Rotationally Collapsible Heart Pump Housing

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1. Project Definition Supporting Documents

1.1 Annotated Bibliography

In order to design a device that assists in the recovery of a patient following a cardiac infarction, it is important to understand current medical devices and research the current state of the field. For us to understand the design problem at hand, it was important for us to understand the environment in which the device is to be used. As mechanical engineers, our background is not usually in the anatomy of the human body, which required us to research and understand the basic anatomy of the critical parts for this device. This included the femoral artery, aortic arch, as well as the heart itself (including the ventricles and chambers). Because this device is actively moving blood from the left ventricle into the aortic arch by means of an impeller and motor, it is important to understand damage to the blood vessels in the process. Researching hemolysis and its limits allowed us to develop design constraints in order to prevent damage to the blood vessels.

Also important to the design process is ensuring that the new design does not infringe on any current or patented devices. Fortunately, this particular medical device has a fairly limited number of manufacturers, which we were able to research and analyze. Prior to starting our design process, we researched Abiomed’s Impella devices (both 2.5 and 5.0), as well as the Thoratec collapsible device.

References

   This is the link for the Abiomed product page. This was used to find the dimensions and specifications of the medical device.

   This is the link for the Thorotec product page. It was used to find dimensions and specifications about the Thoratec Percutaneous Heart Pump.

   This link describes what a heart attack is and what is happening. It provides useful information on post heart attack problems that occur in the majority of cases, in which our device would be used.

   This article was used to see how current LVAD devices are used and the insertion procedure. It also provided information about infarct size reduction using this technology.
   This is the Abiomed Impella 2.5 user manual page. This was used to find the
   operating procedure and standard usage for the Impella 2.5 device.

   This is the Abiomed Impella 2.5 product page. It was used to find the general
   specifications and claims by the company. It was also used for the illustrations of
   the device.

   http://videos.overcome.fr/eums2011/presentation/vendredi/16h30/parker/parker.swf
   This is a video of the operation of the Thorotec Percutaneous Heart Pump. It was
   used to understand how the radial expansion of the Thorotec device operated.

[8] Diagnostic and Interventional Cardiology. (2010, January 26). Thoratec Acquires Catheter-
   Based Heart Pump Technology (First Edition) [Online]. Available:
   http://www.dicardiology.com/article
   This is an article that describes the development of the catheter based technology
   that Thorotec uses for their heart pump. It also gives multiple dimensions of
   properties of the device as well.

   http://patft.uspto.gov/netacgi/nph
   This patent is used to understand the uses of torsional cables in medical devices
   currently. It provides common materials and strengths currently used and
   available.

    related to Reynolds shear stress [Online]. Available:
    This is a discussion about the relative Reynolds shear stress limits at which
    hemolysis occurs, and the percentage hemolysis at various stress levels.

    This is the Abiomed Impella 5.0 instruction manual page. It is used to understand
    the use and the product specifications of the Impella 5.0 model.

    This is a reference describes the minimally invasive procedure used to implant the
    Impella circulatory support system. It describes common techniques and obstacles
    occurred during surgery.


1.2 Patent Search

The primary criteria in searching for prior art was to determine patents for cardiac assist devices for placement inside the heart, specifically those implanted in the heart without needing open-
heart surgery. The motors, impellers, and actuation methods of such devices are patentable due to specific attributes of their designs. With the help of our advisor, and after searching the United States Patent and Trade Office, we acquired relevant patents. One patent application is taken as the basis of the design process for the axial flow pump described below.

One relevant document for the proposed LVAD design is US patent No. 6139487 and is owned by Impella Cardiotechnik AG, the manufacturer of the Impella LVAD device. This patent was issued October 31, 2000. The title of the patent is “Intracardiac Pump Device” and describes a pump that is inserted into the left ventricle through the aorta “without having to open the ventricles”, alluding to the lack of a need for open-heart surgery to insert the device [13].

Another relevant patent is US patent No. 6921414, held by Vascular Architects, Inc. (currently produced by Thoratec) and was issued July 26, 2005. The patent describes a prosthesis with a coiled body and a graft material covering it, officially referred to as a “Endoluminal Prosthesis and Tissue Separation Condition Treatment Method”. The primary claim is the range of width to diameter ratios that the prosthesis encompasses and the radial expansion of the device [14]. While not a specific patent for an LVAD device, the housing is of great importance because it comprises a collapsible stent.

While not a design criterion of this project, the impeller must also be expandable to fill the cross section of the housing in the expanded state. Accordingly, related patents were researched, with the most relevant being US patent No. 7393181, for an “Expandable Impeller Pump”, issued July 1, 2008. The blades of the impeller are stated to fold radially, with indentations on the hub allowing the blades to fold elastically [15]. This patent shows that prior art exists for an impeller of the necessary design to accommodate a rotationally collapsible pump housing.

The final and most applicable patent to the project is US patent No. 6660032 which describes an “Expandable Coil Endoluminal Prosthesis”, pertaining to a coiled stent body that is rotationally collapsible [16]. This patent is jointly held by the advisor for the project and is the basis for the initial concept of the project. The coil is contracted in length and is torsionally rotated simultaneously. This causes the diameter to expand as the coils become tightly wrapped. The connection to this patent through the advisor allows us to continue with our design with a low risk of patent infringement on other designs.

1.3 User Need Search

Shown below is the complete list of user needs developed with a medical device expert as well as a cardiologist from the University of Minnesota. See Appendix D for notes from the interview with cardiologist Dr. Peter Eckman.
1.4 Concept Alternatives

Early in the design phases of the project we had discussed a multitude of variations among the design ideas. Among them were the option to have an external or internal motor, and creating a collapsing mechanism that could expand the housing to twice its undeployed size. We were fortunate to start with a rotationally collapsing mechanism that was already patented and given to us by our advisor. In the end when all of the ideas were weighed against each other the rotationally collapsible housing was chosen for a few different reasons which will be discussed in greater detail below.

An external motor would have certain benefits that an internal motor could not as it can be any size. This is because an external motor would not have to travel through any blood vessels. However, if the motor were to be designed to be external to the body it would need some way of driving the impeller, which would be inside of the body. In order to do this a torsional cable would need to be utilized. In the end we decided that eliminating the torsional cable and driving the impeller with the motor directly would be the best and easiest course of action.

When deciding what type of collapsing mechanism would be used there were a few factors to consider. First among them was the suggestion of our advisor. As was stated earlier he currently held a patent on a rotationally collapsing mechanism. This patent was given to us to start our project, having this information it was easy to see that this would be the most practical approach to solving our problem. However, this was not the only option considered. We considered many options, among them were: an axial actuation method, a balloon or inflatable actuation method, something similar to a Hoberman sphere, or altogether get rid of the deployment phase and try to achieve 4+ l/min of flow with a 4 mm diameter housing.

---

**Table 1. User Needs**

<table>
<thead>
<tr>
<th>#</th>
<th>Need</th>
<th>Importance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Rotational Collapsible Housing is small enough to be deployed in Femoral Artery</td>
<td>5</td>
</tr>
<tr>
<td>2</td>
<td>Rotational Collapsible Housing expands to largest possible area in Aorta</td>
<td>5</td>
</tr>
<tr>
<td>3</td>
<td>Rotational Collapsible Housing can be collapsed from proximal end</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>Rotational Collapsible Housing is easy to insert</td>
<td>3</td>
</tr>
<tr>
<td>5</td>
<td>Rotational Collapsible Housing is low risk</td>
<td>4</td>
</tr>
<tr>
<td>6</td>
<td>Rotational Collapsible Housing is manufacturable</td>
<td>3</td>
</tr>
<tr>
<td>7</td>
<td>Rotational Collapsible Housing is able to be implanted for sufficient time</td>
<td>3</td>
</tr>
<tr>
<td>8</td>
<td>Rotational Collapsible Housing is able to be removed without damage</td>
<td>4</td>
</tr>
<tr>
<td>9</td>
<td>Rotational Collapsible Housing enables sufficient blood flow</td>
<td>5</td>
</tr>
<tr>
<td>10</td>
<td>Rotational Collapsible Housing minimizes hemolysis</td>
<td>4</td>
</tr>
<tr>
<td>11</td>
<td>Rotational Collapsible Housing minimizes shear stress on blood vessels</td>
<td>4</td>
</tr>
<tr>
<td>12</td>
<td>Rotational Collapsible Housing is made of material that wont corrode inside of body</td>
<td>3</td>
</tr>
<tr>
<td>13</td>
<td>Rotational Collapsible Housing is made of material that wont react with blood cells</td>
<td>3</td>
</tr>
<tr>
<td>14</td>
<td>Rotational Collapsible Housing must be flexible enough to follow path to the heart</td>
<td>3</td>
</tr>
<tr>
<td>15</td>
<td>Rotational Collapsible Housing is made of materials that will not plastically deform for this design</td>
<td>4</td>
</tr>
<tr>
<td>16</td>
<td>Rotational Collapsible Housing is approved by FDA</td>
<td>4</td>
</tr>
<tr>
<td>17</td>
<td>Rotational Collapsible Housing is not traumatic to Aortic valve</td>
<td>4</td>
</tr>
<tr>
<td>18</td>
<td>Rotational Collapsible Housing integrates functionality of motor and Impeller</td>
<td>3</td>
</tr>
<tr>
<td>19</td>
<td>Rotational Collapsible Housing provides greatest offloading of the left ventricular pressure</td>
<td>4</td>
</tr>
<tr>
<td>20</td>
<td>Rotational Collapsible Housing can pass through the aortic arch</td>
<td>4</td>
</tr>
<tr>
<td>21</td>
<td>Rotational Collapsible Housing must be able to follow guide wire</td>
<td>3</td>
</tr>
<tr>
<td>22</td>
<td>Rotational Collapsible Housing had deployed length sufficient for adequate flow</td>
<td>4</td>
</tr>
<tr>
<td>23</td>
<td>Rotational Collapsible Housing is to be transported by supporting catheter</td>
<td>2</td>
</tr>
<tr>
<td>24</td>
<td>Rotational Collapsible Housing can be collapsed/expanded quickly</td>
<td>2</td>
</tr>
<tr>
<td>25</td>
<td>Rotational Collapsible Housing is not traumatic to body</td>
<td>4</td>
</tr>
</tbody>
</table>
After deciding an actuation method we started producing final design ideas for the system. There were 5 design ideas created, and a design matrix was used to analyze them and choose the best one.

