

W. L. Gore Stent Crimper

Final Proposal

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Mechanical Engineering

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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

The team's primary goal, as required by our client, is to develop a low-force stent crimper that uses a crush iris radial force readout. The team completed comprehensive study on the market accessible devices in present day to expand knowledge and current targeted goals related to the devices through benchmarking at the beginning of the semester after receiving the project proposal from our client. We clarified our customer and engineering needs related to the device after absorbing sufficient knowledge from the devices and related issues. After establishing the functional for the device and keeping the customer's needs in mind, the team created a black box model and functional model based on the clients' needs.

The team followed the House of Quality and a QFD to improve the correlation between Engineering and Customer requirements. Following up on our results, our teams created entire system designs with the help of concept generation after having a lively conversation about novel ways to improve the device. Our three objective concepts for our iris crimping device and GUI readout were a curved leaflet with AC plug system and touchscreen input, a curved leaflet with AC plug system and Analog knob, and a straight leaflet with an AC plug system and Touchscreen input. The team opted to move forward with a curved leaflet with AC plug system and touchscreen after completing each system's pros and downsides with a Pugh chart and a redacted decision matrix.

With the completed device components in mind, team began prototyping and determining the testing processes for our prototype as the semester progressed. We 3D printed the iris design required for the device using the CAD modelling the team developed, since it might be deemed a good prototype to prevent failures that could occur by critical inspection of the rather than utilizing a low-resolution model by hand. The major five functions were primarily considered through the FMEA. They are failures that can occur when the iris is crimped, the force and diameter readouts are obtained, the crimped stent is released, the stent is crimped according to the intended forces and diameters, and the emergency stop button is pressed. Crimping the iris and having the emergency stop work as a result received the highest severity rating out of these primarily examined functions. As a result, our primary goal in testing will be to reduce the number of failures that occur during these courses.

Furthermore, the team is now conducting an Engineering Analysis for the device's diameter ranges, force needs, and power requirements. Overall, the anticipated results show the team can achieve a progressive result that is more appealing to our consumer without compromising the device's capabilities.

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1 BACKGROUND

1.1 Introduction

The project goal is to develop, produce, and evaluate a low-force stent crimping device that utilizes a crush iris and a radial force readout. The project would be multidisciplinary, with the electrical engineering team and our mechanical engineering capstone team working together under the direction of the Gore Medical product division. The mechanical engineering team will primarily focus on machine design and material component selection, as specified by the client. Our client and sponsor for the project is Tanner Moll from W.L GORE, team advisor Dr. Pete. Endovascular stent grafting is the treatment used to help patients with aneurysms. An aortic aneurism is a balloon-like bulge in the aorta, the main artery that delivers blood from the heart through the chest and body. The strain of blood pumping can separate the layers of the artery wall, enabling blood to flow in between them, causing aortic aneurysms to dissect or rupture [6]. The best method to repair an aneurysm depends upon several factors, including the location and shape of the aneurysm as well as the physical condition of the patient [6]. Surgeons perform surgery inside your aorta using thin, long tubes called catheters. It involves placing a stent surrounded with a fabric liner. Endovascular grafting is a minimally invasive method to treat an aortic aneurysm instead of an open aneurysm repair [6].

If the machine regulates the force, the diameter is dependent on the stent. If the machine sets the force is a dependent variable, however, both mechanisms have their own advantages and disadvantages.

1.2 Project Description

The following project description, submitted by the client, focuses mostly on the requirements that the team must meet to finish the overall design output focusing on the mechanical components of the device. “The scope of this project is to design, build, and evaluate a low force stent crimping machine utilizing a crush iris with a radial force readout.”

Apart from the main scope given in the general context, the client gave the overall compatibilities, the design should contain. The device should correlate under the safety standards given by the ANSI (American National Standards Institute), OSHA, and or other available safety standards. The team needs to generated iris designs for the device per requirements. As mentioned previously under the introduction range of diameters, radial forces and the team need to establish stent lengths and the team needs to justify the selections. Moreover, the team must ensure the designs meet the stepwise design process. Additionally, Graphic User Interface (GUI) shows the crimping forces and diameter data for the crimped stent.

Apart from the focus on the project requirement the client also believes the project will be iteratively attribute understand customer requirements into design specifications in the real world. Whereas students will learn how to develop and utilize the design process to prototype & build a machine and iteratively improve it. Also, since this project have demands on both electrical and mechanical components client the project introduces the team into the field of mechatronics (how mechanical and electrical components interface). Students will learn about Gore's culture and what it is like to work as an engineer daily, while improving the essential skills as a leader, team player and how to understand business aspects of a real-world project.

2 REQUIREMENTS

When designing, teams must certain criteria for the client, as well as details that specify what details the engineer must meet to properly complete the project. This section outlines the requirement given by the customer as well as the engineering requirements that the team determined. The customer needs and the engineering requirements are seen based on correlating requirements in table 1.

