead extraction. Ultimately, the controls would be simple enough for the procedure if the extraction tool can be easily operated by one person.

Corresponding Engineering Parameters:

- Extraction tool can be operated with only one person, two hands.

Must Have the Ability to Disengage Lead:

Requirement Justification:

There are times when the snare may need to disengage for repositioning or abandonment. For example, some leads can become weak as a result of erosion. A weakened lead could snap when a snare grasps it. Disengagement of the lead will also allow the physician to abort the lead extraction procedure if the removal process would cause damage/harm to the patient. To ensure the snare is flexible enough to disengage the lead, the Young's Modulus must be within a range of 80-420 GPa.

Corresponding Engineering Parameters:

- The Young's Modulus of the material used for the snare must be within the range 80-420 Gigapascals (GPa).

Conceptual Design Evaluations

The team evaluated multiple designs to determine the most viable solution that would not only meet the sponsors requirements but exceed them. Over many brainstorming sessions the team came up with a few design ideas that were presented to Philips. The following section describes each design and how well each one satisfied the design requirements.

"Jaws" Design

The "Jaws" design would utilize two distinct rigid links with ridges that would add to the friction force when grasping the lead. This design wouldn't incorporate the deflection capability with the snare apparatus. The rigid links with ridges added concern about the design being traumatic to tissue.

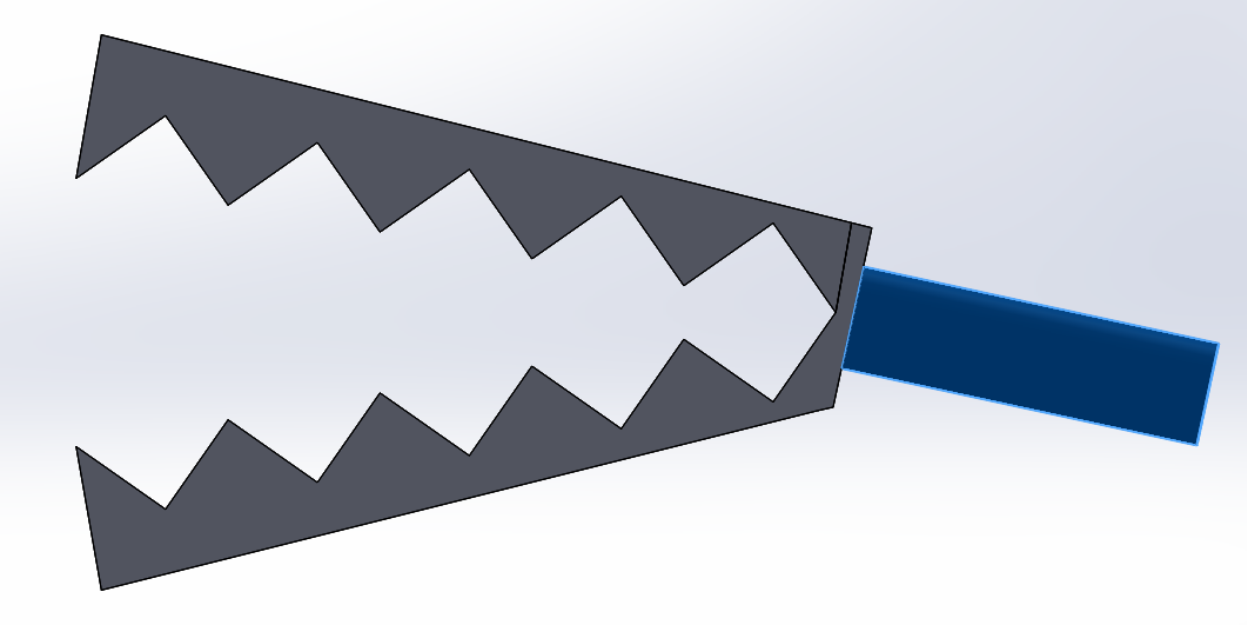


Figure 3: Initial Sketch of the Jaws Snare Design.

"Suction" Design

The "Suction" design would utilize a suction force to grasp the lead. The suction would be created from a pressure difference in the sheath. The implementation of this design would require a pump to create the pressure change.

The main issue of this design was the grasping capability of the snare. The suction force required to grasp a lead, which has a minimal surface area, would cause damage to the rest of the heart if it were achieved. Rather than grasping the lead, the suction would only pull the less dense blood into the catheter, rather than holding the snare long enough to extract it. Having an external pump to provide the suction would make the design extremely complicated and would not be practical.

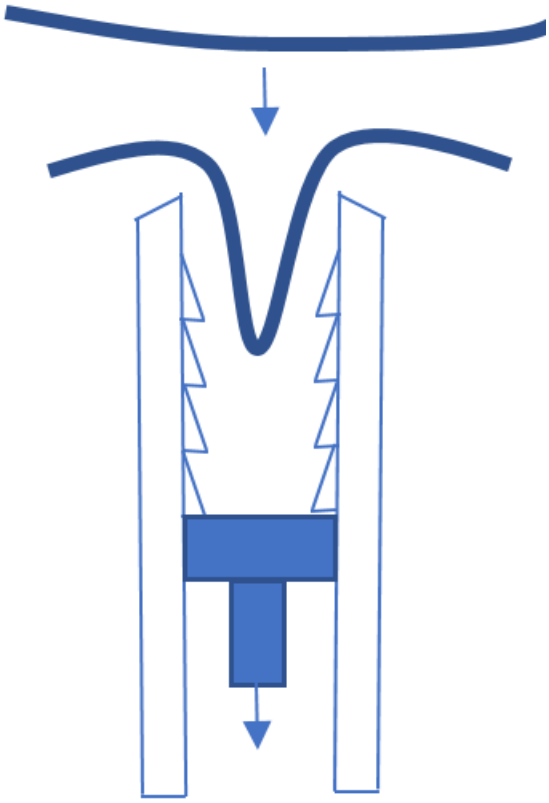


Figure 4: Initial Sketch of Suction Snare Design.

"Finger Trap" Design Elimination

The "Finger Trap" design would utilize a Chinese Finger Trap type concept to have a snare that would compress around the lead. Chinese finger traps are known to collapse when they experience a force in the horizontal direction, as shown in the figure below. The idea of this concept was to utilize the compressive characteristic of a Chinese Finger trap to grasp the lead.

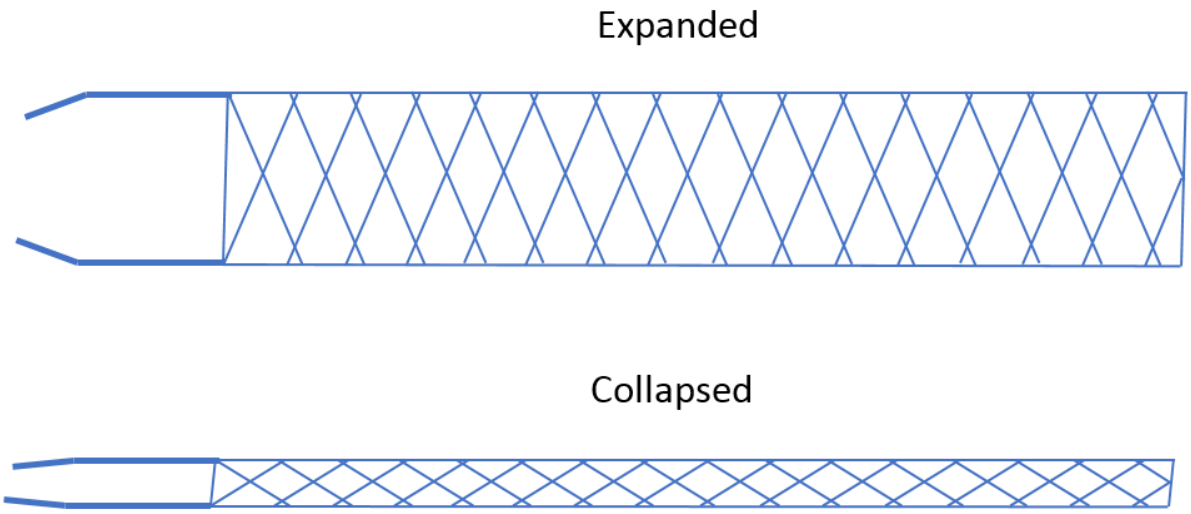


Figure 5: Initial rendering for the functionality of the Chinese Finger Trap Design.

"Spring" Design

The "Spring" design would utilize a spring that collapses to grasp the lead. The snare would need to be positioned so that the lead falls in one of the springs coils. Compression of the spring would be actuated via a compression wire that the physician would pull. If the spring reaches it maximum load, the grasping force should be large enough to remove the lead. A deflectable outer sheath would need to be implemented in the design to achieve the maneuverability necessary to position the snare.

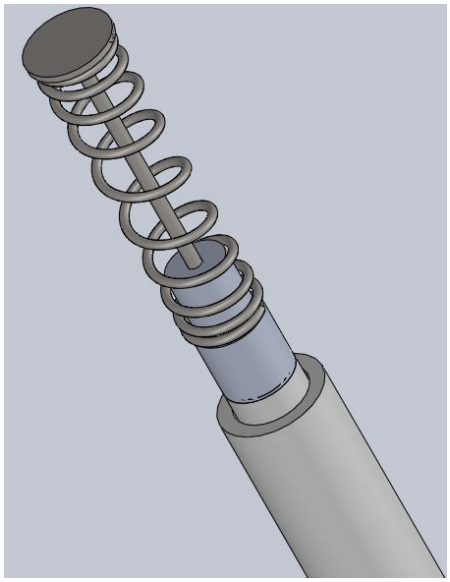


Figure 6: Rendering of the Spring Snare Concept.

Easily Distinguishable Under Fluoroscopy:

For the "Suction" design to be easily distinguishable a radio opaque band would need to be fixed to the end of the sheath since there would be no metal parts and catheters are typically made from a light density extruded plastic. The level of visibility that the "Finger Trap" design would have under fluoroscopy is uncertain. If the design could be composed of metal, it would be easily distinguishable. If plastic would be needed to create the design, the fluoroscopy wouldn't be effective in creating a visual and a radiopaque band would be needed.

The "Jaws" design would be easily distinguishable under fluoroscopy. Since the two-rigid links for the jaws would be composed of metal, they would show up clear on the fluoroscopy image. The two links wouldn't mimic any biological figures in the upper right atrium, so the physician would clearly be able to pick it out. The "Spring" design would also be highly visible under fluoroscopy due to both the material and geometric properties of the snare. For the snare to satisfy other requirements, it would be made of a stainless-steel alloy, which would be dense enough to appear on the monitor used by the physician. By using a spring, the snare would have a unique shape that would not be confused by the physician as a lead or any part of the body.

Atraumatic:

The "Jaws" Design would be traumatic to tissue. The teeth/ridges needed to add friction could potentially puncture the vein or the upper right atrium.

The "Suction" design would be atraumatic as similar tools are commonly used in medical procedures. The only concern would be that if a significantly large vacuum force were to be used, the tool would be difficult to control and may have the potential to tear away tissue. Both the "Finger Trap" design and the "Spring" design would be atraumatic to tissue. Neither design would have and sharp or protruding edges. The spring design would use a round wire to help ensure low risk of tissue damage.

Unique Design:

There is a design currently on the market known as the Alligator Snare, that mimics the "Jaws" Design. In this design, multiple rigid links are utilized to grasp the lead, with ridges/teeth to add friction. Therefore, if such a design was used the "Jaws" design would not be unique.

There are no snares, currently on the market, the utilize either the "Suction", "Finger Trap", or "Spring" design. Each design would take a unique perspective on femoral lead extraction. It is possible that the "Suction" and "Finger Trap" designs have not been utilized since they may not produce sufficient forces to grasp the lead. Springs are

typically used to resist forces on a system, not grasp and hold on to something between the coils.

Deflectable and Maneuverable:

The delectability and maneuverability of the "Jaws" design was a concern. The jaws would be significant in size and could limit the amount of space in the right atrium where they could be maneuvered. It is unknown how deflectable and maneuverable the "Finger Trap" design would be. The design would grasp leads by collapsing around them. When it is in the collapsed position, there would be a concern that the snare might be difficult to move and deflect.

The "Suction" and "Spring" designs could easily accommodate a built-in maneuverable sheath system. The controls needed for this would be similar to what is commonly used in other medical devices.

Flexible Snare Material:

For the "Jaws" design, the snare material would not be flexible. The jaws would need to be rigid, prohibiting flexible material from being used. Since the "Suction" design would utilize a suction force to grasp the lead, having a flexible snare material would not apply to this design.

The "Finger Trap" design would rely on utilizing flexible snare material. Whether metal or plastic is utilized, the snare would need to collapse to effectively grasp the lead. If the material wasn't flexible, the snare would be stiff and wouldn't be able to obtain a grasping force. Although stainless steel isn't a flexible material on its own, a spring would give the "Spring" design reasonable flexibility. The gaps between coils and wire thickness for the spring would allow the spring to bend and compress relatively easily.

Easily Modifiable to Accommodate Different Snare Lengths and Diameters:

All the designs would be able to easily accommodate different snare lengths and diameters. The jaws in the "Jaws" design would need to be maximized in size to ensure that the friction force on the lead can result in proper removal. This would mean that any sized lead could be grasped. The snare would not be impacted by the length of the apparatus, so this design would accommodate different sheath lengths. The "Suction" design workstation could come with multiple sheaths having different diameters that would accommodate different sized leads. Similarly, the sheath length could vary as needed and would be easily replaced with a universal fitting at the base of the handle. The "Finger Trap" would be the entire length of the sheath, if needed. The diameters could also be varied, in theory, but they could alter the effectiveness of the grasping force or ease of lining the lead up with the snare. The "Spring" design would be easy to modify for

different conditions since it would use a spring for the snare. The length, outer diameter, and distance between coils of the spring could be easily adjusted to fit all lead and sheath sizes.

Manufacturable:

Each design would be manufacturable as there would be no new processes necessary to make any of the parts. The "Jaws" design was like a similar design that is currently being produced. Rigid links are commonly used for grasping in a multitude of other purposes, making the manufacturability of such devices attainable. The "Suction" design was developed so that off the shelf sheaths could be used. Vacuum pumps don't not present an issue with regards to manufacturability so such a system would be easily attainable. The "Finger Trap" design utilized a concept that is currently being mass produced for entertainment purposes. Issues for this design could arise if different or stiffer materials were to be used. Spring production has become one of the easiest manufacturing processes to complete due to the extreme number produced daily. Making mass amounts of springs could be easily accomplished and completing the required welding would be automated with laser welding as well.

Snare Effectively Grasp Leads for Removal:

In the "Suction" design, the contact between the lead and the sheath would need to be perfect in order to achieve a large enough force to remove the lead. If there was a gap between the lead and the sheath, then the less dense blood would flow into the catheter. It was believed that this snaring method would therefore not effectively grasp leads for removal.

The "Jaws" design would allow for effective grasping of the lead for extraction. The rigid links with teeth would make the grasping force the biggest strength for this design. In theory, the "Finger Trap" design would be capable of grasping leads for removal due to the axial force applied, however Chinese finger traps weren't designed for grasping objects. The effectiveness of the grasping force from this design would be uncertain. The "Spring" design would effectively grasp leads for removal. Once a lead would be positioned into one of the springs coils, the spring would be fully compressed and would provide enough grasping force to remove the lead.

Simple Controls:

The controls for all the designs would be straightforward and simple. The rigid links on the "Jaws" design would have 1 degree of freedom, collapsing and expanding, which would require one input. The controls on the "Suction" design would be very familiar to physicians as deflection tools are commonly used. The only other control needed would be to turn the suction on and off. The "Finger Trap" design would solely rely on collapsing

and expanding the snare, utilizing one degree of freedom and requiring a single input. In the "Spring" design, there would be only two major controls for the physician to manipulate: pulling on the compression wire to collapse the spring to capture the lead and relax the compression wire to expand the spring and release the lead. The deflectable portion of the tool, as stated above, is commonly used.

Must be Able to Disengage Lead:

The "Jaws" design would be able to easily disengage by simply moving the links to the open position. This requirement would be easily met for the "Suction" design as the suction force could simply be turned off by a physician and the tool could promptly be removed from the patient without any complications. If an elastic material would be utilized in the "Finger Trap" design for the composition of the snare, disengagement would be possible. The "Spring" design would allow for the lead to easily be abandoned, if needed, by relaxing the tension on the compression wire.

To determine which design was the most viable option, a decision matrix was created, which allowed the team to quantitatively determine the best design. Each requirement was given a number based on importance, then each design was ranked based on its ability to satisfy the requirements. The design that would best satisfy all of the requirements would have the largest score and would therefore be the design of choice. Ultimately, based on the quantitative results of the decision matrix, the "Spring" design was chosen in moving forward with the project. The decision matrix can be found in Appendix J.

Testing Summary

To ensure that the spring snare design was effective at grasping a lead, several tests were completed. The initial tests were essentially proof of concept tests, while the latter tests were completed to fine-tune and improve upon the spring snare design.

Longitudinal* Stress Test

A longitudinal stress test was conducted to determine if the welds* between the compression* wire and the cross bracing/plate were strong enough to withstand expected loads in clinical usage.

The Instron, a machine that precisely and accurately puts objects in tension or compression, was used to complete many of the tests since it allowed for force measurements on the spring snare. The compression wire was fixed in the Instron clamp and the spring was mounted on a fixed platform as shown below. For each test, a load of 10 lbs in tension was applied to the compression wire. To allow the spring to compress linearly, a plastic piece was clamped down to the bottom Instron clamp and a hole was drilled through the center of the plastic piece. This hole was large enough to fit the compression wire through with ease, but small enough to prevent the spring from squeezing through. The compression wire was mounted to the spring by welding the compression wire to the cross brace. The spring was then epoxied to the cross brace using JB weld. In the latter part of this test, since the cross bracing became an issue due to deformation, the setup changed, as the compression wire was welded to a flat plate and the spring was epoxied to the flat plate.