One possible design was centered around a threaded center shaft, shown in the figure below. As the device is inserted into the ventricle each end will have helices attached to it. The end of the shaft that is situated in the ventricle will have the helical spring directly attached to it to restrict its movement. On the other end of the shaft, a hub which rotates about the center shaft would have a radial arm that connects to the spring. The hub would ride along a threaded path which would precisely control the amount of rotation and axial displacement all in one simple motion. The shaft would be a constant length, equal to the length of the spring at its smallest diameter (4mm). As the hub slides down the shaft, it would force the spring together causing it to decrease in length but increase in diameter (to 8mm). The difficulty with this design would be ensuring the correct pitch for the threaded rod, stiffness requirement for the center shaft, and manufacturability of such a small shaft. A drawing of this design is shown in Figure 1.
Another possible design separates the push/pull cable, fluted shaft, and flexible torsion cable within the expandable housing, making the push/pull cable and housing shaft able to rotate independently. Within the catheter is a push/pull cable leading up to the motor housing, where the cable is connected to a solid, fluted portion via a miniaturized thrust bearing. This allows the fluted portion to rotate independently of the push/pull cable. The fluted shaft is coaxial with the motor, which houses a rifled barrel that rotates the shaft as the push pull cable is extended or retracted axially. The fluted shaft only spans a length slightly longer than the motor housing, thereby having a minimal decrease in flexibility. The impeller blades are elastomeric and expand to fill the housing when it is in the expanded state. The housing itself is constructed of multiple helical Nitinol [17] windings that form the skeleton of the housing. A PTFE membrane surrounds the windings and expands and contracts elastically with the housing. Connected to the upstream end of the fluted shaft is a torsion cable that runs the length of the expandable housing.
and attaches to the housing inlet. The surgeon would retract the push/pull cable, decreasing the housing length while expanding the diameter from 4mm to 8 mm as a result of the rotation of the fluted portion. Openings in the PTFE membrane between the helices adjacent to the motor allow blood to exit the housing downstream of the impeller. A drawing of this design is shown in Figure 2.

![Figure 2. Split-Fluted Shaft Design](image)

A third design seen in Figure 3 would utilize a threaded shaft to actuate the collapsing/expanding mechanism in the housing. However, the threaded shaft would be more of a fluted shaft as the threads would be extremely coarse. This would allow for rapid expansion and contraction in the housing. The coil is made from Nitinol [17] and would have one end statically attached to the end of the threaded rod (end furthest into the body), while the other end would be attached statically to a tube into which the shaft would be threaded. This tube would be connected to the catheter or the outermost layer of the system. There would then be a torsional cable attached to the threaded shaft at its proximal end. This cable would run through the body and out to the doctor who could control the actuation. The doctor would actuate this cable and the threaded rod itself would rotate, expanding and collapsing the housing. Beyond this there are a few concerns with this method. There has not been much thought put into how an impeller might be attached to this design, or if this impeller would be collapsible or not. On the same note, there has not been much thought about how to drive this impeller. Whether this be through another torsional cable and the motor itself be outside of the body, or if the motor is inside of the body and directly connected to the impeller. It would be difficult to enclose a motor, impeller, threaded shaft, and torsional cable all within the same system.
The next design considered was a helical design wrapped in a medical textile such as Dacron. This would be attached to a window-pane style tip to allow blood flow into the cannula. The tip would be attached to an industry standard pigtail to prevent damage to the left ventricle. Next a helix would be made out of a hollow tube of thin metal with a guidewire running through it. This helix is attached to the motor at the proximal end, and will power the impeller which is in the medical textile sheath. The motor is attached to a cable that runs to the outside of the body. This cable houses the electrical wiring for the motor as well as the guidewire that runs through the helix. The doctor will hold a device, which, when actuated will stay stationary while a grooved inside tube runs along a tab to both rotate and push the motor and helix assembly to expand its diameter. At that point, the motor could be engaged to begin displacing blood. This design is displayed in Figure 4.
Figure 4. Wire Through Helix Design

The design shown below in Figure 5 will eliminate the need for a threaded rod down the center axis of the housing. One end of the housing will be fixed (the end placed in the ventricle), while the other end will be attached to a center hub that is allowed to rotate about the center axis (catheter or concentric, flexible tube). This hub will then be attached to a torsional cable that will run the length of the catheter until it reaches the outside of the body. Because there is no way to control the expansion or contraction of the housing from the inside via threaded rod, this will be done outside the body from the proximal end. The torsional cable that exits the body will run to a lock device that will allow the cardiologist to rotate/collapse the housing to 4 mm prior to insertion. Once the housing is positioned, the torsional cable will be unlocked, and the housing will expand to 8 mm by controlling the torsional cable. This will be done using a button or tab which will follow a groove into the lock mechanism. By controlling the groove geometry we will be able to accurately determine the expansion and contraction of the device. When the housing is removed, the torsional cable is pulled back through the lock mechanism. It is likely that the motor will be mounted outside the aortic valve, while the impeller will be concentrically mounted along the center axis.
1.5 Concept Selection

When deciding on a final design to implement, multiple methods of selection were utilized. Primarily, each design was discussed, with each component that differentiated it being put under scrutiny. Secondly, the sponsor of the project weighed in on methods of actuation and insertion, as he was our resident expert on the actual implementation of the device. Lastly, and most important, was the design selection matrix which is shown below.
Table 2. Design Selection Matrix Snapshot

<table>
<thead>
<tr>
<th>Design In Question</th>
<th>Major Design Criteria</th>
<th>Non-Deployed Housing Diameter (mm)</th>
<th>Deployed Housing Diameter (mm)</th>
<th>Blood Flow Through Device Body (L/min)</th>
<th>Ease of Procedure Completion</th>
<th>Ability to Maneuver Through Aorta (Radius of Curvature of 0.03 mm)</th>
<th>Total Scores</th>
</tr>
</thead>
<tbody>
<tr>
<td>Threaded Center Rod w/ Threaded Collar</td>
<td>Alex Andrews</td>
<td>5</td>
<td>5</td>
<td>4</td>
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<td>4</td>
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<tr>
<td></td>
<td>Chris Fiegel</td>
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<td>3</td>
<td>1</td>
<td>2</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>Jake Higgins</td>
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<td>5</td>
<td>4</td>
<td>2</td>
<td>2</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>Total Scores</td>
<td>25</td>
<td>25</td>
<td>19</td>
<td>8</td>
<td>10</td>
<td>87</td>
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<tr>
<td>Concentric, Un-Threaded Rod Design</td>
<td>Alex Andrews</td>
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<td>4</td>
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<td>22</td>
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<tr>
<td></td>
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<td>4</td>
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<tr>
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<td>4</td>
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</tr>
<tr>
<td></td>
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<td>5</td>
<td>2</td>
<td>3</td>
<td>26</td>
</tr>
<tr>
<td></td>
<td>Jake Higgins</td>
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<td>5</td>
<td>5</td>
<td>4</td>
<td>4</td>
<td>23</td>
</tr>
<tr>
<td></td>
<td>Total Scores</td>
<td>25</td>
<td>25</td>
<td>23</td>
<td>18</td>
<td>19</td>
<td>110</td>
</tr>
<tr>
<td>No Center Rod, Only Helices</td>
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<td>5</td>
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<td>4</td>
<td>5</td>
<td>23</td>
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<tr>
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<tr>
<td></td>
<td>Total Scores</td>
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<td>25</td>
<td>22</td>
<td>20</td>
<td>19</td>
<td>111</td>
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<tr>
<td>Fluted Shaft w/ Push Pull Cable</td>
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<td>3</td>
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<tr>
<td></td>
<td>Alex Brown</td>
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<tr>
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<td>Tom Schultz</td>
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<tr>
<td></td>
<td>Chris Fiegel</td>
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<td>22</td>
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<tr>
<td></td>
<td>Jake Higgins</td>
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<td>4</td>
<td>3</td>
<td>2</td>
<td>21</td>
</tr>
<tr>
<td></td>
<td>Total Scores</td>
<td>25</td>
<td>25</td>
<td>20</td>
<td>19</td>
<td>14</td>
<td>103</td>
</tr>
</tbody>
</table>

This matrix shows the evaluated concepts, as well as the evaluation criteria. These criteria were determined from the list of customer needs in the Product Design Specification and are described below.

