# Gore Stent Crimper Project

# Final Report

**Ashley Blood**
**Nick Green**
**Jennifer Lawson**
**Cameron Lissarrague**

**November 23, 2020**

NAU NORTHERN ARIZONA UNIVERSITY

**Project Sponsor: W.L Gore and Associates**
**Faculty Advisor: Sarah Oman**
**Sponsor Mentor: Tanner Moll, William Reilly**

# DISCLAIMER

This report was prepared by students as part of a university course requirement. While considerable effort has been put into the project, it is not the work of licensed engineers and has not undergone the extensive verification that is common in the profession. The information, data, conclusions, and content of this report should not be relied on or utilized without thorough, independent testing and verification. University faculty members may have been associated with this project as advisors, sponsors, or course instructors, but as such they are not responsible for the accuracy of results or conclusions.

# EXECUTIVE SUMMARY

This project was given to the team by W.L. Gore and Associates. The goal of the project is to create a stent crimper using an iris crushing mechanism. The end device must display the amount of force being applied to the device and the diameter of the iris.There are six main subsystems designed by the team. The six subsystems include the leaflets, guiding plates, motor attachment, motor, housing, and electronics. Through the iterative engineering process, the team chose an Arduino Mega to control the device. The Arduino receives input through a keypad, and displays information to the user via an LCD display. The team chose a worm gear attachment system that allows for the team to acquire the needed force from a stepper motor which was chosen as the motor system. There are two guiding plates, one that rotates and one that is stationary. The stationary plate guides the leaflets into place, and the rotating plate forces the leaflets to close. The stationary plate has linear slots placed at an angle and the rotating plate has linear slots perpendicular to the inner hole. The iris consists of 18 leaflets that are teardrop shaped. The leaflets have an extruded knob on the front that are placed within the slots on the stationary plate and they have a threaded hole on the back for shoulder screws to be inserted through the rotating plate. The housing was designed around the other subsystems to enclose the design. The plates were originally made to be manufactured out of aluminum for the prototype and steel for the final design. Due to our budget, steel was not feasible and this design is considered to be a prototype. Our source for manufacturing the plates was not able to machine the plates from aluminum and thus they were 3D printed. Leaflets were machined out of aluminum. Due to 3D printed plates, the device faced issues such as heavy friction and tolerance stackups, which prevented the leaflets from moving within the guides in the plates. Future recommendations for resolving the frictional issues is creating all the rotating components (leaflets, rotating plate, stationary plate) out of stainless steel as well as including bearings within the slots to create a fluid movement between the plates and leaflets. Another solution proposed by the team is to decrease the number of leaflets which would provide more spacing between the slots. The slots could then be modified such that they have a larger width, allowing for less strict tolerances. All electronics and actuation systems were successful including the LCD screen for user input/output, the keypad for user input, the load cell for force readings, and the stepper motor. The code successfully translated the counts from the stepper motor to the desired diameter as well as the load cell force to radial force conversion. This system was tested multiple times (while detached from the iris) and was executed successfully each time. Although the major component of our system failed, the team enjoyed engaging in a difficult project that challenged each of us as engineers. We consider this project a success as it developed our design, processing, and execution skills while providing us with knowledge that will be carried into our careers as professional engineers.

# ACKNOWLEDGEMENTS

The Gore capstone team would not have completed this project without the financial support from W.L. Gore and Associates. We would like to thank our mentors Tanner Moll and William Reilly, as well as the rest of the team from W.L. Gore and Associates, for guiding us through this project and providing us with the knowledge to become better engineers. We would also like to thank our technical advisor, Sarah Oman and David Trevas, for providing the team with guidance and wisdom throughout the project. A final thanks to all of the help from others around the team that inspired us each and every day.

# TABLE OF CONTENTS

# 1 BACKGROUND

## 1.1 Introduction

The goal of this project is to utilize an iris design to create a stent crimper that outputs radial force and diameter. A stretch goal for this team is to automate the device so that it will not be hand actuated. A graphical user interface (GUI) for the output of radial force and diameter is also a desired feature but not required. The sponsor for this project is W.L. Gore and Associates, a medical device company, that works to improve the quality of life for individuals worldwide. One product distributed by Gore to accomplish this is an implantable stent used to restore blood flow to arteries. Before stents are inserted into the body they must be crimped to a specific diameter over a balloon. The current device used to crimp stents before deployment is hand actuated and does not provide radial force and diameter output. These issues will be addressed by the novel design created in this project.

## 1.2 Project Description

Following is the original project description provided by the sponsor.

> "The scope of this project is to design, build, and test a low force stent crimping machine utilizing a crush iris with a radial force readout. Depending on team size and background, an option to create a novel test method to verify stent diameter."

# 2 REQUIREMENTS

This project requires the construction of an automated stent crimper that accommodates stents with a range of diameter and lengths. One main goal for this project was to treat it like a start-up company, and therefore required the team to define the requirements rather than having the requirements pre-defined. The specifications of a stent crimper details the customer requirements and engineering requirements. The design's ability to meet the desired goal will be measured through these specifications. The customer requirements were obtained from the project proposal and the engineering requirements were defined based on literature research. The functional decomposition for this project includes a black box model, functional model, and house of quality.

## 2.1 Customer Requirements (CRs)

Customer requirements are characteristics or specifications of a design that a customer identifies for a desirable product. The customer requirements for this project include an iris design, safety and manufacturing standards, range of diameters and lengths, radial force, accuracy, cost, safety, and visual data outputs. The highest ranked customer requirements include an iris design and safety standards due to medical concerns and functional purposes of the design. The device must be accurate in terms of diameter, length, and radial force as to ensure the user is properly crimping the stent. The least important customer requirement was data outputs because this requirement was considered optional.

## 2.2 Engineering Requirements (ERs)

Engineering requirements are quantifiable parameters or conditions used to measure the design's ability to meet customer requirements. The engineering requirements for this project include an iris design with at least 10 leaflets, a diameter range of 1 to 30 mm, a length range of 8 to 76 mm, a minimum radial force of 108N and maximum radial force of 823N, cost under $3000, as well as a visual display through use of a GUI [1-3]. The tolerances for the diameter and length have to be +/- 0.025 mm and +/- 3 mm, respectively [4]. The tolerance for the radial force has to be +/- 10N. The diameter and length range is a minimum range set by the team to ensure a successful design.

## 2.3 Functional Decomposition

A functional decomposition investigates the functional flows of material, energy, and signal of a device. The functional decomposition provides the team with a comprehensive guide that correlates functions with customer needs. A black box model and functional model were created to visualize the flow of the device. A house of quality diagram was also created to transform customer requirements to engineering requirements.

### 2.3.1 Black Box Model

A black box model was constructed to express the overall function of the design and identify input and output flows [Figure 1]. Flows are defined as material, energy or signal inputs that are utilized by the device. Material flow is represented by the bold line, energy flow is represented by the regular line, and signal flow is represented by the dotted line. The overall flow of the device is to crimp a stent which means the reduction of the diameter of a stent to conform to a catheter. The material flow consists of the input of a stent and human hands and returns the stent and hands. The energy flow consists of the input of electrical energy and human energy and returns mechanical strain energy . The signal flow consists of the on/off signal and returns the on/off signal, radial force output, and diameter reduction. The flows discussed in the black box model impact each other which will be addressed in the functional model. This black box model helps with deconstructing the problem and identifying which sections of the device the team will need to create solutions for.


Figure 1: Black Box Model

### 2.3.2 Functional Model/Work-Process Diagram/Hierarchical Task Analysis

A functional model provides operational guidelines to the broad overview of flows addressed in the black box. The operational guidelines or function chains is the process of transformation from the input flows to output flows [Figure 2]. Each customer need is addressed in the functional model.

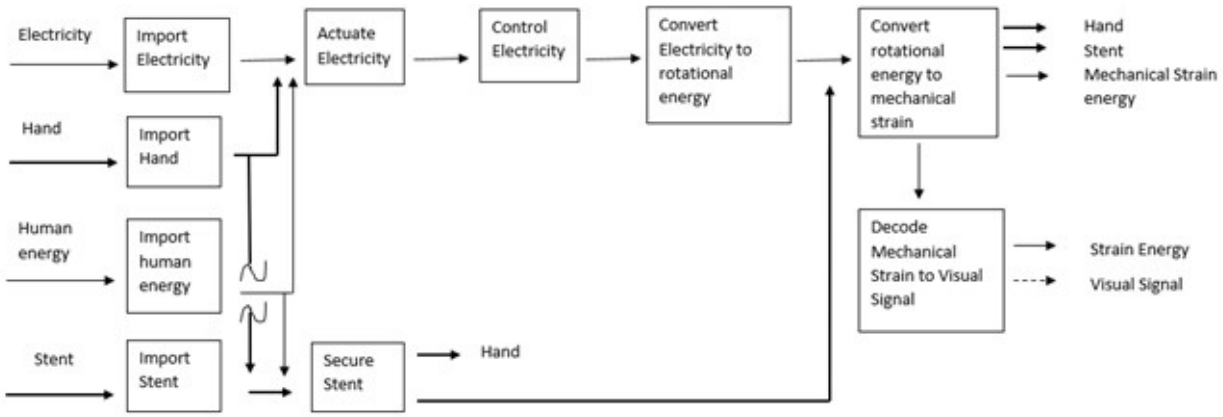


Figure 2: Functional Model

The functional flow of electricity addresses the customer needs of the diameter, length, radial force, accuracy, iris design, and safety. The function of converting rotational energy to mechanical strain energy represents the customer needs of diameter, length, radial force, iris design, and accuracy. Accuracy is also represented by the securement of the stent. The functional chain of electricity from importing electricity to converting rotational energy to mechanical strain represents the customer's need for safety. The function of decoding mechanical strain to visual signals represents the customer's need for data output.

The functional model generated simple sub-functions to assist with the discovery of information. This model identified critical functions and functional chains of the design that the team should concentrate on for an effective and safe device.

## *2.4 House of Quality (HoQ)*

A house of quality (HOQ) was constructed to translate customer needs into engineering requirements based on customer's specifications of importance. The customer needs are related to engineering requirements based on the determined strength of their relationship. From this relationship, the technical importance of each engineering requirement was determined to assess the significance of each design aspect. The engineering requirement with the highest technical importance was the radial force due to safety concerns and functionality of the design [Figure 3]. The least important engineering requirement, based on technical importance, was the visual display. Based on the HOQ, the team considered the radial force of the design a critical element to consider within the designing process.

| 1: low, 5: high<br>Customer importance rating | Functional Requirements (How) →<br>Customer Requirements - (What) ↓ | Iris Design | Diameter | Length | Radial Force | Cost | Visual Display |
|---|---|---|---|---|---|---|---|
| 5 | Iris Design | 9 | | | 3 | | |
| 5 | Meets Safety Standard | 1 | 9 | 1 | 9 | | |
| 4 | Range of Diameters | 3 | 9 | | | 3 | 3 |
| 3 | Range of Lengths | 3 | | 9 | | | |
| 4 | Appropriate Radial Force | 3 | 3 | | 9 | | 3 |
| 1 | Outputs Data | | | | | 1 | 9 |
| 4 | Accuracy | 1 | 9 | 1 | 9 | 3 | |
| 2 | Cost | | | | | 9 | |
| | Technical importance score | 87 | 129 | 36 | 132 | 43 | 33 |
| | Importance % | 19% | 28% | 8% | 29% | 9% | 7% |
| | Priorities rank | **3** | **2** | **5** | **1** | **4** | **6** |
| | Target | >10 leaflets | 0.5-30 mm | 8-76 mm | 108-823 N | $3,000 | LCD/LED screen |
| | Tolerance | - | +/- .02 mm | +/- 3 mm | +/- 5 N | -$300 | - |

| Relationships: | 9 | 3 | 1 | |
|---|---|---|---|---|
| | Strong | Moderate | Weak | None |

Figure 3: House of Quality

## 2.5 Standards, Codes, and Regulations

Standards must be acknowledged and followed for this project as the device is used in medical device manufacturing. The standards and regulations this team has explored include the following organizations:

- American Society of Testing and Materials (ASTM)
- American National Standards Institute (ANSI)
- Food and Drug Administration (FDA)
- Occupational Safety and Health Administration (OSHA)

The standards that were found for this project are shown in table 1. These regulations are of great importance because the proposed device will be used with medical instruments and factors such as biocompatibility, compression force, and tolerances must be considered. Biocompatibility ensures that the material used for the stent crimper will not flake onto the stent and negatively affect human tissue when deployed. Understanding the correct compression force protects the stent from being over compressed and damaged. Tolerances for the diameter and length establish safety for the device by determining how well it performs.

Table 1: Standards of Practice as Applied to this Project

| Standard Number or Code | Title of Standard | How it applies to Project |
|---|---|---|
| ANSI/AAMI HE 74:2001 [5] | Human Factors Design Process for Medical Devices | Helps in the design of how the device will interface with the user in a safe manner. |
| ASTM F2257 [4] | Standard Specification for Wrought Seamless or Welded and Drawn 18 Chromium-14Nickel-2.5Molybdenum Stainless Steel Small Diameter Tubing for Surgical Implants | Helps in the determination of tolerances for diameter and length measurements in accordance to stents. |
| FDA 876.5011 [6] | Title 21- Food and Drugs<br>Chapter 1, subchapter --Medical Devices | Helps in identifying what factors must be considered for design construction such as material and compression force. |
| ASTM F639 - 09 [7] | Standard Specification for Polyethylene Plastics for Medical Applications | Helps in identifying specific polyethylene (PET) plastics requirements for medical use |

# 3 DESIGN SPACE RESEARCH

The design space research incorporates design research and benchmarking of existing devices. The design research involves understanding stent sizes and materials, motors, radial forces, and components of a stent crimper. This research was applied in the benchmarking section for assessment of the existing designs.

## *3.1 Literature Review*

The literature review entails the process of individual research as well as specified information that was utilized to assess existing designs and refine engineering requirements. The literature review encompassed stent design and tolerances, motor and motor control, radial force calculations, and a brief overview of various stent crimper subsystems.

The research of standard diameter and length sizes of stents was conducted for the purpose of defining engineering requirements. The GORE Excluder Endoprosthesis aortic stents have nominal diameters of 23 mm to 35 mm with lengths from 12 to 18 cm [8]. The desired crimped diameter sizes of the aortic stents were determined to be 4.4 mm to 8.6 mm [9]. For intracranial stents, the nominal diameter and lengths are 2.0 mm to 4 mm and 8 mm to 28 mm, respectively [10]. The desired crimped diameters of intracranial stents are 1.67 mm to 2.67 mm [11]. The diametral tolerance of both a stent and stent crimper should be +/- 0.025 mm or smaller [12,13]. The length tolerance was determined to be approximately +/-3 mm [13].