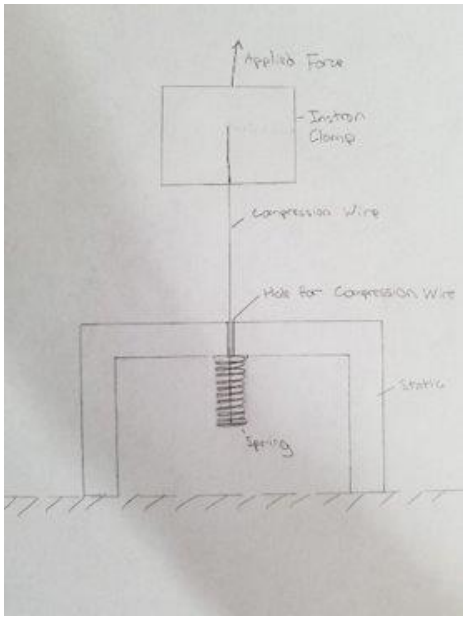


Figure 6: Test Setup for the Majority of Tests Completed, Including the Longitudinal Stress Test.

Table 1: Compression Wire Diameters and Qualitative Results to the Longitudinal Stress Test.

Compression Wire Radius (inches)	Did the weld hold under the 10 lbs. of force?
0.016	No
0.019	Yes
0.022	Yes

The wire with a radius of 0.016" did not hold 10 lbs of force. During that test, the cross bracing continuously deformed until the weld failed. When the compression wire with a radius of 0.019" was tested it held the required 10 lbs of force, but the cross bracing was severely deformed just after one test. The final test with the largest compression wire was the most successful as it held the required 10 lbs with little deformation, but it was decided that utilizing a flat plate would alleviate any deformation issues. Using the flat plate setup, the compression wire was able to withstand 10 lbs of force and the weld showed no signs of breaking. Testing done subsequently showed that the weld was able to withstand forces upwards of 35 lbs of force.

Since the wire with the radius of 0.016" failed and assembling the apparatus was difficult, the 0.016" wire was ruled out for the spring snare. It was determined that welding the compression wire to a circular, flat plate and JB welding the spring to the plate increased the manufacturability and structural integrity of the snare. Although the wire with a 0.019" radius did hold the 10 lbs of force, it was concluded that a compression wire with a diameter of 0.022" was to be used for the snare, as it fared the best consistently throughout the test.

Sheath Compatibility Test

The purpose of the sheath compatibility test was to determine if the spring snare would be able to function properly after being twisted, maneuvered, and deflected while inside the outer sheath.

Using an introducer*, one of the 0.156" outer diameter springs was fed through a 0.17" inner diameter catheter that was used to model the outer sheath of the snare. While the spring was inside the sheath, the sheath was bent to model the deflectable ability of the sheath.

After the spring was removed from the sheath, it was inspected for deformation. The main coils of the spring had no noticeable deformation and the spring compressed correctly. There was slight deformation at the top coil of the spring near the weld, but the deformation did not cause the spring to become inadequate for the purpose of grasping the lead.

Based on the results, it was determined that the spring would be able to withstand the contact within the outer sheath, including the deflection of the sheath. There were no inclinations leading to believe that the spring would be deformed in a manner that would

cause the spring to not be able to function as intended. Therefore, the idea of spring being used as a snare remained feasible.

Sheath and Spring/Lead Contact Test

Since springs had not been used in lead extraction before, the contact test was used as a baseline proof of concept for the design. Essentially, the purpose of this test was to determine if the combination of the compression of the spring's coils and the contact between the lead and the outer sheath would cause the lead to dislodge from within the coils due to an outward force applied to the lead.

To complete this test, the test setup was identical to that of the longitudinal stress test, but instead of an empty spring being tested to a load of 10 lbs, a lead was placed inside the coils of the springs and a force of approximately 7.5 lbs was applied to the compression wire. Furthermore, two locations of the compression wire were tested. The compression wire was tested in an offset position, as well as a centered position. (i.e. the compression wire was welded to both the center of the plate and the near the end of the plate.)

The following springs were utilized for the contact test. They were selected because their diameter complied with the inner diameter of the inner sheath on Cook's Needle's Eye Snare. Since this was the most important constraint, this was the baseline for spring testing.

Table 2: Springs Tested in the Sheath and Spring/Lead Contact Test with Spring Specifications.

Spring	Outer Diameter (in)	Hole Diameter (in)	Wire Diameter (in)	Free Length (in)	Rate (lb/in)	Solid Length (in)	Rod Diameter (in)	Material
1	0.156	0.172	0.011	0.750	0.77	0.121	0.125	SS
2	0.156	0.172	0.012	0.500	1.59	0.101	0.123	SS
3	0.156	0.172	0.012	0.563	1.40	0.110	0.123	SS
4	0.156	0.172	0.012	0.625	1.25	0.119	0.123	SS
5	0.156	0.172	0.013	0.500	2.09	0.115	0.121	SS

The test setup for the spring/lead contact test was a slight variation of the initial lead grasping test setup and was illustrated below. The same structure was used, but instead of compressing an empty spring, a lead was placed in the middle coil of the spring and then compressed. The plastic piece that allowed the compression wire to go through it was used to mimic the contact that the spring would have with the outer sheath of the extraction tool.

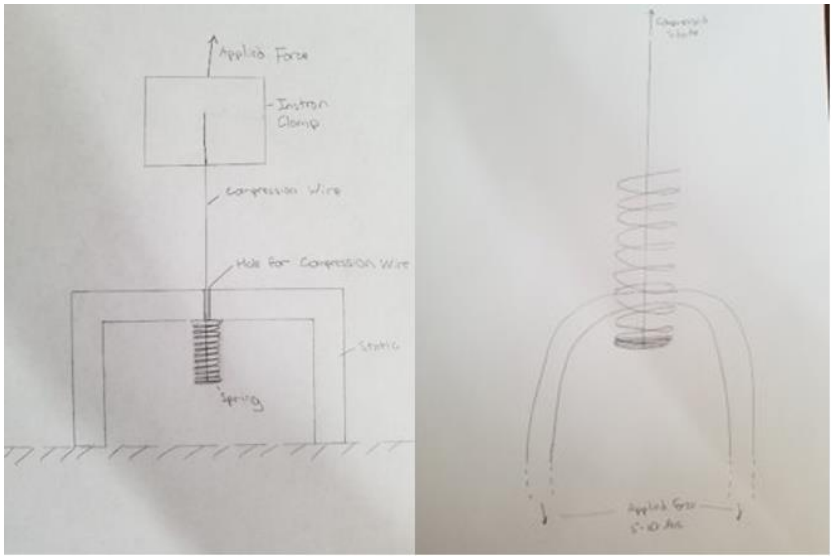


Figure 7: Sheath and Spring/Lead Contact Test.

At the beginning of the test, it was noted that the springs purchased for this test did not have the ability to grasp all lead sizes, as the distance between the coils of the springs were too small to grasp the largest size lead, which had a diameter of .088". So, to remedy the issue, a smaller lead size was used, with a diameter of .048".

While under 7.5 lbs of force, the leads placed in the offset compression wire springs held in place and did not slip out at any point during the tests. However, deformation did occur at the top of the spring, as well as the weld joint. Although deformation occurred, the deformation did not hinder the spring's ability to successfully grasp and hold the lead.

In the case of the centered compression wire, while under 7.5 lbs of force, the leads stayed in place initially. However, in one trial, the compression wire slipped out at about 30 s of compression of the spring. This was considered an outlier, as lead placement into the spring for said trial may have allowed the lead to easily slip out of the spring. The deformation on the centered compression wire configuration was significantly less than that of the offset compression wire configuration.

For the final stages of this project, the distance between the coils of the spring must be larger than the largest size lead (.088 in. diameter). Based on the results, the proposed idea of a spring being used in the application of lead extraction was feasible since the contact between the sheath and lead didn't cause the lead to become dislodged, aside from a single outlier. Furthermore, each compression wire configuration was concluded to be reasonable since they both performed well when grasping and holding onto the lead. Based on the deformation that occurred in the springs, it was determined that stronger, stiffer springs were going to be necessary to have a successful snaring of the lead.

Initial Lead Grasping Test

In clinical applications of lead extraction, when a lead is being extracted, there is typically tissue growth that acts as a force opposing the lead extraction. Furthermore, some force is necessary to remove the end of the lead from the heart, which also causes a force opposing the extraction of the lead. Therefore, the purpose of the initial lead grasping test was to determine if the springs used in the contact test would be able to grasp and hold a lead while an opposing force was applied to the lead to mimic tissue growth on the lead and overall resistance the lead will have against extraction.

The same springs used in the contact test were utilized in this test as well. The setup was essentially an elongated version of the previous tests, as the spring and compression wire was placed in the same configuration with respect to the Instron, but in order to have a directly opposing force on the lead, it was necessary to provide room to pull directly down on the lead. To remedy this, two long PVC pipes were used as the legs of the setup. A picture of the setup was illustrated below to give a clearer understanding of the experimental setup. The combination of a force scale and a traditional fish scale was utilized to get measurements of the force on the lead.

Figure 8: Initial Lead Grasping Test Setup.

With 7.5 lbs of force applied to the compression wire, none of the springs exceeded 2 lbs. of force on the lead without slipping out of the lead. In some cases, the lead slipped out before being able to get an accurate reading from the force scale. In general, the centered compression wire performed better than the offset compression wire, as the centered setup had a maximum force of 1.89 lbs, while the offset setup had a maximum force of

0.79 lbs before the lead slipped out of the spring. Regardless of the configuration, the lead took minimal force to dislodge from the spring's coils.

Based on the results, it was clear that the springs tested would not satisfy the primary requirement for the project, which is to successfully grasp and remove a lead. The main issue that caused the lead to dislodge from the spring with little force applied was the fact that the springs tested were relatively soft, with each of the springs being fully compressed with less than a pound of force on the compression wire. In order to remedy this issue, more springs were ordered, and further lead grasping tests followed.

Second Lead Grasping Test

The purpose of the second lead grasping test was to determine which spring could produce the required grasping force while complying with all other requirements and parameters of the project. For the purpose of the project, the spring snare must be able to withstand a force of at least 5 lbs on the lead.

The following springs were found based on their max load and rate. The initial lead grasping test, although it was mostly qualitative, showed that springs with a smaller rate or max load wouldn't produce enough grasping force to pull the lead out of the patient, as it slipped out with little force applied to the lead. Springs with a larger diameter and max load were selected to increase the parameters that were expected to increase the grasping force. The same experimental setup as the initial lead grasping test was used to remain consistent. To remedy the fact that each of the springs had different max loads, each of the springs were tested at three specific compression wire forces, which were max load, 2.5, and 5.0 lbs above the max load. Furthermore, to remain consistent, each spring was tested with an offset and centered compression wire. Lastly, to more accurately represent the clinical application of the snare, the snare and lead were tested dry, along with lubricated. The springs used for this test were tabulated below.

Table 3: Spring Used in the Second Lead Grasping Test with Specifications.

Spring	OD (in)	ID (in)	Wire Dia. (in)	Compressed Length @ Max Load (in)	Max Load (lbs.)	Spring Rate (lbs./in)	Material	End Type
Spring 1	0.36	0.284	0.038	0.42	7.41	19	Zinc-Plated Music-Wire Steel	Closed and Ground
Spring 2	0.24	0.176	0.032	0.58	6.72	16	Zinc-Plated Music-Wire Steel	Closed and Ground
Spring 3	0.3	0.236	0.032	0.46	5.4	10	Zinc-Plated Music-Wire Steel	Closed and Ground
Spring 4	0.36	0.27	0.045	0.85	11.7	18	Zinc-Plated Music-Wire Steel	Closed and Ground
Spring 5	0.48	0.37	0.055	0.47	15.58	38	Zinc-Plated Music-Wire Steel	Closed and Ground
Spring 6	0.3	0.23	0.035	0.19	10.50	32.8	Zinc-Plated Music-Wire Steel	Closed and Ground

To make the results less repetitive, the tests that had no failures at any point throughout the testing process were placed in the Appendix. The springs that did not fail at all were springs that were clearly too large to work within the parameters of the project and were used as an upper bound. In other words, they were used to see if 5 lbs was even possible with a much larger spring. The springs that did not fail and held 5 lbs for every trial were springs 4, 5, and 6. Graphical representations for the springs that were closest to the parameters of the project were highlighted and explained below.

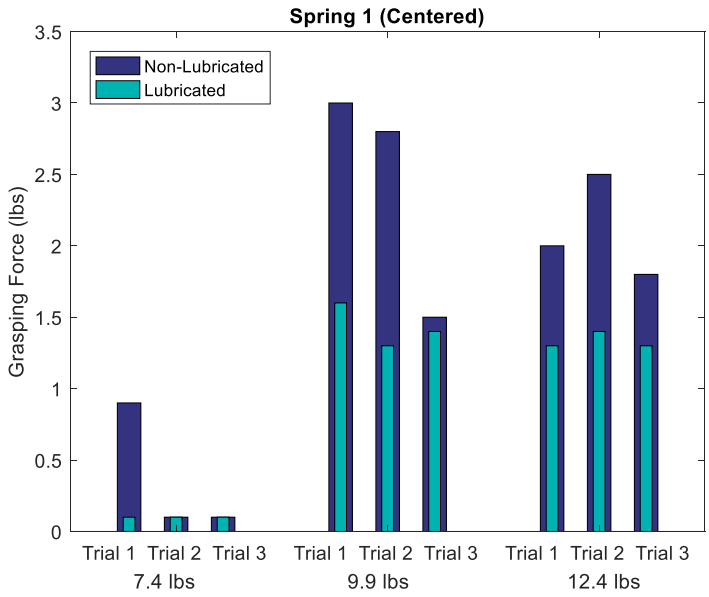


Figure 9: Spring 1 Centered Configuration, Grasping Force vs. Compression Force.

Spring 1 had the worst performance of the three springs with a max load between 5 and 10 lbs. At max load, it held less than 1 lb of force. Although raising the force by 2.5 lbs and 5.0 lbs did show an increase in grasping strength, the spring still failed to reach 5 lbs of force on the lead. This could've been because the spring didn't appear to be fully compressed at its advertised max load, but regardless, after it was fully compressed, it still did not perform well.

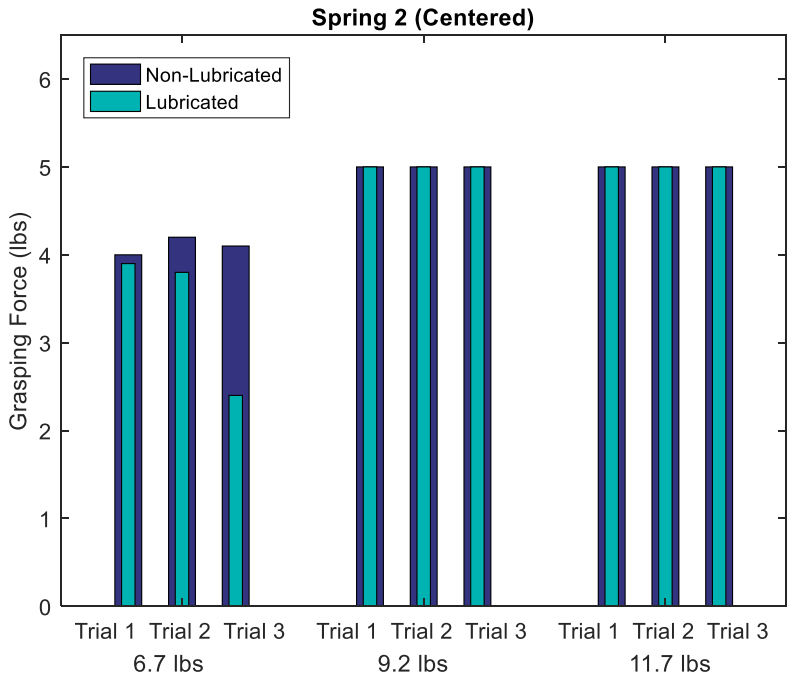


Figure 10: Spring 2 Centered Configuration, Grasping Force vs. Compression Force.

Spring 2 failed to hold 5 lbs of force at its maximum load but was significantly stronger in grasping the lead that Spring 1. However, Spring 2 fared well in the centered compression wire configuration, as once it was placed above its max load, it held the lead at 5 lbs of force consistently. Whether the lead was dry or lubricated, the spring held 5 lbs of force on the lead.

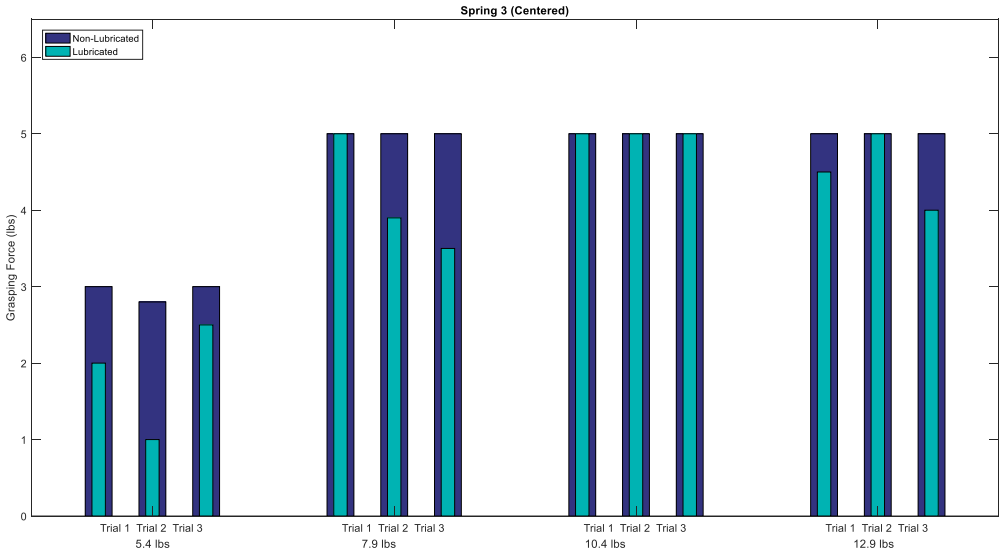


Figure 11: Spring 3 Centered Configuration, Grasping Force vs. Compression Force.

Spring 3 failed to hold 5 lbs of force on the lead while at max load, but it was able to reach 5 lbs of force on the lead when raised above its max load. Since this spring performed better than the other springs aside from Spring 2 and had the smallest max load, it was brought up to 7.5 lbs above its max load, however, it appeared that this had no effect on the grasping strength, as the 12.9 lbs data set was slightly weaker than the 10.4 lbs. data set. Up to this point, Springs 2 and 3 had the best performance for springs that were closest to the design constraints of the project.