The non-deployed diameter must be 4 mm to ensure safe transport of the device from the femoral artery to the aorta. If the device has a larger diameter than what is specified it will run the risk of damaging cell walls, and will lose its functional purpose.

The deployed diameter must be able to expand to 8 mm to maximize flow. An existing product uses a 4 mm diameter which achieves 2.5 L/min, whereas this device must achieve 5 L/min. The larger diameter of this device will compensate for the lack of flow.

The housing must allow for the natural flow of the human body, which is 5 L/min. During heart failures this flow rate will decrease and the housing must be able to accommodate compensating flow.

Through an expert opinion we discovered that one of the reasons devices like these are not widely accepted is because of complications that can arise during insertion. This makes the ease of insertion, and successful procedures important.

The last design criteria that is important is the ability to maneuver through the aortic arch. The arch has a radius of about 4 cm. In order for this device to be successful it must be able to traverse this arch without damaging the surrounding vessel.
These criteria are the most imperative factors due to their importance in both the operation of the device, as well as its insertion process. After consideration of all alternatives, a design similar to the one outlined in Figure 4 was chosen. This design has the most flexible undeployed state for insertion purposes. Also, it does not include a central axis running down the axis which will allow for much greater flexibility. This device also will utilize a locking mechanism that will allow for quick expansion. This design is likely to change as prototyping progresses, and may be very different in its final phase.

2 Design Description Support Documents

2.1 Manufacturing Plan (Product)

2.1.1 Manufacturing Overview

The complete housing design incorporates 6 functional components: the control box interface, the concentric catheter and torsional cables, four offset Nitinol helices, Nitinol column structure, PTFE textile covering, and tip with pigtail. Although each part is independently constructed from various materials, they must be manufactured to produce a seamless integration from one to another.

The design begins by encasing the collapsible impeller with the four-helix Nitinol structure. The helix structure is to be created by laser cutting four independent helices from 4 mm diameter Nitinol tubing. Once all four helices of equal length and pitch are extracted, they are to be offset 90 degrees from each other so that they can ride along each other and maximize the strength of the structure. At one end the helix structure would be attached to the motor driving the impeller, and at the other end attached to the device tip. Since there are four helices, there would be four adhesive contact points on the motor casing and four connection points on the device tip. The device tip is to be injection molded from a polymer to achieve the shape, along with the window cut-outs for the blood inlet. The tip and pigtail would be a single molded piece.

The motor would be connected to a torsional cable running to the outside of the body and will be controlled by a handheld control box. On the outside of the motor housing the catheter is to taper to the diameter of the Nitinol column structure which is used to allow for rotational resistance of one end of the helices. The rotation of the catheter remains still while the torsional cable is controlled by the control box outside of the body.

The three column structure is to be cut from a hollow cylindrical tube of Nitinol with 4 mm inside diameter. The column widths are to be evenly spaced 120 degrees apart with windows cut between them. One end of the column structure would be attached to the device tip and helix structure, while the other end is attached to the catheter. The columns are to be made of a Nitinol to ensure that as the helix structure begins to expand in diameter the columns could buckle outward without plastically deforming. In addition to buckling outward, the columns still need to transmit torque to hold the tip end from rotating while the helix is rotated into expansion.

On the outside of the four-helix and three-column Nitinol structure a PTFE textile layer is wrapped around to encase the housing and enclose the flow path for the blood. Similar to the
Nitinol helices, the medical textile will be attached to the columns at both ends just short of the motor housing and the tip to allow an outlet for the blood.

The motor is attached to two concentric cables (catheter and torsional cable) running the length of the body and exiting through the femoral artery into a handheld controller. The catheter is to be held stationary and not visible to the user. The torsional cable (connected to the motor and helix) is to be controlled by a spin wheel which the user turns to collapse the diameter of the attached helix structure. Also traveling through the center of the torsional cable connected to the motor are the electrical connections to control the speed of the motor and impeller (in revolutions per minute). The controller is to be a simple structure with a dial for the motor speed, and a dial for rotating the torsional cable connected to the motor which is connected to the helix structure.

2.1.2 Part Drawings

![Catheter and Supporting Lines](image)

The catheter is attached to the end of the pump housing and carries the torsion cable, electrical connection, and purge fluid lumen inside of it. The catheter is used to guide the pump through the femoral artery, around the aortic arch, and then into the left ventricle. The catheter remains in place within the femoral artery for the duration of the procedure. The catheter is a 9 Fr (3 mm outer diameter); the purge lumen supplies a saline solution at a rate of 30 ml/hr to the motor housing to prevent blood from entering and corroding the internals of the motor.
The impeller blades fold inward when compressed by the housing in its undeployed state; as the housing is deployed and the diameter increases, the blades spring to their natural state at the deployed diameter due to the high elongation percentage the elastomer can undergo without permanent deformation.

The motor, while out of the scope of the project, must fit within the 4 mm diameter of the housing and have an overall length less than 10 mm to be able to pass through the aortic arch. Simple hand calculations of flow work requirements indicate that the motor must produce 0.78 Watts of power to move an inviscid flow of 5 L/min at a differential pressure of 70 mmHg (average of systolic and diastolic cycle differential pressure between left ventricle and aorta). Due to inefficiencies in the impeller and viscous losses in moving the blood, shaft output of the motor should have a factor of safety well above this lower limit. Speed must be variable and range from 0-30,000 RPM in order to provide up to 5 L/min of flow. The base is flared outward to guide blood out of the device and reduce recirculation of blood flow as it exits ahead of the motor.
The function of the pigtail is to protect the fibrous tissue within the left ventricle from being damaged by the device if inserted too far or drifts into the heart. This small hook would be hollow, allowing the guidewire to be fed through the pigtail and guide the device into place. Therefore, this part would be made of a flexible material, allowing it to straighten to maneuver through the body, and then curl once the guidewire is removed.

The helical windings form the structure of the pump housing and allow the expansion and contraction of the housing diameter through rotation of the helices. 4 interwound helicies of Nitinol construction (0.018” diameter) of 100 mm length and 62.5 mm pitch are formed at a 4mm outer diameter, and are connected at the ends by a toroidal collar. When one end is rotated counter to the winding direction 0.8 turns, the diameter of the housing is expanded from 4 mm to 8 mm. Because the ends remained fixed at 4 mm, the center 10% of the length on either end is below the required 8 mm diameter, but the inlet windows in the PTFE covering are offset 10 mm from either end.
The columns exist to provide a fixture for the end of the helical windings that is not attached to the motor and the torsional cable used to deploy the device, and are constructed of Nitinol. The end of the columns on the motor side connects to the catheter, which does not rotate with the torsional cable. Because the columns are rigid in torsion but flexible in bending, the inlet end of the helices remains fixed as the opposite end of the helices are rotated. The outward force from the helical windings causes the columns to buckle slightly in the middle to accommodate the increased diameter.

### 2.1.3 Bill of Materials

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<th>Description</th>
<th>Quantity</th>
<th>Unit of Measure</th>
<th>Procurement</th>
<th>Notes</th>
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2.1.4 Manufacturing Procedure

The manufacture assembly process for a housing design which encases an axial flow pump with a collapsible/expandable impeller must be constructed essentially from the inside and work its way radially outward. That is, since most of the parts are concentrically located to one another the outer components must be assembled around the innermost parts; otherwise there will be no way to insert them.

Start by attaching the shaft of the impeller to the electric motor. Separately, cut four independent helices from Nitinol tubing and offset them 90 degrees from each other. This helix structure will encase the impeller and is used for reference placement of other components. Next, place the impeller within one end of the four-helix structure. The electric motor should not be inside the helix structure, but rather just beyond the end of each helix. Now take the four ends of the helices and fasten them to the motor housing with industrial adhesive. This will fix one end of the helix structure to the motor. See Figure 7 below to see the positional relation between the impeller, motor, and one end of the 4-helix structure.

![Figure 7: Impeller, motor, and helix-structure attachment](image)

Next, position the Nitinol column structure over the helix structure. The column structure is flexible enough to be placed concentrically and will rest tightly against the helices once positioned. Now take and place the 4 millimeter collar over the motor housing. With one end of the housing still open, slip the PTFE textile over the helix structure, leaving a gap between the end of the helix and the end of the textile covering for the blood inlet. See Figure 8 below to see a visual of how the column structure and PTFE textile encase the helix structure and impeller.

![Figure 8: Nitinol columns and PTFE textile encasing helices](image)

On the other end of the housing, the four open ends of the helices along with the other end of the column structure are to be fastened to the device tip. The PTFE textile is once again to stop prior to reaching the end of the helix structure, to form the blood outlet. That completes the rotationally collapsible housing components, and all that is left is the catheter, torsional cable, and the handheld controller. See Figure 9 below.