2.1 Customer Requirements

The requirements are given weights out of 5 points with 5 being the most important. The client wanted the stent crimper to follow all relevant safety guidelines to protect the user from hazards which has a weight of 5. They also wanted the device to read out the current force and diameter of the iris which each has a weight of 4. The team must present the client with a working model that follows multiple tests and iterative designs with a weight of 4. The model must be durable and reliable which will be a part of the testing process with a weight of 3. For this project, the entire team has \$3000. This requirement is given the weight of 3 since the parts shouldn't come near the allotted budget. Further into the project, the team may share funds as necessary. The client wanted the stent crimper to be for endovascular stents. This requirement has a weight of 3 since, the dimensions for an endovascular stent are included, but others can be crimped as they also fall into the same range of criteria as endovascular stents.

2.2 Engineering Requirements

Based on the customer needs, the team developed engineering requirements and specified values as necessary. To meet compliance, the team needs to include warning labels and safety features seen in table #. The team will contain the components in a box so there are no loose wires exposed. The team decided to include a graphic user interface that will contain specifications such as force and diameter readouts. The iris must be able to crimp a variety of endovascular stents. After researching endovascular stents, the team determined the iris must be able to crimp to the specifications seen in table #. The device will have a start and stop button in addition to the emergency stop so the user can have complete control over the device. The team broke up the funds with starting values of \$2500 for the mechanical engineering team and \$500 for the electrical engineering team. The mechanical engineering team is responsible for designing the iris crimp and base, while the electrical engineering team is responsible for the user interface, code, and wiring of the systems. The team will also include a minimum of 5 iterations of the iris and sufficient testing to ensure the device is reliable and durable.

Table 1: Design Requirements

Customer Needs	ME Engineering Requirements
OSHA Safety Standards	Warning Labels - Pinch Point, electrical shock, safety glasses [1,2]
ANSI Safety Standards	Emergency Stop [1,2]
Readout: Force	User Control of Force or Diameter
Readout: Diameter	Iris style clamp
Cost Control	GUI force
Iterative Design Process	GUI Diameter
For endovascular stents	Iris Crimping Diameter (mm) $6 < X < 50$ 16mm-45mm devices [3]
Working Model	Iris crimp depth 46mm devices 80 mm length can be 1.5 times size [4]
Reliable	Force 132.94(N) 28.9 N/cm max [6]
Durable	Start/Stop Button
	<\$2500 ME <\$500 EE
	Individual Part Testing and Iterations
EE Engineering Requirements	
	Microcontroller with 2 inputs for user input & 2 inputs for sensors & 1 drive motor
	4 Display Buttons: 2 for changing diameter inputs & 2 for changing force inputs
	2 Sensors: Force Sensor & Diameter Sensor
	Stepper Motor

2.3 Functional Decomposition

The team discusses the main subsystems of the stent crimper above: the iris crimping unit, power source, and the output screening system. The functional modeling process includes a full diagram of the operations of the device given in figure 1. that details the inputs and the outputs of the device based on the black box indicated in figure 1. The purpose of the black-box model is to identify the major flows of operation and their inputs and outputs. For this project, the black box is the operation of an endovascular stent crimper under the given diameter or the radial force.

2.3.1 Black Box Model

The Black box model included in figure 1 identifies the major flows for input and output for crimping a stent using an iris design. The purpose of the black-box model is key when identifying primary features, the overall stent crimping machines inputs, and outputs. Under the given structure presented in figure 1 the main inputs to the device would be energy using a power source; most definitely electric power using a motor as the user can control easier compared to a complete mechanical system; with the guidance of human conduct. The material flows were the Endovascular stents under a given length. For the signal flow, it was the start/ pause button, emergency stop, and selected force or diameter read

per requirement. The outputs of the system would be a crimped stent with minimal error, power cut off if given to emergency, an indicator to stop the process, and force and diameter readouts.