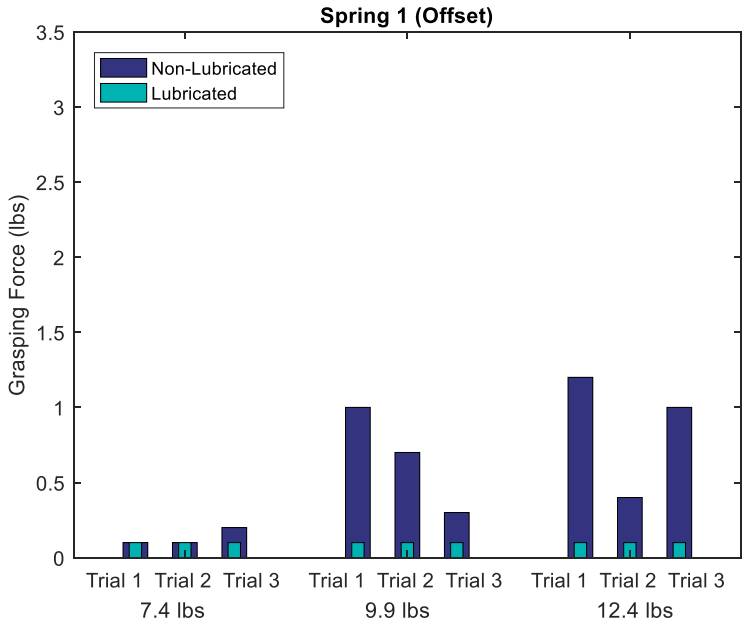


Figure 12: Spring 1 Offset Configuration, Grasping Force vs. Compression Force.

The offset configuration for Spring 1 had absolutely no success. Failing to reach even 2 lbs of grasping force on the lead even after being raised to 5 lbs above its maximum load. When the lead was lubricated, there was virtually no grasping force on the lead, as it slipped out almost immediately in each trial.

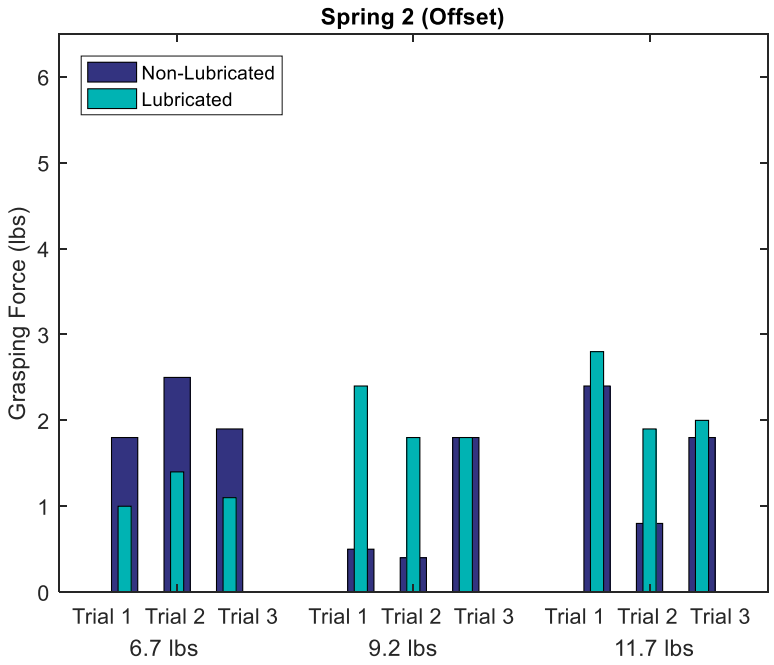


Figure 13: Spring 2 Offset Configuration, Grasping Force vs. Compression Force.

Spring 2 performed much worse in the offset configuration when compared to the centered configuration. Unlike the centered configuration, Spring 2 failed to supply a satisfactory grasping force of 5 lbs, even when compressed to 5 lbs above its maximum load. With that, Spring 2 was still one of the better performing springs that had been tested, but it's poor performance in the offset configuration caused doubt in its ability to grasp more difficult leads.

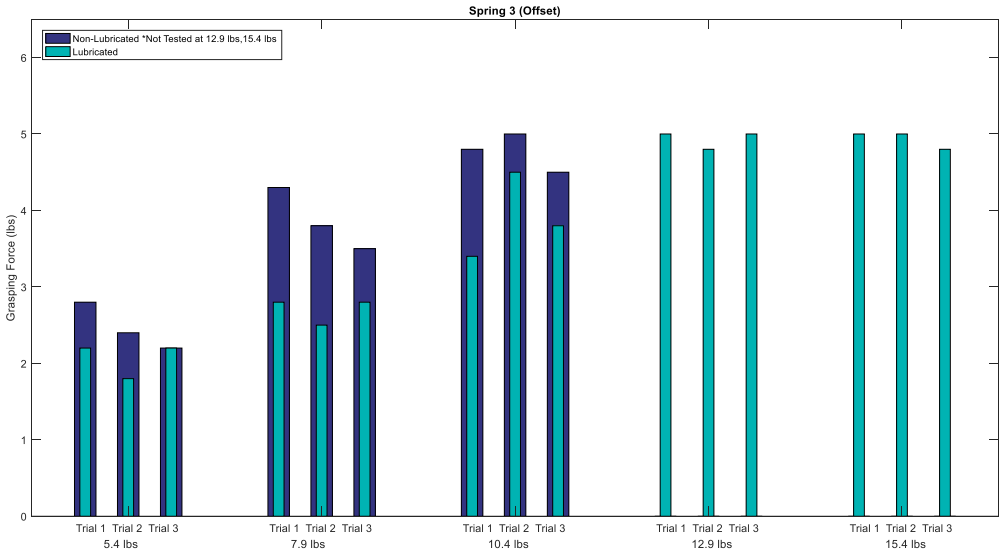


Figure 14: Spring 3 Offset Configuration, Grasping Force vs. Compression Force.

Spring 3 performed the best out of the three springs that were tested in the offset configuration, as it was able to reach 5 lbs of grasping force on the lead when compressed to 5 lbs above its max load. The spring was then tested lubricated at higher compression forces, since lubrication caused the springs to perform worse in general. Although the higher forces did allow for slightly larger grasping forces, it did not appear to cause a great jump in grasping force.

Multiple springs had a satisfactory grasping force to meet the parameters of the project. Specifically, Spring 3 with an outer diameter of 0.3", was able to meet the 5 lbs requirement for the grasping force in both the centered and offset configurations, unlike Springs 1 and 2. This spring showed that there was a strong possibility that springs could generate a grasping force that would lead to a successful design in extracting a lead. Furthermore, since the centered compression wire was consistently stronger than the offset configuration, it was concluded that the final prototype would have a centered compression wire configuration and the final tests only utilized the centered configuration.

Maximum Lead Grasping Test

In the Second Lead Grasping Test, the grasping force on the lead was only tested to 5 lbs. The Maximum Lead Grasping Test was necessary to show that the highest performing springs could hold higher than 5 lbs. The two springs being tested proved to be the most beneficial for later testing and integration with the controls.

Two springs from the table in the Second Lead Grasping Test were utilized: Spring 2 and Spring 3. The force that they were placed under increased until the spring was unable hold the lead between its coils. The force that it took to dislodge the lead from the spring was the maximum lead grasping force. The process of this test differed from the other lead grasping tests because they merely tested up to 5 lbs. This test allowed for the determination of if a spring could produce a larger grasping force than 5 lbs.

The following two graphs show the results of Spring 2 and Spring 3 using only the centered compression wire configuration since they performed better in the Second Lead Grasping Test. Lubricated tests were conducted, and it was noticed that in some trials, the lubricated lead outperformed the non-lubricated lead. This was unexpected since lubrication would decrease the friction force that allowed the spring to stay between the coils.

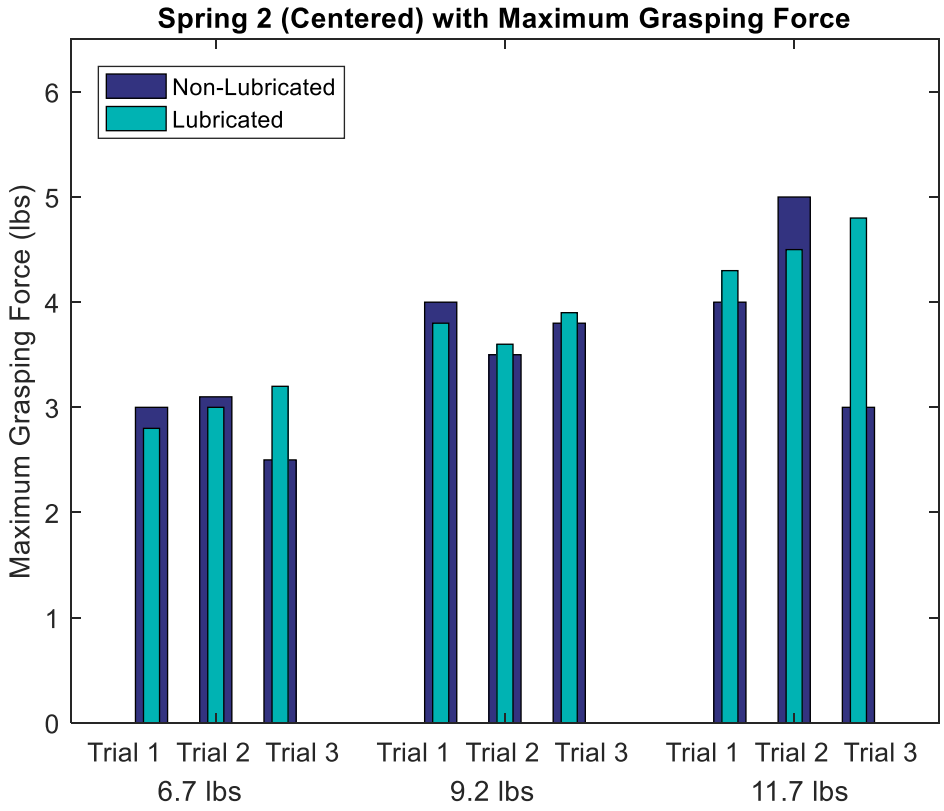


Figure 15: Spring 2 Centered Configuration, Maximum Grasping Force vs. Compression Force.

Spring 2 performed poorly and was unable to consistently create a grasping force of at least 5 lbs. At the max load, the spring was only able to hold a maximum of just over 3 lbs. As the compressive force increased the grasping force also increased, but not significantly. The spring's grasping force was inconsistent, as it performed worse than it did in the Second Lead Grasping Test. This may have been due to deformation due to repeated testing.

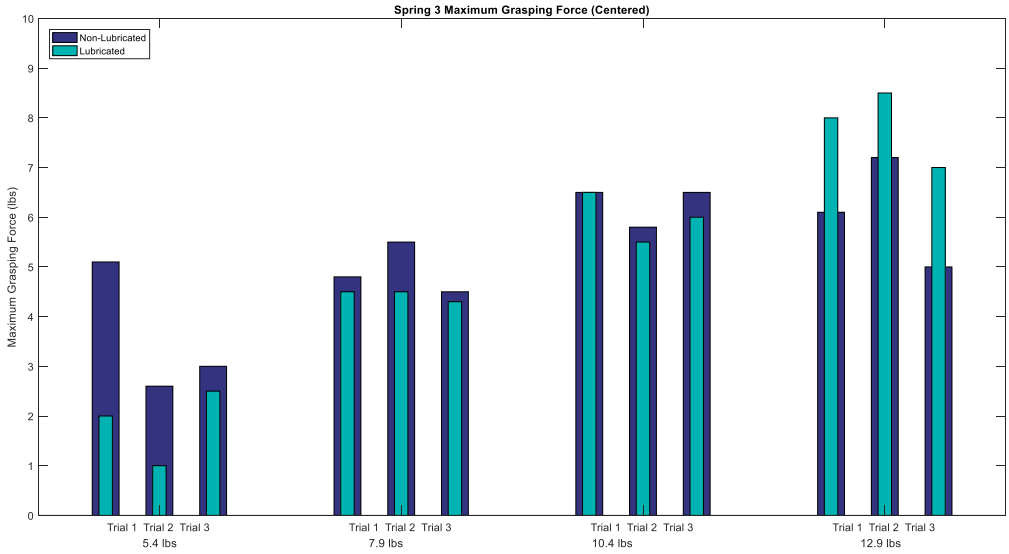


Figure 16: Spring 3 Centered Configuration, Maximum Grasping Force vs. Compression Force.

Spring 3 was able to successfully create a grasping force that was larger than the minimum requirement. When compressed to it max load the spring was unable to consistently hold 5 lbs of force, however, as the compressive force was increased the grasping force was larger than the minimum requirement and increased significantly. When compressed with a force of 10.4 lbs, Spring 3 was able to attain a maximum grasping force of over 5 lbs consistently. Even when the lead was lubricated the spring was still able to create grasping forces that exceeded the minimum requirement of 5 lbs.

The results from this test concluded that it was feasible to utilize a spring to grasp a lead. Furthermore, a spring that nearly satisfied all the parameters of the project was able to achieve grasping forces that would suffice in clinical application. Unfortunately, the spring that was most successful, Spring 3, had an outer diameter that was slightly to large, at an outer diameter of 0.3". After consultation with the sponsor, the outer diameter for the spring could be no larger than 0.21". Since Spring 3 was the most successful at grasping the lead, additional custom order springs were ordered that had similar characteristics to Spring 3. The custom order springs were utilized in the final test, which was covered in the following section.

Final Lead Grasping Test

The purpose of this test was to determine if the custom order springs that complied with all project requirements and parameters could successfully grasp a lead, which was quantified by determining if the spring had a grasping force that exceeded 5 lbs.

The same test setup was used for this grasping test as the previous grasping tests. Unfortunately, one of the two custom order springs did not ship in time to be tested, so this test was only performed on one of the springs.

The custom order spring had an advertised max load of 7 lbs, but when tested, the spring was not fully compressed at its max load. The lack of compression at its advertised max load may have been due to a communication error between the team and McMaster, or McMaster and WB Jones, which was the company McMaster sources their custom order springs from. At some point, the definition of max load may have been misinterpreted, causing the team to receive a spring that did not perform as well as expected. Regardless, the lack of compression caused the lead to slip out before even 1 lb of force was placed on the lead.

The problematic results were brought up to the sponsor. Based on sponsor feedback and the fact that custom order springs were out of the question due to timeline restrictions, it was concluded that the prototype would be built with the custom order spring that was tested since the spring adhered to all the project parameters aside from being able to grasp the lead with 5 lbs of grasping force.

Final Design Summary

Final Design Description

The final design for the tool includes a spring snare, which is composed of a compression wire, compression plate, spring stabilizer, and spring. The design also includes a handle with a plunger on the bottom end to compress the compression wire which in turn would compress the spring, a side-mounted knob that is used for moving the spring snare in and out of the outer sheath, as well as knobs to deflect the outer sheath. Finally, the design includes inner and outer sheaths which are used for maneuvering the snare through the femoral vein. The spring snare would rely on a compressive grasping force that would be applied when the lead is caught between one of the coils. The grasping force needed to remove the lead was found to be attainable during testing. The handle would contain an array of simple to use controls that would give the physician the needed maneuverability to position the spring snare.

From the experimental testing, the team determined that a custom spring would need to be designed to achieve the required grasping force. This custom spring would need to meet the dimensions and requirements given below.

Table 4: Custom Spring Dimensions.

Outer Diameter (in)	Free Length (in)	Wire Diameter (in)	Maximum Load (lb)	Length Between Coils (in)	End Type
0.21	1.0	0.03	5 – 10	0.09	Closed and Ground

The outer diameter of the spring would need to comply with the stated dimension in order to freely move inside the outer sheath. The free length of the spring was chosen to be 1 in. to provide enough coils for snaring and allow the spring to not buckle during compression. The wire diameter for the custom spring was the same as the Spring 3 which performed the best. Maximum load was chosen to be similar to the properties of Spring 3. The length between each coil was set to be 0.09 in. to allow leads the size of a defibrillator lead to fit. Having a closed and ground end type allows the spring stabilizer and flat plate to rest on the spring evenly.

The following isometric views display all the parts needed to create the femoral lead extraction tool. The handle assembly consists of multiple parts that fit into the handle, shown in Figure 17. The deflector disk, shown in Figure 17, sits and rotates freely in a circular extrusion in the handle. The inner sheath slider, shown in Figure 19, is connected to the inner sheath and allows the spring snare to be extended and retracted. The inner sheath, shown in Figure 19, slides through the outer sheath, Figure 20, which is connected in the handle. The spring snare rests on the spring stabilizer, shown in Figure 22, which in turn rests on the inner sheath. Finally, the compression plunger, shown in Figure 21, is connected to the compression wire and is fitted in the handle.

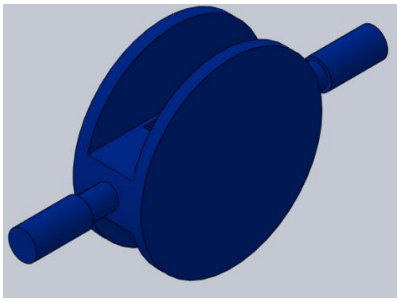


Figure 17: Isometric View of Deflector Disk.

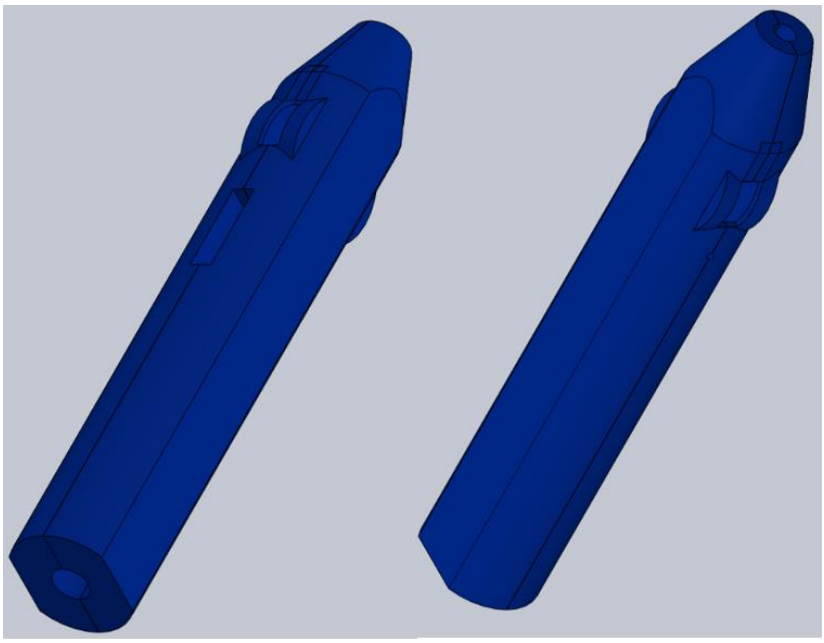


Figure 18: Isometric Views of Handle.