![Figure 9: Device Tip, column structure, and helix connection](image)
Starting once again with the inner most component, take the electrical feeds from the motor and insert them through the length of the catheter to where it would exit the body. Then fasten the end of the catheter to the column structure. Next, locate the torsional cable and place it concentric to the catheter and connect it to the motor. Lastly, insert the purge lumen through the length of the catheter as well. See Figure 10 below for visual of catheter and torsional cable connections.

![Figure 10: Catheter, torsional cable, and purge lumen](image)

At the opposite end of the cables, the catheter should be secured to the inside of the handheld control box to hold it stationary. The torsion cable (connected to the motor housing) is to have a spin wheel attached so that the user can rotate and control the rotational motion of the helices. Finally, leading from the catheter, take the electric motor cables which were run down the cable and connect them to the circuit board of the controller for precise speed control.

### 3 Evaluation Support Documents

#### 3.1 Evaluation Reports

**Criterion 1: Undeployed Housing Diameter**

**Introduction**
The rotationally collapsible housing design is important because it needs to be percutaneous. Percutaneous is a minimally invasive surgical process where the device is inserted through the skin into an artery instead of traditional surgery. This device will be fed through the femoral artery by a surgeon using a catheter and therefore needs to be small enough to fit into the femoral artery for insertion. The average femoral artery is roughly 4mm, thus, the housing was designed to be 4 mm upon insertion. Insertion of an undeployed device diameter beyond the artery diameter could cause severe damage to the femoral artery. It is therefore essential that the device is 4 mm in its undeployed state.

**Methods**
To confirm that this undeployed diameter of the housing is 4 mm we will measure it. This could be done physically with a caliper, or visually realized through computer software. Our device is small and would be expensive to prototype, so we have decided to create a virtual prototype using SolidWorks CAD software. This model will allow us to confirm of the undeployed housing diameter of 4 mm. While modeling the device to meet this constraint is straightforward, the geometry of the Nitinol helices at the 4 mm diameter state was considered as well to determine the pitch and number of turns of the helices.

First, a mathematical model of the helices with the dimensions of the helix given in Figure 11:
Where $S$ is the arclength of the helix, $T$ is the number of rotations along the helix’s centerline, $H$ is the height of the helix, $a$ is the radius of the helix, and $b$ is the pitch length. The arclength of the helix is expressed by Equation 1:

$$S = T \sqrt{4\pi^2 a^2 + b^2} \quad \text{Equation (1)}$$

Since the number of turns is simply the height, $H$, divided by the pitch length, $b$, Equation 1 can be rewritten in terms of $H$, $b$, and $a$.

$$S = H / b \sqrt{4\pi^2 a^2 + b^2} \quad \text{Equation (2)}$$

Solving for $H$:

$$H = S b / (4\pi^2 a^2 + b^2)^{1/2} \quad \text{Equation (3)}$$

If we plot the height of the helix against the pitch length and arclength for the undeployed (4 mm) and deployed (8 mm) diameters, we find two surfaces that represent the solution spaces for the helical structure, which is shown in Figure 12.
For the 4mm geometry to be able to expand to the 8 mm diameter, a combination of axial and rotational displacements must be used to traverse from (helix height and pitch length displacements, respectively. The 4 mm diameter geometry must be chosen with this expansion in mind.

**Results**
When creating the SolidWorks model of this device the undeployed diameter was set to a diameter of 4 mm. From Figure 2 the geometry selected for the 4 mm diameter was a 100 mm height and 62.5 mm pitch length, the selection of which will be outlined in evaluating the deployed housing diameter. Throughout the entire creation of the model the maximum undeployed diameter seen was 4 mm. Additionally, this confirms our first criteria ensuring no damage will be done to the femoral artery upon insertion.

**Discussion**
While measuring the undeployed diameter of the virtual prototype housing is a reliable method to confirm the design criteria, the geometry of the helical structure needed to deploy the device to the desired 8 mm deployed diameter is heavily influenced by the results of that analysis. During the creation of the virtual prototype model, the user has complete control over the size of the part, but the helical geometry comprising the 4 mm diameter structure must be evaluated based in the deployed diameter criterion and how well the 4 mm geometry meets that goal. Also, a virtual model of the device is a simple method to confirm the undeployed diameter but it does
not consider manufacturing complications due to the small diameter and complicated geometry. Tolerances on parts of this size must be held tight, significantly increasing the cost of the part.

Criterion 2: Deployed Housing Diameter

Introduction:
The undeployed housing diameter criterion of diameter of 4 mm is to ensure proper insertion through the femoral artery and into the heart. However, once positioned across the aortic valve the blood flow through the undeployed diameter will not be sufficient enough to off load the heart after a cardiac infarction. There are two solutions. The speed of the impeller can be increased or the impeller and housing size can be increased. Increased impeller speed will cause hemolysis problems due to shear stresses imposed on the blood cells. The safest method to increase the blood flow through the housing is to increase the cross-sectional area of the housing. This will supply more blood through the housing while not causing more cell damage due to hemolysis. Therefore, the cross-sectional area of the housing will double in size to 8 mm, actuated externally by the attending surgeon.

Method:
In-vivo deployment will be performed by the surgeon rotating a torsional cable outside of the body that will cause the housing to deploy by rotating one end of the helical structure. Once the housing is fully deployed it will have a cross-sectional area of 8 mm. This criterion must be tested, and in order to accomplish this we conducted a structural simulation of the device deployment procedure. A mathematical model was developed to determine the relation between axial rotation of the helical windings and increases in diameter. From these results, a finite element analysis (FEA) simulation was performed on the helix structure defined in criterion 1 using SolidWorks Simulation, where a rotation of the calculated amount was applied to the upstream end of the housing. The inlet side end of the housing was made fixed to simulate the restraint of the column supports. At full loading, the increase in diameter of the housing was confirmed to be greater than 8 mm and the required torque was determined from the simulation as well.

In order to determine how many rotations are required to deploy the housing for input into the FEA analysis, a mathematical model was constructed. From the development of the models for criterion 1, we can equate the final and initial states by writing Equation 1 in the deployed and undeployed states. Equation 4 represents this relation where the subscripts $i$ and $f$ correspond to the 4mm and 8 mm diameter of the housing, respectively.

$$\frac{H_i}{b_i\sqrt{4\pi^2a_i^2 + b_i^2}} = \frac{H_f}{b_f\sqrt{4\pi^2a_f^2 + b_f^2}}$$

Equation (4)

From this relation and the assumption that arclength is equal between the deployed and undeployed states and housing diameter and pitch length is constant along each helices’ length, it can be determined that the number of reduction turns, $T$, (turns of the helix in the opposite direction of the helix winding) that are required to increase the diameter is given by Equation 5:
With the initial and final heights fixed at 100 mm, Equation 5 reduces to equation 6:

\[ \Delta T = \frac{H_i - b_i}{b_i} \cdot \frac{H_f}{\sqrt{4\pi^2 a_i^2/(H_i^2/H_f^2 + 4H_i^2\pi^2 a_i^2/H_f^2b_i^2-1)}} \]  
Equation (5)

With these initial and final heights, an initial pitch length of 62.5 mm, and the 4 to 8 mm diameter expansion (a is the radius), the device requires a 0.8 turn reduction (5.03 radians) to meet the required expansion ratio.

In order to model the expansion of the Nitinol windings under this loading scenario, a SolidWorks Simulation was constructed to analyze the structure for plastic deformation or buckling failure. A non-linear analysis was used with the solution being in the time domain to analyze the expansion at different time steps. A total simulation time of 1 second was used with a 0.025 second time step, which gave 41 steps in the solution. The mechanical properties used for Nitinol were an Elastic modulus of 75 GPa and a yield stress of 690 MPa. The 0.018” diameter wire housing consisted of four helices interwound and offset by 90 degrees, each with a 100 mm height and 62.5 mm pitch length. The upstream end was fixed and the downstream end was rotated 5.03 radians counter to the helix winding direction. A mesh of 40,700 nodes was used. Figure 13 shows the setup of this simulation.

![Figure 13: SolidWorks Simulation nonlinear analysis setup (bottom end is fixed, top end fixture to be rotated counter-clockwise 5.03 radians)](image)

From these results, the torque required to produce this rotation was measured and a similar simulation was run on the column structure with this reaction force applied to verify the columns.
will not fail under this loading scenario. Also, the resultant radial force measured from the torsional expansion of the helices was assumed to be a uniformly distributed and was applied as an outward force on the interior of the columns. The setup for this simulation is shown in Figure 14.