Radial force of stainless steel and chromium cobalt stents were researched to specify a range for the engineering requirements. Multiple articles were examined but [14] was the major source for identifying the minimum and maximum radial force. The article stated that hoop strength was found by multiplying stent circumference by the pneumatic pressure used to crimp the stent. That pressure was not given in the article but the hoop-strength obtained was given. Using the given hoop strength of 28.9N/cm and diameter of 8mm, I had back calculated the pressure used in the article using equation 1, where HS is hoop strength, C is circumference, and P is pressure.

$$HS/C = P \qquad (1)$$

The pressure found, 11.5N/cm^2, was used to determine the hoop strength needed to crimp a 3mm stent at lengths of 10cm and 76cm. The circumference at 3mm was plugged back into equation one and multiplied by the length to

provide a target minimum radial force of 108.3N and a target maximum radial force of 823.1N.

The motor that will activate the iris to close will need to be able to supply enough torque to overcome friction and crimp the stent effectively. The team looked into linear actuators along with electric motors. The two electric motors that the team researched are a stepper motor and a servo motor. Both of these motors utilize a DC electrical input. Stepper motors operate in an open loop constant current mode. This motor requires no encoder but creates heat. Stepper motors are stable at rest and hold their position without fluctuation. Servo motors require an encoder to control and supply current to the motor. Servo motors require current to hold the position. Typically a stepper motor is ideal for applications that require low-to-medium acceleration rates and for high holding torque. Servo motors are ideal for high speed applications with high torque [15]

## *3.2 Benchmarking*

The team was not able to complete on-site visits to handle a stent crimping device. Benchmarking was conducted with thorough online research. The whole system was researched along with three subsystems. The subsystems selected are the iris, the motors, and the motor attachment to plates. Three complete systems were selected for benchmarking three designs were selected for each subsystem.

### 3.1.1 System Level State of the Art - Benchmarking

The team began with researching the complete system to gain knowledge about hardware that was already on the market. The systems either use hand actuation, pneumatic actuation or electrical actuation. The most common actuation is pneumatic. The research completed on the complete systems allowed the team to have a better understanding of what the design consisted of.

#### *3.1.1.1 Existing Design #1: Hand Actuated Stent Crimper with Hard Stop*

The MSI SC100/200 model is a hand actuated benchtop stent crimper as seen in figure 4. This product features a uniform segmental compression head for uniform compression [16]. Other features of this product are an optional heated stainless steel or thermoplastic crimp head and a micrometer that stops the hand actuator for precise diameter control [16].

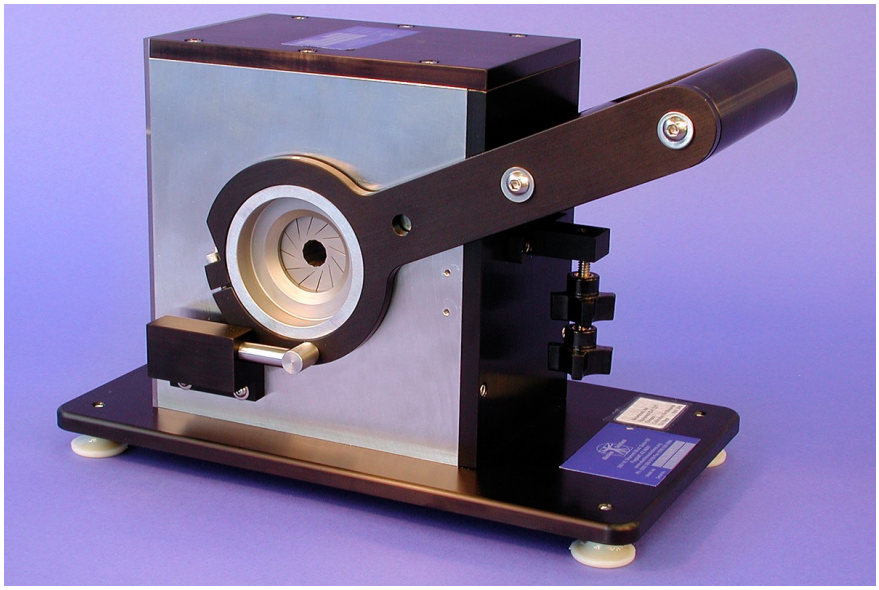

Figure 4: MSI SC100/200 Benchtop Hand Stent Crimper[16]

This crimper uses a stainless steel die material and is hand actuated. The micrometer is a basic concept to stop the crimper for precise diameter measurements. The design the team must make also must have an accurate diameter measurement system. The team would like to pursue an automatic system which could be able to utilize similar

methods to obtain precise diameter measurements.

#### *3.1.1.2 Existing Design #2: Pneumatic Stent Crimper*

The Model RJ with J-Crimp Compression Station, seen in figure 5, is used for medium sized general-purpose crimping [17]. The stent crimping machine uses a pneumatic activator to close the iris. A pneumatic device is just a device that uses compressed air to initiate movement. This model can support a diameter from 0mm to 16mm and a length of 62 or 124mm [17]. This model has a max radial force of 955N and uses hardened stainless steel for the die material used in the iris.

Figure 5: Model RJ with J-Crimp Compression Station [17]

Figure 5 above shows the stent crimping device with a compression station to the right of it. The pneumatic actuator is located on top of the crimping device. A pneumatic actuator would be one way the team could actuate the iris to close effectively crimping a stent, but this would require an air compressor seen on this workstation and causing the price to rise for the unit. This unit does not appear to have a digital readout for the forces and diameter when crimping a stent. This unit has a gauge to read the pressure the compression station is producing. This could be used to create a digital readout of forces and diameters, but it is a complex design. This product utilizes small gaps between the dies within the iris to reduce wear. While this does reduce wear this also reduces the range of diameters this crimping device can crimp. With the small gaps between die the larger of the diameter the larger these gaps become causing issues while attempting to crimp larger stents this is why different models with zero gap between die have a larger range for diameters seen with the model RJ with Zero-G compression station.

#### *3.1.1.3 Existing Design #3: Small Pneumatic Crimping Device*

The Model CX with Alpha-Crimp Compression Station allows for the crimping of stents of smaller size. This crimping device uses a compression station to allow for accurate control of the iris and utilizes stainless steel leaflets [18]. This device can be seen in figure 6.

Figure 6: Model CX with Alpha-Crimp Compression Station

Figure 6 shows the device layout with the crimping device and the compression station. This device uses a pneumatic actuator to control the iris and a compression station to supply the compressed air. The device is small and has zero gap between the leaflets which allows for the device to crimp small stents with a range of diameters of 0-8mm [18]. The zero gap between the leaflets is the goal the team is interested in. This allows the stent crimper to get a smaller range of stents.

### 3.1.2 Subsystem Level State of the Art Benchmarking

The complete system can be broken down into subsystems. Each of the subsystems have a purpose and a different function that come together and produce a functioning system. There are several different existing designs.

#### *3.1.2.1 Subsystem #1: Iris*

The iris subsystem is the part of the design that will be in contact with the stent. This part has the potential of having a lot of friction when closing. Designing an iris with minimal friction will allow for the most force to be translated from the motor to the stent when crimping. There are several different types of existing designs. For the iris design to function correctly in a stent crimper it must be able to be extruded to create a length of crimping. It needs to create a circle or a shape similar to a circle and must be capable of diameter reduction to specified diameter ranges.

##### 3.1.2.1.1 Existing Design #1: Drug Coated Stent Crimping

This iris design is from the company MSI and uses triangular leaflets with two layers of PTFE film as a protective layer between the stainless-steel leaflets and the drug coated stent. The stent is inserted between these layers of PTFE and the iris closes around the stent crimping it [19]. This method makes the process of crimping drug coated stents easier and less time consuming. Drug coated stents need to be protected from being damaged by the stainless-steel leaflets in the iris. These layers of PTFE also help shape the stent because it will form a circle around the stent as the iris closes which does not make a perfect circle.

##### 3.1.2.1.2 Existing Design #2: Iris with gaps between leaflets

This iris design has gaps between the leaflets within the iris. The gap between the leaflets reduce the friction when operating the device which puts less strain on the motor and overall system. This will increase the lifespan of the

device and make it more reliable. The disadvantage to this is it reduces the diameter range of stents it can crimp. The gaps close and form a small diameter range. The team wants to design a product that has a large range of diameters so this method of iris design is not ideal.

#### 3.1.2.1.3 Existing Design #3: Plastic Leaflets

This design uses plastic leaflets instead of stainless steel. The plastic used is not specified but has a lower coefficient of friction than stainless steel. This increases the lifespan of the product but does not increase the durability. The plastic leaflets are not as durable as the stainless-steel leaflets. The tips of the plastic leaflets can wear due to high pressure contact with stents.

### *3.1.2.2 Subsystem #2: Motor Attachments*

The motor attachment is the part that connects the motor to the iris plates. This transfers the motion from the motor to the iris. This subsystem can affect the systems reliability, the torque transmitted from the motor and the manufacturability of the product.

#### 3.1.2.2.1 Existing Design #1: Worm Gear

A worm gear motor attachment system consists of a worm, a screw like gear, and a helix gear. Worm gears amplify torque from the motor but reduce speed. The worm will have an angular velocity similar to that of the motor and the gear, depending on the size, will have a greatly reduced angular velocity. This can be both an advantage and a disadvantage. The advantage is that it will be easier to control because the iris will be closing slowly. The disadvantage is that it could cause the iris to close too slowly and reduce productivity while using the device. One major advantage to a worm gear is that it is self locking. It is self locking because the worm will drive the gear but the gear will not drive the worm. This will allow the crimping device to hold its position when it needs to.

#### 3.1.2.2.2 Existing Design #2: Simple Lever

The simple lever is just a lever that is attached to the iris plate. When a force acts on the lever the iris will close or open. The lever is typically used in hand actuated crimping devices, but could be used with a linear actuator, or a servo motor. To be used with a servo motor there would need to be additional linkage to properly attach the motor to the lever. The advantages of the lever is that it is easily manufacturable, reliable and simple to work with. The disadvantages are that there are no self-locking features and it is not as controllable as the other options listed here.

#### 3.1.2.2.3 Existing Design #3: Motor Bracket

A motor bracket would use a bracket to directly attach the motor to the iris plates. This method would have less parts than any gear set up but one more than the simple lever method. This method would directly transfer the torque from the motor with no amplification of torque input from the motor. This would require a motor which has more torque. The motor would have to be designed to handle the extra workload or this could reduce the lifespan of the product.

### *3.1.2.3 Subsystem #3: Motor*

The motor is an essential part of the system because the iris must be closed and opened. The iris can be actuated using a motor or by hand. The team is going to design the stent crimper as an automatic stent crimper, so a hand actuated device is not an option. The motor will have to supply a sufficient amount of torque to overcome friction within the device and apply enough force to crimp the device.

#### 3.1.2.3.1 Existing Design #1: Stepper motor

Stepper motors create high torque at lower speeds. This is due to the design of the motor. The motor requires more current exchanges per revolution when compared to a DC motor or a servo motor. For this reason, the stepper

motor does generate more heat than other motors. A stepper motor also typically has a high holding torque which is perfect for crimping a stent where a stent is crimped down to the desired diameter and held at that position for a specific amount of time. These motors are an inexpensive option that the team is considering. To implement this motor in the design a system of gears will have to be designed for the system or it can be attached using a direct bracket to an iris plate.

#### 3.1.2.3.2 Existing Design #2: Linear Actuator

Linear actuators exist in stent crimping devices and are typically pneumatically driven. These types of linear actuators use compressed air to close the iris. These devices create a lot of thrust and are relatively easy to control. Linear actuators provide a smooth movement into position. They are more expensive than the other two designs in this subsystem costing anywhere from 30 to 500 dollars. Another disadvantage to this type of motor is it must be supplied with compressed air and this compressor must be supplied with electricity. This causes the design to have more parts and more parts means less reliability of the system overall.

#### 3.1.2.3.3 Existing Design #3: Servo

A servo motor is controlled by electric signals typically received as a pulse and not a constant current. A servo motor can supply a high amount of torque and high dynamic load changes. A servo motor typically operates and is suitable for high speed and high torque applications. This may not be ideal for the stent crimping design but it can work and will supply an effective amount of torque. Another drawback of the servo motor is that it can only rotate 90 degrees in each direction with a total range of 180 degrees of rotation. This motor will require a linkage to be designed to connect the motor to the iris assembly.

# 4 CONCEPT GENERATION

From the first semester, the design ideas generated during concept generation are presented to show the iterative process of the designing process.

## *4.1 Full System Concepts*

Three alternative stent crimping devices were considered for the purpose of generating a final design of the project. Each design was examined based on the individual sub-systems.

### 4.1.1 Full System Design #1: Slotted Plate Design

The slotted plate design is named after the slotted back plate that guides the leaflets into position. The design consists of a stationary front plate, a movable back plate with a motor attachment, a servo motor, and housing. The front plate has slots that enable the leaflets to slide into position and a back plate that actively advances the leaflets. A motor attachment is secured to the back plate and actively rotates due to a servo motor placed at its center. The leaflets are positioned due to an extruded slot that fits into the front plate and an incised hole for a knob that glides into the slots of the back plate. Each component is placed inside a housing which is shown in the exploded view [Figure 7].

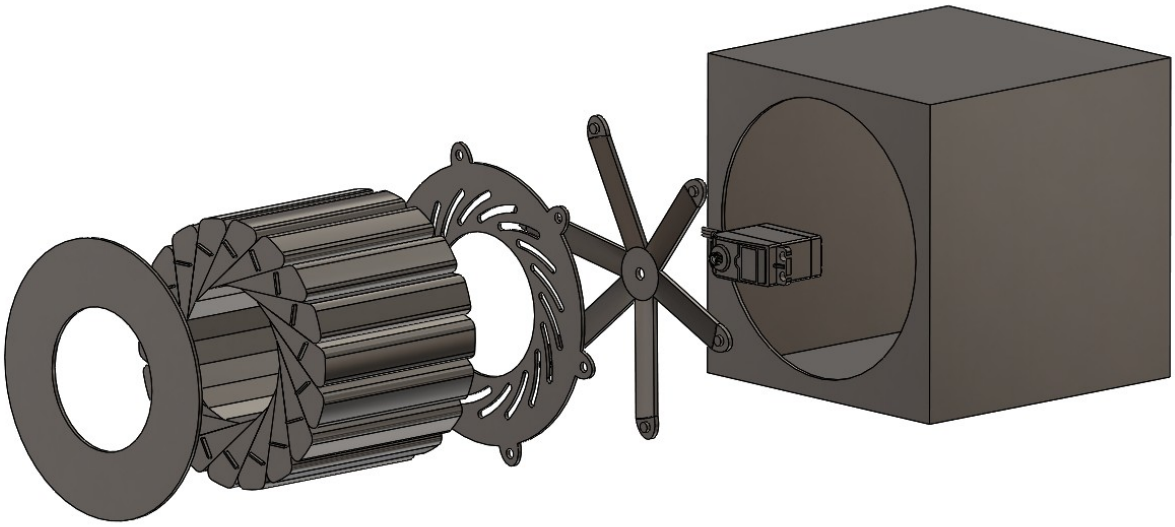

Figure 7: Slotted Plate Design

The advantage of this design is the number of leaflets. The 18 leaflets produce an octadecagon shape that provides a relatively accurate crimping structure. The disadvantage of this design is the high machining costs due to complex geometries and the required tolerances.

