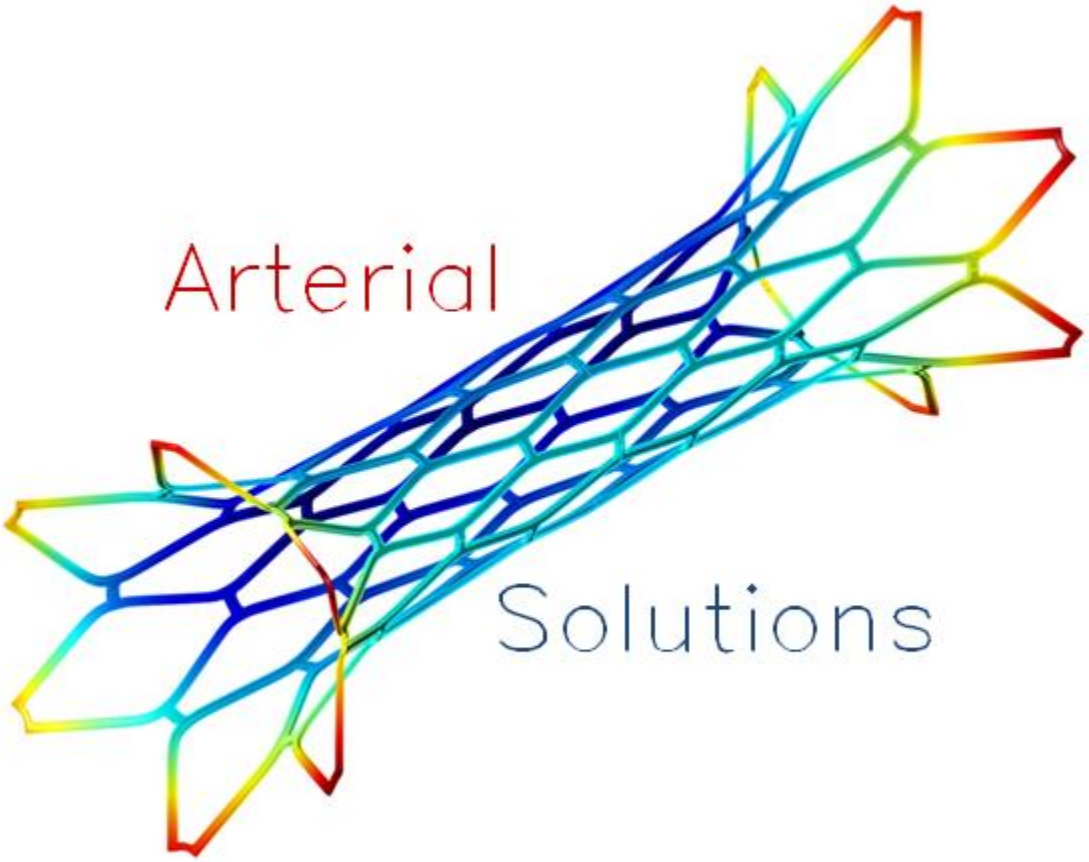
Final Report:

Quantifying Proximal Conformability Of a Thoracic Aortic Stent Graft



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Executive Summary: This report is documentation of a Senior Project completed by Dylan Reinsdorf and Kendall Smith, in partial fulfillment of a Bachelor of Science in Mechanical Engineering at Cal Poly, San Luis Obispo. Medtronic Inc. approached the team with a need to quantify proximal conformity of stent grafts in the thoracic aorta. A solution was designed that included an aorta model that simulates clinical conditions, and a measurement method for stent graft conformability. This report documents all phases of the project, from sponsor requirements to final design to product realization and testing.

Chapter 1: Introduction

1.1 Sponsor Need/Problem Statement

In the area of Endovascular Aortic Repair (EVAR), the process of using stent grafts to fix damaged arteries without open surgery, surgeons are treating more complex anatomies and pushing stent grafts to their functional limits. For stent grafts used in the aortic arch, poor wall apposition at the proximal end has been especially problematic. The complications can result in discomfort, additional medical procedures, or even death. To address this issue, our team will create a model of the thoracic aorta that our customer, Medtronic Cardiovascular in Santa Rosa, CA, can use to test the proximal conformability of their stent grafts. Our team is comprised of two senior mechanical engineering students, Dylan Reinsdorf and Kendall Smith, at California Polytechnic State University in San Luis Obispo, CA. The team is advised by Professor Sarah Harding, of the Cal Poly Mechanical Engineering department. The stakeholders in this project are Medtronic, cardiothoracic surgeons, and future patients treated with EVAR. This report will document our ideation process, final design, manufacturing, and testing plan.