**Figure 14:** Torsional and expansion simulation of the column setup with fixed bottom end, torque applied to top end, and uniformly distributed load along inner surface

**Results:**
Applying this rotation, we see that it is feasible to apply a torque to the device and achieve a deployed diameter of 8 mm after actuation. When this rotation of one end is applied there is an increase of cross-sectional area along the entire length of the helix, with the middle portion expanding the most. Compared to the analytical model, the real device has a fixed 4 mm diameter at the ends, which restrains the ends as was done in the simulation. However, 80% of the housing length is expanded up to or greater than 8 mm in diameter. Since the inlet windows in the PTFE covering is offset 10 mm from either end, the inlet diameters are still above the required 8 mm diameter. In terms of material stress, the maximum observed was 15.9 MPa, giving a factor of safety of more than 40 with respect to the 690 MPa yield stress of Nitinol. The torque required to actuate deploy the device was 0.099 lb-in. Figure 15 shows the results of the simulation.
The radial force was determined to be roughly 1.0N; to analyze the 0.025 mm thick columns’ deflection under the torsion (0.099 lb-in) and radial loads, the radial force was assumed to be uniformly distributed along the inside of the column structure. With a surface area of 6 square centimeters, a uniform pressure of 1500 N/m² was applied to roughly equal the total outward radial force imposed by the helices. The results of the simulation are shown in Figure 16. The columns held quite rigid in torsion, deflecting less than a quarter of a rotation, while expanding under the assumed uniform pressure distribution to the required 8 mm diameter while having a maximum stress of 248 MPa, giving a factor of safety of 2.8 with respect to the yield stress of Nitinol.
Discussion:
From the prior criterion, the virtual study is a good way to achieve proof of concept before a physical prototype is made. It would be expensive and time consuming to obtain a physical prototype, making simulation a much higher priority. Using SolidWorks to complete this testing is a time efficient method to obtain the same results, and spares the expense of having to produce multiple iterations of prototypes. Compared to the analytical model, these results fare well, proving the expansion of the housing is mechanically possible with a Nitinol material, and that the affect of fixing the end diameters to 4 mm does not decrease the expansion of the housing below an 8 mm diameter along the critical middle 80% of the device length where the blood will actually flow. The fact that the Nitinol windings are lowly stressed with a FOS of roughly 40 means failure due to poor operation or accidental movements is less likely, improving the reliability of the device and reducing the risk of failure within the body. The columns, however, are more highly stressed, but still maintain a significant factor of safety when subjected to the maximum loads produced by the helical windings.

Criterion 3: Blood Flow

Introduction:
The rate of blood flow in the average adult human is approximately 5 L/min, and was the criteria that was set for the development of this product. Although this instrument is meant to be used when the heart is weakened, and not necessarily in complete failure, it was determined to be useful to be able provide this maximum for short periods of time. The end users in this scenario would be heart attack victims that may be able to physically obtain an ambulance, but the transit to the hospital would be too long. However, when achieving this blood flow rate, it is of utmost importance that the hemolysis involved is kept to a minimum. As stated in previous design requirements, the hemolysis rate needs to be kept sufficiently low so as to not harm the patient, and, perhaps more concisely, meet all requirements imposed by the National Institute of Health and the Food and Drug Administration.

Methods:
Because our prototype is not a physical model but instead a virtual one, this volumetric flow rate was modeled in ANSYS, using the geometry developed in SolidWorks. This geometry was imported into the software and because the flow rate could not be specified, the RPM of the impeller was chosen and multiple simulations were ran to determine the best rotational speed to produce the proper flow. When the simulation is complete, the shear stresses were also examined to ensure that the patient would not be injured.

Results:
After the simulations were ran in ANSYS, it was determined that the at 40,000 RPM the volumetric flow rate was about 3.3 L/min. Additionally, it was discovered that the shear stresses on the blood caused by the wall and impeller never exceeded 400 Pa. This is well below our threshold limit of 800 Pa laid out to prevent hemolysis.

Discussion:
These results are promising, as they produce flow rates that are within the realm of devices on the market, but they do fall short of our target of 5 L/min. However, the impeller has an enormous effect on the blood flow with increasing RPM, and therefore the impeller that was
used in the simulation is clearly not the most effective. This impeller was chosen arbitrarily and designed as a helical extrusion of a simple drawing. This is not the best way to design an impeller, but impeller design could be an entire project in itself and was outside the scope of this project.

Criterion 4: Manufacturability

Introduction:
While the manufacturability of the device is something to consider, the manufacturing costs, given a set volume, are a much more pertinent consideration. In reality, almost anything can be manufactured if the amount to be paid is infinite. However, for the purposes of a real, marketable product such as the rotationally collapsible housing being developed, the costs need to be sufficiently low. The manufacturing cost of the housing will only be a portion of the entire device, therefore it must remain low through the use of standard industry processes. The development of medical devices results in very large profit margins (on the order of 60-65%) to cover all research, development, manufacturing, and overhead costs associated with them.

Methods:
While the costs of many materials, processes, and labor of manufacturing can be estimated, it is beyond the scope of this project team to provide any realistic price points. Therefore, an industry expert was brought in to consult on the realistic costs that would be incurred in both the manufacturing of the housing and the cost of assembly. For confidentiality purposes, the engineer’s name will not be included in this report. Their experience with similar high risk, high complexity projects make them a reliable source that can be thought of as an accurate first approximation.

Results:
After the discussion with the senior manufacturing engineer, the design of the rotationally collapsible housing was deemed to be very promising and could certainly be constructed through use of standard industry processes. Dissecting the design part by part led to a high level cost analysis which determined the cost of the motor would account for approximately 25 percent of the total cost. Beyond the cost of the motor, the Nitinol material used to construct the helices and columns comprises the next largest cost of the design. The cost of the catheter, torsional cable, and PTFE mesh were assessed to be only a few dollars each, therefore the major remaining costs of the design are attributed to the machining and assembly of the product.

Prior to meeting with the manufacturing expert it was thought that the helical windings of the design would need to be laser welded to the motor housing in order to achieve sufficient strength to withstand the applied forces. From expert opinion the laser welding could adequately be replaced with a sterilized adhesive joint connection. By eliminating the complexity of welding small joints the cost of manufacturing is reduced significantly.

Due to strict non-disclosure limitations of the manufacturing expert the exact cost of materials and manufacturing processes were not allowed to be discussed in conversation. However, when citing our design specification of a cost below $2000 the expert indicated that the design could be manufactured for much less and that $2000 was a very conservative estimate.
Discussion:
The results of the manufacturing analysis offered validation that our design is feasible and marketable from a manufacturing and cost aspect. As stated previously, exact details regarding cost or manufacturing procedures could not be included in our results as they would infringe upon company non-disclosure agreements. The main result of the analysis was determining that an adhesive bond between the Nitinol helices and the motor housing is strong enough to transmit the applied forces and reduces the overall cost of the design to be well within the specified limit.

Criterion 5: Flexibility

Introduction
With the increasing cost of surgery time and doctor’s salaries, surgical procedures are rapidly becoming percutaneous and minimally invasive. Devices that must be inserted percutaneously must be able to navigate safely through the body to reach the surgical site, and in the case of a femoral artery insertion the device must be able to navigate through the femoral artery and around the aortic arch. Of primary concern when dealing with devices such as these is navigating curvature of the aortic arch. The smallest curvature of the aorta has a radius on average of approximately 4 cm, which the device must be able to conform to without mechanical failure or resultant stresses in the aorta wall to cause vessel damage.

Method
For the same practical reasons as described above, a virtual prototype was used in a finite element analysis simulation to determine the average distributed force necessary to bend the device to the required 4 cm radius of curvature and to determine the stress in the Nitinol windings at this bend radius. The SolidWorks model outlined in criterion 3 was used in this bending simulation. One end of the helices was restrained while on the other a torque was applied; this torque was increase in magnitude until the device conformed to a 4 cm radius of curvature. A graphic of this setup is shown in Figure 17.

Figure 17: Bending simulation setup with fixed end on right end and applied torque on left end
Once the required torque was determined, its magnitude was used to calculate the average pressure on the blood vessel walls assuming a uniform pressure distribution against one side of the housing, and this value was then compared to literature values for the tensile strength of artery walls.

**Results**

After the simulation was completed, the stress results were most useful in the form of factors of safety. The maximum stress in the helices was 25.7 MPa, which gives a factor of safety of 27 with respect to yield stress, which is much greater than is generally needed, as even aircraft components only have a factor of safety about two [19]. This result confirmed that the helices would not plastically deform upon this curvature. Additionally, the torque that was required to impose this bend on the helices was only 0.25 lb-in. From this, the equivalent distributed load that was required was found to be 0.127 lb in magnitude. Using this and the following equation, the average pressure on a vessel wall required to create this radius of curvature was calculated.

\[
P = \frac{F}{Ap} = \frac{0.127 \text{lb}}{(100 \text{mm} \times 4 \text{mm})} = 25.4 \text{mm in} = 0.205 \text{lb in}^2.
\]

Converting this pressure to kPa correlates to 1.41 kPa, which is orders of magnitude below the tensile strength of an ordinary artery, found to be between 1,099.0 kPa and 2,505.0 kPa [20]. Figure 18 shows the deformed structure, bent to the minimum 4 cm radius of curvature.