### 4.1.2 Full System Design #2: Double Slotted Plate Design

The double slotted plate design is named after the plate that uses two concentric slot patterns to guide the leaflets into position [Figure 8]. The design consists of an outer plate mentioned before with two different sets of slots. A worm gear that has slots on the face of the gear to move the leaflets. A worm that is driven by a motor. The leaflets which have two knobs on the leaflets. The knobs on the leaflets will be inserted in the slots on the gear and on the outer plate to guide them into a closed and open position. Then there is housing which all of these parts are placed in. An exploded view of this system can be seen in the figure below.

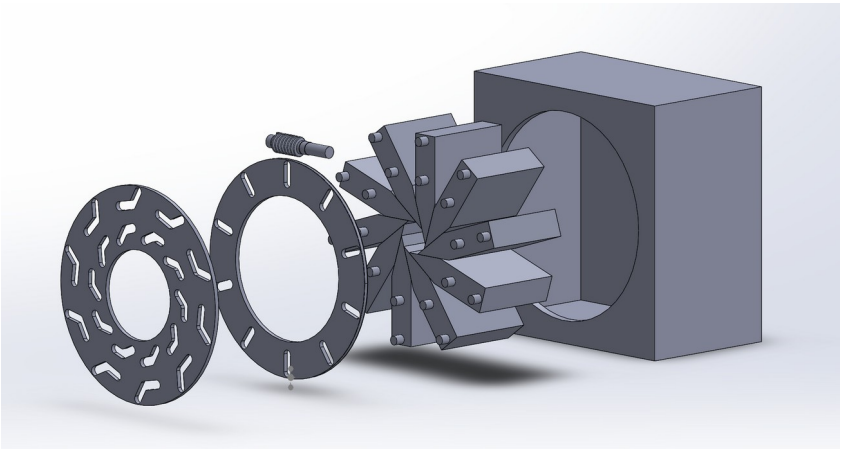

Figure 8: Double Slotted Plate Design

The advantage of this design comes from the worm gear. The worm gear allows for the iris to be closed slowly and precisely. The disadvantages are that this design only utilizes a ten-leaflet design which causes the iris to close into

a decagon and not a circle. This design will also cost a lot to machine because of the complex geometry.

### 4.1.3 Full System Design #3: Single Slot Plate Gear

The single slot plate gear design is named after the slotted gear plate that connects with a rack gear. The design consists of a stationary slotted back plate, leaflets, a slotted gear plate, a rack and gear, worm gear motor, and housing [Figure 9]. The slotted gear plate has the same slotted design shown in Design 1 and it enables the leaflets to slide into position. This gear plate has added teeth to connect with a rack and gear to enable motion from a worm gear motor. The stationary back plate enables leaflets to guide into position through narrow slots. The leaflets are positioned due to an extruded slot that fits into the front plate and an incised hole for a knob that glides into the slots of the slotted gear plate. Each component is placed inside a housing which is shown in the exploded view.

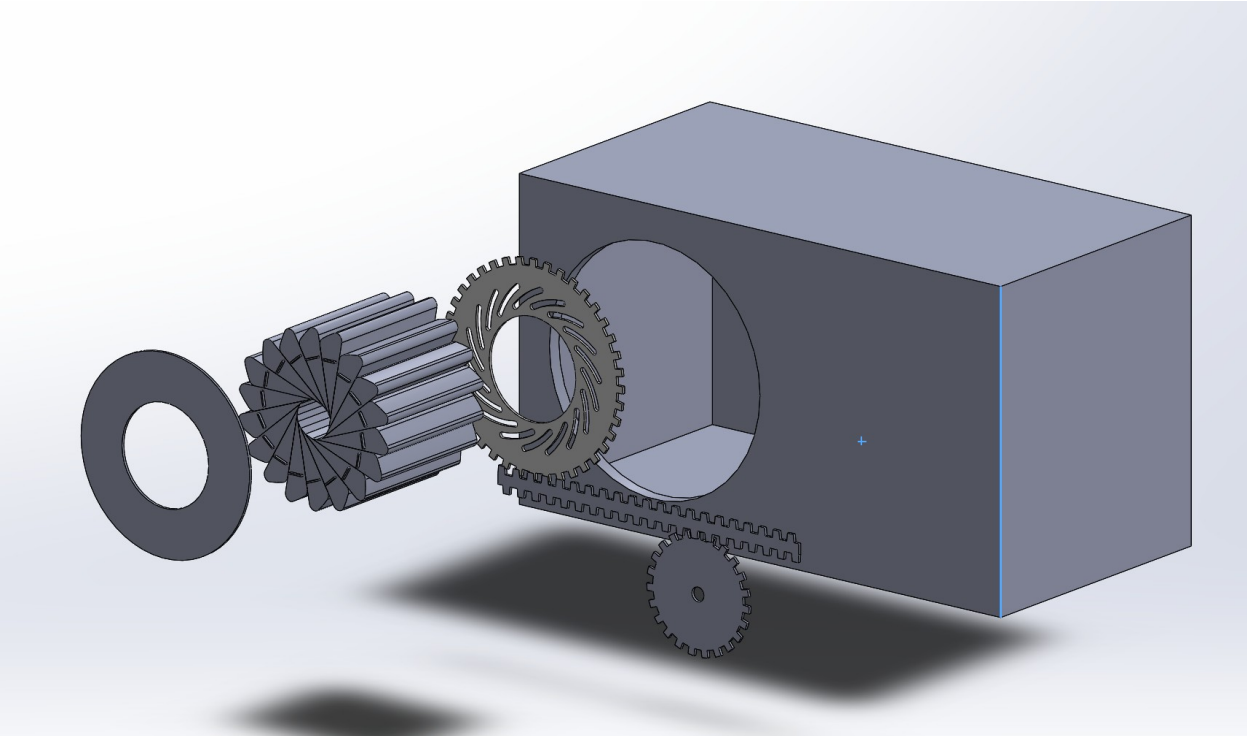

Figure 9: Single Slot Plate Gear

## *4.2 Subsystem Concepts*

Five subsystem concepts for three distinctive stent crimping designs will be evaluated based on the functional decomposition. The five subsystems that will be examined are the leaflets, plates, motor attachment, motor, and display. The subsystems of the leaflets, plates, and motor attachment address the function of converting electricity to rotational energy. The subsystem of leaflets will, also, address converting rotational energy to mechanical strain energy. The subsystem of motor addresses the functional chain of electricity from actuating electricity to controlling electricity. The subsystem of the display will address the function of decoding mechanical strain to output signals.

### 4.2.1 Subsystem #1: Leaflets

The subsystem of the leaflets addresses the functions of converting electricity to rotational energy and converting rotational energy to mechanical strain energy. This subsystem is vital for addressing the engineering requirements of leaflet numbers and diameter.

#### *4.2.1.1 Design #1: Single Knobbed Triangular Leaflets*

The single knobbed leaflets consist of a knob attachment area and an extruded slot [Figure 10]. The knob attachment initiates movement between the moveable back plate and the leaflets. The extruded slot enables the leaflet to slide across the stationary front plate during motion. The angle of the leaflets allows up to 18 leaflets within an iris and can be adjusted for various leaflet numbers. The leaflet has a thickness of 20 cm, which is not shown in Figure 10, to allow a large range of stent lengths.

Figure 10: Single Knobbed Triangular leaflets

The leaflets must rest at a specific angle for a circular configuration of the leaflets. This requires a unique front plate to facilitate motion.

#### *4.2.1.2 Design #2: Two Knobbed Triangular Leaflets*

These leaflets are different between other leaflets because there are two knobs on this design [Figure 11]. The two knobs allow for this leaflet to follow a different slot pattern on the plates and it allows for the leaflets to change the angle at which they close. This helps widen the range of diameters the iris can crimp. This design can be seen in the figure below.

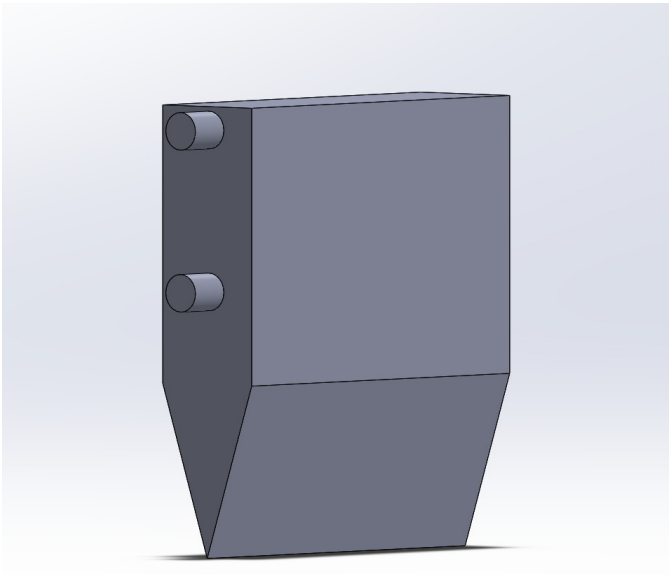

Figure 11: Two Knobbed Triangular Leaflets

Figure 11 is a Solidworks model of the leaflet with two knobs. The shape of this leaflet will only work if it is

moving at an angle. This will require an unique front plate. This specific design in figure 11 is designed for ten leaflets to form the iris but this will cause the iris to close forming a decagon. The more leaflets that are added to the iris allow the shape formed when the iris closes to be closer to a circle.

#### *4.2.1.3 Design #3:* Single Knobbed Triangular Leaflets With Curved Tips

The triangular leaflets with curved tips are designed so that the tips have a subtle curve to create a circle to crimp the stent. This creates a smooth curved surface to ensure no damage comes to the stent when crimping. This design can be seen in the figure below.

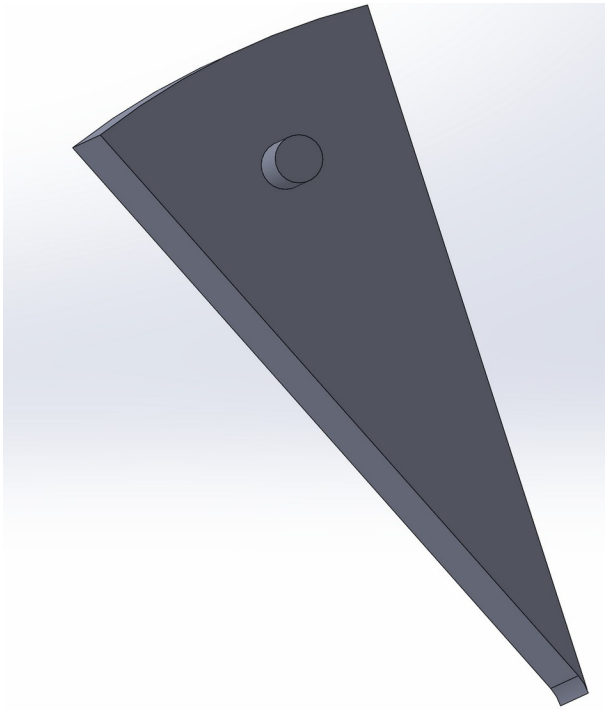

Figure 12: Triangular Leaflet with Curved Tips

Figure 12 displays a 3D CAD model of a leaflet that has a curved tip to create a perfect circle when iris is completely closed. There is a knob that is located on the front face of the leaflet to be inserted into the plates to guide the leaflets into position. The disadvantages of this design are that the diameter of stents it can crimp are limited because of the curve. it can only go down to a 5 mm diameter stent.

### 4.2.2 Subsystem #2: Plates

The subsystem of the plates addresses the function of converting electricity to rotational energy. This subsystem addresses the engineering requirements pertaining to diameter, cost, and iris design. The plates direct the leaflets to the correct position to crimp the stent.

#### *4.2.2.1 Design #1: Single Slotted Plates*

The single slotted plates utilize slots to facilitate the motion of the leaflets. The slotted back plate is a movable plate that utilizes curved slots that connect to the knob attached to the leaflets to facilitate motion [Figure 13]. The slotted back plate requires specific manufacturing potentially increasing the overall cost of the stent crimping design. This design, however, provides precise movements of the leaflets.

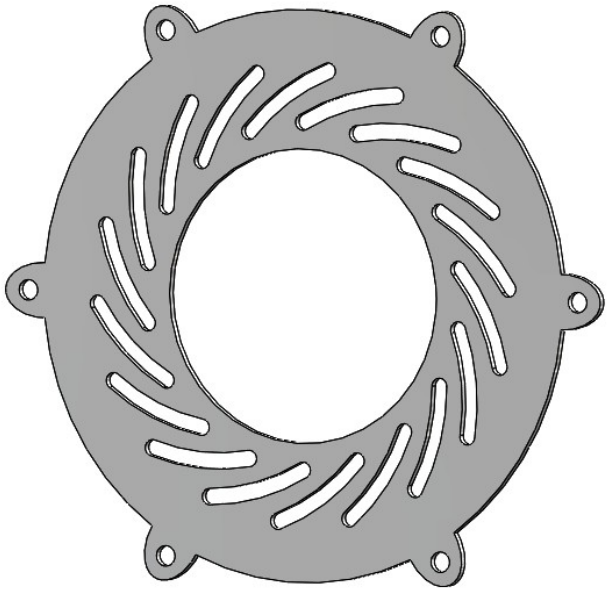

Figure 13: Slotted Back Plate

The slotted front plate is a stationary plate that leaflets will glide along during motion. The slotted front plate has linear slots with a width of 1 mm and a length of 44 mm [Figure 14]. The slots on this plate prevents the stent crimping design from completely closing due to the limitation of the length of the slots. The number of slots can be adjusted for fewer leaflet numbers which will potentially allow the iris to completely close during crimping. The leaflets, however, are capable of reaching a diameter of approximately 0.3 mm with this plate.

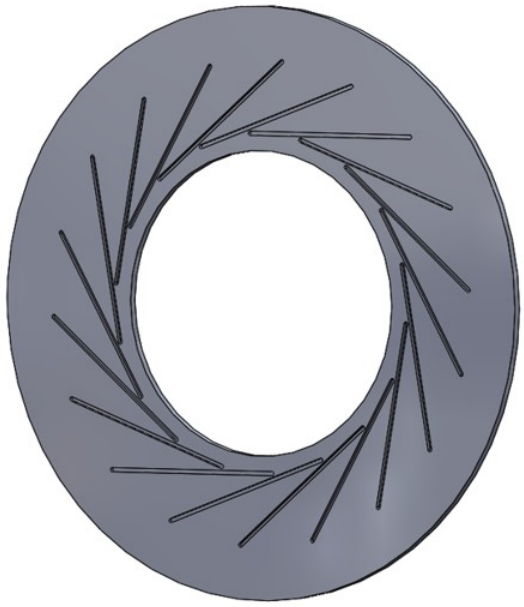

Figure 14: Slotted Front Plate

#### *4.2.2.2 Design #2: Double Slotted Plate*

The double slotted plate design uses two slots on the front plate to maneuver the leaflets into position to crimp the stent. This design changes the angle of the leaflets as they close. This allows the leaflets to create different

diameters and do not damage the stent when closing. This design can be seen in the figure below.