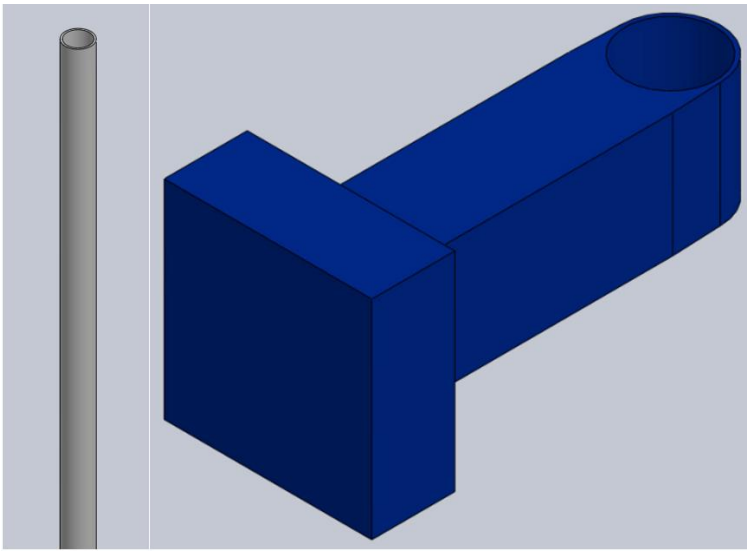


Figure 19: Isometric Views of Inner Sheath (Left) and Inner Sheath Slider (Right).

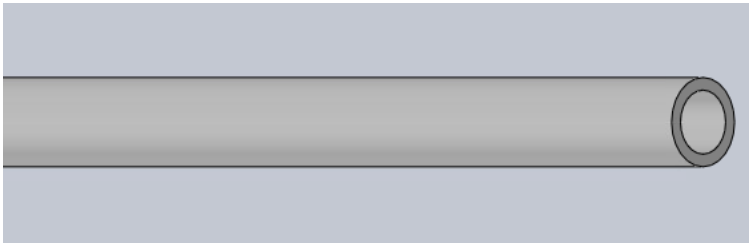


Figure 20: Isometric View of Outer Sheath.

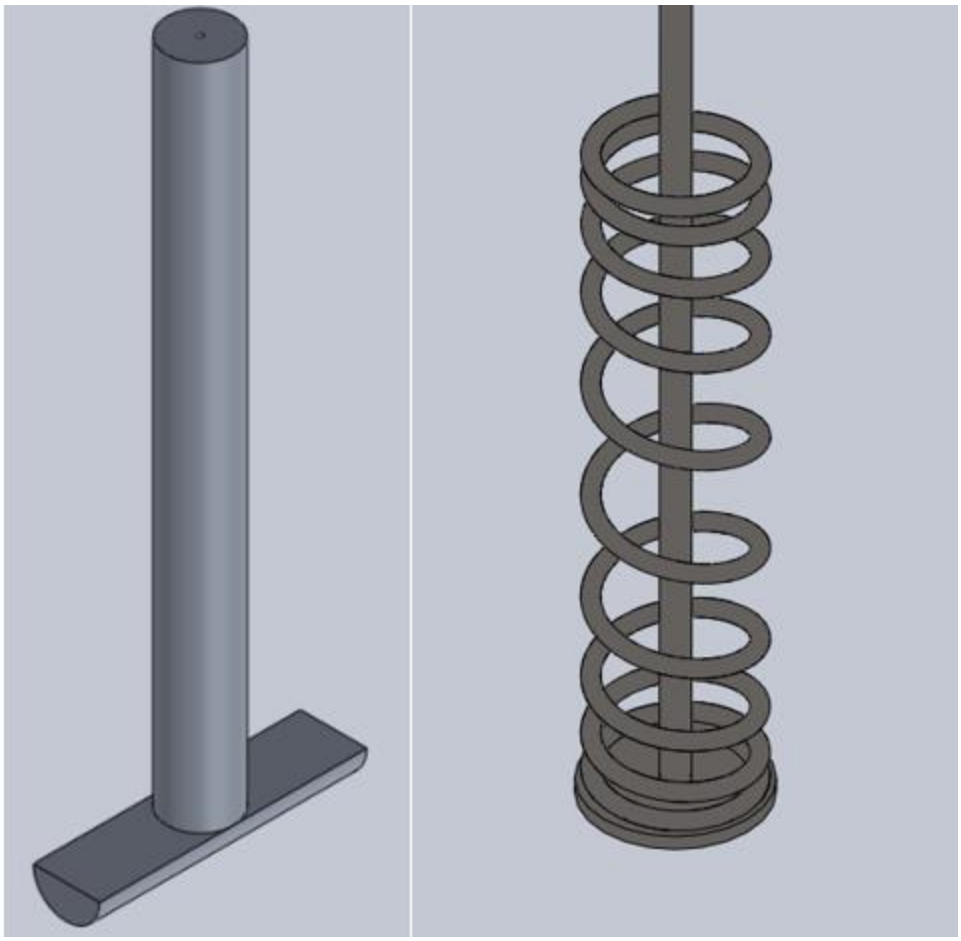


Figure 21: Isometric Views of Compression Plunger (Left) and Spring with Compression Plate and Compression Wire (Right).

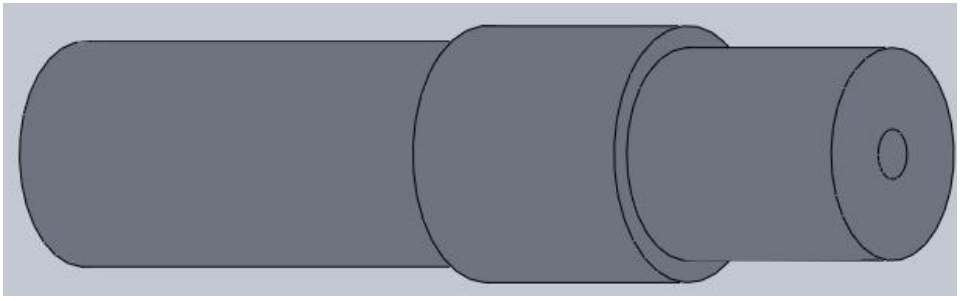


Figure 22: Isometric View of Spring Stabilizer.

Figures 23 and 24 show the full assembly of the extraction tool with the spring snare extended from the outer sheath.

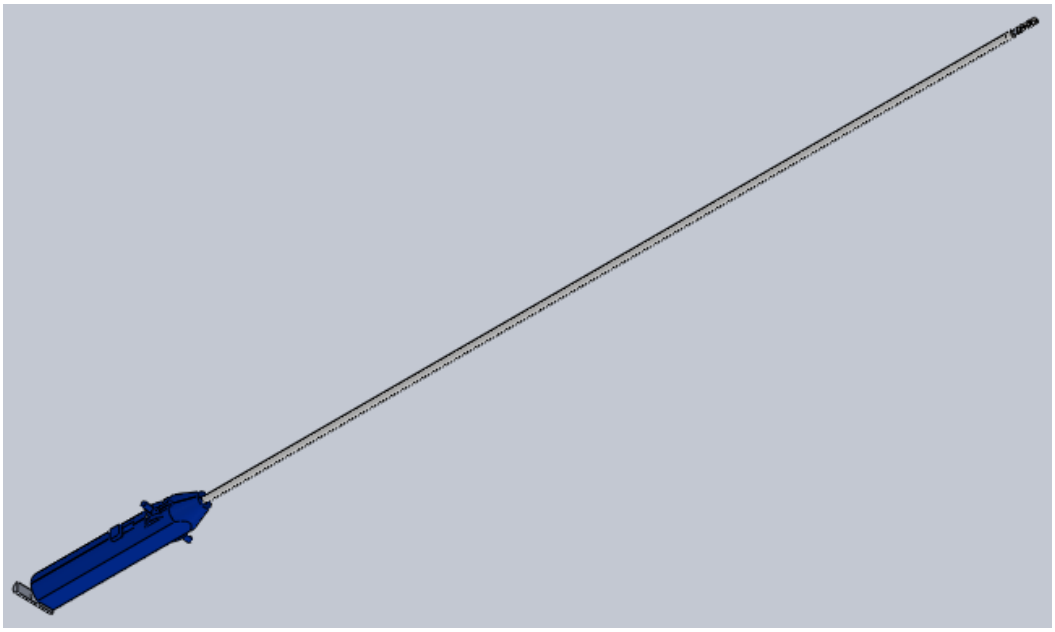


Figure 23: Isometric View of Full Assembly.

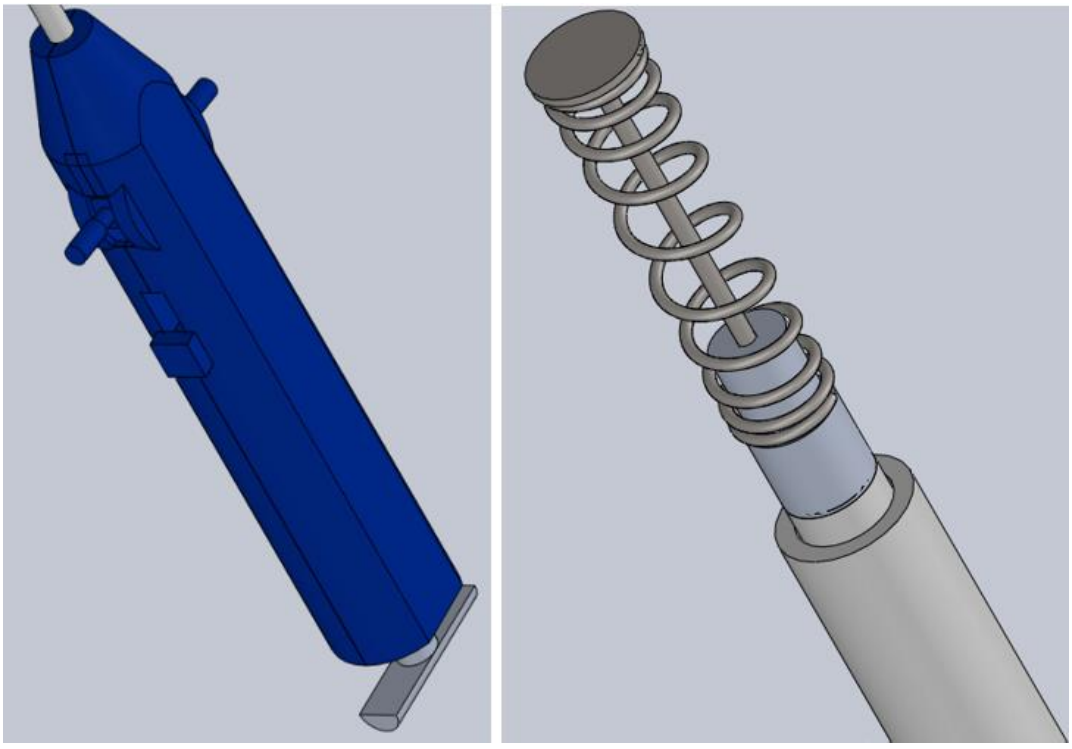


Figure 24: Close Isometric Views of the Handle Assembly (Left) and Snare Assembly (Right).

To operate the femoral extraction tool, the physician would be advised to follow a workflow as devised by the team. The tool would first be introduced into the femoral vein with the spring snare in the retracted position. Once the tool is positioned in the upper right atruim of the heart, the physician would extend the spring snare using the inner sheath slider. The physician would be able to use the deflector disk to maneuver the spring snare as needed to capture the lead. Once the lead is positioned in the coils of the spring, the physician would pull the compression plunger located on the handle to compress the spring. A locking mechanism would be utilized to hold the compression plunger in its compressed state allowing the physisican to remove the extraction tool and lead from the patient. If needed, the inner sheath slider could be retracted until the lead comes into contact with the outer sheath. This would provide more contact area between the lead and the extraction tool providing additional friction forces to grasp the lead.

Conclusion

The project was successful in proving that a spring could generate a grasping force that would pull a lead out of the right atrium. Through testing, it was determined that the max load was the main factor in the grasping force performance. Initially, springs were tested that only contained a max load less than 1 lb. Although these springs were able to hold the lead between the coils, they were not able to generate a grasping force over 1 lb. When a spring that had a max load of 7.4 lbs. was tested, a maximum grasping force of approximately 8.5 lbs. was achieved. The project successfully proved through the relationship between max load and grasping force, springs could generate a grasping force sufficient for the femoral approach to lead extraction.

Although the spring could grasp a lead under ideal conditions, it was restricted in its ability to grasp a lead in a clinical model. The spring snare design was more linear in nature than other snares currently in use, so it had a more difficult time positioning itself for a lead to properly fit between the coils. While not included in the final model, a deflectable sheath would reduce the limitations of the snares linearity so the spring's coils could be placed around the lead with relative ease. The final model also required the user to hold the inner sheath out and pull the compression wire for the duration of the lead extraction. This made it difficult to put a consistent force on the lead through the spring and could tire out the user attempting to grasp the lead. This could be solved by using a locking mechanism on the inner sheath slider and compression plunger so once the snare has grasped the lead the user wouldn't need to apply force on the spring as they extract the lead.

Although the prototype failed to meet some requirements, the actual design would incorporate more features to satisfy the remaining requirements. Furthermore, the actual design would have a spring that has the correct specification to effectively grasp a lead based on the testing results. The table below showed the differences between the prototype and the actual design in terms of success in satisfying the requirements of the project.

Table 4: Requirements Satisfied by the Prototype and Actual Design.

Requirement	Prototype	Actual Design
Easily Distinguishable under fluoroscopy	Satisfactory	Satisfactory
Atraumatic	Satisfactory	Satisfactory
Unique Design	Satisfactory	Satisfactory
Deflectable and maneuverable	Unsatisfactory	Satisfactory
Flexible snare material	Satisfactory	Satisfactory
Easily modifiable to accommodate different snare lengths and diameters	Satisfactory	Satisfactory
Manufacturable	Satisfactory	Satisfactory
Effectively grasps lead for removal	Unsatisfactory	Satisfactory
Simple controls	Satisfactory	Satisfactory
Must be able to disengage lead	Satisfactory	Satisfactory

Appendix A: Glossary

Atraumatic: Design to eliminate cause of injury or trauma by minimizing tissue damage [1].

Compression: The act of pressing together (pressing together/compressing the coils of the spring) [2].

Deflectable: The ability to turn (something) aside especially from a straight course or fixed direction [1].

Density: The mass of a substance per unit volume [1].

Electronic Implantable Devices: A small battery-operated device that helps the heart beat in a regular rhythm [3].

Electrophysiologist: A biomedical expert that deals with the study of electric activity in the human body [2].

Femoral: Of or relating to the femur or thigh [1].

Flexible: Characterized by a ready capability to adapt to new, different, or changing requirements [1].

Fluoroscopy: A type of medical imaging that shows a continuous X-ray image on a monitor, much like an X-ray movie [4]..

Inferior Vena Cava: A large vein that receives blood from the lower extremities, pelvis and abdomen and delivers it to the right atrium of the heart [2].

Introducer (sheath): A sheath that protects vessels during coronary procedures [5].

Leads: A special wire that delivers energy from an EID to the heart muscle [6].

Longitudinal: Of or relating to length or the lengthwise dimension [1].

Maneuverable: Capable of being steered or directed and easy to maneuver [7].

Manufacturable: The ability to make or produce a product [7].

Right Atrium: The right upper chamber of the heart that receives deoxygenated blood from the body through the vena cava [2].

Root Mean Square (error): A method for calculating error. It is defined as followed [8]:

$$RMS_{Error} = \sqrt{\frac{\sum(\bar{y}_i - y_i)^2}{n}}$$

Sheath: A specially designed tubular instrument through which special obturators or cutting instruments can be passed or through which blood clots, tissue fragments, and calculi can be evacuated [9].

Snare: A surgical instrument consisting usually of a wire loop constricted by a mechanism in the handle and used for removing tissue masses (such as tonsils) [1].

Vein: A blood vessel that carries blood, low in oxygen content, from the body back to the heart [2].

Vessel: A tube or canal (such as an artery) in which a body fluid is contained and conveyed or circulated [1].

Weld: To unite by heating and allowing the metals to flow together or by hammering or compressing without previous heating [1].

Appendix B: Testing Graphs

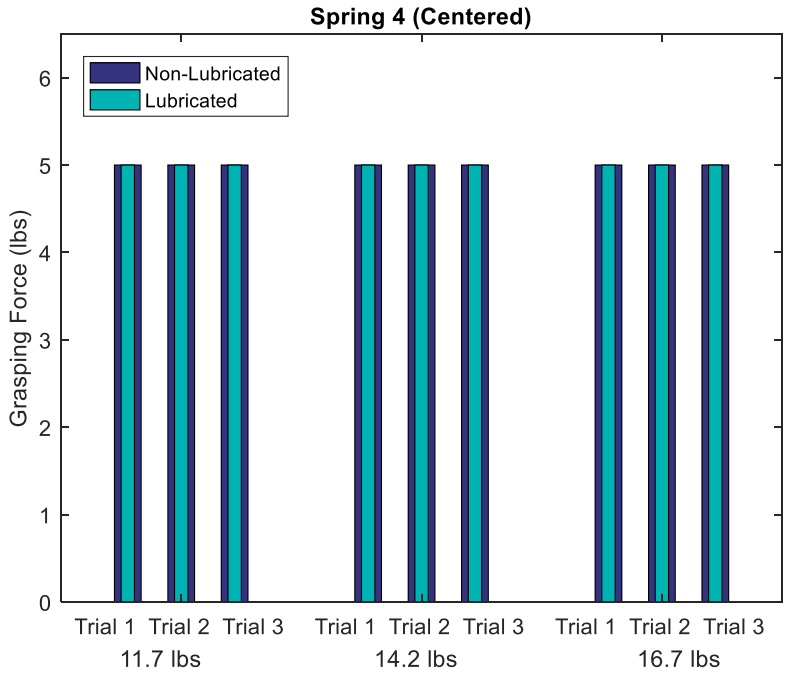


Figure 25: Spring 4 Centered Configuration, Grasping Force vs. Compression Force.