**Figure 18:** SolidWorks Simulation Deformed housing at required minimum radius of curvature
Discussion
Although it is positive that the factor of safety provides assurance that the product will be sufficiently strong so as to not plastically deform, this high safety factor could be thought of as too high from a materials and manufacturing standpoint. As stated previously, many human lives depend on critical components every day that have safety factors a fraction of this design. However, high safety factor is largely due to the material properties that many companies have achieved in their metals. The wire diameter that was used for the helices is sufficiently small so as to not present an excessive burden on the manufacturing process cost, so the factor of safety was determined to be acceptable. Also, due to the length of the Nitinol wire, buckling may be a problem under compressive loads such as accidental contact against the left ventricle wall. While these types of loads would be unusual and largely due to operator error, it is prudent to design a critical life support device to withstand these untested loading scenarios, which would support maintaining a healthy factor of safety.

3.2 Cost Analysis
The manufacturing costs of the rotationally collapsible heart pump housing, although not a marketable product in itself would be coupled with the costs of the rest of the LVAD device upon completion. One of the key design requirements for the housing was to ensure a manufacturing cost of below $2000. In a market in which competitive medical devices can be sold within a range of $20,000 - $25,000 this will leave a large profit margin around 65%. Refer to section 3.3 in Volume 1 for a complete analysis.

Due to the specialized nature of manufacturing techniques and processes inherent to this type of the device, exact costs for labor and manufacturing are difficult to estimate. After discussing with industry experts, specific costs would be difficult to obtain due to nondisclosure problems.

The benefits of this housing design would increase hospital and physician confidence in such devices. This would increase the demand for percutaneously delivered LVADs, which are currently deemed insufficient and prohibitive for frequent use. A discussion with University of Minnesota cardiologist, Peter Eckman, indicated that the University of Minnesota hospital uses approximately 6-12 similar LVAD devices per year. If this device is deemed a viable solution, the demand for the device could increase dramatically. With increased doctor confidence, more applicable patients, and the single use nature of this device could lead to incredible sales potential.

3.3 Environmental Impact Statement
Purpose and Need
The need for this product is illustrated by the increasing number decompensated heart failures in the U.S. and abroad every year. Additionally, there is an increasing trend in the healthcare field to minimize invasive surgeries. These two facts merge to underscore the need for a percutaneously deliverable heart pump that would be able to assist in blood flow immediately following a heart attack. Therefore, this device is a contribution to the overall good of public health.
Impact to the Environment

During production, this device would not produce any more unwanted waste than any other manufactured product. Therefore, while not entirely good for the environment, it is no worse than any other product. While this is not a concrete metric, the environmental impact of such devices is relative to each other.

During operation, this device has almost insignificant impact on the environment, and the only impact it may have is the power consumed by the motor.

During the devices end-life, there are a few things to consider. This device will not be reusable, therefore instantly making it detrimental. Additionally, this device will be bio contaminated, forcing the use of harsh cleansers before it can be handled again.

Alternatives to Design

Any alternative for this design that would be more environmentally friendly would include more degradable materials or a more efficient motor. However, altering the materials selection to be more eco-friendly would not be an applicable method, as the metal windings are what makes the design work. Additionally, the motor, since it is custom made, would be difficult to improve upon unless another manufacturer could provide them.

Discussion

The primary things that could be done to improve the environmentally friendly aspects of the design are the selection of a manufacturer and the selection of an efficient motor. The cost of utilizing a more efficient motor would likely not offset the cost of paying for one, and therefore should not be pursued. When selecting a manufacturer, one should be selected that utilizes environmentally sound recycling practices and complies with all government regulations. This design, as a medical device, is inherently not reusable, and therefore could be thought of as a detriment to the environment. However, since this device is an asset to the public health, these effects are offset.

3.4 Regulatory and Safety Information

Since the design being discussed is a medical device, there are some obvious regulatory issues that must be faced. These requirements will significantly slow the time to market for this product, and this needs to be expedited as much as possible so as to be an advantageous choice when it reaches the market. Of particular interest will be regulations that are imposed by the federal government through the Food and Drug Administration. These regulations are far reaching, and control everything from manufacturing and packaging to record of use and classification of the device.

Since the product being developed is only a portion of the final product, the regulation for our project will be significantly different than the entire product. However, the primary regulations applying to the housing itself are the establishment registration – 21 CFR Part 807, which dictates that all manufacturers, both domestic and foreign, must register their establishments with the FDA. Additionally, these establishments must be verified and approved annually to retain
their status as a trusted manufacturer. These manufacturers also have to list their products and pay a fee annually to the FDA to be on the list of certified and approved establishments. [21]

In contrast to the individual housing aspect, the end product as a whole has an entirely separate set of regulations that it must conform to. Primarily, it has to adhere to the FDAs strict approval process, which involves classification, clinical trials, analyzing all test data, and approval of the data through the Investigational Device Exemption (IDE) process. This device would likely be classified as a Class III device, due to its life supporting nature. However, an exception to the FDAs rule would likely apply to our device; the Premarket Approval 510(k). This stipulation states that if it can be proved that the device being approved is similar in operation to a device already on the market and is approved, the entire process can be expedited. This would be a useful lever to pull to accelerate the approval of the device, as the final device operates very similarly to the Abiomed Impella devices, with an additional actuation method included. [21]

Whenever there is someone’s life and well-being in consideration, the safety concerns are obviously an utmost concern. There are a multitude of things that could go wrong, even with only the housing being designed in this project. For instance, if the product was handled improperly prior to insertion, the helices or columns could be deformed. This would cause unreliable performance and possibly failure of the parts. To prevent this, it is recommended that the device be packaged such that a sturdy material until just before insertion will protect the helices and columns. Another safety concern could be the infection rate when having a catheter in the leg for an extended period of time. However, this risk of infection is greatly outweighed by the benefits of relieving the heart after a heart attack. Therefore, this risk will have to be accepted.
Appendices

Appendix A - Flexing Spring Constant Calculations

\[ F_{net} = P \times A_p = (120 \text{ mm Hg}) \times (400 \text{ mm}^2) \times \left( \frac{25.4 \text{ mm}}{1 \text{ in}} \right)^2 \times \left( \frac{16 \text{ lb}}{50.8 \text{ mm}^2 \text{ in}} \right) \]

\[ = 1,476 \text{ lb} \]

\[ \theta_{overall} = \frac{P \times L}{2} = 1,476 \times \frac{1}{2} = 738 \text{ degrees} \]

\[ \theta_{total} = \frac{L}{R} = \frac{10 \text{ cm}}{4 \text{ cm}} = 2.5 \text{ radians} = 143.23 \text{ degrees} \]

Bending Stiffness Ratio

\[ = \frac{\theta_{overall}}{\theta_{total}} = \frac{738 \text{ degrees}}{143.23 \text{ degrees}} = 0.0202 \text{ lb-deg} \]
Appendix B - Wall Shear Stress Calculations using Moody Diagram

\[ f = \frac{8 \tau_w}{d \rho V^2} \quad \text{(Darcy friction factor)} \]

Friction Factor

- Calculate loss from Moody Diagram

Moody Diagram

Relative Pipe Roughness \( \left( \frac{e}{d} \right) \)

\( e \)

10

Laminar Flow

Turbulent

\( \rho_{\text{blood}} = 1025 \text{ kg/m}^3 \)

\( \mu_{\text{blood}} = 0.35 \times 10^{-3} \text{ Pa s} \)

\( Q \) (flow rate) = \( \frac{\pi}{4} \) \( V \cdot A \rightarrow V = \frac{Q}{A} \)

\( V = \frac{\pi}{4} \frac{8 \times 5 \times 10^{-5}}{\mu_{\text{blood}} (\pi/4)^2} \)

\[ Re = \frac{(1025 \times 4/3) (1.65 \times 10^{-5}) (1.0028 \text{ m/s})}{(3.5 \times 10^{-3} \text{ Pa/s})} \]

\[ Re = 3865.71/4 \]

\[ V = 1.65 \text{ m/s} \]
Relative Pipe Roughness

Design to use PET (euro) or PTFE (eiflow)

Some medical textiles for reference:

<table>
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<tr>
<th>Material</th>
<th>Coefficient of Friction</th>
<th>Surface Roughness (μm)</th>
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<td>0.020</td>
<td>9.016</td>
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<tr>
<td>Sheeplin</td>
<td>0.028</td>
<td>6.294</td>
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<tr>
<td>Welf Lint</td>
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<td>6.393</td>
</tr>
<tr>
<td>Fabric face</td>
<td>0.517</td>
<td>6.592</td>
</tr>
<tr>
<td>Fabric reverse</td>
<td>0.357</td>
<td>6.138</td>
</tr>
</tbody>
</table>

If we take a conservative estimate and assume our material will have $\varepsilon = 4.11 \mu m$,

$$\text{relative roughness} = \frac{\varepsilon}{d} = \frac{0.001 \times 10^{-3} \text{ m}}{0.008 \text{ m}} = 0.0011975$$

Use this on Moody diagram

At $Re = 4000$ and $\frac{\varepsilon}{d} = 0.0011$ → Friction Factor $= 0.0425$

Fanning Friction factor

$$f = \frac{2\tau_{wall}}{\rho V^2}$$

shear stress at wall

friction factor

$$f = \frac{2\tau_{wall}}{\rho V^2}$$

velocity

$$\frac{f \cdot \rho \cdot V^2}{2} = \left(0.0425 \times 10^{22}\right)(1.65)^2 = 59.29 \text{ Pa}$$
At 8mm diameter $\rightarrow$ $T_w = 59.29 \text{ Pa}$

If calculated at 4mm diameter

\[ V = 6.65 \text{ m/s} \]
\[ Re = 7767 \]
\[ f = 0.035 \] $\rightarrow$ $T_{wall} = 788.47 \text{ Pa}$

(high enough to cause hemolysis)

($T_{wall} > 600 \text{ Pa}$)
Appendix C - Meeting Notes with Manufacturing Expert

Glue or laser weld
- Sterilize adhesive at 122°F

Motor cost (25% ~)

Nitinol Helices:
- Laser cut from hollow Nitinol tube. 90° offset is no problem and can easily be done.