Figure 15: Double Slotted Plate

This figure shows a plate with two concentric slot patterns on it. The leaflets would have two different knobs on the surface to go into the slots. These slots would guide the leaflets as a plate behind it moves. This design does have drawbacks. The pattern would require machining and because of the complex geometry. This complete pattern also restricts the amount of leaflets permitted to be in the design. The design in figure # is designed for ten different leaflets. To increase the number of leaflets the total size of the face plate would need to be increased causing the stent diameter range to increase as well.

#### *4.2.2.3 Design #3:* Single Slot Gear Plate

The single slot gear plate design utilizes curved slots and gear teeth to enable the motion of the leaflets [Figure 16]. The curved slots connect to a knob that enables the motion of the leaflets and the gear teeth translates the motion of a motor and gear system to the leaflets. This plate requires specific manufacturing especially of the gear teeth. The gear teeth will increase the costs of the design compared to the slotted back plate of design 1 [Figure 13]. This design may, however, provide significantly better torque than the slotted back plate of design 1.

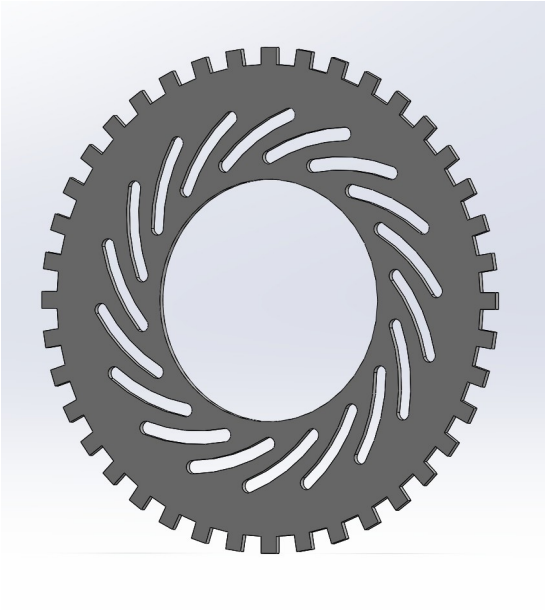

Figure 16: Single Slot Gear Plate

The stationary front plate is the same design shown in design 1 Figure 14.

### 4.2.3 Subsystem #3: Motor Attachment

The motor attachment addresses the function of converting electricity to rotational energy. This subsystem involves the engineering requirement of radial force and cost.

#### *4.2.3.1 Design #1: Servo Motor Attachment*

A six arm plate is used as the servo motor attachment to the movable back plate. The motor attachment plate has a hole in the center for motor placement and knobs along the end of each arm that attach to the back plate [Figure 17, Figure 18]. Friction within the iris design could potentially reduce the life expectancy of the motor attachment and motor due to the strain experienced within the arms.

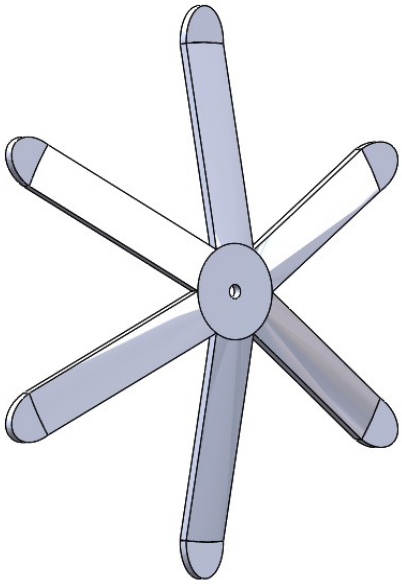

Figure 17: Servo Motor Attachment

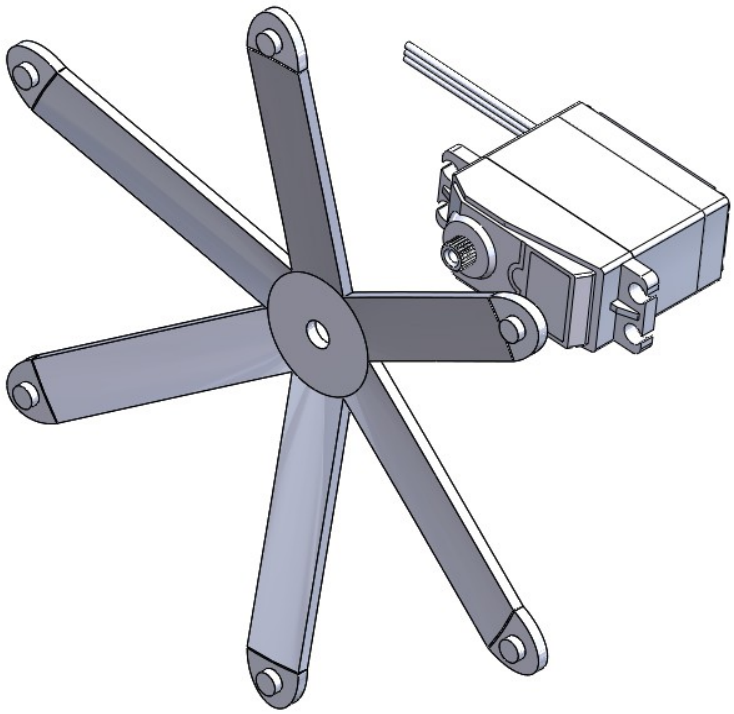

Figure 18: Mount Attachment with Servo Motor

The motor attachment will be expensive due to the distinctive nature of the design. The motor attachment should be able to translate the supplied torque of the motor with minimum losses as long as the friction of the components are reduced.

#### *4.2.3.2 Design #2: Worm Gear Plate*

The worm gear plate is the combination of a worm and a worm gear. the worm gear would have slots on the face of the gear allowing for the knobs on the leaflets to be inserted. The gear would rotate and cause the leaflets to move. The worm would be linked to the gear on one of the sides or on top as seen in the figure below.

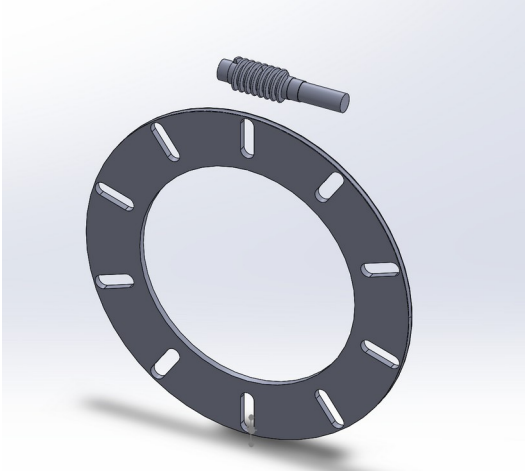

Figure 20: Worm Gear Plate

Figure 20 shows the worm and worm gear with slots on the gear face for the knobs on the leaflet to be inserted. This method of motor attachment allows for a dc or stepper motor to be utilized and will supply sufficient torque when required. The pitch of the gear teeth would determine the torque this set up would produce. Using a worm gear would make the system self locking. A crimper that is self locking is beneficial because once the iris is closed it will not move due to the force the stent is exerting on the iris. The iris would only move when the motor is activated. This method would also allow for precise measurement and control of the device. This is because one revolution of the gear would be several revolutions of the worm. This could also be considered a bad thing because the motor would have to rotate several times just to close the iris. This would reduce the longevity of the device and the time required to operate the device.

#### *4.2.3.3 Design #3:* Gear Rack System

A gear rack system utilizes a gear system with a gear rack to actuate the leaflets. This system would be connected to a dc motor or a stepper motor. The main advantage to this system is that the gearing ratio would increase the amount of torque that the iris receives. The motor would not need to supply a large amount of torque for the required radial force needed to properly crimp the stent. Another advantage is that the rack gear could be separated into two halves and a pressure gauge could be placed between the two halves which would give the user a force output signal. The main disadvantage to this system is that the gear rack takes up alot more space then the other concepts in this report. This concept can be seen in the figure below.

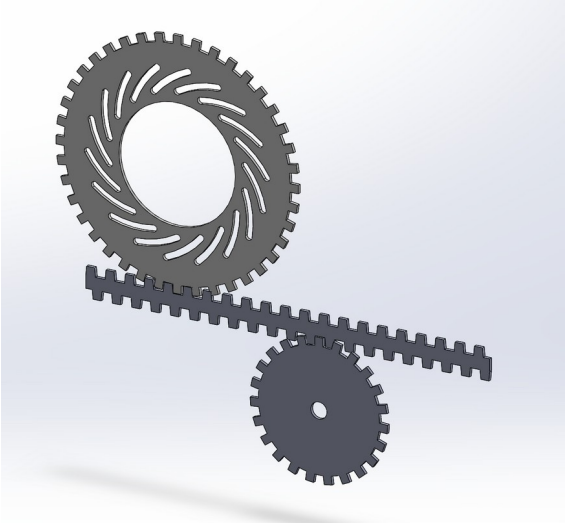

Figure 21: Gear Rack

Figure 21 displays the motor attachment system using a gear rack. The gear in the lower right hand side is the gear that is attached to the motor. This gear drives the gear shaft, the straight gear placed between the two round gears. The large gear is an iris plate which the knobs on the leaflets would glide inside the slots effectively closing and opening the iris.

### 4.2.4 Subsystem #4: Motor

The motor addresses the functions of actuating electricity and converting electricity to rotational energy. This subsystem involves the engineering requirements of radial force and cost. This subsystem directly impacts the type of motor attachment that each design can support.

#### *4.2.4.1 Design #1: Servo Motor*

A servo motor is a self-contained electronic device with a rotating shaft that supplies torque to the design [20, Figure 22]. The servo motor delivers high accuracy positioning and consistent torque due to a feedback mechanism [21]. The servo motor, however, is generally more expensive than a stepper motor due to its complex design such as the feedback mechanism. The size of a motor may vary due to the required torque of the design.

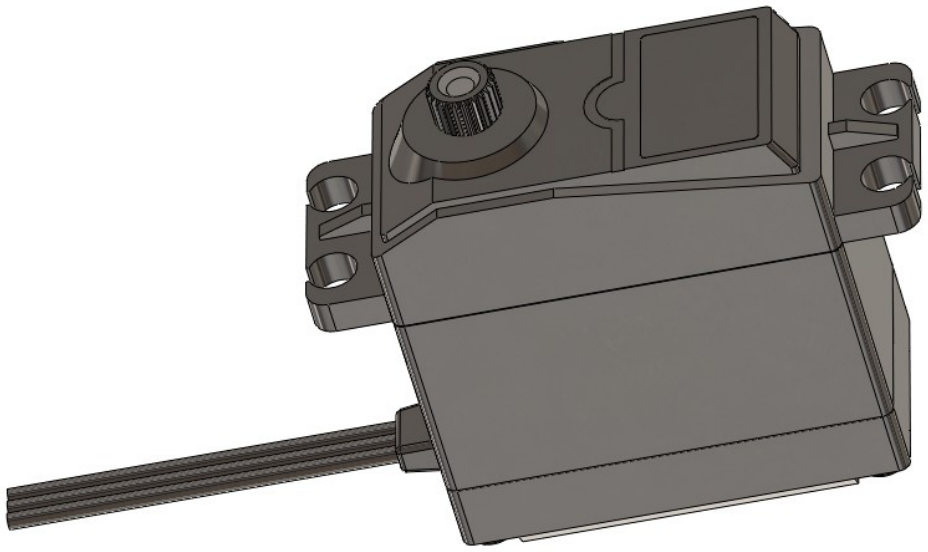

Figure 22: Servo Motor

#### *4.2.4.2 Design #2:* DC Motor

The DC motor can be easily implemented in any of the motor attachments subsystem designs. The DC motor has an output shaft that rotates and supplies torque. The output shaft would be mated with the attachment system directly. If the motor was being mated with the worm gear system it would attach directly to the worm, the screw like gear. If it were to be mated with the gear rack system it would be directly mated with the driving gear and not the plate gear. It could also be attached to the servo motor attachment system; it would just need to be placed directly in the center with the output shaft attached to the motor attachment. A DC motor would likely need to be attached to a gearing system because of the angular velocity and the torque output of the motor. This is the main disadvantage of the DC motor is that it does not produce a large amount of torque, and it spins relatively fast.

#### *4.2.4.3 Design #3:* Stepper Motor

A stepper motor can be attached in the same method the DC motor is. There are more advantages when using the stepper motor than there are for a DC motor. The first advantage is that it produces more torque then the DC motor. The stepper motor produces high torque at low angular velocities. The stepper motor also has high holding torque which means it would be able to supply high torque when the iris needs to hold a position which is beneficial when crimping a stent. The low velocity of the stepper motor means it would be ideal for a gear set up or a direct mounting system. The disadvantage for the stepper motor is that it requires more current exchange per revolution then the DC motor. The stepper motor also requires more coding and circuitry than a DC motor.

# 5 DESIGN SELECTED – First Semester

The design the team selected can be seen below in figure 23 as a CAD model. This design consists of five different subsystems. These subsystems all have an essential role in the operation of the stent crimper.

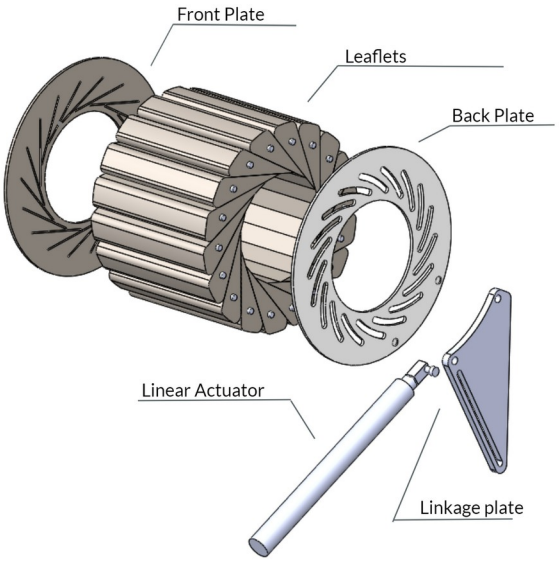


Figure 23: CAD Model

The first subsystem are the leaflets. This design consists of 18 leaflets that make up the crushing surface and the main part of the iris design. These leaflets are placed at an angle that creates a circular pattern. The leaflets are held in place by a front and a back plate. The front plate is stationary and has straight slots to guide the leaflets as they rotate and close. The back plate rotates which forces the leaflets to rotate and close. The back plate will attach to the linkage plate. The linkage plate is connected to the linear actuator which will force the linkage plate to rotate the back plate. The housing, not shown in Figure x, is a simple box with a circular opening and will be iterated in a future prototyping phase.

## *3.2 Leaflet Description*

The leaflets consist of a knob attachment area with a diameter of 4 mm and depth of 2 mm and an extruded slot with the length of 10 mm and thickness of 1 mm [Figure 24]. The leaflets were designed by setting a wedge of 20 degrees inside of a circle with a diameter of 120 mm and extruding the part out to a length of 100 mm [Figure 24]. A displaced circle of 130 mm was utilized as the basis for the fillet placement [Figure 24]. The fillets of the leaflets have a radius of 5 mm and are designed to minimize potential friction between leaflets. In total, there are 18 leaflets that facilitate the crimping diameter.