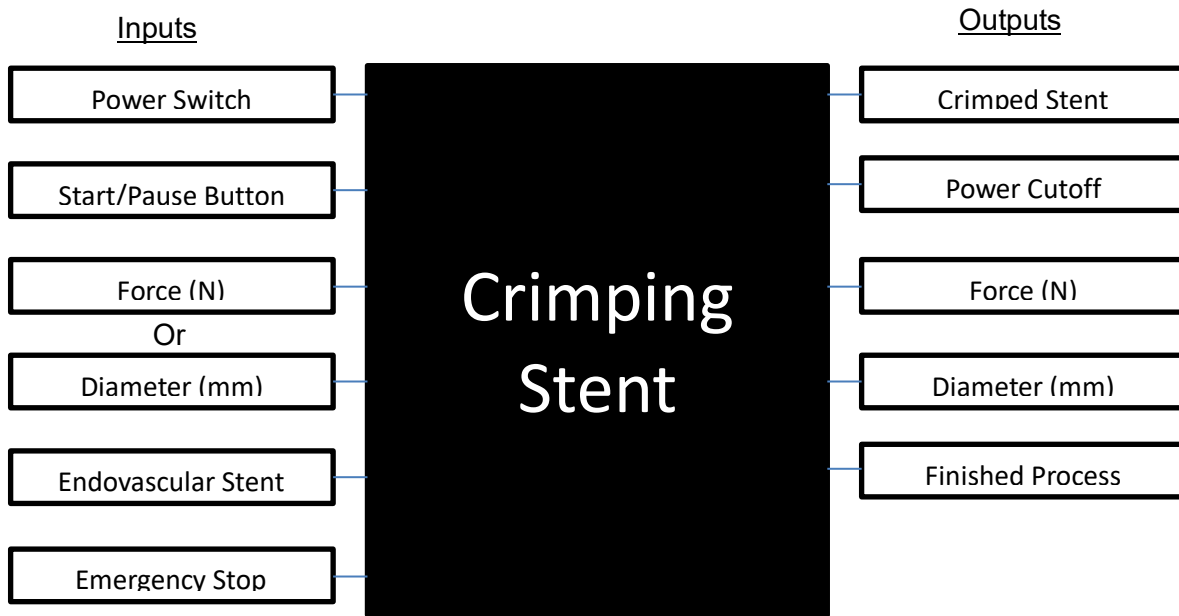


Figure 1: Black Box Model

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

Using the black-box model and the highly ranked customer needs, the team developed the hypothesized functional model, for example, the device having the ability to crimp the stent for a given diameter or a radial force and the client wanted the stent crimper to follow all relevant safety guidelines to protect the user from hazards what has a weight of 5. He also wanted the device to read out the current force and diameter of the iris which each has a weight of 4 reflected in the functional model. Table 2 shows the functional basis table which relates the customer needs to the black-box model input and output flows. The functional model table separates primary and secondary models. The team indicated each function separated by a comma in these categories. The secondary functions are all related to the primary function.

Table 2: Functional Model

Class	Primary Function	Secondary Function
Material	Human conduct, Determine force or diameter selection	Endovascular stent
Energy	Electric energy stored in a Battery, Releases energy, Releases heat, Releases vibrations	Rotation, Crimping, Display
Signals	Power switch, Emergency Stop, Force or Diameter selection,	Finished process indicator, Power cutoff, Force and diameter readouts

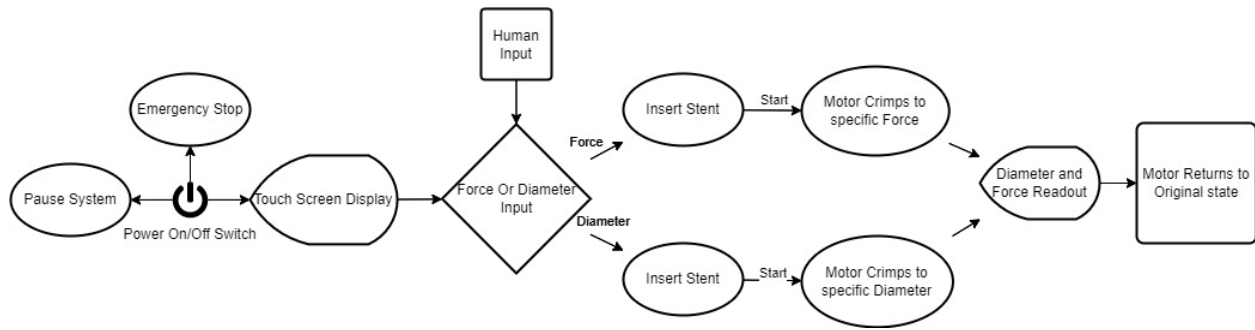


Figure 2: Functional Decomposition Model

2.4 House of Quality

Based on the correlation between the technical requirements to the customer needs, the team found the individual part testing and iterations to be the most important requirement to focus on. The team needs to have multiple iterations of the design that can be evaluated based on the client's needs for an iterative design process, so the team set a goal of 5 prototypes for the first semester. The next relative technical importance is the max force. The team needs to determine how the machine will apply the force and accurately read said force from a sensor as the device crimps. The third important concept is the user control of force or diameter. The team must determine for the sensor will read to allow the device to accurately apply the force or crimp to the diameter the user has preset into the graphic user interface. The user will have the option to choose whether the device crimps based on a given force or based on a given diameter. Figure 3 shows the weights the team gave to each of the correlations from the customer needs to the technical requirements, as well as the technical requirements to each other. The bottom row shows the overall technical importance of the engineering requirements. The tests for the engineering requirements can be seen in figure 3 across the top of the house of quality.