1.2 Objectives and Specifications

Our goal for this project is two part: (1) to model the thoracic aorta, simulating relevant clinical conditions, and (2) to design a test method that quantifies proximal stent graft conformability in that model.

Through our weekly meetings with Lauren Rush, Endovascular R&D engineer at Medtronic, we gained a better understanding of the project requirements. We utilized Quality Function Deployment (QFD), located in Appendix A, to develop engineering specifications from the project requirements.

QFD is a tool that allows us to quantify and prioritize specifications while gaining a better understanding of the problem. It identifies the customer and lists their requirements. We then quantify those requirements and list them as engineering targets. Each requirement is weighted in its importance and correlations are formed between the customer requirements and engineering targets. If a target does not have a high correlation with at least one of the customer requirements, it is usually discarded as a specification. The following is our list of engineering specifications:

- Model must accurately replicate thoracic flow environment:
    - Fluid temperature of 37 °C
    - Fluid pressure of 160 mmHg (systole) 80 mmHg (diastole)
    - Flow rate of 2.7 liters per minute

- Arch radius of curvature
- Replicate material wall properties
    - Smooth surface finish
    - 10% diametral dilation
- Must function properly after four foot vertical drop
- Must fit in a 2 ft by 3 ft area
- Must weigh less than 25 lbs
- Stent can be added or removed in less than 10 minutes
- Test method must measure radial distance between stent and model
- Must accommodate stents up to 250 mm in length
- Model must be compatible with current Medtronic lab setup

As illustrated in our QFD in Appendix A, the specifications most critical to project success involve: indication of stent conformability to the arterial wall, replication of the arterial flow environment, and thoracic aortic geometry. The compliance matrix found below in Table 1 indicates the difficulty, or risk, that each specification poses and the respective test method we will use to prove compliance.

Table 1. Compliance Matrix of Formal Specifications

Spec #	Parameter Description	Requirement or Target	Tolerance	Risk	Compliance
1	Fluid temperature	37˚C	±3˚C	M	T
2	Fluid pressure	160(max)/80(min) mmHg	±5 mmHg	H	T
3	Flow rate	2.7 Lpm	±1 Lpm	M	T
4	Arch radius of curvature	'Tight'		M	I
5	Material elasticity	Allows 10% diametral dilation		H	A, I
6	Material surface finish	Smooth	-	M	I
7	Withstands vertical drop	4ft	Max	L	T
8	Fixture footprint size	2x3ft	Max	L	A, T
9	Weight	25lbs	Max	L	A, T
10	Stent addition/removal time	10mins	Max	M	T
11	Descending aorta length	250mm	Min	M	A, T

In the compliance matrix above, each specification is given a risk based off our assessment of its difficulty. H, M, and L stand for high, medium, and low respectively. The compliance column indicates how we will prove the specification was met. A is for analysis, I for inspection, S for similarity, and T for testing.

Specifications 1, 2, and 3 are a result of the requirement that the model replicates the thoracic aorta flow environment. In order to mitigate the high risk of these specifications, we will use sound engineering analysis to guarantee the components we use will fulfill these specifications.

The process of determining model geometry, which corresponds to specification 4, is ongoing. Every aorta has a unique geometry, thus determining the geometry for our model is a major part of the design process. The high risk of meeting this specification will be diminished through extensive research of actual patient aorta geometry. The goal is to design the model such that its geometry is challenging for the stent grafts, but is still representative of actual aortas.

Chapter 2: Background

2.1 Stent graft applications

The aorta, the largest artery in the human body, can be divided into three parts: the ascending aorta, aortic arch, and descending aorta. The ascending aorta stretches from the left ventricle of the heart to the aortic arch. The descending aorta, which is partitioned into the thoracic (upper) and abdominal (lower) aortas, extends from the aortic arch to the common iliac arteries. A visual of this anatomy can be found in Figure 1. For our project, we will be focusing on the thoracic aorta and aortic arch.