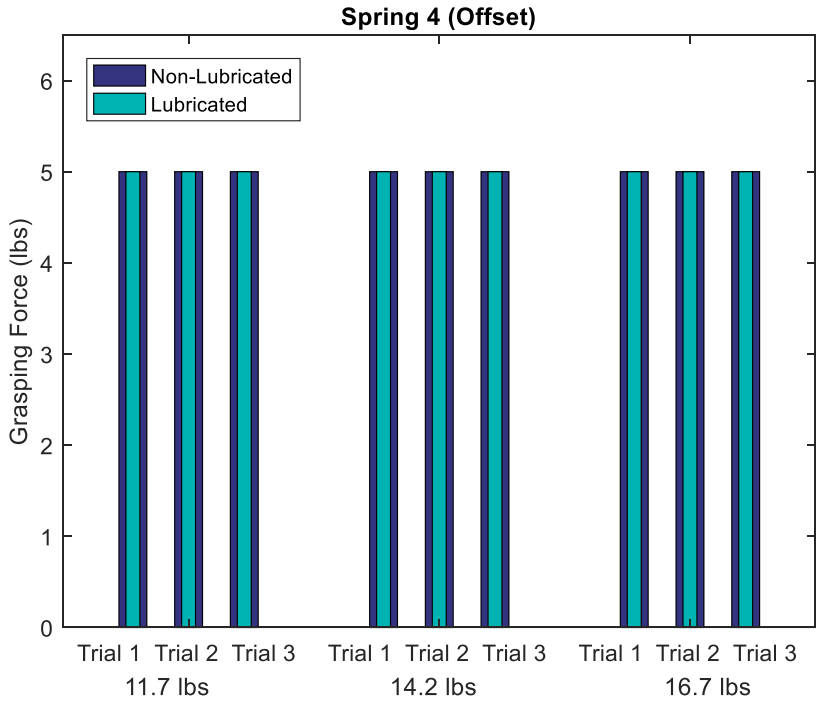


Figure 26:Spring 4 Offset Configuration, Grasping Force vs. Compression Force.

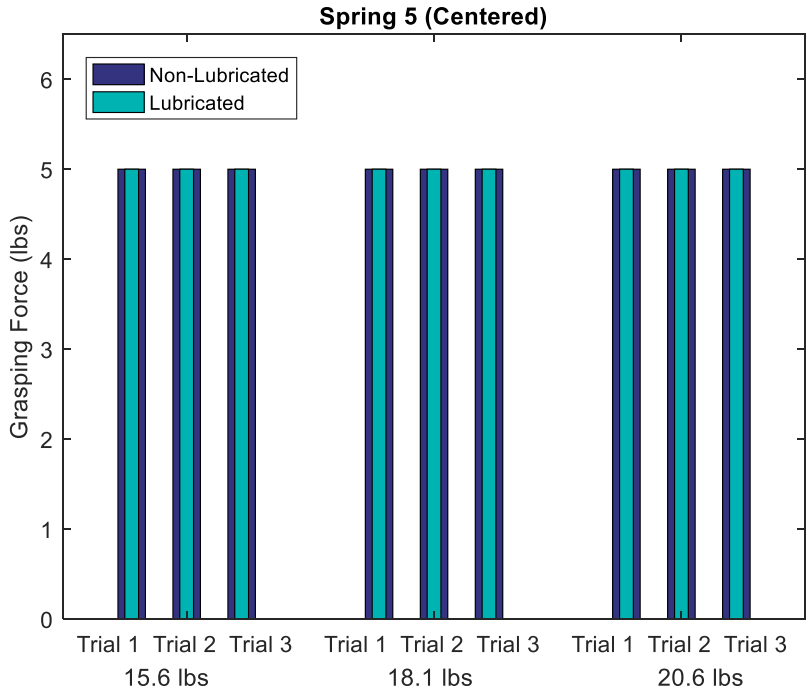


Figure 27:Spring 5 Centered Configuration, Grasping Force vs. Compression Force.

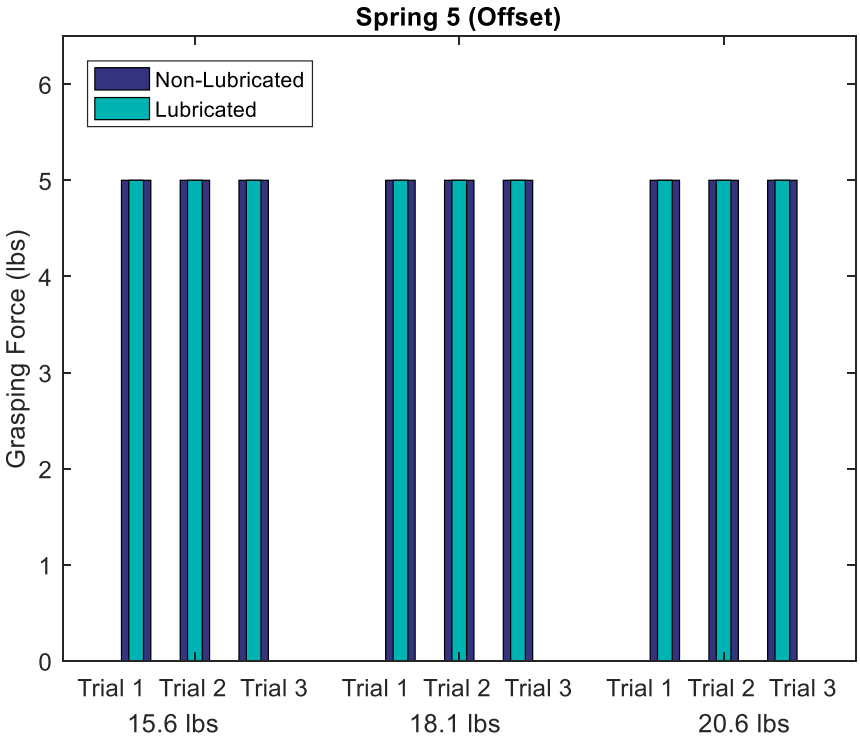


Figure 28: Spring 5 Offset Configuration, Grasping Force vs. Compression Force.

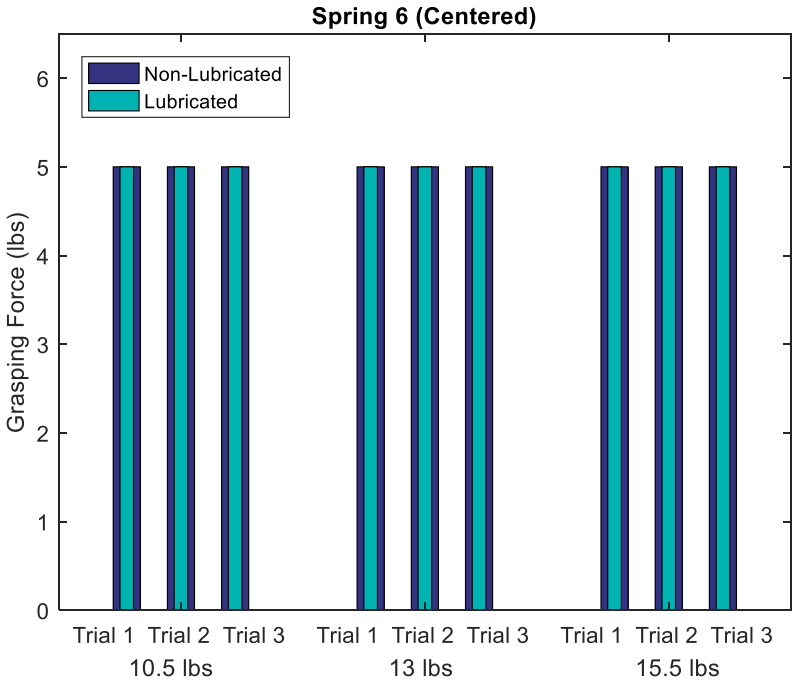


Figure 29: Spring 6 Centered Configuration, Grasping Force vs. Compression Force.

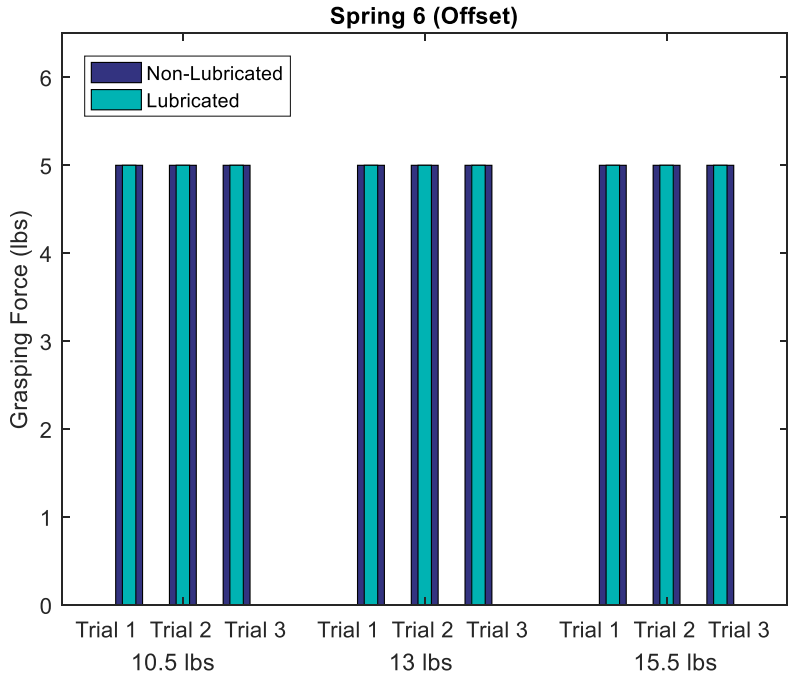


Figure 30: Spring 6 Offset Configuration, Grasping Force vs. Compression Force.

Appendix C: BoM

Compression Spring – OD 5.334 mm, Length 2.54 cm, Material: Steel
Compression Wire – Diameter 1.016 mm, Length 140.03cm, Material: Steel
Circular Plate – Diameter 5.334 mm, Thickness .5 mm, Material: Steel
Inner Sheath – OD 16 Fr (5.333 mm), Length 126.77 cm Material: PTFE
Outer Sheath – OD 18 Fr (6 mm), Length 118.49 cm Material: PTFE
Controller Handle – Length 158.76 mm, Diameter 38.1 mm, Material: ABS
Sheath Deflection Disk – Dimension Below, Material: ABS
Inner Sheath Slider – Dimension Below, Material: ABS
Spring Stabilizer – Dimension Below, Material: Aluminum
Compression Plunger - Dimension Below, Material: Aluminum

Appendix D: SolidWorks Drawings

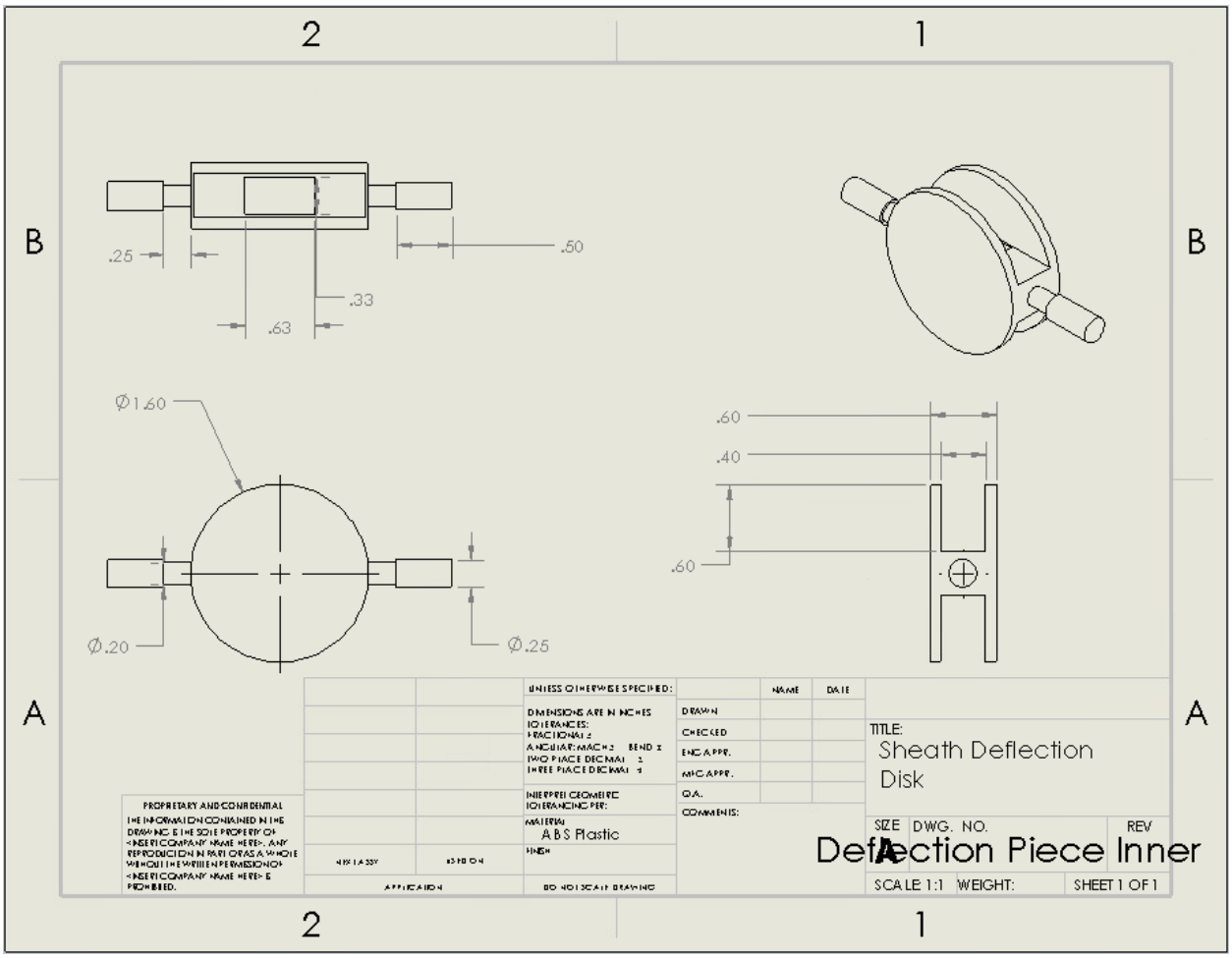


Figure 31: Solidworks Drawing for the Deflector Disk.

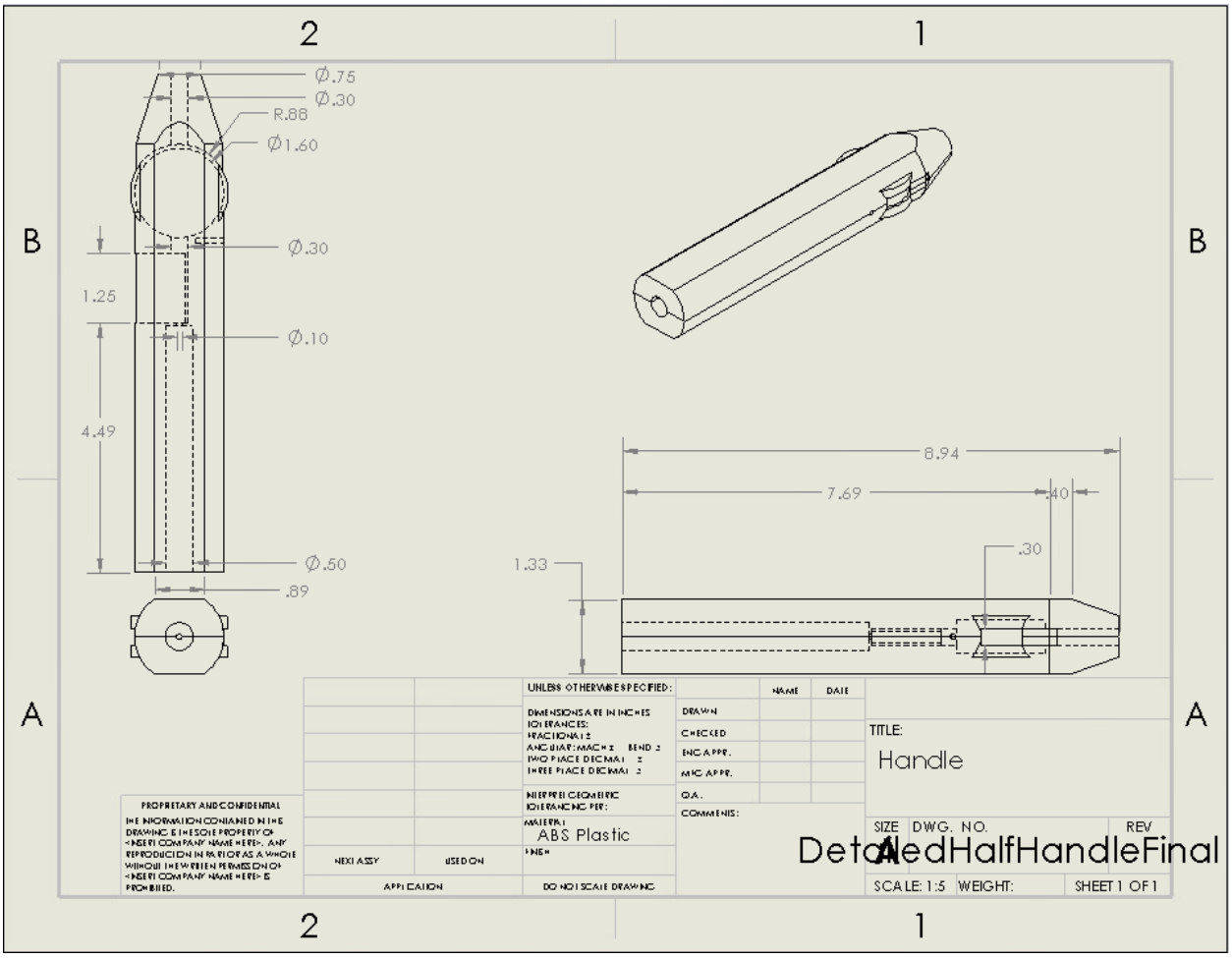


Figure 32: Solidworks Drawing for the Handle.