											Test Description				
Warning Labels											Visual N/A				
Emergency Stop											Repetitive Emergency Stops				
User Control of Force or Diameter											Accuracy using known forces and diameter				
Iris style clamp											Visual N/A				
GUI force											Compare Readout to known force				
GUI Diameter											Compare Readout to known diameter				
Iris Crimping Diameter (mm) 6<X<50 - minimum											Measure smallest diameter crimped to				
Iris crimp depth 80mm											Measure depth of leaflet				
Max force X(N)											Plug in high forces and see where motor stops				
Start/Stop Button											Repetitive starting and stopping, Reliability				
<\$2500 ME <\$500 EE											N/A				
Individual Part Testing and Iterations - 5 Minimum											Visual N/A				
											Customer Opinion Survey				
											A Blockwise				
											B CSI				
											C NAU Cap 2020				
											1 Poor				
											2				
											3 Acceptable				
											4				
											5 Excellent				
Customer Needs											Customer Weights				
Warning Labels - Pinch Point, electrical shock etc.											Warning Labels - Pinch Point, electrical shock etc.				
Emergency Stop											Emergency Stop				
User Control of Force or Diameter											User Control of Force or Diameter				
Iris style clamp											Iris style clamp				
GUI force											GUI force				
GUI Diameter											GUI Diameter				
Iris Crimping Diameter (mm) 6<X<50 - minimum											Iris Crimping Diameter (mm) 6<X<50 - minimum				
Iris crimp depth 80mm											Iris crimp depth 80mm				
Max force 133(N)											Max force 133(N)				
Start/Stop Button											Start/Stop Button				
<\$2500 ME <\$500 EE											<\$2500 ME <\$500 EE				
Individual Part Testing and Iterations - 5 Min											Individual Part Testing and Iterations - 5 Min				
OSHA Safety Standards											5				
Ansi Safety Standards											3				
Durable											5				
Readout: Force											4				
Readout: Diameter											4				
Cost Control											3				
Iterative Design Process											5				
For endovascular stents											3				
Max Stent Length											3				
Reliable											3				
Working Model											4				
QTY											4				
Y/N											Y/N				
Y/N											Y/N				
Fin #											4				
Y/N											Y/N				
Y/N											Y/N				
mm											9				
mm											12				
N											2				
Y/N											8				
\$											5				
# of tests											1				
Technical Requirement Targets											1				
Absolute Technical Importance											11				
Relative Technical Importance											6				

Figure 3: Stent Crimper House of Quality

2.5 Standards, Codes, and Regulations

The team must ensure that all safety and design standards are met based on the design being built. For this project, most of the applicable standards are for the iris and the electrical components of the project. The user's safety is the top priority as they cannot be hurt while using the product. To complete this the team must follow all standards outlined in table 3. This includes the team putting labels and signs on the device where the user could potentially injure themselves as well as the user wearing protective equipment such as safety glasses and gloves. The standards that pertain to the design include the containment of the electrical components and a shield protecting the user from pinching themselves in the iris. The last standards pertain to the structure of the system. This includes a base where crimper is mounted to prevent movement of the machine, the weld specifications to ensure quality welds, and lockout/tag-out and emergency stop so potential users do not use the device if it is malfunctioning. How these standards are incorporated into the design

and affect the overall design are explained based on the correlating standard in table 3.

Table 3: Standards of Practice that Apply to this Project

<u>Standard Number or Code</u>	<u>Title of Standard</u>	<u>How it applies to Project</u>
OSHA 1915.16	Warning signs and labels.	The team must have safety labels and sign on the machine to protect the user [1].
OSHA 1910.133	Eye and face protection	To protect the user's eyes, they must wear safety glasses in case the stent or machine breaks [1].
OSHA 1910.137	Electrical Protective Equipment	To protect the user, the electrical components must be covered, or the user must wear rubber gloves to prevent electric shock [1].
ANSI ISO 13850:2016	Safety Of Machinery - Emergency Stop Function	The team must include an emergency stop in case an accident occurs while using the device, this will function as a kill switch [2].
OSHA 1910.212(a)(3)(ii)	Lockout/Tag-out (LOTO) Requirements	The team must develop a system that the user can lockout/tag-out the device if it is not functioning properly [1].
OSHA 1910.212	General requirements for all machines	The machine must have a guard protecting all risk factors such as wiring and crimping pinch points. The device must also be anchored to prevent it from moving while in use [1].
AWS B2.1	Specification for Welding Procedure and Performance Qualification	The welds that hold the iris together must not fail and must pass the quality check based on fragments within the weld [5].

3 Testing Procedures (TPs)

The Gore Capstone team will be extensively testing the Stent Crimper as further adjustments and corrections are made. The team will be primarily testing the User control and GUI in test 1 and the Max crimping force and start/stop button in test 2. These two tests will cover the technical requirements for the project that the team can test and record outcomes for. This will give the team a better idea on how to improve the prototype.