Nitinol Column Structure:
- Similar to helix for manufacture. “Nitinol is an amazing material, but its not as cheap as others.”

Attaching helices to motor housing:
- Welding is uncommon, difficult, and expensive. More commonly used is a super strong adhesive.

Me: Will adhesive be strong enough to transmit torque to increase diameter?

YES

Cable/Torsional cable/etc:
- Super cheap, only $5-10 a piece. Not much of a factor.
More about adhesive:

Extra cost because of sterilized process, but actually temperatures will already be reached.

Best way to join Nitinol & stainless and Nitinol and polymer tip.

Total cost:

Can’t give any specifics.

Me: Would it be under $2000 to produce it in large quantity?

Yes, absolutely. That is a very conservative estimate.

Processes and materials would account for roughly 75% of cost, and custom motor would account for the other 25%. But well below $2000 total.
Appendix D – Meeting Notes with Dr. Peter Eckman

Peter Eckman Meeting with the Axial Flow Team 3/12/13

Background:

- Heartmate II came out in 2006, it was transformative. He’s consulted to them the whole time.

- Survival times on permanent LVAD’s went from 12 months to up to 8 years for a couple of his patients.

- LVAD’s still disrupt the blood path, anticoagulation is an issue, clotting can occur, aspirin and Coumadin need to be taken.

- 2% clotting risk, 5% stroke risk, 20% bleeding risk

- Von Willebrandt’s Factor is a large blood protein and an important factor in clotting. Data has shown that high shear stresses will cause the molecule to change conformation and cleave.

- Heme (sp?) is also a significant factor, when released from cells it can soak up free radicals and otherwise change blood chemistry.

Key issue is the indication for acute support, possible indications are AMI’s (Heart attacks), certain EP procedures, high risk stenting/PCI

Acute cardiac support tends to be left ventricle focused.

They don’t use Impella much, haven’t found a great need. 2.5l/min is not enough, if 5l/min is needed then other types of pumps – Centermag – are better.
Impella migrates which is an issue

Another issue is DRG based reimbursement – they only get one payment for an LVAD hospital stay – so that if the patient is likely to need a permanent implant, they will pass on the temporary device and go straight to this.

Believes the Thoratec device is 9-10 Fr – will check on this.

Challenge: Who to put this in to? Need to find the right niche – needs vary by niche. Retrograde approach can get in the way of EP procedures.

PHP – smaller entry profile, more output, incremental.

Right ventricle support – rare but no products for this, can be tough to do this surgically through the venous system.

4l flow – may be enough

Different applications – procedural support – only need pump for a couple hours, hospital transfer- only need for a couple hours.

Longer term, stabilization of cardiac function – need the device for longer periods.

CardioHelp is something they use a fair bit, provides biventricular support, not just LV. Its percutaneous.

A significant issue for CardioHelp is that you need a perfusionist there 24/7. Fairview had 2000 CardioHelp perfusionist hours recently but that has gone to 6000 last year – very expensive.
Knowing that the flow is laminar would be good for controlling hemolysis, some devices offer “flow estimators” based on power consumption – don’t need to know actual flow.

Coagulopathies frequently occur at the transition between laminar and turbulent flow.

Asked about the PHP device, said that he’s not sure how you get the sheath back on. Also, mentioned that human use would not occur until next year.

With Abiomed, you need a D5 glucose drip infusion, can be annoying for diabetics but generally is not a big issue.

A device that could lock in place would be interesting.

Bob Wilson and Ganesh Raneendraw are the ones to talk with about percutaneous valves.

Thinks that tricuspid valve and valve replacement in the presence of an LVAD would be interesting applications.
Appendix E - ANSYS Solution Data

Velocity streamlines as well as the numerical values from the simulation.
Wall shear analysis done in ANSYS. We can see from the scale on the left that the maximum shear experienced throughout the simulation occurred around the impeller.
Shown here is the function calculator used to calculate the mass flow rate of blood through the housing.

<table>
<thead>
<tr>
<th>rpm K</th>
<th>kg/s</th>
<th>lpm</th>
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<tr>
<td>30</td>
<td>0.056589</td>
<td>3.395346</td>
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<tr>
<td>40</td>
<td>0.054368</td>
<td>3.262098</td>
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<td>60</td>
<td>0.031979</td>
<td>1.918728</td>
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</table>

Shown here is a table of RPM values and the corresponding mass flow rates and volumetric flow rates.
## Appendix F - Design Selection Matrix

<table>
<thead>
<tr>
<th>Total Scores</th>
<th>Major Design Criteria</th>
<th>Minor Design Criteria</th>
<th>Dimensional Accuracy</th>
<th>Material Properties</th>
<th>Assembly</th>
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**Design Selection Matrix**

**Parameters:**
- Fluid Shaft w/ Push Pull Cable
- No Center Rod, Only Holes
- Concentric, Un-threaded Rod Design
- Threaded Center Rod w/ Threaded Collar

**Criteria:**
- Major Design Criteria
  - Dimensional Accuracy
  - Manufacturing
- Minor Design Criteria
  - Material Properties
- Assembly
- Testability
- Availability

**Scores:**
- 1 to 5 scale
Appendix G - Patents Used

**United States Patent**

**Klumb et al.**

**Patent No.:** US 6,921,414 B2  
**Date of Patent:** Jul. 26, 2005

**Inventors:** Katherine J. Klumb, Los Altos, CA (US); Thomas J. Fogarty, Portola Valley, CA (US); Kirti P. Kamdar, Sunnyvale, CA (US); Bradley B. Hill, Portola Valley, CA (US)

**Assignee:** Vascular Architects, Inc., San Jose, CA (US)

**Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 51 days.

**Appl. No.:** 10/308,574  
**Filed:** Dec. 3, 2002

**Prior Publication Data**


**Related U.S. Application Data**

Continuation of application No. 09/608,281, filed on Jun. 30, 2000, now Pat. No. 6,572,648.

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<td>A61F/2/06</td>
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<td>11/1997</td>
<td>A61B/17/122</td>
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Instruction Manual for Wallstent® Transhepatic Filiary Endoprosthesis with the Unistep™ Delivery System, Pfizer Hospital Products Group, 4 pages.


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**Primary Examiner**—David H. Wilse  
**Assistant Examiner**—Javier G. Blanco

(74) Attorney, Agent, or Firm—James K. Hant; Haynes Beffel & Wolford LLP

**ABSTRACT**

An endoluminal prosthesis includes a coiled body and a graft material covering at least part of the coiled body to create a coiled stent graft. The average stent graft diameter to turns width ratio may be about 0.8 to 1 to about 2.4 to 1 when expanded.

4 Claims, 12 Drawing Sheets

---

![Diagram of Rotationally Collapsible Heart Pump Housing](image-url)
United States Patent

Siess

[54] INTRACARDIAC PUMP DEVICE

[75] Inventor: Thorsten Siess, Wuerzene, Germany

[73] Assignee: Impella Cardiotechnik AG, Aachen, Germany

[21] Appl. No.: 09/194,725

[22] PCT Filed: Mar. 31, 1998

[86] PCT No.: PCT/EP98/01868

§ 371 Date: Dec. 2, 1998

§ 102(g) Date: Dec. 2, 1998

[87] PCT Pub. No.: WO98/43689

PCT Pub. Date: Oct. 8, 1998

Related U.S. Application Data


[51] Int. Cl. A61M 1/12

[52] U.S. Cl. 600/16, 623/3, 415/900

[58] Field of Search 600/16, 623/3, 415/900, 229, 230

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Primary Examiner—Jeffrey R. Jasztazb
Attorney, Agent, or Firm—Fulwider Patton Lee & Utech, LLP

ABSTRACT

The pump device comprises a first pump (10a) that may have its intake side inserted into the left ventricle (42) of the heart, while the delivery side is located in the aorta (40), and a second pump (10b) having its intake side arranged in the right atrium (43), whereas its delivery side is in the pulmonary artery (47). A common control unit drives both pumps in a mutual dependence, the first pump (10a) having taking the lead function, whereas the second pump (10b) pumps only about 90% of the volume flow of the first pump (10a). Pressure sensors at the pumps serve to determine the differential pressure between the intake side and the delivery side of a pump and to determine the volume flow. Both pumps are inserted into the heart without having to open the ventricles.