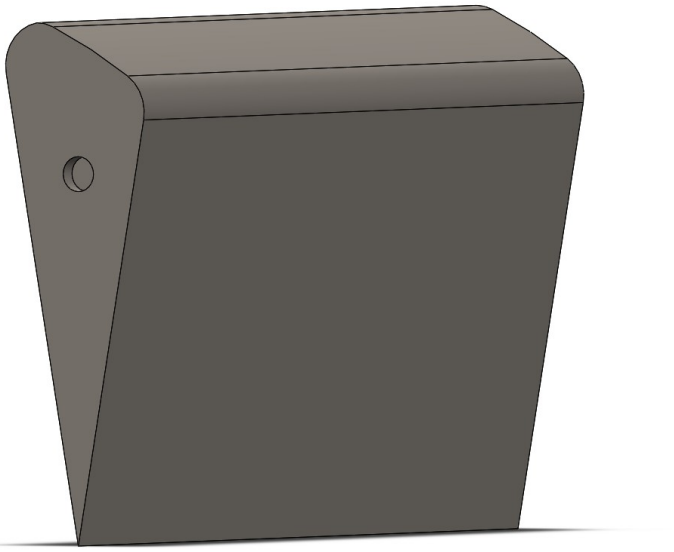

Figure 24: Leaflet

## 3.3 Knob

The knob has a diameter of 4 mm and a length of 4 mm. The ends of the knobs are chamfered with a diameter 0f 0.25 mm and an angle of 45 degrees [Figure 25].

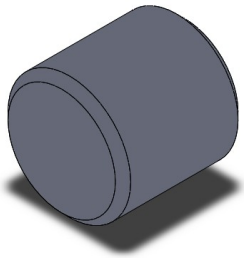

Figure 25: Knob

## 3.4 Front Plate Description

The slotted front plate is a stationary plate that leaflets will glide along during motion. The slotted front plate has linear slots with a width of 1 mm and a length of 44 mm [Figure 26]. The slots are separated by a minimum distance of 0.443 mm. The total number of slots corresponds to the total number of leaflets.

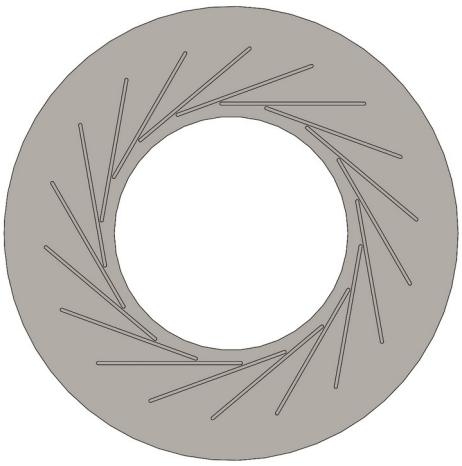

Figure 26: Front Plate

## 3.5 Back Plate Description

The slotted back plate is a movable plate that utilizes curved slots that connect to the knob attached to the leaflets to facilitate motion [Figure 27]. The curved slots were designed by placing a three point slot in between two circles with the diameters of 85 mm and 111 mm. The radius of the curvature is 50 mm and the slot width is 2.05 mm. The total number of slots corresponds to the total number of leaflets. For a detailed drawing of the back plate see Figure 27.

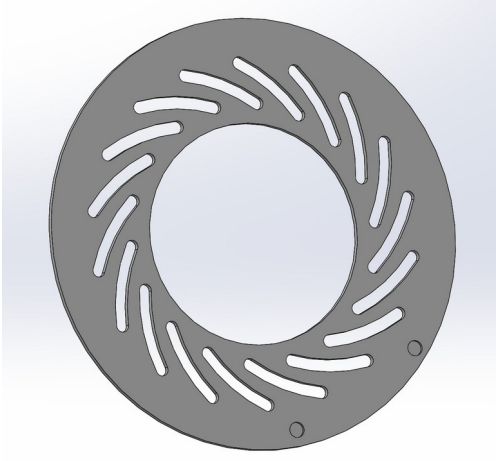

Figure 27: Back Plate

## 3.6 Linkage Plate Description

The linkage plate connects the linear actuator to the back plate. The linkage plate will help convert the linear stroke of the linear actuator to the rotational motion of the back plate. This linkage plate can be seen in figure 28.

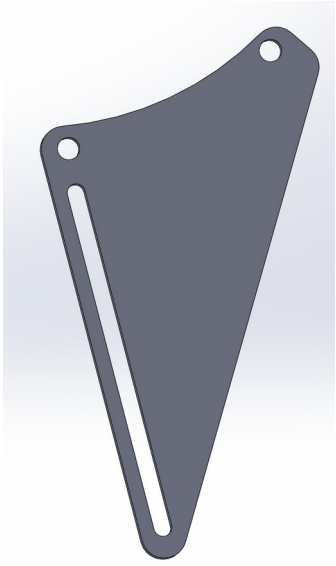

Figure 28: Linkage Plate

The linkage plate has a slot in it that the linear actuator will attach to by a pin. The will allow the linear actuator to push the linkage plate out. The linkage plate is fixed to the back plate so this linkage plate will rotate. As the linear actuators lengthens the pin connection will be able to slide down the slot. This action will force the linkage plate to rotate the back plate.

## 3.7 Linear Actuator

The team is going to purchase a linear actuator to reduce manufacturing time and cost. The team had to calculate the force the actuator must be able to produce and the stroke length. The stroke length was found by evaluating and measuring the CAD model in Solidworks. The team found that the stroke length required for the linear actuator was 130 mm. The stroke length is the distance at which the linear actuator can extend out to. The force that the actuator must supply must be able to produce at least 105 N of radial force. The radial force can be estimated using the following equation:

$$RF = \frac{2}{dD/dx} * F(2) \qquad [14]$$

The radial force is represented by RF and the force supplied by the linear actuator is represented by F. The dD/dx represents a constant that will be specific to the design. This constant is obtained by dividing the change in diameter over the change in actuator stroke. The team was able to calculate the force the linear actuator must supply is 36.7 N of force.

## 3.8 Control Components

The control components consist of an Arduino Mega, an LCD display and user input interface. The interface at this point is a joystick with standard movements. In the future, the display could change to a touch screen to eliminate the need for a separate user interaction piece. Initially, the user will be able to input the desired diameter of the crushed stent and press the joystick to make the device crush to that diameter.

The Arduino will be able to keep track of the motor counts of the linear actuator and, after some testing and calibration, the diameter will be able to be tracked as a relation to the linear motion of the actuator.

# 6 IMPLEMENTATION – Second Semester

Through the process of iteration, the design was developed and modified based on identified improvements for functionality, feasibility, and distinctiveness. The device utilizes a stepper motor to rotate a worm that rotates the gear closing the iris. The worm gear was chosen due to its self locking features and the gear ratio it provides. The leaflets were changed to the teardrop design for ease of manufacturing along with the linear slots in the rotating plate. The housing was changed to enclose the entire design along with the electronic parts of the design. The stepper motor required its own power supply, 24 volts instead of 12 volts. The housing was redesigned for manufacturability, ease of use, and enclosing the entire design protecting it from debris and particles that could infiltrate the iris design.

## *6.1 Design Changes in Second Semester*

In the first semester, the design consisted of a linear actuator, curved rotating plates, and asymmetrical leaflets. Through iteration, the team redesigned the actuation system to a gear and worm driven by a stepper motor. The rotating plate slots were updated to utilize linear slots for ease of manufacturability. The leaflets were changed to a symmetrical teardrop design for ease of manufacturability and overall reduction of part costs. Finally, a fully realized housing system was implemented to protect and secure components.

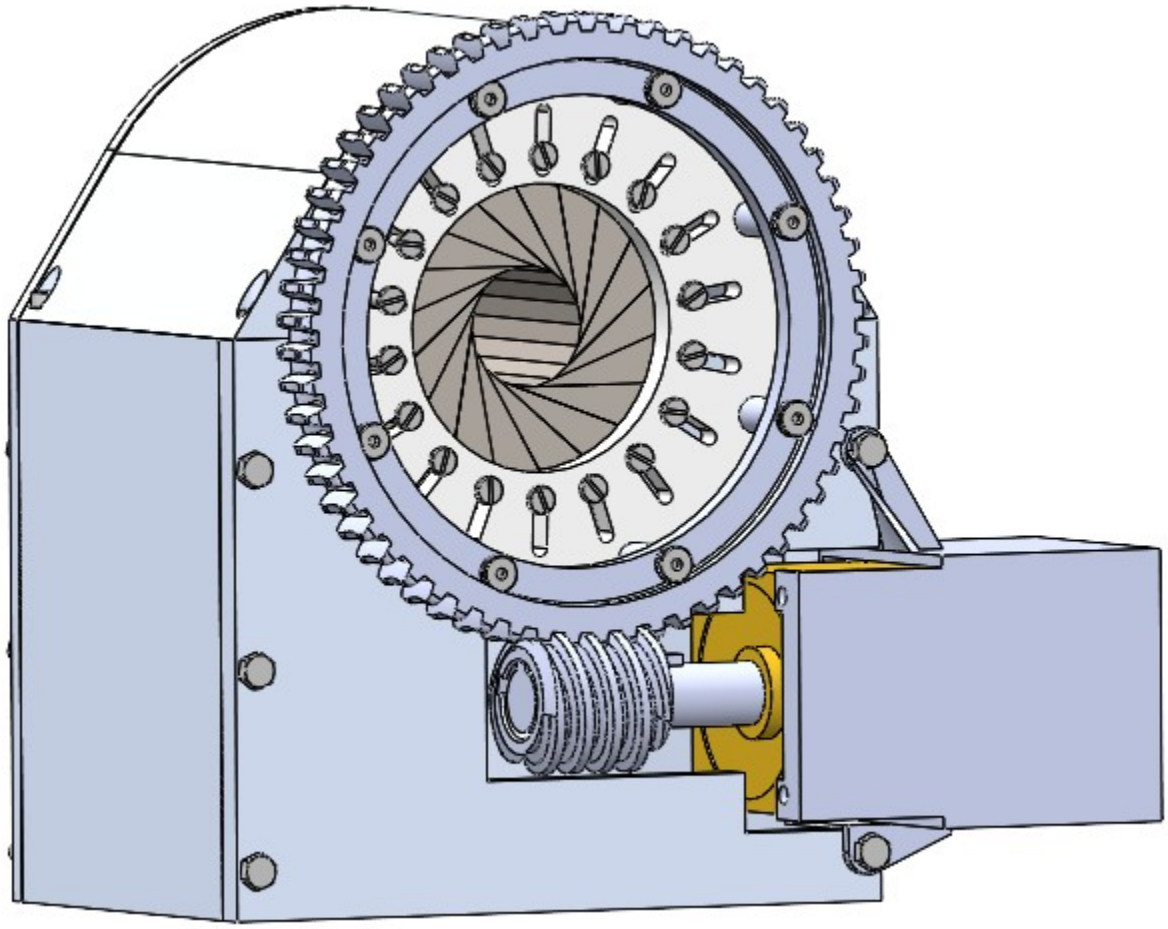

Figure 29: Final Design CAD

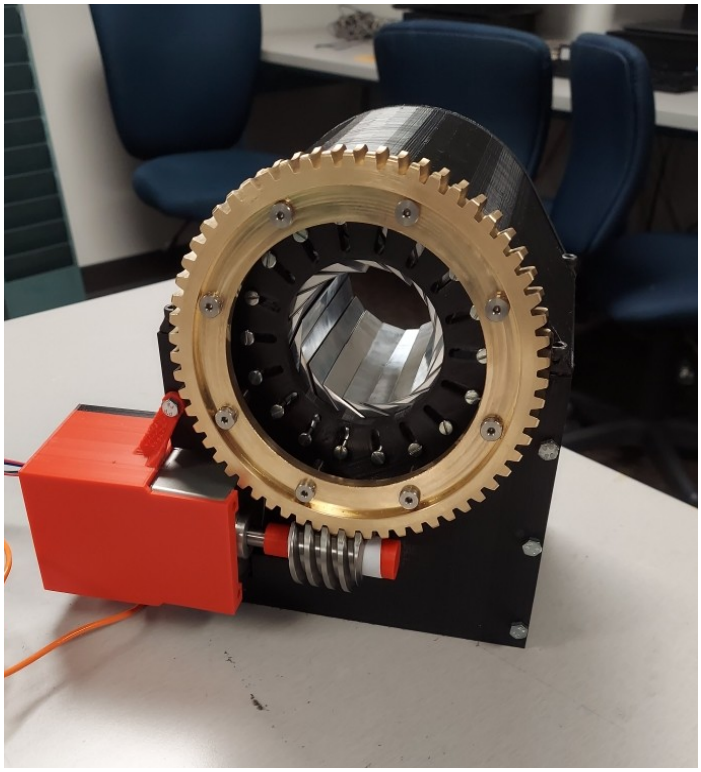

Figure 30: Final Prototype

### 6.1.1 Design Iteration 1: Change in Actuation Discussion

The team started the second semester with a design actuated by a linear actuator. Through iteration, the main design was modified to actuate through a stepper motor and driven by a worm and gear [Figure 31].

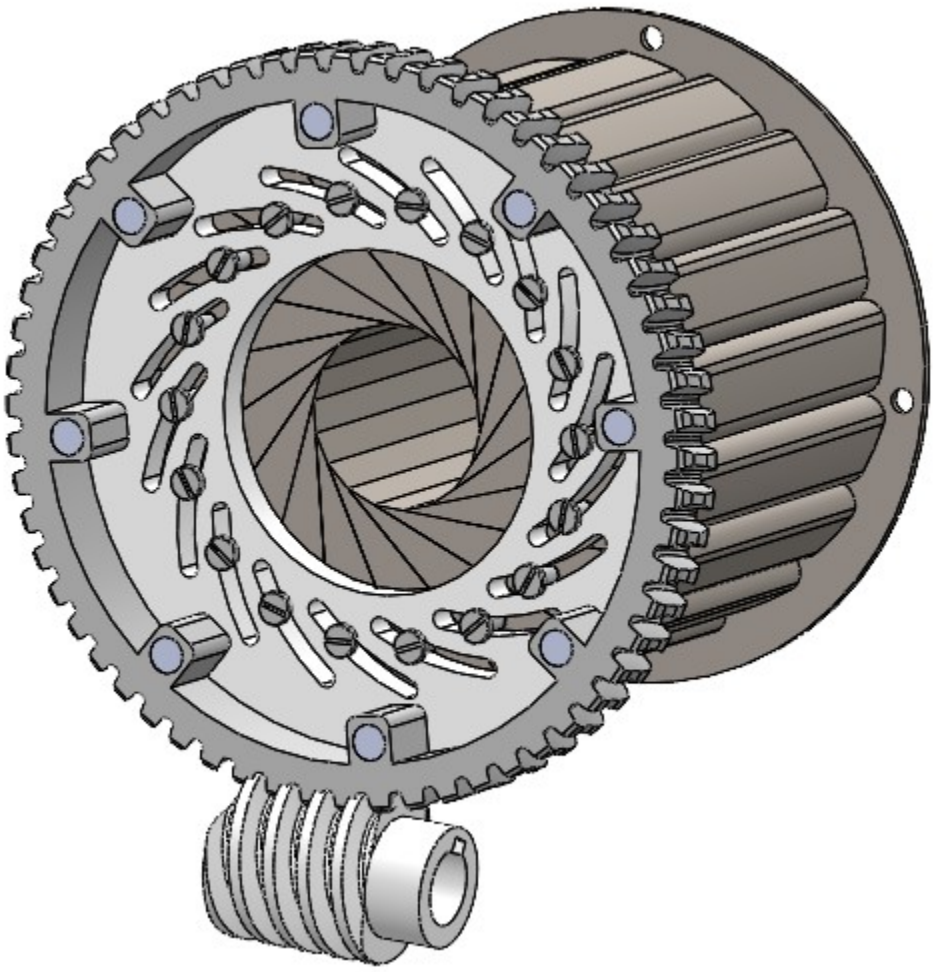

Figure 31: Gear and Worm Actuation

The actuation was changed to a stepper motor driven by a gear and worm to produce a distinct design. The benefits of the worm and gear is the self-locking nature of the system in which only the worm can drive the gear. The self-locking nature of the system prevents the reaction force from the stent from driving the gear or expanding the iris. The self locking feature and gear ratio ensures a high level of accuracy for the diametral measurements of the device.