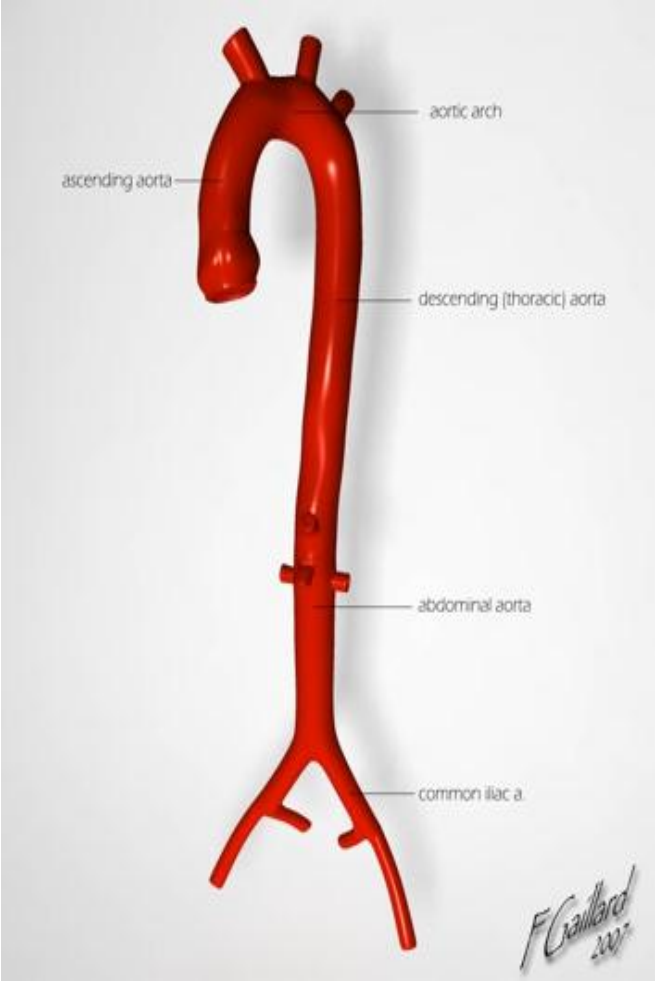


Figure 1. Sections of Aorta

Most EVAR operations are performed on trauma patients or individuals suffering an aortic aneurysm. An aortic aneurysm is an expansion of the arterial wall, due to the weakening of wall tissue. While the aneurysm itself may only cause the individual minor discomfort, the main concern is the risk of

rupture. In this case, the individual experiences severe pain and internal bleeding. For this reason, doctors recommend immediate treatment of the aneurysm.

One of the two main treatment options is open surgery to repair the aneurysm. A synthetic tube is inserted into the artery and the aneurysm sac is sewn around it. This allows blood to flow through the tube and bypass the aneurysm. However, open surgery is undesirable because the vast majority of individuals with aortic aneurysms are elderly. The alternative to open surgery is EVAR, a minimally invasive procedure through which doctors restore normal blood flow by deployment of stent graft. In this procedure, a catheter is inserted into the femoral artery and is used to transport a stent graft to the aneurysm site.

Cardiothoracic surgeons are using stent grafts to treat increasingly complex anatomies, such as aortic arches of tight curvature and aneurysms extending high into the thoracic aorta. Doing so has led to problems with poor wall apposition at the proximal (upper) end of the stent graft, where it contacts the aortic arch. Poor wall apposition can have detrimental effects, such as endoleaks or stent graft collapse. In an endoleak, blood bypasses the stent graft and continues into the aneurysm sac. This is considered a clinical failure and the risk of rupture remains. Stent graft collapse can block blood flow, and requires endovascular or open surgery to repair. Both of these conditions can be fatal without prompt treatment.

2.2 Existing Products

While conducting market research of similar products, we were unable to find any that encompassed the entire scope of this project. However, we did find a few options for a Thoracic Aorta model. The Aortic Arch Vascular Model, manufactured by DialAct Corporation, can be seen below in Figure 2. This model is available in three sizes, or can be custom molded for a much higher price. The redeeming quality of this model is material selection. DialAct has the ability to fabricate products at client specified hardness's, ranging from 10 Shore A to 90 Shore D. However, their model has a constant inner diameter and an arch with a large radius of curvature. An aorta model with variable diameter and small radius of curvature is preferred, as it would better represent the most extreme anatomy for stent graft applications.