13 Claims, 5 Drawing Sheets

Primary Examiner — Ninh H Nguyen

Attorney, Agent, or Firm — Knobbe, Martens, Olson & Bear LLP

ABSTRACT

An impeller includes a hub, and a plurality of blades supported by the hub, the blades being arranged in at least two blade rows. The impeller has a deployed configuration in which the blades extend away from the hub, and a stored configuration in which at least one of the blades is radially compressed, for example by folding the blade towards the hub. The impeller may also have an operational configuration in which at least some of the blades are deformed from the deployed configuration upon rotation of the impeller when in the deployed configuration. The outer edge of one or more blades may have a winglet, and the base of the blades may have an associated indentation to facilitate folding of the blades.

14 Claims, 10 Drawing Sheets
ABSTRACT

A coiled stent (196) has a coiled stent body with a main body portion (106) and end portions (108). The end portions may be substantially less stiff than the body portion to help prevent tissue trauma. A graft material (124) may be used to cover at least the main body portion to create a coiled stent graft (122) in which adjacent turns (126) have gaps defined therebetween to create a generally helical gap (130). The coiled stent may have side elements (10) separated by connector elements (112) and be placeable in a contracted, reduced diameter state and in a relaxed, expanded diameter state. The connector elements are preferably generally parallel to the stent axis when placed in the contracted, reduced diameter state, typically tightly wrapped around a placement catheter (136).

11 Claims, 16 Drawing Sheets
Appendix H – Helix Geometric and Static

Analysis

Formulation of Geometric Model of Helix
From this graph, it is clear that for a fixed helix arc length, pitch must change to increase or decrease the helix length. In order to compress a 4 mm diameter helix to an 8 mm diameter, a rotation must be added to decrease the pitch length following the compression.

For example:

\[ H_1 = \text{uncompressed length} \ [\text{4 mm Diam.}] \ (a_1, b_1, H_1, T_1) \]
\[ H_2 = \text{compressed length} \ [\text{8 mm Diam.}] \ (a_2, b_2, H_2, T_2) \]

\[ b_1, b_2 \leq \frac{5}{4} \Rightarrow \frac{H_1}{H_2} = \frac{\sqrt{4H_1^2a_1^2 + b_1^2}}{\sqrt{4H_2^2a_2^2 + b_2^2}} \]

For a given \( \frac{H_1}{H_2} \) ratio and the given constraints on \( a_1 \) & \( a_2 \), we can determine the necessary pitch, \( b \), for a given \( b_1 \).

\[ \frac{H_1}{H_2} b_2 = \frac{\sqrt{4H_1^2a_1^2 + b_1^2}}{\sqrt{4H_2^2a_2^2 + b_2^2}} \]

\[ \frac{H_1^2a_1^2}{H_2^2a_2^2} \leq \frac{b_1}{b_2} \Rightarrow \frac{c_1}{c_2} = \frac{\sqrt{c_1}}{c_2} = \frac{c_3 + \frac{b_2}{b_2}}{c_2} \]

\[ b_2 = \left[ \frac{c_1 c_2}{c_2 b_2} - c_3 \right]^{1/2} \]

\[ b_1 = \left[ \frac{c_1 c_2}{c_2 b_2} - c_3 \right]^{1/2} = \left[ \frac{H_1^2 b_2^2 \left( 4H_1^2a_2^2 + b_2^2 \right)}{H_2^2 b_2^2} - 4H_1^2a_2^2 \right]^{1/2} \]

\[ b_2^2 \left( 1 - \frac{H_1^2a_2^2}{H_2^2a_2^2} \right) \left( \frac{H_1^2}{H_2^2} \right)^2 \left( \frac{b_2^2}{b_2^2} \right) \]

\[ b_2 \left( 1 - \frac{H_1^2a_2^2}{H_2^2a_2^2} \right) \left( \frac{H_1^2}{H_2^2} \right)^2 \left( \frac{b_2^2}{b_2^2} \right) = \left( \frac{H_1^2}{H_2^2} \right)^2 \left( \frac{b_2^2}{b_2^2} \right) \]
If we assume $T - T_1 = T_0$, the actual pitch can be calculated:

$$T = \frac{H_i}{b_i} = \frac{H_e}{b_e} \Rightarrow b_e = \frac{H_e}{H_i} b_i \quad (2)$$

But according to (1), we need a longer pitch than (2), which is accomplished by reducing the number of turns:

$$T_{free} = \frac{H_e}{b_{free}} = \frac{H_e}{b_{free}}$$

From which we can determine the number of turns decreased to achieve the diameter increase:

$$\Delta T = T - T_{free} = \frac{H_i}{b_i} - \frac{H_e}{b_{free}}$$

$$= \frac{H_i}{b_i} - \frac{H_e}{b_{free}} \left[ 4 \pi^2 a_0^2 / \left( \frac{H_i^2}{H_e^2} + \frac{H_i^2}{H_e^2} \right) - 1 \right]^{1/2}$$

which is the number of turns required to decrease the total turns (and increase the pitch) so the required diameter is attained.

The ratio of axial displacement to required number of turns (decreasing turns) is given below:

$$\frac{\Delta H}{\Delta T} = \frac{H_i - H_e}{\frac{\Delta T}{\Delta T}} = \left[ 4 \pi^2 a_0^2 / \left( \frac{H_i^2}{H_e^2} + \frac{H_i^2}{H_e^2} \right) - 1 \right]^{1/2}$$

which is the effective pitch of the deployment mechanism for the housing.
Height versus Pitch for 4mm Diameter and 8mm Diameter (Arclength = 102 mm)

Height as a Function of Pitch and Arclength for Helical Geometry at 4 mm (solution space)
When it is plotted against pitch length and helix length (for both the 4mm & 5mm diameters), the following two surfaces result:

These two surfaces represent the two solution spaces for the helix; a combination of axial and rotational displacements will be necessary to move between one surface and the other (4mm and 5mm diameters) while all translations between planes are all valid geometric solutions, the selected material may not withstand the stresses applied.
In order to verify the possibility of the selected material (Nitinol) withstanding the deformations necessary to achieve the desired 2:1 diameter increase, FEA analysis was performed on a simplified model:

Structure:
106 mm Arch length Helix w/ Interwound offset at 90°, connecting ring at either end w/ 41 mm diameter, 0.015” o.d. Nitinol

Material: Nitinol: $1.05 \times 10^{10}$ Pa Elastic Modulus (E)
$\sigma_y = 690$ MPa

Mesh: 276,000 Elements
Boundary Conditions: One end fixed, arbitrary torque applied at midpoint.

Feasibility Studies in Mechanical Properties of Helical Structure subjected to Torsion
Calculation of Average Vessel Stress to Produce Minimum Bend Radius

\[ \sigma = \frac{F}{A} \]

\[ F = 0.125 \text{ lbf} \]

\[ P = \frac{F}{A} = \frac{0.125 \text{ lbf}}{(100 \text{ mm} \times 4 \text{ mm}) / (25.4 \text{ mm/in})^2} = 0.205 \text{ lbf/in}^2 
\]

\[ P = 1400 \text{ Pa} = 10 \text{ mPa} \]

This pressure is roughly 10 orders of magnitude less than systolic arterial pressure (\( \approx 120 \text{ mm Hg} \)), meaning the device can pass through without damage to vessel walls.
Calculation of Average Vessel Stress to Produce Minimum Bend Radius (cont.)

\[ P = 120 \text{ mm Hg} \]

(a) Average (Systolic blood pressure)

\[ r = 4 \text{ cm, minimum radius of curvature} \]

\[ A_p = 4 \text{ mm}^2, 100 \text{ mm} = 400 \text{ mm}^2 \]

\[ f_{tot} = P A_p = \frac{400 \text{ mm}^2 \cdot 120 \text{ mm Hg}}{2 \pi \text{ cm}} = 1.2456 \text{ lb ft} \]

\[ \text{Coverall} = f_{tot} = 1.2456 \text{ lb ft} \]

\[ \text{Bend stiffn} = \frac{L}{\text{Radins}} = \frac{10 \text{ cm}}{4 \text{ cm}} = 2.5 \text{ radians} = 143.25^\circ \]

Maximum allowable bending stiffness required

\[ \frac{\text{Coverall}}{\theta_{tot}} = \frac{1.2456 \text{ lb ft}}{143.25^\circ} \]

From bending analysis: \( 0.25 \text{ lb ft in} @ 70^\circ \text{ bend} \)

\[ 4 \text{ cm radius} \]

\[ \text{Bending stiffness from SW model} = \frac{0.25 \text{ lb ft in}}{70^\circ} = 0.0036 \text{ lb ft in} \]

The device is flexible enough to prevent the pressure distribution from exceeding safe limits by 6 orders of magnitude.
SolidWorks Simulation Bending Deformation and Required Radius of Curvature

SolidWorks Simulation Bending Deformation and Required Radius of Curvature Time Steps
SolidWorks Simulation Torsional Deformation and Required Diameter Expansion

SolidWorks Simulation Torsional Deformation and Required diameter Expansion Time Step
SolidWorks Simulation Combined Torsional and Expansion Columns Deformed Result