3.1 Testing Procedure 1: Control and GUI Testing

This test will be run to check if the GUI is displaying the correct diameter and force of the stent crimper, as well as testing the Control system to ensure it is working properly and accurately. This will be done by selecting a vast range of different diameters or forces and then measuring with a ruler or pressure sensor. This is checking the GUI, User Control, and check the crimping diameter technical requirement.

3.1.1 Testing Procedure 1: Objective

The objective of this testing would be to check the accuracy of the GUI systems as well as the user control inputs. This is essential to the project working as it determines the size of the crimped stent as well as shows the user the current state of the stent. The team also needs to understand the diameter that the stent can be accurately crimped to meet the technical requirement.

3.1.2 Testing Procedure 1: Resources Required

To complete this test the team will need to meet up with all the members present, especially the Electrical engineering team. This would allow the team to walk through both the mechanical and electrical components to make sure everything is working correctly. The current prototype of the Mechanical team as well as the circuit/display output. This is a low danger test and can be conducted at households or in the NAU LRC.

3.1.3 Testing Procedure 1: Schedule

The testing will start early to mid-next semester, due to construction and the creation of the circuit and prototypes. The Electrical Engineering team will start prototyping late this semester and will further develop the ideas next semester. This will include the force sensors, GUI display, and touchscreen input. The test will be run for around an hour or two depending on the extent of the test.

3.2 Testing Procedure 2: Descriptive Title

3.2.1 Testing Procedure 2: Objective

The objective of the test two is to find the Max stent crimping force, which is also relate to the smallest stent crimp diameter created by the stent crimper. This is to understand the boundaries of our design and how we can make it better. It will also help us evaluate the start/stop button and the emergency stop button.

3.2.2 Testing Procedure 2: Resources Required

To complete this test the team will need to meet up with all the members present, including the Electrical engineering team. This would allow the team to walk through both the mechanical and electrical components to make sure everything is working correctly. The current prototype of the

Mechanical team as well as the buttons for the start/stop and the emergency stop. This is a low danger test and can be conducted at households or in the NAU LRC.

3.2.3 Testing Procedure 2: Schedule

The testing will start early to mid-next semester, due to construction and the creation of the circuit and prototypes. The Electrical Engineering team will start prototyping late this semester and will further develop the ideas next semester. This will occur sooner than the first detailed testing methods as it will test the most basic functions.

4 Risk Analysis and Mitigation

The NAU Gore stent crimper has many moving and fragile parts, this makes the stent crimper very suitable to failure and malfunctions. To mitigate the frequency of failures the mechanical engineering team will work closely with the electrical team. By taking advantage of our strong points and helping each other with the weakness the team plans to create a strong product. The main points the team will look will be electrical components being accurate and working consecutively. The mechanical components will need to be able to work under fatigue and under several cycles.

Table 4: FMEA Analysis

Process Function	Potential Failure Mode	Potential Effects of Failure	Severity	Potential Causes	Occurrence	Prevention Action
Iris Crimping	Does not crimp the stent, incorrectly deforms stent. Pinches the stent	Deformed Stent. Uncrimped Stent	5	Iris Blades gets stuck on stent. Not an equal force throughout the iris	3	Testing, changing the number of blades and well as the lengths
Force & Diameter Readout	Incorrect readout. Not accurate	Incorrect readout of the current force and diameter. Misinformation	4	Inaccurate measuring system. Calibration Error	2	Accurate testing of the GUI and programming of the software
Crimp Release	Does not release the stent/iris does not open up	Cannot get the stent out. Crushes the stent/deforms stent	4	Gears are stuck and do not release. Not enough range formation	2	Correct gear system to work machine, oil and maintenance.
Emergency Stop	Does not immediately stop and shut down	Does not stop and crushes stent or may injure workers	5	Slow response from button to system. Connection error	1	Secure connection between the emergency stops and the crimping machine
Desired Control of Diameter or Force	Crimps too hard or not hard enough. Does not crimp to desired diameter	Inaccurate measuring crushes/deforms stent. Inaccurate crimping	4	Inaccurate measuring system. Calibration Error. Connection with the control system and machine	2	Accurate testing of the GUI and programming of the software

4.1 Critical Failures

4.1.1 Potential Critical Failure 1: Crimp Blade Fatigue

From several test and actuals runs of the crimp machine a point worry is the fatigue stress and strain it will face. This will need to be calculated using a fatigue life calculation and figuring out which material for the crimping blades will work the best and provide a cost-effective solution. If the blades do suffer

fatigue the stent could be deformed incorrectly and not be an effective device.

4.1.2 Potential Critical Failure 2: Slow Emergency Stop

Emergency stop button is an essential part of our design as it is a necessity to meet the OSHA and AISI safety requirements. This critical component for the design needs to work very time, and swiftly. The time will extensively be measured and tested to ensure a 100% success rate.