### 4.1.2 Design Iteration 2: Change in Control Components

The way the device is actuated is changed this semester. The Arduino remained the same, but the joystick was removed and replaced by a 16 character keypad. The linear actuator was replaced by the worm gear and worm screw, which is powered by a 5-phase stepper motor. The stepper motor is powered by a stepper motor driver which requires a 24v, 5A, power supply. The driver gets signals from the Arduino Mega to actuate the motor and converts them to pulses to step the motor. The LCD remained the same.

### 4.1.3 Design Iteration 3: Change in Linear Slots on Rotating Plate

The curved slots of the rotating plate were changed to linear slots to improve manufacturability [Figure 32]. This design prevents misalignment and ill fit of the slots due to complex geometries that may not be maintained during manufacturing. The overall functionality of the design was not changed with this modification.

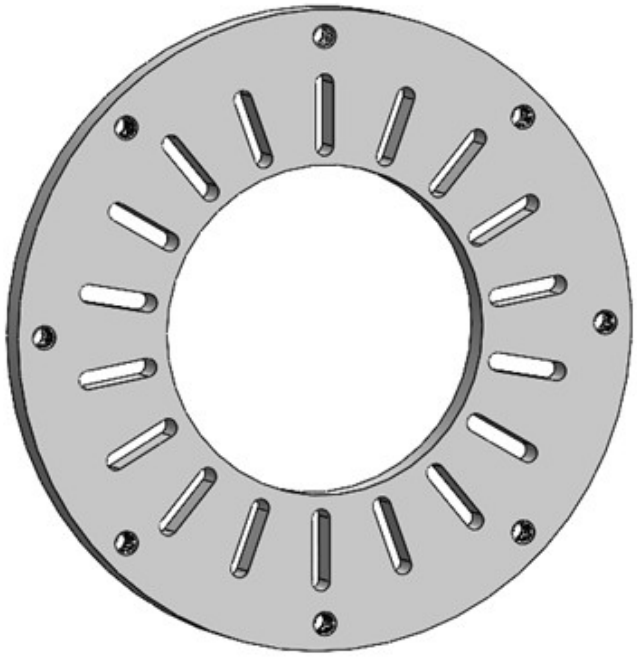

Figure 32: Linear Slots of Rotating Plate

### 4.1.4 Design Iteration 4: Change in Leaflet Design Discussion

The design of the leaflets were modified to a symmetrical teardrop shape design with tapped threads [Figure 33]. The redesign of the leaflets provided an ease of manufacturability, a reduction in friction between components, and a reduction in overall cost per part. The design of the leaflet, also, reduces potential misalignment from the machining process due to complex geometries.

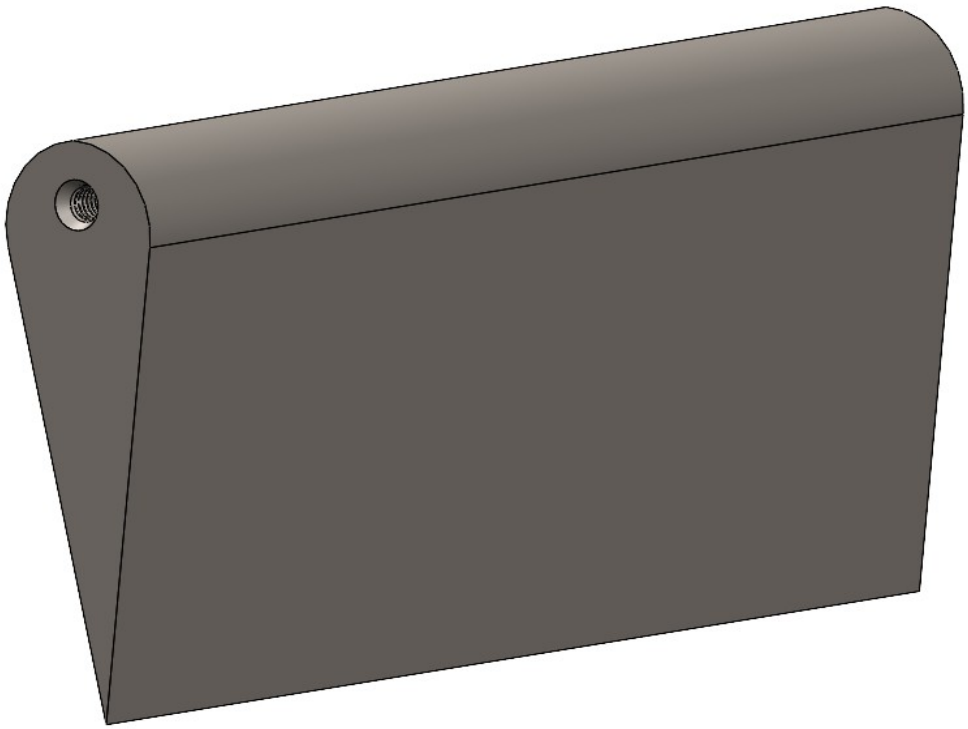

Figure 33: Symmetrical Leaflets

### 4.1.5 Design Iteration 5: Change in Housing Discussion

In the first semester, the housing was simply an enclosed box with one circular opening for simplicity as the housing was not considered an immediate concern. In the beginning of the second semester, the housing was constructed with consideration to 3D printing and component orientation including the addition of the worm gear [Figure 34].

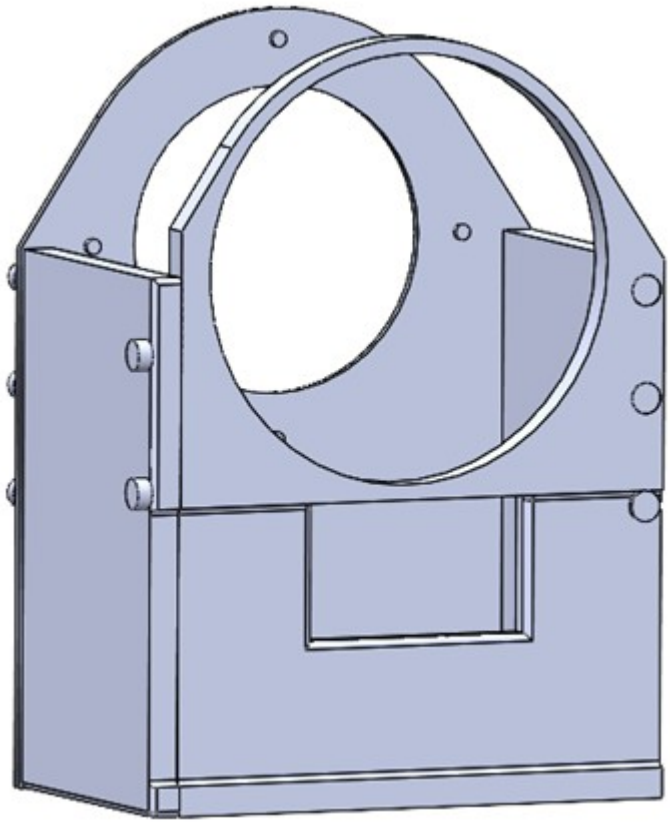

Figure 34: First Housing Iteration

The housing design was iterated to include a top covering and a motor cage attachment for improved orientation, stability, and protection [Figure 35]. The attachments for the housing were, also, changed from simple pins to standardized M5x0.8 screws for secure attachment.

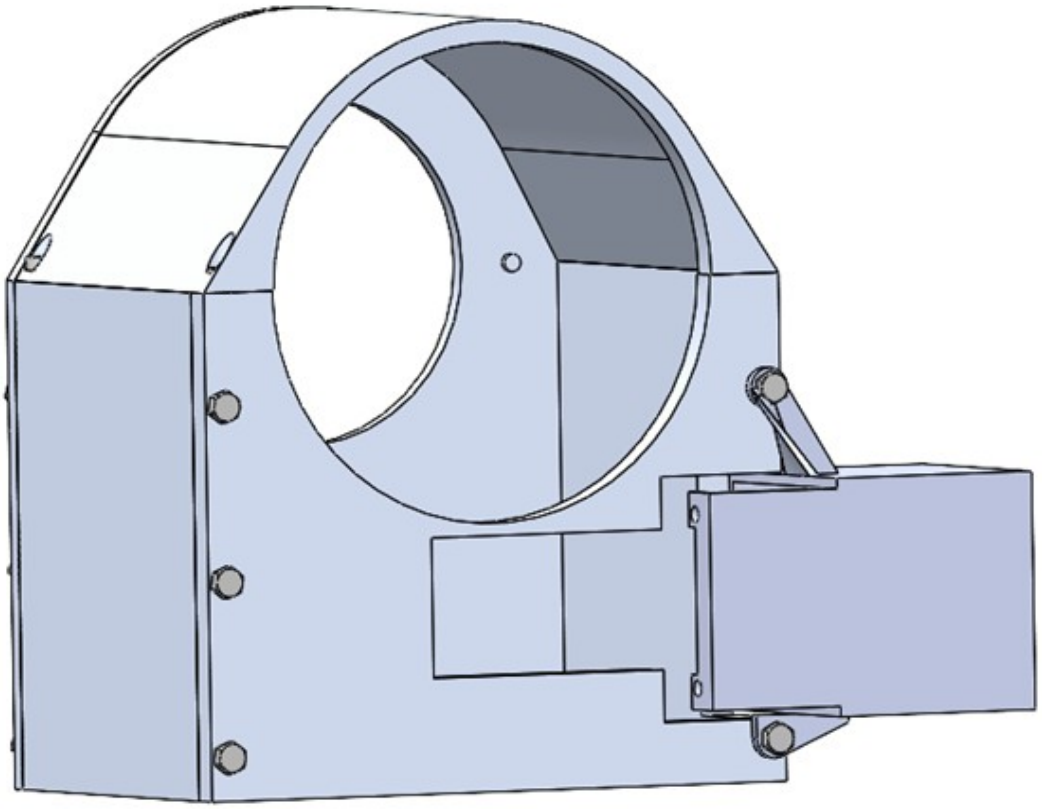

Figure 35: Finalized Housing System

# 7 RISK ANALYSIS AND MITIGATION

The risk analysis and mitigation of the design was performed through the use of a failure modes and effects analysis (FMEA) chart. The risk priority number (RPN) of each failure mode was evaluated with the use of the equation (2) where S, O, and D represent severity, occurrence, and detection respectively.

$$RPN = S * O * D (3)$$

A high-risk priority number indicates a high risk associated with the failure. The failures with the highest risk priority number or recurrent failure modes among multiple components are listed below and a full FMEA can be found in Appendix B. Based on the FMEA results, the high risk potential failures were mitigated through material selection, geometric considerations, and utilization parameters for the design.

## *7.1 Potential Failures Identified First Semester*

The results of the FMEA from the first semester are discussed below for the design selected first semester.

### 7.1.1 Potential Critical Failure 1: Fatigue Failure

Each component of the design is susceptible to fatigue failures that cause microcracks and potentially macrocracks. The design will be exposed to cyclic stresses below the yield stress of the proposed materials. An area of particular concern is areas of high stress concentrations such as the slots on the non-rotating plate. Due to the small spacing between the slots on this plate, the slots are more prone to fatigue cracking and potential failure of the design to initiate movement. A way to prevent fatigue failure is material selection based on a S-N curve and the redesign of areas with high stress concentrations.

### 7.1.2 Potential Critical Failure 2: Linear Actuator Connection

The linear actuator is connected to the linkage plate using a pin. This pin will experience shear stresses along with frictional forces. This can cause the pin to shear and cause a failure between the linkage and the actuator. If the pin were to fail it would cause the linear actuator to not rotate the linkage plate causing the iris not to close. If the iris does not close it will not crush a stent. This pin would be cheap to replace and the pin is designed to fail before the linkage plate for this reason. One way this can be mitigated is to add ball bearing to help reduce friction when the pin slides across the linkage plate.

### 7.1.3 Potential Critical Failure 3: Leaflet Sliding Wear

Sliding wear is caused by the frictional contact between two surfaces as the surfaces slide against each other. The sliding wear results in damage to the leaflets surface which may prevent fluid movement of the design. The failure of this extent would lead to replacement of multiple leaflets to accomplish fluid movement. To prevent sliding wear of leaflets, material selection should consider frictional coefficients, composition, surface finish, and machining methods.

### 7.1.4 Potential Critical Failure 4: Fastener Shear Failure

The linkage plate is connected to the back plate through two fasteners. The fasteners will experience shear stress corresponding to loading from the linear actuator and the resistance of the back plate to motion. Failure of the fasteners would cause displacement or complete disconnection between the linkage plate and the back plate which would disrupt or completely prevent actuation of the design. The fasteners are cheap components that are easy to replace however failure of fasteners may cause damage to the attachment points. To avoid shear failure, fasteners should be chosen based on their shear strength and design.

### 7.1.5 Potential Critical Failure 5: Ductile-Brittle Failures

Ductile and brittle failures occur due to the applied stresses and stress concentrations. Ductile failures include plastic deformation and ductile rupture of the components which will result in the inability to properly actuate the device. Brittle fractures will result in the device failing to actuate due to sudden crack propagation. The material of the individual components, the stress concentrations, the processing methods, and the operating temperature of design will determine ductile vs brittle failures. The design will be operated below the yield stress of the material to prevent ductile rupture and plastic deformation. The design especially around stress concentrations may still fail in a brittle manner. To prevent brittle fracture, the design's component should be thoroughly tested with focus on reducing high stress concentrations.

### 7.1.6 Potential Critical Failure 6: Improper Securement of Leaflets

The leaflets attach to the front plate through a series linear slots however improper fitting of the slots may lead to critical failures. Possible critical failures include sliding wear of the leaflet slot attachment, deformation wear of slots, and ductile-brittle failures of slot attachments. These failures may result in improper movement of the leaflets or detachment of the leaflets from the front plate. To avoid design failures, the slots on the front plate should be redesigned to either a new slot type or a slot with increased depth. Potential for lubrication of the front plate slots should be considered in designing and verified for medical use.