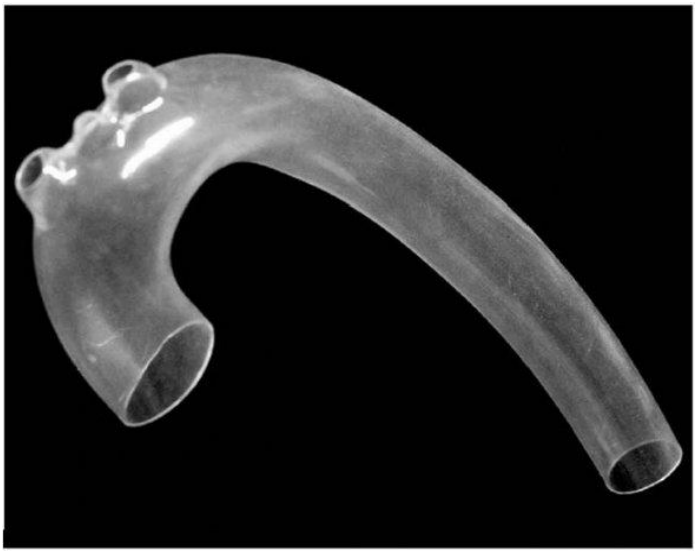


Figure 2. DialAct Aortic Arch Vascular Model

The other product that we found was the Aortic Arch model from SynDaver Labs. They specialize in the production of synthetic tissues that they claim are accurately representative of human tissue. The model geometry is sufficient for the scope of this project, but material viability and model cost are issues that must be evaluated. An image of the SynDaver model is below in Figure 3.

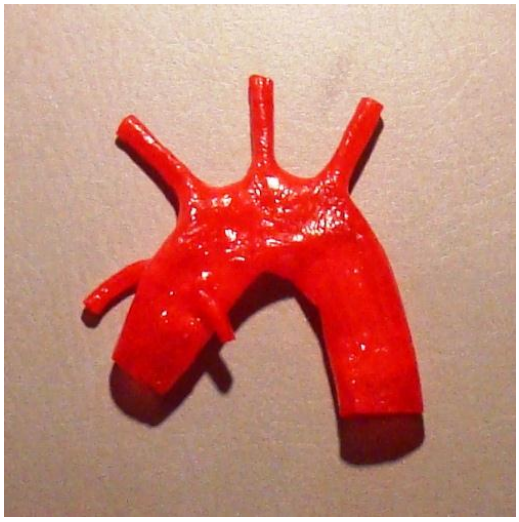


Figure 3. SynDaver Aortic Arch

Chapter 3: Design Development

In this section, the concept generation and selection processes we used will be discussed. Our project can be divided into four sections, each with its own design process. Those areas are as follows:

1. Thoracic aorta model
2. Enclosure components
3. Proximal conformability test/measurement method
4. Fixture components

3.1 Thoracic Aorta Model

Before design of the aorta model could take place, it was necessary to research aorta geometry, material properties, and environmental conditions. We found multiple medical journal articles with real patient statistics for arch angles and aorta diameters. In studying this information, it was determined that all thoracic aortas are unique and have drastically varying anatomies. We decided that the model should have a smaller arch curvature to better represent the geometry in patients who experienced poor stent graft wall apposition. We also decided that while an aorta of varying inner diameter is a

better representation of clinical conditions, a constant inner diameter would suffice for the scope of this project. With this in mind, we generated three concepts for the aorta model:

DialAct

The first option is the aortic arch vascular model, to be bought from DialAct Corp. It has a constant inner diameter, and is available in 20, 25, and 30 mm diameters. The material used is a mix of polymers that can be customized to meet a client specified hardness/durometer. The arch geometry and curvature is a good depiction of aortic anatomy, however, the radius of curvature is much larger than desired. The price ranges from $200-$400 for one of their generic sizes, to over $1000 for a completely custom aorta model.

SynDaver

The next option is the aortic arch from SynDaver Labs. This model has a much more complex geometry, and the material used is claimed to be almost identical to an actual human aorta. While this is the most realistic model possible, the material must be stored in a solution to preserve its longevity. Also, the material is very slippery and pliable, which may cause problems when integrating with the test method. The price ranges from $350, for only the aortic arch, to $950 for the entire aorta.