4.1.3 Potential Critical Failure 3: Excessive Force

This failure could occur when the electrical components are not entirely in sync with the mechanical giving much force to the device than needed. This needs to be mitigated because if this were to continue the team will only have incorrect stent size, or worse deformed stents. To prevent this error the team will check the calibration of the electrical force readout constantly.

4.1.4 Potential Critical Failure 4: Iris Crimp stuck

This would be a massive problem as the stent will be unusable because there is no way to retrieve the stent without deform or making it unusable. This would be a devastating as it would not provide any good stent crimps. To prevent this the team will need to oil and maintain the blade and gears.

4.1.5 Potential Critical Failure 5: Incorrect Force Readout

This could be a very simple failure in our system this, causing our readout of the force to be incorrect or poorly calibrated. The team will often calibrate the force sensor and make sure it is accurate, as well as communicating with the electrical team for the force display.

4.1.6 Potential Critical Failure 6: Inaccurate Diameter Readout

This could be a very simple failure similar to the diameter readout, the force to be incorrect or poorly calibrated. The team will often calibrate the diameter sensor and make sure it is accurate, as well as communicating with the electrical team for the force display.

4.1.7 Potential Critical Failure 7: Touchscreen input difficulties

Touchscreen difficulties are mainly an Electrical Engineering team inquiry as they will be in charge of the inputs and touchscreen. The Mechanical team will be working closely with them to sync the screen the mechanical components.

4.1.8 Potential Critical Failure 8: Stent Pinch with Iris

The Iris stent crimping mechanism has a risk of pinching the stent and causing an incorrect crimp. This can be mitigated by getting the correct number of blades as well as a correct curvature for the blades.

4.1.9 Potential Critical Failure 9: Electrical disconnect

This would be a simply be a disconnect between the electrical and mechanical components. This would need to be mitigated as if not the device will not work or start property. To prevent this the

mechanical and electrical components will have to be design in parallel, meaning they are design for each other and designed together at the same time. Preventing discrepancies between the designs.

4.1.10 Potential Critical Failure 10: Slow Crimp Time

This will be a relatively easy problem to resolve, if the crimping time of the device is too slow it would make our device not as competitive or effective as those on the market. To prevent this from happening the will increase the torque of the motor or increase the number of teeth to make the gear turn easy with lower force.

4.2 Risks and Trade-offs Analysis

The team identified the primary five areas where major failures could occur using the FMEA study. It's normal that some device faults may necessitate stringent measures to resolve. The overall design focuses on addressing and limiting the problems related with the connected iris crimper. Endovascular stent crimping procedures are an important aspect of a serious medical procedure that requires extreme precision and testing. As a result, failure to crimp the stent for the suitable input diameters or force could result in the crimping process being repeated several times until the stent is crimped to the required diameter or force. Additionally, this could lower the device's market worth by increasing the entire cost connected with it. This error could be the result of a deeper issue. With a graphical user interface that reads the input forces, diameters, and errors from the iris crimper's leaflets. If one of the above-mentioned components acts as the carrier, it is not difficult to iterate the solution; nevertheless, if both components have the issue, false investigations may result. In this case, the components will need to be investigated separately to see if the error is related with one or both.

Another significant concern is the use of a crimped stent releasing method. This could be due to a flaw in the proposed gear correlation, or an imperfection in the program used to manage the system so that it can absorb the proper data and signal the sensors to act correctly. This could potentially be due to a fault in both systems in a separate situation. In this case, a device must be in place that allows both to be studied individually using testing methods. If the procedures are linked, an iterative method will be required to rectify the component that is out of order so that the second component can be restored. For example, if the program is reading incorrect data for the releasing point, the program must be updated to align with the gears. However, the team cannot overlook the possibility that this will necessitate a work ranging from tweaking to completely redesigning the component in order to preserve the correct mechanism.

Another major failure that could be an issue is ensuring that the emergency stops are working properly. The device's emergency stop is essential since it operates actively to overcome hazardous concerns. It's vital to remember that this gadget is a mechatronics device that works in tandem with mechanical and electronic components. Either of the associated scenarios should be able to be handled by emergency stop. Given the potential for system failures, having an emergency stop as well as making it run without delay is a difficult task.

5 DESIGN SELECTED – First Semester

The team worked to generate multiple distinctive design concepts. Using a Pugh chart and a decision matrix the team narrowed the concepts down to the two best design. Through prototyping and seeing how the designs would work as a physical model the team produced their final design selected described below. Through the summer and the second semester this design is subject to change based on the technical analysis of the components and the design testing. The current design for the first semester and how this will be implemented is described below.