### 7.1.7 Potential Critical Failure 7: Bearing Shear Failure

The linkage plate is attached to the back plate through two fasteners. The front plate and the linkage plate will experience bearing shear stresses at these points of connection. A bearing shear failure will result in deformation or complete fracture at these connection points and will prevent actuation of the design. The bearing shear failure may be prevented through redesign of the attachment points and increasing thickness of the plates. Potential redesign of attachment points includes adjusting attachment points positions, modifying the attachment methods, or amalgamating the front plate and the linkage plate into one component.

## 7.2 Potential Failures Identified This Semester

The following sections entails the potential failures that the team identified this semester. If the leaflets become misaligned or are not aligned correctly during assembly, the device could fail to actuate and may result in surface cracks due to force induced deformation. The worm and gear system could experience surface fatigue wear in which the gear will form surface cracks and produce deposits of debris before catastrophic failure. The sliders between the gear and the rotating plate may result in surface fatigue along the slider and the contact surface of the housing. The internal gears of the stepper motor can experience surface fatigue failure and that will result in catastrophic failure. Due to the motor, fretting failure caused by vibration may result in the housing and lead to shear failure of the motor cage arms. Excessive torque from the motor may result in deformation wear of the gear, shearing of the bolts attaching the gear to the rotating plate, shear of the motor shaft, and shear of the motor cage attachment arms.

The team also encountered failures this semester and attempted to resolve them to create a working prototype. These failures include inability of leaflets to move within slots due to friction and design flaws and the housing failing to hold the stepper motor securely. Although the team could not build a functioning device, the efforts made to fix these issues are explained in risk mitigation.

## 7.3 Risk Mitigation

The risks and trade-offs analysis was performed to assess and compare the recommended actions to mitigate failure modes. A highly recommended action for all parts includes material selection for several different types of failures however, medical standards, as well as manufacturing standards, keep the number of usable materials to a minimum. Another factor the team must look at for material selection is cost, including manufacturing costs. Material selection will affect certain failure modes and may increase the likelihood of certain failures while minimizing other failures. For example, POM has a lower friction coefficient than 316 Stainless Steel however 316 Stainless steel has improved compressive and shear strength [22, 23].

A major issue that the team encountered in material selection was the friction from the PLA filament in 3D printed parts, which was one factor that prevented the leaflets from moving freely within the guides. To combat this issue, the team attempted to sand the parts initially to create a smooth surface, a PTFE dry lubricant was then used as a next attempt. The dry lubricant helped with the friction issues slightly but the tolerance stackup was the main factor in preventing the leaflets from moving. The team ordered a 3D printed plate from the university library with a resolution of 0.1mm but upon receiving the part, it was found that the accuracy was not within those limits. Due to the project deadline, further modifications were not possible. Suggestions to resolve these issues in future work are presented below.

# 8 ER Proofs

The Engineering Requirements (ER) proofs were developed to verify the design's capability to produce desired results. Each of the previously mentioned engineering requirements were expected to be tested and validated for the design. Due to a non functioning final device, these engineering requirements were unable to be tested. Nonetheless, our process and calculations for testing the engineering requirements are stated below.

## 8.1 ER Proof #1 – Radial Force Calculations

There is currently no available apparatus for measuring radial force directly, thus the team based the accuracy of the radial force on the load cell used to obtain the radial force value. The load cell was also calibrated using Arduino to ensure the values from the load cell were correct. To obtain the radial force of a stent, tangential force from the worm gear was used with equation 4, where RF is radial force, dD/dx or K is the change in diameter over the change in displacement, and F is the tangential force from the worm gear.

$$RF = \frac{2}{dD/dx} * F(4)$$

The tangential force of the worm was found using equation 5, below.

$$F = \frac{2000T}{d} * \frac{cos\alpha_n cos\gamma - \mu sin\gamma}{cos\alpha_n cos\gamma + \mu cos\gamma} \qquad (5)$$

Where F is the linear force or the tangential force of the gear. The other variables are, T, input torque from the motor, d, the diameter of the worm, , being the pressure angle, , the lead angle, and , which is the coefficient of friction.

The uncertainty of the radial force was determined to be 5.92 N. This was found using equation 5, where the uncertainty of the load cell, diameter, and stepper motor were propagated into the error.

$$u_{RF} = \sqrt{\left(\frac{\partial RF}{\partial dD} * u_D\right)^2 + \left(\frac{\partial RF}{\partial x} * u_x\right)^2 + \left(\frac{\partial RF}{\partial F} * u_F\right)^2} \qquad (6)$$

This uncertainty is higher than other products manufactured by companies such as Blockwise, who have resolution as low as 0.05N.

## 8.2 ER Proof #2 – Diametral Measurements

The team intended to take Diametral measurements through the use of pin gauges of various sizes. The pin gauge sizes included 0.25 mm, 3 mm, 15 mm, and 25 mm. The device would be actuated to each diameter by input through the Arduino system. A pin gauge matching the desired input would then be inserted into the iris to validate the diameter.

# 9 LOOKING FORWARD

## 9.1 Future Testing Procedures

To make sure the product is working properly, users will need to test it to make sure the stent is being crimped properly. To do this, the user should use a precision measuring device to measure the diameter of the stent. If the stent is not the right size, the user should contact the manufacturer to come and calibrate the device. Calibration of the device will be performed with pin gauges to ensure that the iris is closing to the correct diameters. To ensure that the correct force is being applied to the stent the user can check the load cell calibration by removing the motor and measuring an object of known mass to ensure that the load cell is still calibrated. If the load cell is not calibrated the user will need to contact the manufacturer to calibrate the load cell and ensure that it does not need to be replaced.

The user will need to run the device to ensure that it is functioning properly. If the device is rotating but the iris is not closing, meaning that the diameter is remaining the same size, the user will need to check that all the leaflets are placed within the slots on the stationary plate. If the device is not rotating the shoulder screws that are threaded into the leaflets through the rotating plate may be too tight and may need to be loosened by a quarter turn.

### 9.1.1 Testing Procedure 1: Diameter

#### *9.1.1.1 Testing Procedure 1: Objective*

The clients requested that the device be able to accurately crimp a stent to a specific diameter. To test that the device meets the standard defined in the engineering requirements, multiple diameters are tested. First a diameter

of 0.25mm is entered into the Arduino system via a keypad. The device is actuated and the LCD returns the calculated diameter to the user. A pin gauge of size 0.25mm is inserted into the iris to verify the accuracy of the device. The results are logged and a linear plot is created. This process is repeated until the results are within +/- 0.25mm. These steps are repeated again at diameters 3mm, 15mm, and 25mm.

#### *9.1.1.2 Testing Procedure 1: Resources Required*

Required for this test are pin gauges between the maximum and minimum diameter of the iris. The more diameters that are tested within this range, the more accurate the device will be. A computer with Microsoft Excel and Arduino software would be needed as well.

#### *9.1.1.3 Testing Procedure 1: Schedule*

The test can be run at any time, so long as the device is operational. The test would take at least ten minutes, more depending on the severity of the miscalculations.

### 9.1.2 Testing Procedure 2: Radial Force

#### *9.1.2.1 Testing Procedure 2: Objective*

The client requested that the device be able to accurately provide the correct amount of radial force to crimp the stent without causing damage. The radial force is a function of the stent material, diameter, and length due to the interaction between material and dimensional characteristics. The radial force would be measured with calculations using diametral measurements, motor counts, and the values from the load cell.

#### *9.1.2.2 Testing Procedure 2: Resources Required*

The load cell that measures the tangential force exerted by the gear will be calibrated with the value of known weight before securement of the motor cage and delivery of the device. The diametral measurements and calibration of the diameter to motor count will be performed with the pin gauges and the provided Arduino code. The readings of the load cell and calibration data will be used to calculate the radial force output based on equation (1) in the Arduino code.

#### *9.1.2.3 Testing Procedure 2: Schedule*

The test can be run at any time so long as the device is operational. The test should take around ten to 20 minutes depending on the severity of miscalculations.

## *9.2 Future Work*

The prototype constructed by the team was unable to rotate due to material selection, tolerance issues as well as design flaws. Learning from the mistakes encountered during this project, the team gained insight for future endeavors to resolve these issues. A major recommendation for the future would include prototyping with a cheaper material, such as aluminum, to reduce friction within the device and adequately assess functionality. The leaflets for the current design were manufactured with aluminum but the plates were 3D printed. Switching the material from the PLA filament to aluminum or steel would greatly reduce the friction between the leaflets and the plates. Resizing the slots of the non-rotating plate and adding length to the knobs on the leaflet to prevent disconnection of the components during operation is another recommendation. Resizing the components would include increasing width and depth of the slots without compromising structural stability. Resizing the components may be accompanied by a reduction in number of leaflets to allow more space between the slots in the non-rotating plate. The current design contains 18 leaflets and thus 18 slots within the non-rotating plate. Eighteen slots in one plate results in closely positioned slots. Reducing the number of leaflets will allow more space in between slots and in return, the slot width can be increased. This modification would benefit the design as it would allow room for more lenient tolerances without compromising the fit of the leaflets within the plate. Another suggestion is to change the leaflets knobs to shoulder screws to ensure the leaflets stay within the slots without using compression. The current design relies on compression to hold the leaflets in the slots which by design will add friction.

Another suggestion for future testing includes friction calculations and testing methods. A pulley force gauge could be used to determine the force required to allow the shoulder bolt to move within the linear slots. This information would in turn provide the frictional force. Understanding the frictional force could provide insight for redesign.

The spacers in the current design should be updated to cylindrical roller bearings of proper size to reduce friction between components and enable fluid rotational movement. It is recommended to add bearings to the rotating plate slots to reduce friction to the smallest possible amount. The device should be assessed for ability to produce desired results based on engineering requirements and safety standards. When desired results are adequately produced, the main body of the design including the rotating plate, non-rotating plate, and leaflets should be manufactured in 316 stainless steel. Changing the components to stainless steel would ensure medical standards for manufacturing are met while also keeping friction to a minimum. The housing of the device should be manufactured in either stainless steel or POM plastic to provide adequate protection for components and a separate compartment should be constructed to properly store the electronic components. Creating the housing from stainless steel would also secure the stepper motor in place, preventing it from rotating outward and disrupting the collinearity of the worm and gear.

# 10 CONCLUSIONS

The project goal was to design and build an actuated stent crimper that accommodates a range of stent lengths and diameters while also outputting diameter and radial force as well as utilizing an iris mechanism. The team first engaged in state-of-the-art literature review to become educated on the purpose of a stent crimper and current designs that are on the market today. Thorough research provided the team with the knowledge to confidently define the engineering requirements based on the customer needs and begin designing a product. Using the design process, multiple design alternatives were created and eliminated, leaving the team with one final design to be constructed. The initial design implemented a linear actuator, 18 leaflets, a non-rotating plate, a rotating plate with curved slots, and a housing. 3D printed prototypes were created to test the feasibility of the design. The initial design was then modified to implement a worm and gear for actuation and a rotating plate with linear slots. Final parts were ordered and machined before assembling the final prototype. Due to late shipping times, tolerance stack-ups within 3D printed parts, and friction between the moving parts, the iris of the final prototype could not open and close. Examination of the failures resulted in a deeper knowledge of the assembly and a thorough plan to advance this prototype to a final product in future endeavors. The goal of this project was not only to build a working device, but also to learn from the failures that we as a team encountered and how to use our engineering skills and teamwork to resolve each issue. Although the final prototype cannot be considered a working device, the team is confident that this project provided each member with the skills to advance their engineering career. The team is also confident that the suggested solutions for future work would significantly improve the functionality of the device.

## *10.1 Reflection*

The team applied engineering principles to produce a stent crimper that abides by medical manufacturing standards and codes. The device, in its final form, will be made from materials approved for medical device manufacturing by the FDA. By using materials and practices that have already been approved and tested, the team can bypass much of the need to get approval from the government on novel processes.

## *10.2 Postmortem Analysis of Capstone*

### 10.2.1 Contributors to Project Success

The team has been successful in many aspects of the project. The team showed expert teamwork during the course of the capstone project. Communication was never compromised throughout the various challenges presented, and

the team showed true motivation for success, even though it was out of their reach. Meeting various milestones, such as the housing being completed and the control code working properly, maintained a stream of motivation for the team. Utilizing a 3D printer has allowed the team to stay within budget, otherwise the team would have been unable to manufacture the essential components.

### 10.2.2 Opportunities/Areas for improvement

The initial design chosen for the device was changed mid-semester, delaying the acquisition of parts for the device. Shipping times due to COVID-19 were also a factor in attaining our parts. This delay was one of the greatest factors that contributed to the non-functionality of the device. The final design should have been chosen as soon as possible, but the team was invested in selecting a design that would meet all the engineering requirements while also standing out from other stent crimpers.

The team encountered complications within components of the design that did not produce the desired results. The reasons for encountered complications pertain to the quality of materials, sizing of components, time management and constraints, design flaws, and unexpected structural failures.

The material originally chosen for the rotating plate, stationary plate, and leaflets was stainless steel which was infeasible in terms of time constraints and ability of the local machine shop as well as budget restrictions. Due to complications with the material, the team was unable to effectively adapt the device. The team encountered difficulties with the shipping for replacement of raw materials and were unable to account for issues with the new material due to time constraints. Difficulties with the raw material and other complications such as improperly sized components were not anticipated or rectified within a timely manner.

Due to unforeseen global circumstances, the team was required to adapt to online communications during the prototyping phase of the project. The inability to establish face-to-face communication hindered the facility of the prototyping phase and generated a decrease in time resources. The decrease in time resources hindered the team's ability to physically iterate the design.

In the future, the construction and ordering of components should be performed at an earlier time to identify complications and improve functionality. Despite complications with online communications, the team should have strived to order machined components by the end of the first semester or prepared to order components at the beginning of the second semester. The team was also not required to construct a prototype at the end of the first semester due to the global pandemic and decided looking back that it would have been beneficial if we constructed one regardless. If the team had constructed a full prototype at the end of the first semester, it would have provided the team with a longer timeline for modifications and testing procedures.

# 11 REFERENCES

[1] S. Hähnel et al., “Small-vessel stents for intracranial angioplasty: In vitro comparison of different stent designs and sizes by using CT angiography,” Am. J. Neuroradiol., vol. 24, no. 8, pp. 1512–1516, 2003.

[2] J. Parodi, “Endovascular repair of abdominal aortic aneurysms and ...,” 1995. [Online]. Available: https://www.jvascsurg.org/article/S0741-5214(95)70186-9/abstract. [Accessed: 12-Sep-2020].

[3] S. H. Duda et al., “Physical properties of endovascular stents: An experimental comparison,” J. Vasc. Interv. Radiol., vol. 11, no. 5, pp. 645–654, 2000.