Arterial Solutions

The final option is for us to mold our own model. This would allow the greatest degree of design flexibility and least costly method. A CAD model of the aorta would be generated and a custom mold based off that. The main disadvantages of this option are time and quality. It is uncertain if acceptable accuracy and surface finish can be reached with the current abilities of the team. This option takes much more time, for design and prototype manufacturing, than the other two options.

After our three concepts were generated, we used a decision matrix to compare them to the current aorta model used by Medtronic. Their model is hard plastic and its arch has a very tight radius of curvature. The main criteria that we used to evaluate the concepts were cost, accuracy, and time. The time and cost criteria were a result of our project scope, since we want to finish on time and under budget. The accuracy standard is a result of our requirements list, and is a measure of how well the model compares to a real aorta. The matrix can be found in Appendix A.

The results of the decision matrix show that there is no clear top concept, as each has its own benefits. The benefits of the two molding companies are offset by their higher costs, while our own model is hurt most by the time it requires. We discussed the results of this matrix with our sponsor, Lauren Rush, and we came to the decision that the best choice was to mold it ourselves. The primary reason is the valuable experience we would gain by molding our own model, since otherwise our project is very light on manufacturing. The secondary reason for this decision was the relative low cost of our own model, when compared to the alternatives.

3.2 Enclosure Components

For the flow environment of our model, we wanted to accurately model the beating motion of the heart. We determined that a pulsatile pump would be needed to mimic the flow rate and pressure changes in the thoracic aorta. In order to more accurately represent the aorta, it was determined that water at 37 degrees Celsius is an acceptable substitute to blood. For this, it would be necessary to include a heating element in our final design.

3.3 Conformability Test Method

The primary step in creating a conformability test method is to select a means to quantify stent graft apposition to the arterial wall. This means is described by the term ‘measurement method’ for the remainder of the report.

The process of determining a measurement method by which to quantify stent graft conformability began with a brainstorming session. The session intentionally lacked structure in order to promote idea generation. We began by brainstorming modes by which stent graft wall apposition could be quantified. Each group member worked independently at their own pace, recording personal ideas, and discussing them when desired. The goal was to produce to the greatest amount of unique measurement solutions, while sustaining a positive group atmosphere. The results ranged from common engineering solutions like proximity sensors, to those more uncommon, like coloring the aorta model wall. These measurement methods are compared in a decision matrix, located in Appendix A.

Referencing the decision matrix totals for each measurement method, the clear choice is the use of displacement sensors. The results are reinforced by the capability of displacement sensors relative to the other proposed methods: it is the only solution which quantifies a linear distance by direct measurement. This validates our measurement method selection, as accurately quantifying conformability is of utmost concern and importance.

The next step was to determine the type of displacement sensor to employ. Our research yielded three available sensor types: photoelectric (optical), ultrasonic, and inductive. Each type utilizes a different physical relationship to quantify a distance. The photoelectric sensor utilizes a light source - commonly LED, laser, or infrared, to determine a distance based on the relation between an incoming and outgoing beam of light. The ultrasonic sensor utilizes sound waves to determine distance based on the time required for an emitted sound wave to return to the sensor. The inductive sensor relates the strength of a magnetic field produced by the sensor, which is disrupted by the presence of metallic objects, to a distance.

A decision matrix was not required to make a selection from the researched candidates. Inductive sensors exhibit a clear advantage over ultrasonic and photoelectric: they present the least risk of measuring undesired objects. When using a displacement sensor, the aorta model and flowing fluid will lie before the stent graft in the sensing path. This poses a potential problem of measuring the distance to an undesired object, like the aorta model. Inductive sensors avoid this issue because they detect magnetic fields, which are not affected by non-metallic objects – like the aorta model material and flowing fluid.

3.4 Fixture Components

At this point, we have defined the enclosure as the existing Medtronic lab equipment that our project will interface with. Henceforth, the assembly that we build will be referred to as the fixture. Based off our other components and requirements list, we have developed a list of functional requirements for the fixture as follows:

- The fixture must have a base that other components can be secured to.
- The aorta model must be firmly attached to the fixture.
- The aorta model must be able to attach to the pump inlet and outlet.
- The aorta model must remain pressurized through the duration of the test.
- The sensor must be able to be attached to the fixture base in a variety of user specified positions.
- The fixture base must conform to the 2 ft by 3 ft size requirement.