5.1 Design Description

From the preliminary report, the design has had two major modifications based on the functionality of the prototypes. The first modification is the leaflet design. The first design had 20 leaflets which were small and short. For the team to use a pin to hold the leaflet in place, there must be enough space on the side of the leaflet to make a hole. The size of this hole was increased to 3.5mm as well as the slot used to control the movement of the leaflet. The team reduced 20 leaflets to 12 leaflets to improve the mobility of the leaflets for the varied diameters need for the different endovascular stents, while still maintaining the iris radial shape. The height of the leaflet was increased to 2 mm more than half of the inner diameter of the shell for a total height of 52mm. The new leaflet is seen in figure 4. The team also implemented an inner ring to control the motion of the leaflets. One side has handles so the team has the ability of move the leaflets manually. The current design prototype is seen in figure 5 followed by the prototypes that the team utilized to achieve the current design in figure 5.

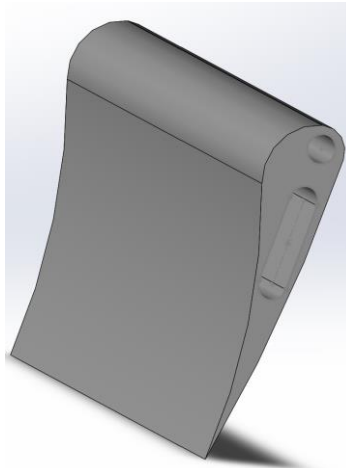


Figure 4: New Leaflet



Figure 5: Current Prototype



Figure 6: Previous Prototypes

The curved blade will have a higher area shown by equation 1 compared to the area of the straight edge shown in equation 2 where r is the radius and A is the area inside the iris eye.

$$A = \pi r^2 \quad 1$$

$$A = 10 * (r * \sin(18)) * (r * \cos(18)) \quad 2$$

For a radius of 50 mm, the decagon would have an area of 0.00734 m^2 while the curved leaflets would have an area of 0.00785 m^2 showing there is a higher area available for the stent when using the curved leaflets. So, if the team uses the curved leaflets, they can use a smaller design, saving money while still meeting the customer's requirements.

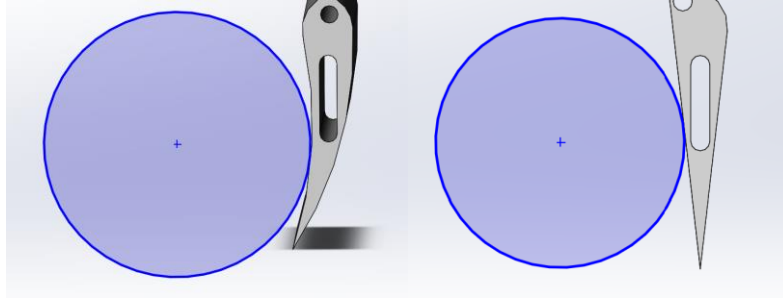


Figure 7: Crimping Reference

During the team's individual analysis, they will be analyzing the required force from the leaflets and system, the diameter of the iris eye, and the motor power requirement. The diameter of the iris eye is shown in equation 3 while the needed force from the system is described by equation 4.

$$H = \frac{PD}{2t} \quad 3$$

$$RF = 2\pi * \frac{\Delta D_i}{(D_i+t)} * E * t * L \quad 4$$

H = Hoop Stress

D = Diameter

T = thickness

P = Internal Pressure

E = Young's Modulus

D_i = Internal Diameter

L = Stent Length

5.2 Implementation Plan

The team has a manually working prototype of the iris crimper. For the implementation of the design, the team is going to work on 3D printing an external pinion gear and worm gear which can attach to a stepper motor controlled by a potentiometer dial. This design will be a complete automated prototype of the mechanical side of the project. The team will be swapping the inner ring with the handles to the worm gear and pinion. The motor will be bought from amazon and the wiring potentiometer from amazon as well. The wiring is already accessible from a team member. These can be seen accounted for in the bill of materials in table 5. The final assembled design is seen in figure 8 and an exploded view of the design is seen in figure 9. The team will have the gear and components printed by April 29th, 2022, if the motor has come in, this will be attached as well, otherwise, the stepper motor will be borrowed from the electrical engineering team.