[4] “Standard Specification for Wrought Seamless or Welded and Drawn 18 Chromium14Nickel-2.5Molybdenum Stainless Steel Small Diameter Tubing for Surgical Implants,” TBT Standard F2257, 2014. [Online]. Available: https://compass-astm-org.libproxy.nau.edu/EDIT/html_annot.cgi?F2257+14

[5] Human Factors Design Process for Medical Devices, ANSI/AAMI HE 74:2001. [Online]. Available: https://my.aami.org/aamiresources/previewfiles/he75_1311_preview.pdf

[6] Metallic biliary stent system for benign strictures, TITLE 21, PART 876.5011, 2019. [Online]. Available: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=876.5011

[7] Standard Specification for Polyethylene Plastics for Medical Applications, ASTM F639 - 09, 2015. [Online]. Available: https://compass-astm-org.libproxy.nau.edu/EDIT/html_annot.cgi?F639+09(2015)

[8] “Catalogue numbers for GORE® EXCLUDER® AAA Endoprosthesis,” Gore Medical. [Online]. Available: https://www.goremedical.com/products/excluder/specifications. [Accessed: 06-Mar-2020].

[9] W. A. Lee, M. P. Brown, P. R. Nelson, and T. S. Huber, “Total percutaneous access for endovascular aortic aneurysm repair (‘Preclose’ technique),” Journal of Vascular Surgery, vol. 45, no. 6, pp. 1095–1101, 2007.

[10] M. Trossbach, M. Hartmann, C. Braun, K. Sartor, and S. HäHnel, “Small vessel stents for intracranial angioplasty: in vitro evaluation of in-stent stenoses using CT angiography,” Neuroradiology, vol. 46, no. 6, Jan. 2004. [Online]. Available doi: 10.1007/s00234-004-1205-3

[11] “Neuron MAX 088.” Penumbra. https://www.penumbrainc.com/wp-content/uploads/2016/12/4900C_NeuronMAX_Flex_Comparison_Ordersheet_USA.pdf (Accesses: March 12, 2020).

[12] Wrought Seamless Nickel-Titanium Shape Memory Alloy Tube for Medical Devices and Surgical Implants, TBT Standard F2633, 2019. [Online]. Available: https://compass-astm-org.libproxy.nau.edu/download/F2633.36443.pdf

[13] “Stent Crimping Machine: Datasheet C-150,” Medical Production Technologies. [Online]. Available: https://www.mpteurope.com/wp-content/uploads/2018/03/Datasheet-CR-150-2.pdf (Accessed: March 12, 2020)

[14] Measuring Radial Force, “Blockwise Engineering LLC” p://www.blockwise.com/assets/knowledge/K050-Measuring%20Radial%20Force.pdf

[15] “Stepper vs Servo,” AMCI. [Online]. Available: https://www.amci.com/industrial-automation-resources/plc-automation-tutorials/stepper-vs-servo/. [Accessed: 14-Mar-2020].

[16] “R & D/Pilot Production Stent Crimping,” MSI. [Online]. Available: https://msi.equipment/product/sc500700/. [Accessed: 14-Mar-2020].

[17] “RJ - Stent Crimping Machines,” RJ - Stent Crimper. [Online]. Available: http://www.blockwise.com/stent-crimpers/rj/#largetwin. [Accessed: 14-Mar-2020].

[18] “CX - Stent Crimping Machines,” CX - Stent Crimper. [Online]. Available: http://www.blockwise.com/stent-crimpers/cx/#cx-alpha. [Accessed: 14-Mar-2020].

[19] “Automated Drug Coated Stent Crimping equipment,” MSI. [Online]. Available: https://msi.equipment/product/sc1775s1875s/. [Accessed: 14-Mar-2020].

[20] Science Buddies, “Introduction to Servo Motors,” Science Buddies, 10-Jan-2020. [Online]. Available: https://www.sciencebuddies.org/science-fair-projects/references/introduction-to-servo-motors. [Accessed: 11-Mar-2020].

[21] StackPath. [Online]. Available: https://www.machinedesign.com/mechanical-motion-systems/article/21836868/whats-the-difference-between-servo-and-stepper-motors. [Accessed: 11-Mar-2020]

[22] “Acetal Copolymer (Delrin®) (Celcon®) (Acetron®),” Acetal Copolymer, 2011. [Online]. Available: https://www.polytechindustrial.com/products/plastic-stock-shapes/acetal-copolymer. [Accessed: 30-April-2020].

[23] “Iron Alloy,” MakeItFrom.com, 30-May-2020. [Online]. Available: https://www.makeitfrom.com/material-properties/AISI-316-S31600-Stainless-Steel. [Accessed: 20-Nov-2020].

# 12 APPENDICES

## *12.1 Appendix A: Arduino Code*

```
//Built for the 2020 Gore Stent Capstone Team
//Code written by Nick Green with help from Jenny Lawson
#include <Stepper.h>
#include <LiquidCrystal.h>
#include "HX711.h"
#include <avr/wdt.h>
#include <Wire.h>
#include <Keypad.h>
#define STEPS 15000
#define numberOfDigits 2

String inputString;
long inputInt;
const int DOUT = 8;
const int CLK = 9;
int micro = 10;
float calibration_factor = 7.605;
float units;
long val;
float dia;
int stepSpeed = 20;
int counts = 0;
int homeForce = 1500;
int force = 0;
long diameter;
int resetPin = 7;
HX711 scale;
LiquidCrystal lcd(2, 3, 4, 5, 6, 7);
Stepper stepper(15000, 10, 11, 12, 13);
int stepsToTake;

//setting up keypad
//int signalPin = 12;

const byte ROWS = 4;
const byte COLS = 4;
char hexaKeys[ROWS][COLS] = {
  {'1', '2', '3', 'A'},
  {'4', '5', '6', 'B'},
  {'7', '8', '9', 'C'},
  {'*', '0', '#', 'D'}
};

byte rowPins[ROWS] = {34, 36, 38, 40};
byte colPins[COLS] = {42, 44, 46, 48};
```

```
Keypad keypad = Keypad(makeKeymap(hexaKeys), rowPins, colPins, ROWS, COLS);
char entryStr[8];
int i = 0;


void setup() {
  // put your setup code here, to run once:

  inputString.reserve(numberOfDigits);
  lcd.begin(16, 2);
  lcd.clear();
  lcd.setCursor(0, 0);
  lcd.print("Welcome!");
  lcd.setCursor(0, 1);
  lcd.print("Starting up...");
  Serial.begin(2000000);
  delay(1000);
  scale.begin(DOUT, CLK);
  lcd.clear();
  scale.set_scale(calibration_factor);

  scale.tare();

  stepper.setSpeed(stepSpeed);

  home the iris
  while (units < homeForce)
  {
    stepper.step (-1);
    delayMicroseconds(micro);
  }
  lcd.clear();
  scale.tare();
  //Serial.println("LCD Cleared");
  //Serial.println("Choose diameter");
  lcd.setCursor(0, 0);
  lcd.print("Choose Diameter");
  lcd.setCursor(0, 1);
  loop();
}

void loop() {
  char key = keypad.getKey();

  if (key) {
    //Serial.println(key);

    if (key >= '0' && key <= '9') {     // only act on numeric keys
      inputString += key;               // append new character to input string
      lcd.setCursor(0, 1);
      lcd.print(inputString);
```

```
      lcd.setCursor(3, 1);
      lcd.print("Press # to go");
      //Serial.println("Key added");
    } else if (key == '#') {
      if (inputString.length() > 0) {
        val = inputString.toInt(); // YOU GOT AN INTEGER NUMBER
        inputString = "";          // clear input
        // DO YOUR WORK HERE
        lcd.print(val);

        operate();
      }
    } else if (key == '*') {
      inputString = "";          // clear input
    }
  }

}
void operate() {
  long stepsToTake = StepsCalc(val);
  long counts = accuate(stepsToTake);
  printForce();
  printDiameter(counts, stepsToTake);
  reset();
}

long StepsCalc(long val) {
  long stepsToTake;
  //Serial.println(val);
  stepsToTake = (-757.79 * val);
  //Serial.println(stepsToTake);
  stepsToTake = stepsToTake + 53258;
  //Serial.println(stepsToTake);
  ceil(stepsToTake);
  //Serial.println(stepsToTake); Serial.println("after ceil");
  return stepsToTake;

}

long accuate(long stepsToTake) {
  stepper.setSpeed(stepSpeed);
  lcd.clear();
  //Serial.println(stepsToTake);
  lcd.setCursor(0, 0);
  lcd.print("Accuating");
  //Serial.println("Accuating");
  long counts = 0;
  for (int i = 0; i <= stepsToTake; i++) {
    //while (counts <= stepsToTake) {
    stepper.step(1);
    //Serial.println("in the for loop");
```

```
    counts = counts + 1;
    //Serial.println(counts);
    delayMicroseconds(micro);
    //return counts;
    if (counts == stepsToTake) {
      break;
      Serial.println("broken in crushing");
    }
  }
  // Serial.println(counts);
  return counts;
}
void goBack(long stepsToTake) {
  for (int j = 0; j <= stepsToTake; j++) {
    stepper.step(-1);
    //Serial.println("going backwards");
    delayMicroseconds(30);
    //int counts = counts++;
    if (counts == stepsToTake) {
      break;
      Serial.println("Broken in opening");
    }
  }
}
void printForce() {
  units = scale.get_units(), 5;
  if (units < 0)
  {
    units = 0.00;
  }
  lcd.setCursor(0, 1);
  units = units * .00981;
  lcd.print("Force: ");
  // Serial.print("Force: ");
  lcd.setCursor(8, 1);
  lcd.print(units); //displays the weight in 4 decimal places only for calibration
  //Serial.print(units, 5);
  lcd.setCursor(15, 1);
  lcd.print("N");
  // Serial.print("N");
  // Serial.println();
}

void printDiameter(long counts, long stepsToTake) {
  //Serial.println(counts);
  diameter = -0.001319619 * counts;
  diameter = diameter + 70.28;//calculate the diameter from steps
  lcd.setCursor(0, 0); // Sets the cursor to col 0 and row 0
  lcd.print("Diameter:"); // Prints Sensor Val: to LCD
  lcd.setCursor(11, 0);
  lcd.print(diameter); // Prints value of diameter to LCD, manipulate formula here
```

```
  goBack(stepsToTake);
  delay(10000);

}

void reset() {
  wdt_disable();
  wdt_enable(WDTO_15MS);
  while (1) {}
}
```

## 12.2 Appendix B: FMEA

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Part 1 - Leaflet | Surface Fatique | Surface cracks that effect movement of leaflets | 5 | Frictional contact between individual leaflets and slots | 3 | Subject design to repeated cyclic loading | 4 | 60 | None at this time |
| | Sliding Wear | Fracture or deformation of leaflets that prevents fluid movement | 7 | Cyclic loading and frictional contacts between leaflets or slot attachments | 5 | Subject design to repeated cyclic loading and frictional testing | 2 | 70 | Assess material frictional coefficients; redesign slot attachments or add lubrication |
| Part 2 - M3 Shoulder Screws | Surface Fatique | Surface cracks that effect movement of leaflets | 3 | Frictional contact between the shoulder screw and the slots of rotating plate | 3 | Subject design to repeated cyclic loading | 4 | 36 | None at this time |
| | Shear Failure | Fractures across knobs prevent or hinder actuation | 4 | Shear stress caused by the leaflets and the back plate | 4 | Assess shear stress on knobs and subject knobs to shear stress | 2 | 32 | None at this time |
| | Surface Fatique | Surface cracks that effect movement of leaflets | 7 | Frictional contact between the slots of the non-rotating plate and the leaflets | 3 | Subject design to repeated cyclic loading | 4 | 84 | None at this time |
| Part 3 - Non-Rotating Plate | High Cycle Fatique | Fracture of Slots | 7 | Cyclic stress apllied by leaflets slots on the edges of the non-rotating plate slots | 4 | Subject design to repeated cyclic loading | 2 | 56 | Material selection based on S-N data and redesign of slots to reduce stress concentration |
| | Ductile Rupture | Fractures across the surface that prevents movement | 8 | Deformation caused by high heats or stress | 2 | Subject design to various loads and operating temperatures | 3 | 48 | Assess appropriate operating temperatures for material |
| | Deformation Wear | Failure to actuate design | 7 | Manufacturing errors of slot attachment | 5 | Assess tolerances of the manufacturing process | 2 | 70 | Redesign Slots, reevaluate tolerances of slots, or add lubrication to slots |
| Part 4 - Rotating Plate | Surface Fatique | Surface cracks that effect movement of leaflets | 5 | Frictional contact of slots and shoulder screw | 3 | Subject design to repeated cyclic loading | 4 | 60 | None at this time |
| | Bearing Shear Failure | Complete or partial fracture around the fasteners | 7 | Stresses imposed by fasteners | 4 | Test Design for bearing shear failure | 4 | 112 | Change material or add material around holes |
| Part 5 - Gear | Bending Fatique | Surface cracks at the root of gear teeth that effect movement of gear | 7 | Frictional contact with hardened steel worm | 4 | Subject design to repeated cyclic loading | 3 | 84 | Change Material of Gear |
| | Adhesive Wear | Inappropriate actuation of rotational motion | 6 | Pitting on surface of Gear due to Worm | 5 | Operate at high speeds and test for impurities | 2 | 60 | Change Material of Gear, operate at slow speeds or utilize lubricants |
| Part 6 - Worm | Surface Fatique | Failure to actuate design | 6 | Fractures across the worm teeth | 3 | Subject design to repeated cyclic loading | 4 | 72 | None at this time |
| Part 7 - Motor | Surface Fatique | Failure to actuate design | 7 | Frictional contact of internal gear system | 3 | Subject design to repeated cyclic loading | 6 | 126 | Follow guidelines recommended for life cycle for motor |
| | Shear Failure | Fractures across motor that hinder or prevent actuation | 3 | Cyclic bearing stress on shaft or excessive torque | 2 | Repeated cyclic loading or run motor above operating conditions | 2 | 12 | Operate motor within recommending specifications |
| Part 8 - Motor Cage | Shear Failure | Fractures along attachment arms causes misalignment | 8 | Load on arms or vibrations from running motor | 5 | Subject Motor Cage arms to Shear Stress | 4 | 160 | Design secure attachment with minimal load on attachment arms |
| Part 9 - Housing | Fretting Fatique | Fracture along surface of housing | 5 | Vibration from operating motor | 2 | Vibrational testing during operation | 3 | 30 | Operate motor at speeds lower than resonance of the housing |
| | Surface Fatique | Fracture along surface of housing | 4 | Frictional contact of sliders with the housing | 3 | Subject design to repeated cyclic loading | 2 | 24 | Add low frictional material to sliders |
| Part 10 - Slider | Surface Fatique | Fractures or delimination of slider prevents or hinders actuation | 3 | Frictional contact of sliders with the housing | 4 | Subject design to repeated cyclic loading | 4 | 48 | Change to cylindrical roller bearings |
| Part 11 - Electronics | Hydrogen Corrosion | Breakdown of circuit board | 7 | Exposure to contaminants | 2 | Visional inspection | 2 | 28 | None at this time |
| | Short circuit | Unable to actuate design | 6 | Wire Crossing | 5 | Voltmeter to test connection or excessive heat | 3 | 90 | Ensure proper connection and refer to operations manual |