We have decided to use a pegboard as the fixture base. This will allow for variable positioning and easy securing of components. The pegboard may be an off-shelf item, or we might make our own so that the holes are closer together.

The plan is to use clamps to secure the model to the base, and pipe clamps/couplers to attach the model to our piping system.

The sensor will be mounted to a shaft and bolted to the base. A conceptual reference design was built in SolidWorks and is seen below in Figure 4.

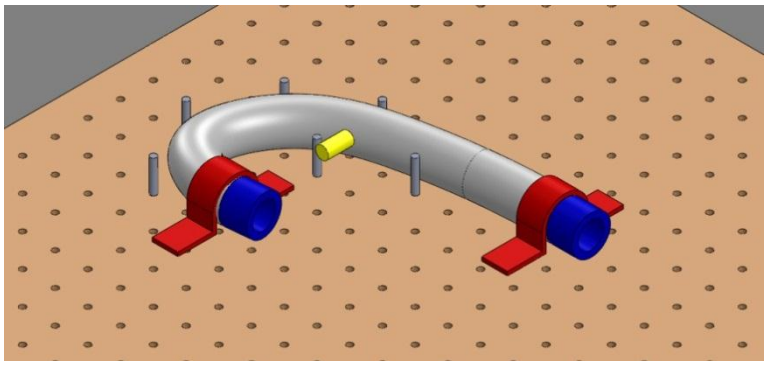


Figure 4. CAD reference model

Chapter 4: Final Design

This section will document our final design and provide detailed descriptions of each component with regard to function, analysis, cost, and manufacturing.