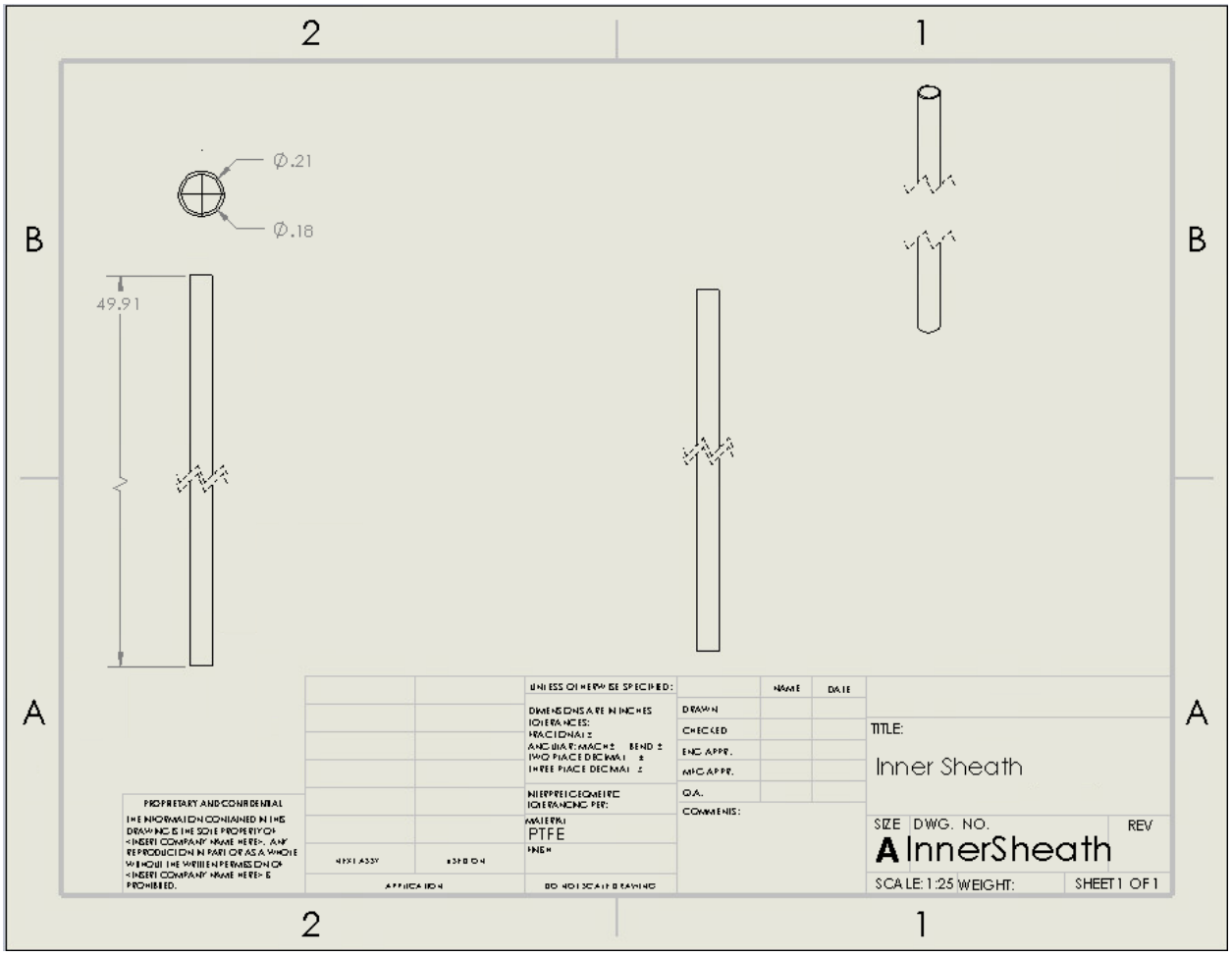


Figure 33: Solidworks Drawing for the Inner Sheath.

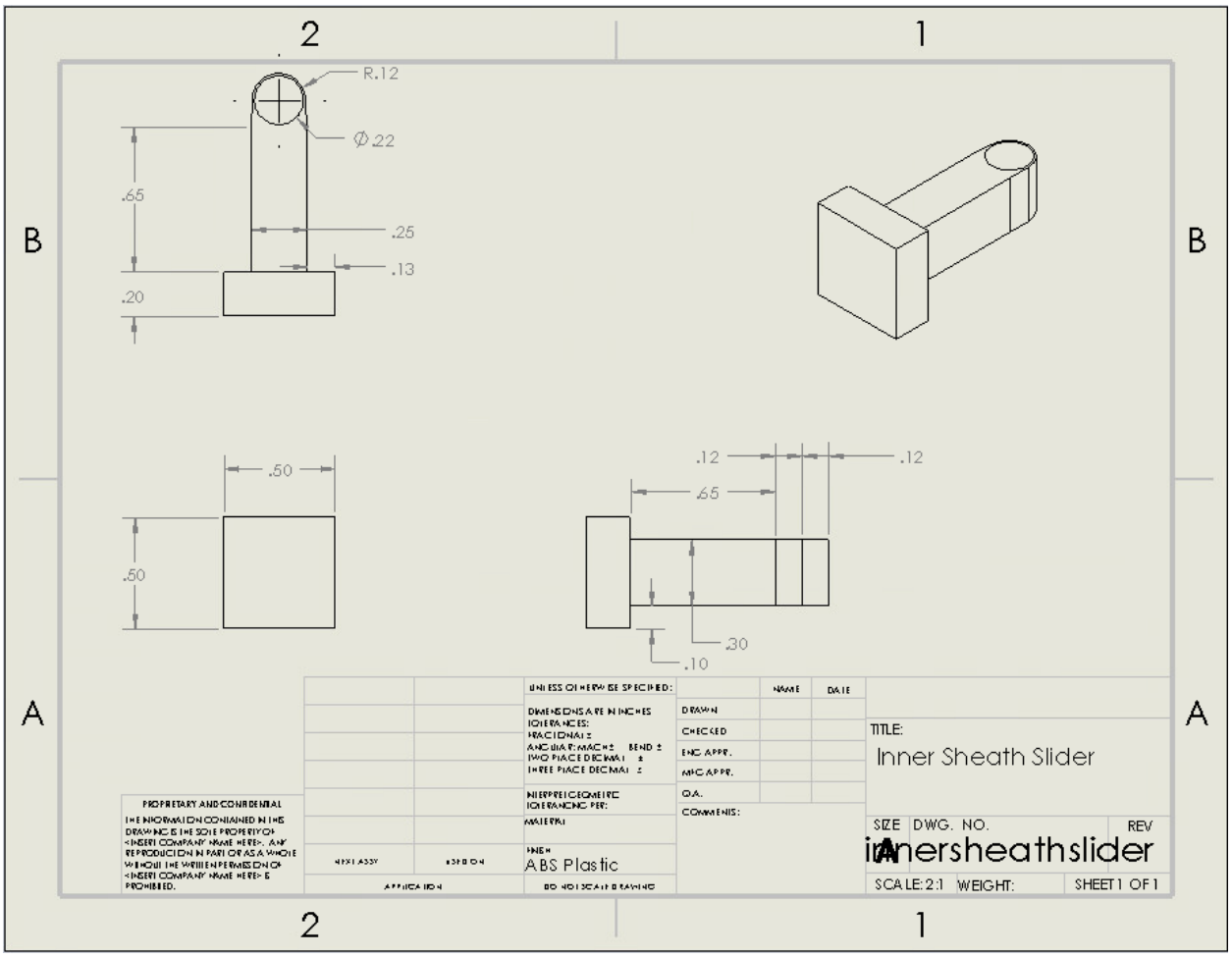


Figure 34: Solidworks Drawing for the Inner Sheath Slider.

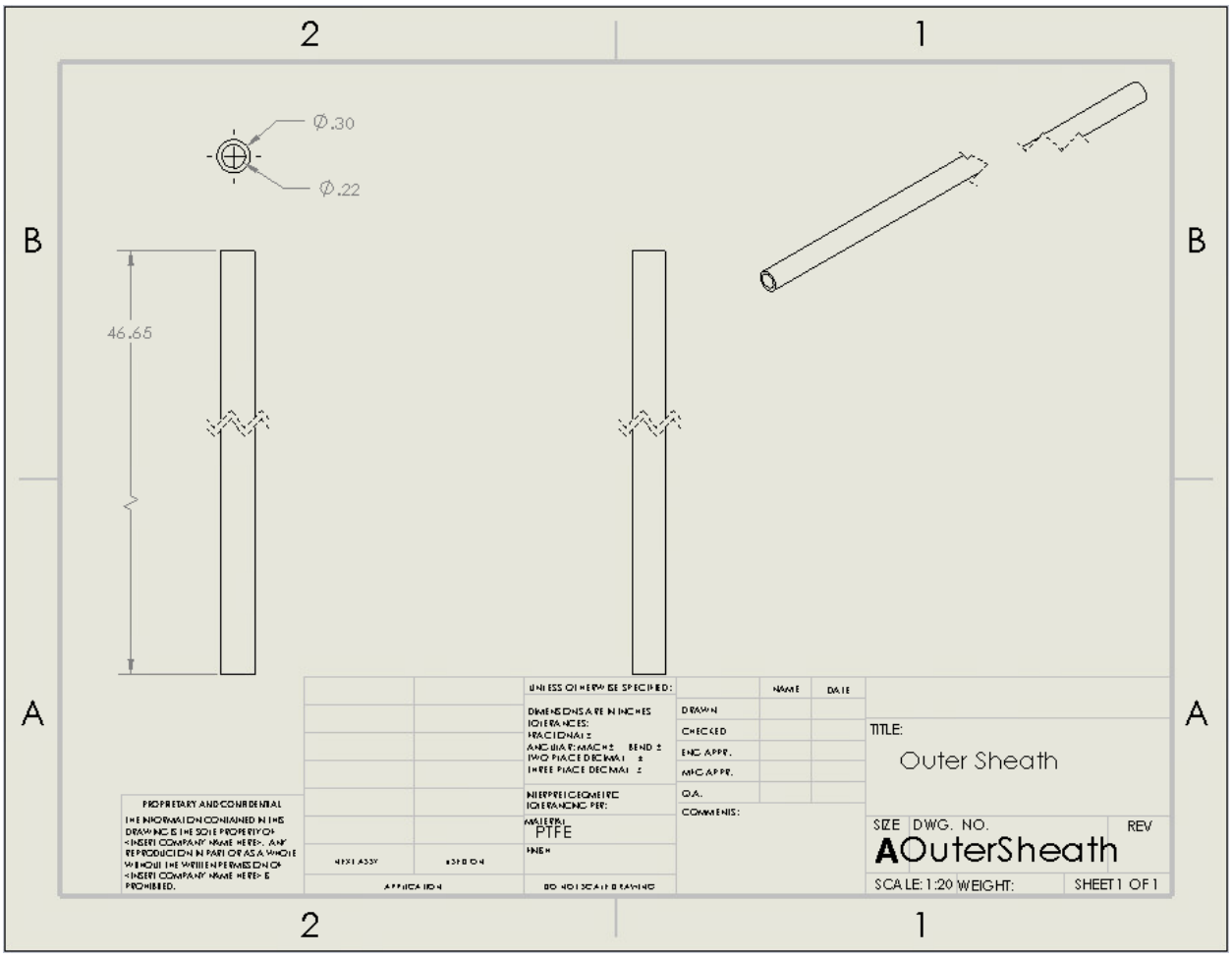


Figure 35: Solidworks Drawing for the Outer Sheath.

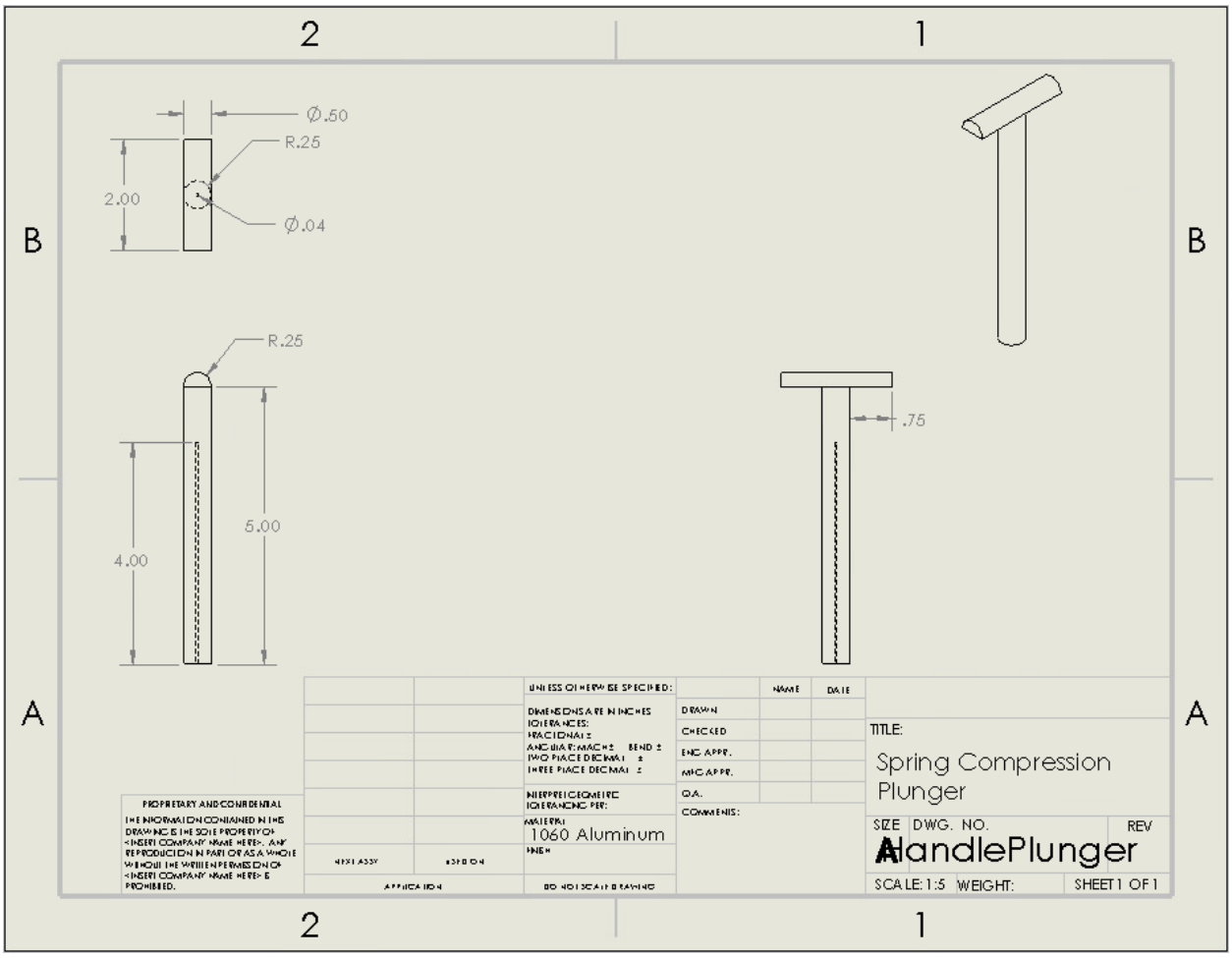


Figure 36: Solidworks Drawing for the Compression Plunger.

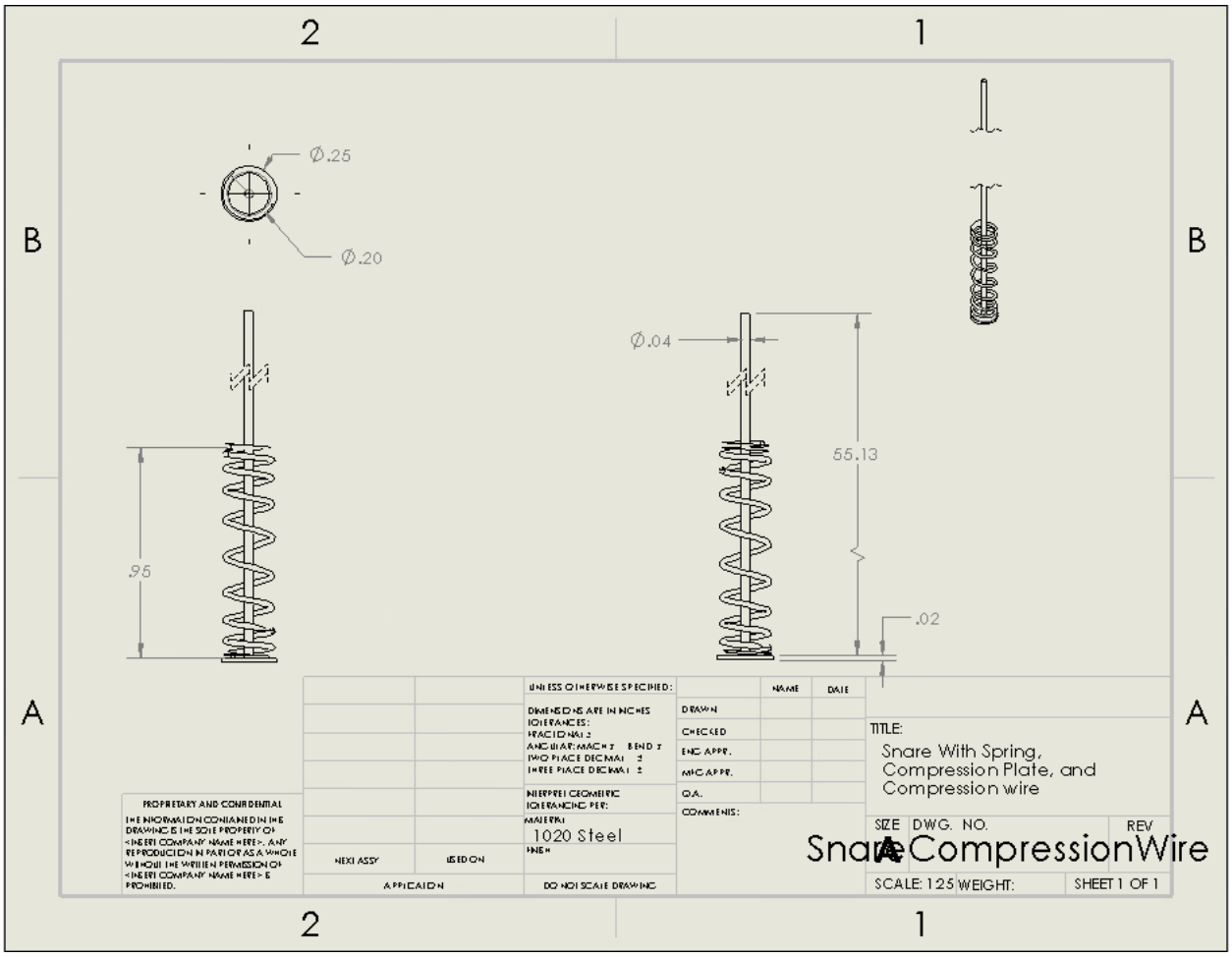


Figure 37: Solidworks Drawing for the Snare.