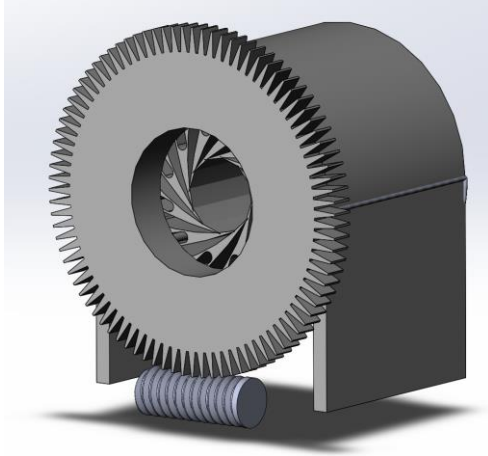


Figure 8: Final Design

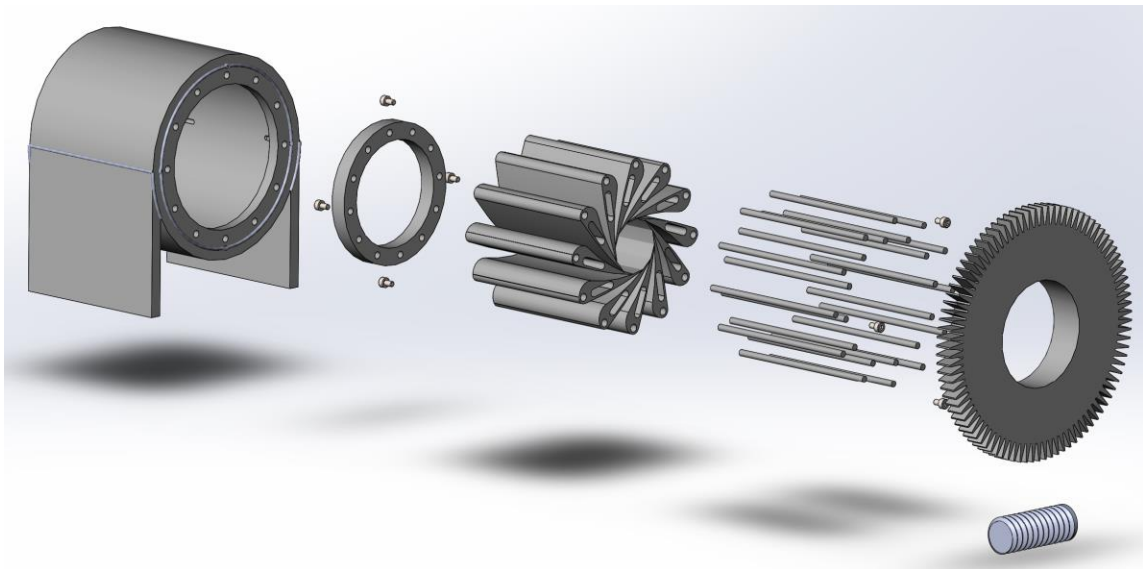


Figure 9: Exploded View

Table 54: Bill of Materials

Part	QTY	Associated Cost	Budget Remaining
Curved Leaflet	12	\$0	\$2940
Outer shell	1	\$0	\$2940
First ring	2	\$0	\$2940
Inner ring	1	\$0	\$2940
Inner ring with Gear	1	\$0	\$2940
Pins	24	\$0	\$2940
Worm Gear	1	\$0	\$2940
Stepper Motor	1	\$20.99	\$2911
Potentiometer	1	\$10	\$2901

6 CONCLUSIONS

The ability to crimp the stent for both diameter and force reading is one of the project's primary needs, as indicated in the project description. The team completed the design to include a curved iris and touch screen GUI to best match our customer requirements and engineering constraints after weighing the design concepts. Through the Engineering analysis, the team will finalize the overall diameter range, force, and power requirements to operate the device under the stated conditions in the coming week. The mechanical team concentrated on perfecting the crimping mechanism during the process of achieving the overall requirements. The team created a workable prototype that may now be improved to reduce testing time. Now it's time to move on to the next phase of the project. The team created a workable prototype that may now be improved to improve accurate testing. The team will 3D print an external pinion and worm gear that can be coupled to a stepper motor controlled by a potentiometer dial in the next phase of the project. This design will serve as a completely automated prototype for the project's mechanical element.

7 REFERENCES

- [1] *Law and Regulations | Occupational Safety and Health Administration*. (n.d.). Retrieved March 3, 2022, from <https://www.osha.gov/laws-regs>
- [2] *ANSI Safety Standards*. (n.d.). Retrieved March 3, 2022, from <https://webstore.ansi.org/industry/safety-standards>
- [3] Arko, F., Nussbaum, T., Lalka, S., & Holleman, J. (n.d.). *The Endurant Stent Graft - Endovascular Today*. Retrieved March 3, 2022, from <https://evtoday.com/articles/2012-may-supplement/the-endurant-stent-graft>
- [4] Georgakarakos, E., & Schoretsanitis, N. (2018). The Various Types of Endovascular Stent Grafts for EVAR: How Do They Compare? *New Approaches to Aortic Diseases from Valve to Abdominal Bifurcation*, 415–421. <https://doi.org/10.1016/B978-0-12-809979-7.00037-7>
- [5] *Standard Welding Procedure Specifications (SWPS) : Resources : Standards : American Welding Society*. (n.d.). Retrieved April 6, 2022, from <https://www.aws.org/standards/page/standard-welding-procedure-specifications-swps>
- [6] Schiavone and Q. Tian-Yang, "Crimping and deployment of metallic and polymeric stents -- finite element modelling," *Vessel Plus*, vol. 1, no. 1, pp. 12-21, 2017.