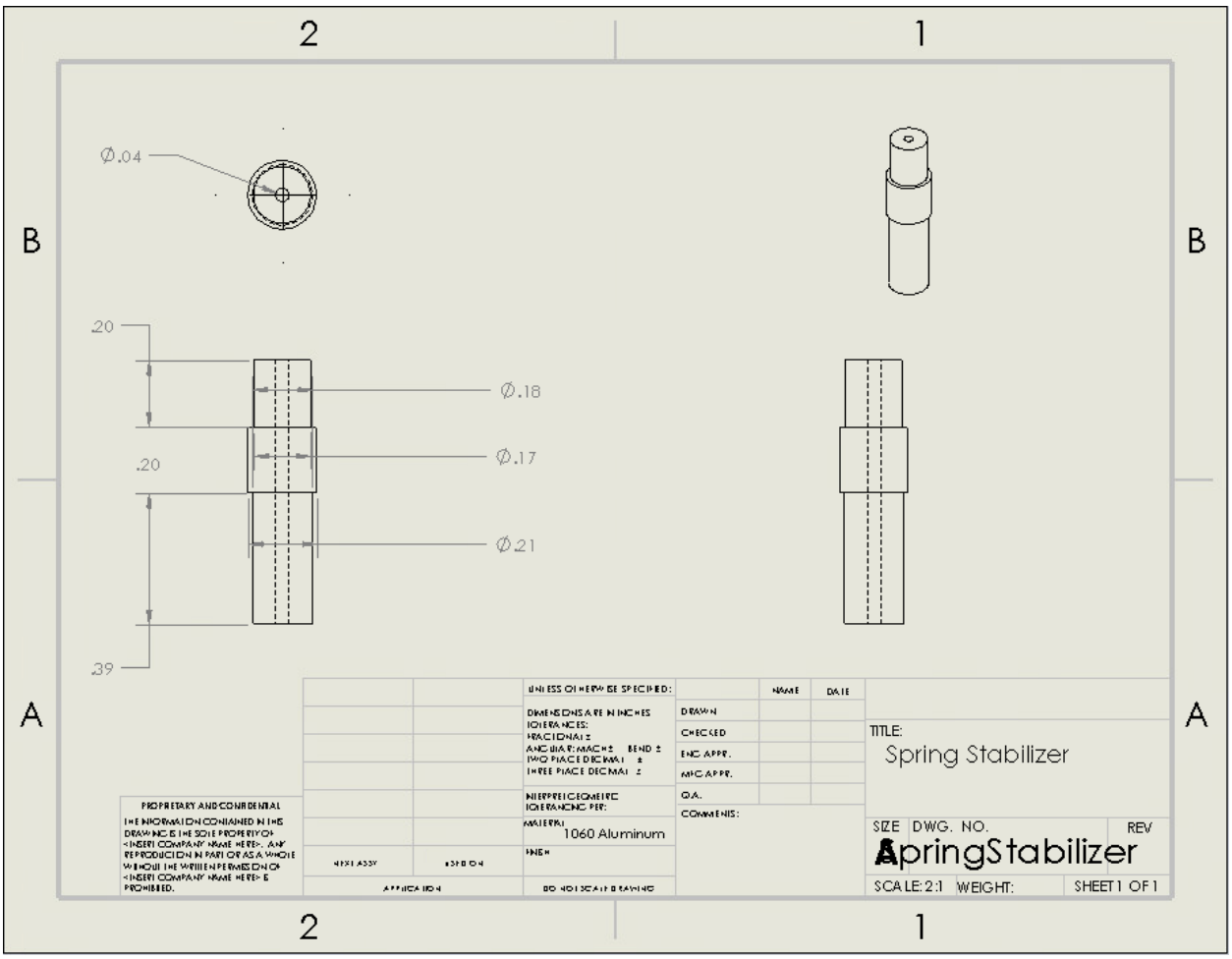


Figure 38: Solidworks Drawing for the Spring Stabilizer.

Appendix E: Project Plan

Task #	Tasks	Subtasks	Input	Task Action	Output	Resource	Weekly Update Progress	Solutions	Start Date	End Date
1										
1.1		Assign Group Leaders	N/A	Group leader and communication leader were assigned.	Trevor Gerken was appointed project lead and Chase Williams was appointed communications lead.	All Team Members	100%	Complete	9/29/2018	10/2/2018
1.2	Team Allocations and Project Planning	Contact Sponsor	N/A	Email was sent to Nathan and Michael.	Primary communications (email) was established and weekly meetings were scheduled.	Email	100%	Complete	10/1/2018	10/1/2018
1.3		Gantt Chart	N/A	Create Gantt chart	Gantt chart was created and updated as neccesary	Zach, Excel	100%	Complete	10/2/2018	1/22/2019
1.4		Meet with sponsor	N/A	Meeting with Nathan and Michael	Project was discussed and questions were answered	All Team Members	100%	Complete	9/28/2018	10/12/2018
2										
2.1	Research	Research Background	N/A	Reading documents and watching videos provided by Nathan and through the internet.	Better understanding of project details	Internet, clinical studies, videos, all team members	100%	Complete	10/12/2018	1/10/2019
2.2		Research Competition	N/A	Reading documents pertaining to competitor products	Better understanding of competition	Internet, clinical studies, videos, all team members	100%	Complete	10/12/2018	11/2/2018
2.3		Research Other Prevailent Fields	N/A	Trade (Electrical, Plumbing, etc.) documents	Ideas for project design from other relevant fields were made	Internet, clinical studies, videos, all team members	100%	Complete	10/12/2018	12/14/2018
2.4		Voice of User	Physician, Sales rep, Manufacturing expert, and patient	Schedule physicians, manufacturing experts, and patients meetings	Meetings scheduled with physicians, manufacturing experts and patients	Sponsors contacts	100%	Complete	10/12/2018	10/26/2018
2.5		Other Research	N/A	Reading documents about other topics as they come up	Better understanding of topics that were neccessary for project	Internet, clinical studies, videos, all team members	100%	Complete	10/12/2018	12/14/2019
3										
3.1	Problem Specification Document	Define Problems	2.1, 2.2, 2.3, 2.4	Define problems with existing tools and what can be done to improve	Problems wth existing tools defined and turned into requirements	Zach, Phillip	100%	Complete	10/19/2018	11/2/2018
3.2		Define Requirements	2.1, 2.2, 2.3, 2.4, 1.4	Define requirements based on research neccesary to make a succesful extraction tool	Based on research requirements were developed	All Team Members	100%	Complete	10/19/2018	11/9/2018
3.3		Analyze Competitors	2.1, 2.2, 2.3, 2.4	Analyze existing femoral exraction tools and compare to requirements	Competitors tools were analyzed and requirements met were tabulated	Chase, Trevor	100%	Complete	10/19/2018	11/2/2018
3.4		Get Sponsor's Input	N/A	Sponsor will set requirements they want to see met for the design	Sponsor set and approved requirements for extraction tool	Sponsor, All team members	100%	Complete	10/19/2018	10/26/2018
3.5		Get Customer's/Users Input	6.1, 6.2, 6.3	Interview customers about femoral tools and requirements	Customers set requirements they deemed necessary for extraction tool	Clem, Dr. Gonzalez, Ryan, All Team Members	100%	Complete	10/12/2018	11/15/2018

4										
4.1	Tree Diagram	Create Tree Diagram	3.1	Format requirements from Problem Specification Document and parameters into a tree diagram	Tree diagram with complete requirements and parameters	Phillip, Internet	100%	Complete	10/25/2018	11/11/2018
5										
5.1	Analyze Competitor Tools	Take Measurements	2.2	Measure dimensions of competitor tools	Utilize to conclude requirements for snare design	Calipers, tape measure, extraction tools, Trevor, Zach, Phillip	100%	Complete	10/22/2018	10/25/2018
6										
6.1	Voices of Customers	Physican/Sales Rep	2.4	Meeting with Clem Cenci and Dr. Jaime Gonzalez	Valuable information and insight into project was obtained	All Team Members	100%	Did not get the chance to meet with Dr. Gonzalez	10/22/2018	11/20/2018
6.2		Manufacturing	2.4	Meeting with Ryan	Valuable information and problem requirements into project was obtained	All Team Members	100%	Complete	11/2/2018	11/8/2018
6.3		Patients	2.4	Patients interviews	Information and requirements for project was obtained	All Team Members	100%	Complete	10/22/2018	10/25/2018
7										
7.1	House of Quality Document	Requirements from Problem Specification Document	3.1, 3.2	Format reqirements from Problem Specification Document into HOQ	Requrements tabulated in HOQ	Chase	100%	Complete	10/13/2018	11/10/2018
7.2		Define Parameters	4.1	Designate paramteters to each requirement	Parameters for each requirement were finalized	All Team Members, Sponsor, Customers	100%	Complete	10/13/2018	11/16/2018
7.3		Voices	3.4, 6.1, 6.2, 6.3	Input requirement priorities from the sponsor and customers	Each requirement was ranked by the sponsor and customers	Sponsor, Customers	100%	Complete	10/13/2018	11/16/2018
7.4		Competitors	3.3	Rank a few competitors tools on how well they satisfy requirements and parameters	Competition was ranked for each requirement and parameter	Chase	100%	Complete	10/13/2018	11/9/2018
8										
8.1	Preliminary Design Review	Power Point Presentation	3.1-3.5, 4.1, 7.1-7.4	Create a presentation showing all requirements and parameters	Presentation for PDR was prepared	Trevor, Phillip	100%	Complete	10/29/2018	11/15/2018
8.2		Preliminary Design Reveiw with Sponsor	3.1-3.5, 4.1, 7.1-7.4	Meet with sponsor to present the preliminary design presentation	Presented PDR to sponsor	All Team Members, Sponsor	100%	Complete	11/2/2018	11/16/2018
8.3		PDR Agreement Form	N/A	Get sponsors signature on PDR agreement form	Sponsor signed off on PDR agreement form	Sponsor	100%	Complete	11/16/2018	11/16/2018
9										
9.1	Engineering Specification Document	Begin Rough Draft	8.1, 8.2	Start on framework for the document	Early rough draft was created	Chase, Zach	100%	Complete	10/31/2018	11/8/2018
9.2		Dividing Workload	8.1, 8.2	Each team member will justify a couple requirements and their parameters	Rough draft of the engineering specification document was divided and written	All Team Members	100%	Complete	11/9/2018	11/20/2018
9.3		Rough Draft Review	9.1, 9.2	Submit rough draft to Stella and Dr. Wilcox to review	Rought Draft was submitted for review	Dr. Wilcox, Stella	100%	Complete	11/20/2018	11/25/2018
9.4		Final Draft	9.3	Review spec document and create a final draft	Final draft was submitted to sponsor and Dr. Wilcox	All Team Members, Sponsor, Dr. Wilcox	100%	Complete	11/29/2018	11/13/2018
10										
10.1	Conceptual Designs	Conceptual Design Drawings	2, 5, 6, 7	Braingstorm and create design drawings for extraction tool	Multiple designs were produced	All Team Members	100%	Complete	10/20/2018	12/7/2018

11	Decision Matrix									
11.1		Concept Ideas	2, 5.1, 6.1, 6.2, 9.4	Display concepts created by the team	Concepts were created to be implemented in decision matrix	Previous Research	100%	Complete	12/14/2018	1/16/2018
11.2		Matix Draft	2, 5.1, 6.1, 6.2, 9.4	Develop the matrix using the concept ideas	Compared concepts to each other and weighed the accordingly	Previous Research	100%	Complete	12/14/2018	1/16/2018
11.3		Final Decision Matrix	2, 5.1, 6.1, 6.2, 9.4	Finalize all decisions made	Developed final concepts to present to sponsor	Previous Research	100%	Complete	12/14/2018	1/16/2018
12	Conceptual Design Review									
12.1		CDR Document	9.3, 10.1, 11.3	Present conceptual design ideas and project plan in a document	Finalized a plan to move foward with in the spring semester	All Team Members	100%	Complete	12/14/2018	1/18/2019
12.2		CDR Powerpoint	9.3, 10.1, 11.3	Create a presentation showcasing the conceptual designs	Created a presentation to show the sponsor	All Team Members	100%	Complete	12/14/2018	1/18/2019
12.3		CDR Presentation	9.3, 10.1, 11.3	Schedule and present the CDR to sponsor	Presented semester plan to sponsor	All Team Members	100%	Complete	12/14/2018	1/18/2019
13	CAD Designs									
13.1		CAD Drawings for Components	10.1, 12.1	Create CAD drawings using conceptual designs and existing products	Created rough draft of parts needed for extraction device	All Team Members	100%	Complete	1/21/2019	4/5/2019
13.2		CAD Drawing Adjustments	10.1, 12.1, 15.1	Ajust dimensions and design as needed per test results and sponsor recommondations	Changed the design and CAD drawings as needed to create final design	All Team Memebers	100%	Complete	2/8/2019	4/27/2019
14	Prototype Snare Design Concept									
14.1		Parts/ Materials	12.1, 12.3, 13.2	Contact sponsor to order materials/parts needed to construct a test	Springs were ordered through the sponsor	All Team Members, Sponsor	100%	Complete	1/25/2019	2/15/2019
14.2		Laser Welding	14.1	Contact sponsor to laser weld spring to compression wire for testing	Sponsor used some of the springs that were ordered and laser welded compression wire with bracing	All Team Members, Sponsor	100%	Complete	2/15/2019	2/22/2019
14.3		Build Snare Design	14.1, 14.1	Prototype snare design using springs supplied by the sponsor	Snare mechanism was build in order to do testing for viability	All Team Members	100%	Complete	2/22/2019	3/1/2019
15	Test Snare Design									
15.1		Test Objectives	2, 9, 12	Design experiments that will test the snare design	Experiments were conceptualized that will test the success/failure of	All Team Members, Sponsor, Dr. Wilcox	100%	Complete	1/25/2019	2/16/2019
15.2		Build a test apparatus	14	Build a rig that will be used in testing of snare design	Apparatus for testing each experiment were created	All Team Members	100%	Complete	1/25/2019	2/18/2019
15.3		Perform Tests	14, 15.2	Perform experiments designed by team to test success of design	Each experiment was perfomed and data was collected	All Team Members	100%	Complete	2/29/2019	4/26/2019
15.4		Updated Snare Design	15.3	Using data from first round of testing adjust parameters and order new batch of springs	New springs were ordered using data from testing that should perform better	All Team Members, Sponsor	100%	Complete	3/5/2019	4/5/2019
15.5		Final Spring Design	15.4	Design a final custom spring that would fit all parameters and order through the sponsor	A final spring was designed and the sponsor made a custom order to aquire the spring	All Team Members, Sponsor	100%	Complete	4/5/2019	4/26/2019

16										
16.1	Prototype Handle Design Concept	Handle Design CAD Drawings	12.3, 13.1	Adjust CAD drawings to fit the final anticipated parameters	CAD drawings were changes per Dr. Wilcox and the sponsors suggestions	All Team Members, Sponsor, Dr. Wilcox	100%	Complete	4/8/2019	4/12/2019
16.2		3D Print Handle and Controls	16.1	Coordinate with team and machine shop to 3D Print parts	The machine shop 3D printed all parts needed to assemble the prototype	All Team Members, UCCS Machine Shop	100%	Complete	4/12/2019	4/18/2019
16.3		Test Fit Handle and Snare	16.3	Make sure all parts manufactured will fit before the final assembly	All parts were succesfully test fitted to ensure they would fit for final assmebly	All Team Memebers	100%	Complete	4/18/2019	4/19/2019
17	Test Handle Design									
17.1		Test Controls of Handle	14.3, 15.5	Test manuverability of controls (only the snare controls will be functional)	Basic controls on the handle were tested for functionality	All Team Members	100%	Complete	4/18/2019	4/26/2019
18	Final Prototype									
18.1		Construct Prototype	15.5, 16.3	Put together the entire design using the prototype snare and handle	The final prototype was constructed to display at the Expo and for the sponsor	All Team Members	100%	Complete	4/25/2019	4/26/2019
18.2		Test Prototype	18.1	Use the final prototype to test the snare in the sponsors model	Final prototype was tested in the sponsors model at Philips	All Team Members, Sponsor	100%	Complete	4/26/2019	4/26/2019
19	Final Report									
19.1		Begin Final Report	2--17	Create a rought draft of final report so that Dr. Wilcox can check the format	Basic layout and format for the final report was created	Trevor, Dr. Wilcox	100%	Complete	4/5/2019	4/11/2019
19.2		Writing Final Report	2--17, 19.1	Team will write the final document detailing the project	Final Report was completed after feedback from Dr. Wilcox	All Team Members, Dr. Wilcox	100%	Complete	4/11/2019	4/26/2019
19.3		Complete Final Report	19.2	Team will complete the final report as required by UCCS	Team completed the final report	All Team Members	100%	Complete	4/26/2019	4/30/2019
20	Poster									
20.1		Create Poster	19	Create a poster to present project at the senior design expo	Poster was created for the senior design expo	All Team Members	100%	Complete	4/12/2019	4/30/2019
21	Brochure									
21.1		Create Brochure	19.3, 20.1	Create a brochure for the senior design expo	Brochure with our picture and final design was created	All Team Members	100%	Complete	4/19/2019	4/25/2019

Appendix F: Gantt Chart

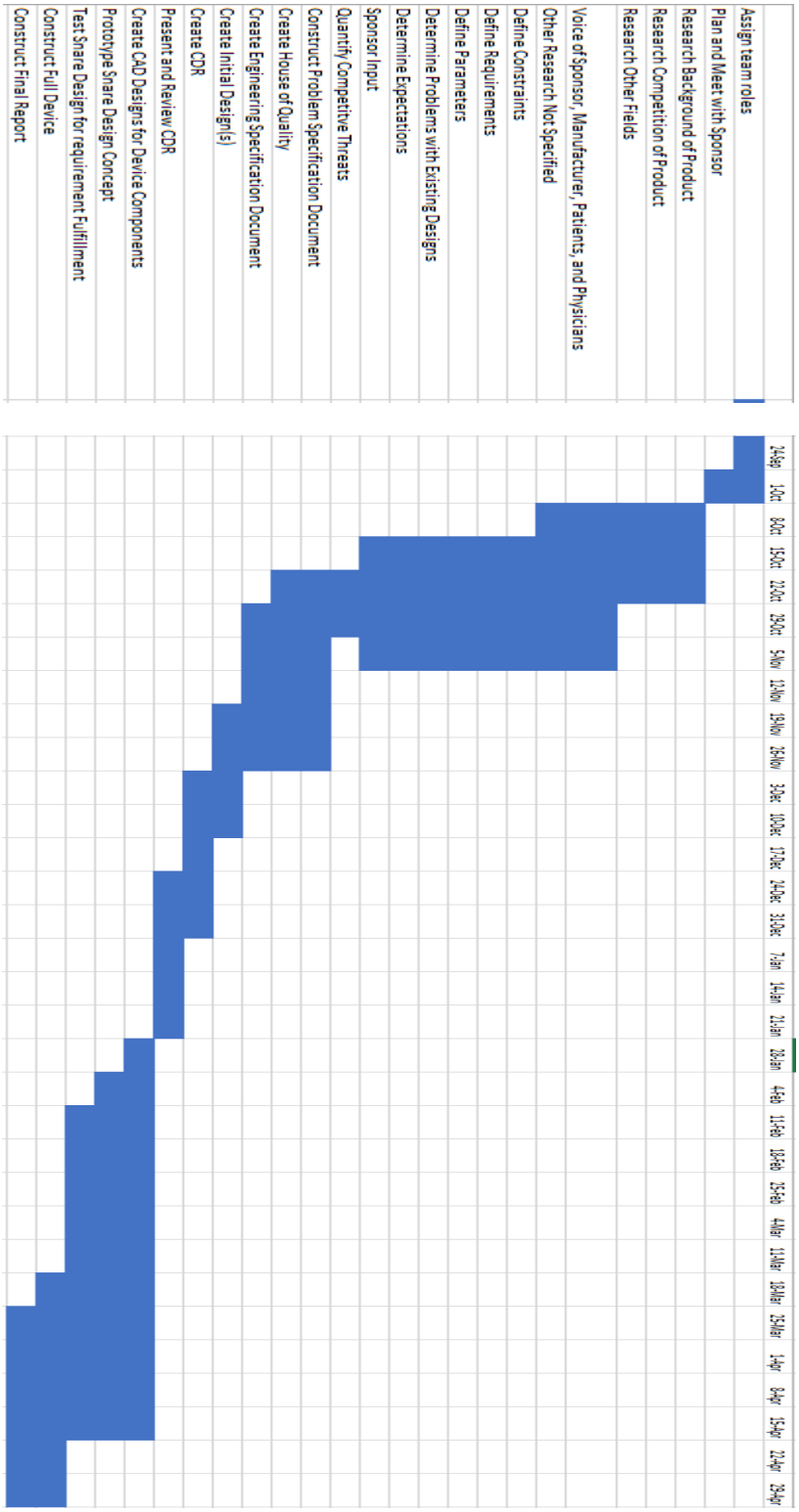


Figure 39: Gantt Chart

Appendix G: House of Quality

1,3	Voices and their priorites: 1= high, 2 = med, 3 = low
2	List of all requirements
4,5	Competitor satisfaction: 1 = high, 2 = medium, 3 = low
6,7	Relevance of of EP to req: 1 = high, 2 = medium, 3 = low
8	Not used in this version
9,10	Paramater values: competitors and design target values

		Voices and requirement priorities					Engineering parameters and relevance to requirements						
	Requirements	Philips (Sponso	Manufacturers	Sales	Patients	Team Phylis	Density of material used for snare must have density between 6,000-20,000 kg/m3	Density of material used for radiopaque band must be between 20,000-25,000 kg/m3	Density of material used for the catheter must be between 2,000-2,500 kg/m3.	The Young's Modulus of the catheter material must be between .4-.6 GPa.	The Young's Modulus of the snare material must be between 80-420 GPa.	The length of the extraction tool must be between 90-120 cm.	The snare must have a grasping diameter of between 15-20 mm.
R1	Extraction tool should be easily distinguishable under fluoroscopy screenings	1	1	1	2	1	1	1	1	3	3	3	3
R2	Extraction tool should be atraumatic to tissue	1	2	1	1	1	3	3	2	2	1	3	2
R3	[illegible] copycat design, must be unique and innovative	2	3	3	3	1	3	3	3	3	3	2	3
R4	Catheter should be deflectable and maneuverable	2	3	1	2	2	3	3	2	1	3	1	3
R5	Material of snare should be flexible	2	1	2	2	2	2	3	3	3	1	2	2
R6	Modifiable to Accommodate Different Lengths and Diameters of Snares	3	1	2	3	3	3	3	3	3	3	1	1
R7	Extraction tool is maunfactureable	1	3	1	3	2	2	2	2	2	2	2	2
R8	Snare effectively grasps leads for removal	1	1	2	1	1	2	3	3	3	1	2	1
R9	Extraction tool controls are straightforward/simple	1	2	1	3	1	3	3	3	3	3	2	2
R10	Snare must be able to disengage from the lead for repositioning and abandonment	1	3	1	2	1	2	3	3	3	1	3	3
						Cook Medical	1	3	3	1	1	1	1
						Medtronic	2	1	1	1	1	1	1
						Merit Medical	1	1	1	1	1	1	1
						Argon Medical	1	1	1	1	1	1	1
						PFM Medical	1	1	1	1	1	1	1
						BD Interventional	1	1	1	2	2	2	1

							Competitors					
Snare must fit through and function after being retracted 10 times in a catheter with OD 12 Fr without plastically deforming	Materials used for extraction tool must adhere to Sterilization and Biocompatibility Standards	Design of extraction tool must be patentable.	Extraction tool can be operated by one person (one or two hands).	Guiding catheter must be no larger than 16 Fr in diameter.	Material used for snare must have maximum surface roughness of 2.00 nm RMS	The snare must be able to withstand a pulling force greater than 10 lbs	Cook Medical (Needle's Eye Snare and SteadySheath)	Medtronic (Amplatz Gooseneck Snare)	Merit Medical Systems, Inc. (EN Snare System)	Argon Medical Devices Inc. (Atrieve Vascular	PFM Medical Inc. (Multi-Snare)	BD Interventional (Bard Snare Retrieval Kit)
3	2	3	3	3	3	3	2	1	1	1	1	1
3	2	3	3	3	1	2	1	1	1	1	1	1
3	2	1	2	3	3	3	1	2	1	2	2	2
3	2	3	3	1	3	3	2	2	1	2	3	1
1	1	3	2	2	3	2	2	2	2	2	3	2
1	3	3	3	1	3	3	1	1	1	2	1	2
2	1	2	3	2	2	3	1	1	1	1	1	1
1	2	3	2	2	3	1	1	1	1	2	2	2
2	3	3	1	2	3	1	2	1	2	1	2	2
1	3	3	2	1	3	2	2	1	3	3	1	1
1	1	1	1	1	1	N/A						
1	1	1	1	1	1	N/A						
1	1	1	1	1	1	N/A						
2	1	1	1	1	1	N/A						
2	1	1	1	1	1	N/A						
2	1	1	1	1	1	N/A						

Appendix H: Problem Specification Document

Problem Specification

Main Customer's End Goal:

The goal of this project is to develop a competitive design for Philips / Spectranetics that can successfully complete a lead extraction through the femoral vein. The design should comply with all sterilization and biocompatibility standards and fit within the femoral vein. The snare should refrain from any sharp edges to eliminate tissue tear and damage to the walls of the vein.

Main Customer's Requirements through interview

Requirement	Why Requirement is in Place	Mandatory, Should Be Included, or Optional?
Extraction tool should be easily distinguishable under fluoroscopy screenings	The fluoroscopy (real time x-ray imaging) is the only way for the electrophysiologist to have a visual for the snare/sheath location.	Mandatory, Yes
Extraction tool should be atraumatic to tissue	The snare will go through the femoral vein, to the vena cava, and then to the upper right atrium (part of the heart). Hospitals, such as John Hopkins, have surgeons prepared to perform open heart surgery in case of tissue tear or damage.	Mandatory, Yes
Extraction tool should not be a copycat design, must be unique and innovative	Phillips and Spectranetics consistently compete with other companies in the biomedical industry. To remain competitive, the design has to be different and more innovative than anything else on the market.	Mandatory, Yes
Sheath (catheter) should be deflectable and maneuverable	Since the sheath will have to maneuver through veins and different parts of the cardiovascular system, there is a limited amount of access in the upper right atrium. Flexibility is the only way to increase maneuverability which makes it easier for the electrophysiologist to snare the lead.	Mandatory, Yes
Material of snare should be flexible	This eliminates tissue tear and increases the rate of success. When the snare deforms on impact, the tissue will be less susceptible to damage or tear. The rate of success would increase because flexibility would increase the chances of the snare grasping the lead.	Should be Included, Yes

Snare effectively grasps leads for removal	The success of this procedure stems to the apparatus' capability to grasp the lead. Without this, the procedure can't be successful.	Mandatory, Yes
Snare must be able to disengage from the lead for repositioning and abandonment	In case of an emergency where the physician needs to abandon the procedure or to reposition the tool, it is important that the snare can release the lead and adjust the tool as necessary	Mandatory, Yes

Other Customers:

1. Clement Cenci (Sale Representative at Spectranetics) / Dr. Jaime Gonzalez (Physician)
1. Ryan (Manufacturing Engineering at Phillips)
1. General Patients

Additional Requirements that should be in place based off other customers

Requirement	Why Requirement is in Place	Mandatory, Should Be Included, or Optional?
Extraction tool is manufacturable (Ryan)	The design of the snare/sheath should be considered because it has a lot of financial implications.	The scope of this project is to create a competitive design, so the manufacturing should be included. However, if the prototyping stages are reached, manufacturing will be mandatory.
Extraction tool controls are straightforward/simple (Clement)	Having a tool that is familiar to other tools that are commonly used it very important for physicians. That familiarity allows them to have more control and be more efficient. Therefore, the controls should be simple and familiar to physicians.	Mandatory, Yes
Design of device should be easily modifiable to accommodate different lengths and diameters of snares (Clement)	Not all patients' cases for lead removal are the same and some require a different sized snare/tool. Having an pparatus with a smaller diameter could allow for this apparatus to be used on all patients.	Optional, No

Analyzing the Competitors

Competing Product	Requirements met by competitor	Feature(s) of competitor that meet that/those requirement(s)	Risks that can occur from the way the competitors fulfilled the requirements
Merit Medical Systems, Inc.: EN Snare Standard Snare System	Maneuverability.	Three loops that rotate, providing coverage of many vessel sizes.	May be hard to visualize under fluoroscopy and could potentially get tangled.
Cook Medical: Needle Eyes Snare	Effective at grasping.	Needle's eye snare.	Hard to visualize under fluoroscopy.
Medtronic: Amplatz GooseNeck Microsnare Kit	Straightforward design, high manufacturability, multiple working diameters.	Horizontal, simple design, multiple catheter sizes/lengths, working diameters, and snare lengths.	Can only snare lead fragments by itself. Requires another object to side snare lead.

Mandatory Requirements

Requirement	If quantitative, write in target value, otherwise write "See Attached"
Extraction tool should be easily distinguishable under fluoroscopy screenings	See Attached
Extraction tool should be atraumatic to tissue	See Attached
Extraction tool should not be a copycat design, must be unique and innovative	See Attached
Snare sheath (catheter) should be deflectable and maneuverable	See Attached
Snare effectively grasps leads for removal	See Attached
Extraction tool controls are straightforward/simple	See Attached
Snare must be able to disengage from the lead for repositioning and abandonment	See Attached

Should Be Included Requirements

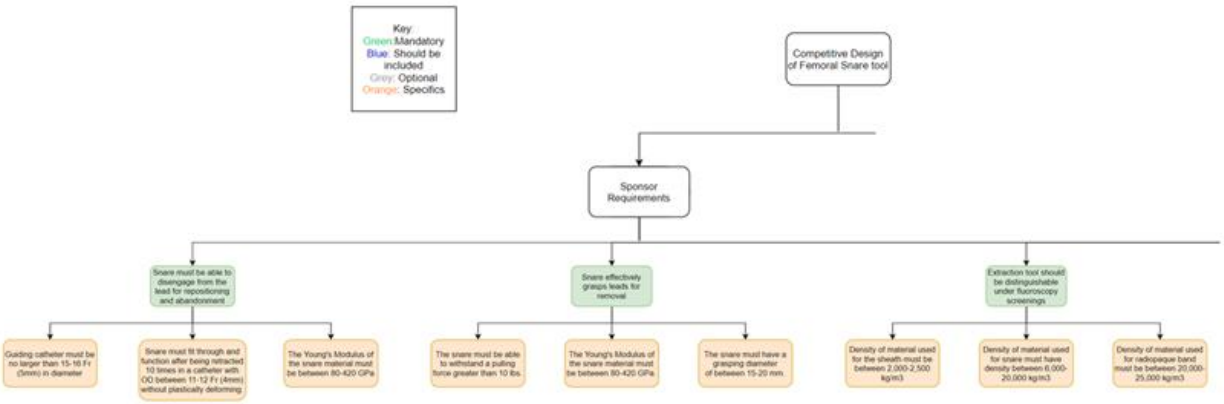
Requirement	If quantitative, write in target value, otherwise write “See Attached”
Extraction tool is manufacturable	See Attached
Material of snare should be flexible	See Attached

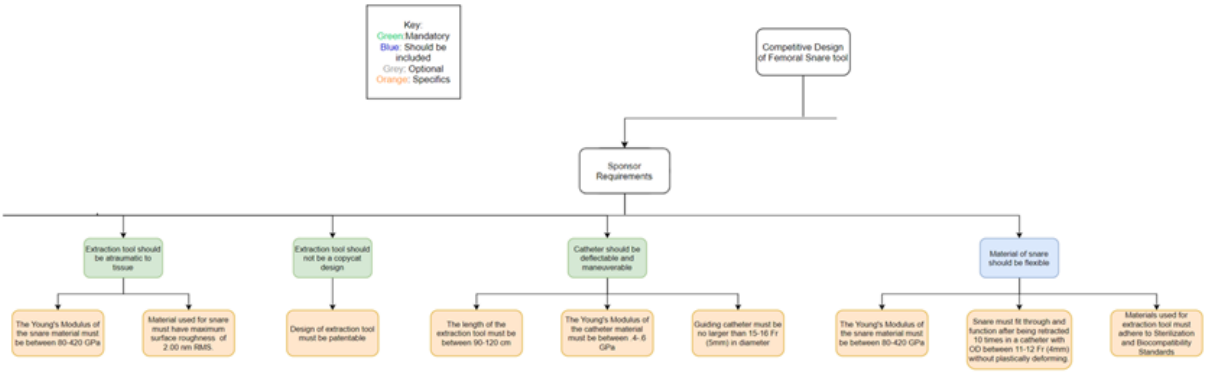
Optional Requirements

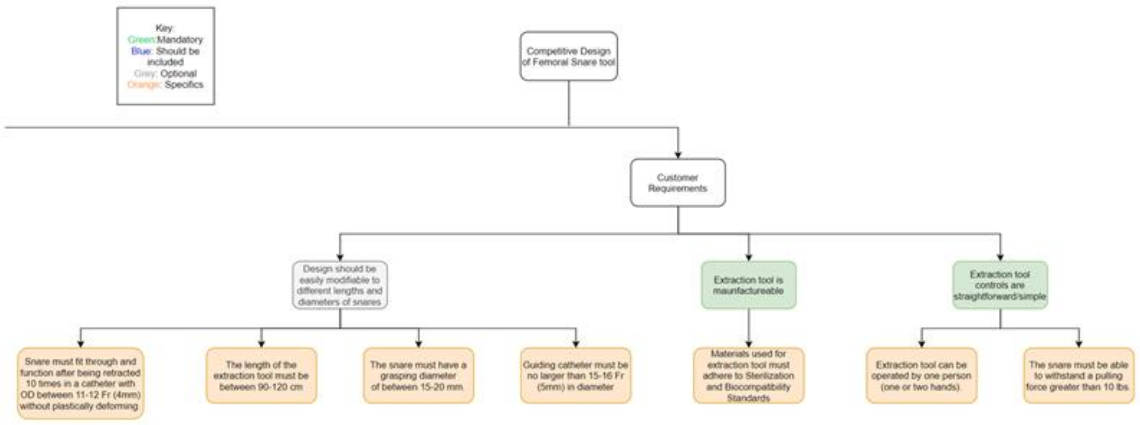
Requirement	If quantitative, write in target value, otherwise write “See Attached”
Design of device should be easily modifiable to accommodate different lengths and diameters of snares	See Attached

The attached document should be the Tree Diagram

Appendix I: Tree Diagram







Appendix J: Decision Matrix

		Criteria	Distinguishable Under Fluoroscopy	Atraumatic to Tissue
Rankings	Importance	Solutions		
1	Low	Suction	1	3
2	Medium	Fingertrap	2	3
3	High	Spring	3	3
Max Possible: 66		Jaws	2	1

Unique and Innovative	Catheter-Deflectable and Maneuverable	Snare Material-Flexible	Easily Modifiable to Accommodate Different Lengths and Diameters of Snares
3	1	1	1
3	1	1	1
3	1	3	3
1	1	1	1

Manufacturable	Snare Effectively Grasps Lead	Controls are Straightforward and Simple	Snare Must be able to Disengage	
				Totals
3	1	2	3	41
2	2	2	3	45
3	3	3	3	64
2	3	2	3	40

Appendix D: Works Cited

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