4.1 Detailed Design Descriptions

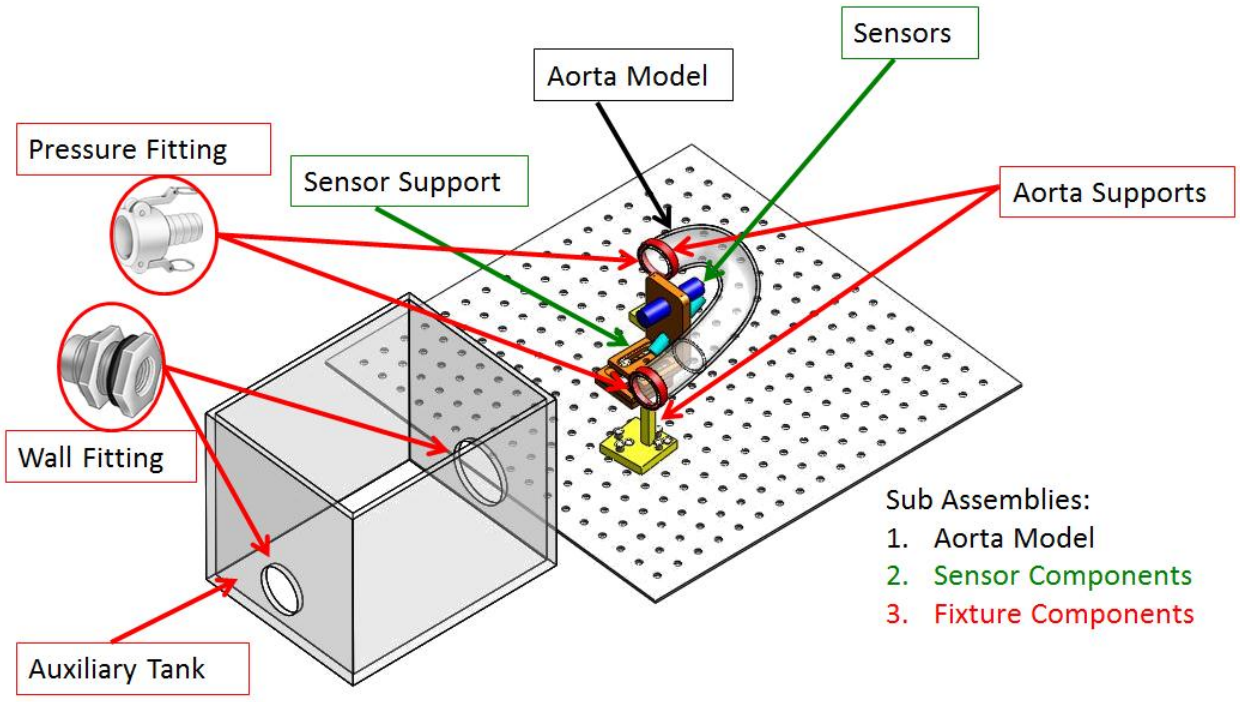


Figure 5. Final Design Assembly

4.1.1 Thoracic Aorta Model

4.1.1.1 Geometry

The Aorta model geometry is based on a curve and constant circular cross section. The curve is based on five radii of curvature in a single plane, meaning the lumen of the aorta does not vary in elevation. The model meets a primary geometric requirement: a “tight” aortic arch. The goal of this project is to quantify proximal conformability because doing so can be quite difficult in application. We need to capture the small radius of curvature of the aortic arch in order to reveal its effects on stent conformability.

4.1.1.2 Analysis

The wall thickness of the model will be manipulated because it is the easiest variable for us to regulate to obtain the proper diametral dilation. Doing is so is of primary import because aortas change in size during the cardiac cycle and we want to capture the effect this has on stent graft conformability.

The wall thickness is estimated based on the pulsatile pressure load, material hardness, diametral dilation desired, and inner diameter during diastole. The calculation is made by treating the model as a pressure vessel, both thin and thick walled, then checking the results for the validity of wall thickness assumptions. Assuming the walls of the model to be ‘thin’ or ‘thick’ is critical when applying pressure vessel equations to the system. For thin walled vessels, the ratio of thickness to radius should be less than one tenth ($t/r<1/10$). This requirement is verified for each wall thickness calculation, and if unsatisfied, thick-walled equations are applied. The calculations were carried out with EES, with the utilized code included in Appendix E. Appendix E also contains tables of results for wall thickness calculations.

The results indicate that Shore 20A hardness material should be utilized for the casting procedure, as obtaining wall thicknesses less than 2mm will be difficult with the casting resources available. It should be noted that these results are an estimate of the wall thickness required for a desired dilation due to the assumptions made to obtain them. The equations used assume a linear elastic material, which rubber is not, especially for the deflections desired. Therefore, these calculations will be used only to determine an initial thickness. We will cast tube shaped material samples using this initial thickness, and then manipulate it to obtain the desired dilation amount.

4.1.1.3 Manufacturing

The model will be molded on-site, at the California Polytechnic University, San Luis Obispo campus. We are in the process of creating a model casting procedure with the aid of a resident molding expert: Martin Koch. The procedure will involve a vacuum molding process to draw the plastic through mold, and a pressure molding process to aid the curing of the material. Utilizing vacuum pressure to 'pull' the material through the mold is necessary to achieve the complex, thin geometries desired in the model. The mold will be constructed from a split mold and machinable wax mandrel. The mandrel will be turned to a desired inner diameter, then heated and bent to the desired curvature.

The selected model material is Smooth-On Encapso K. The material is a silicon rubber formulation, optically clear, and smooth in surface finish. The paramount material property, however, is the 20A durometer. This material hardness will allow us to capture the desired diametral dilation resulting from the variable pressure load of the cardiac cycle. Test sections are currently being molded in order to validate use of the Encapso K product.

4.1.2 Enclosure Components

The enclosure and accompanying components consist of a material shell to house the aorta model fixture, and fluid regulatory machines. The machines include a pulsatile pump to mimic the varying pressure load of the cardiac cycle, and an electric heater to control fluid temperature. These items, including enclosure, will be made available to us on site at Medtronic, in Santa Rosa, CA. Utilizing this resource will cut down on design time, specification time, and component costs, but will increase both travel time and travel cost. This tradeoff is favorable because making use of these resources will allow us to concentrate our efforts toward other areas of greater importance, like quantifying stent graft conformability.

4.1.3 Conformability Measurement Method

This section discusses our conformability measurement method, which uses inductive and photoelectric displacement sensors to measure the position of the stent graft relative to the aorta wall. We determined that the photoelectric sensor would be needed due to the dilation of the aorta wall. Since the position of the aorta relative to the sensor array will be constantly changing due to dilation, an accurate measurement requires two sensors. Both sensors will be mounted in the same plane, and directed normal to the flow in the aorta. The position of the stent graft will be determined by the following formula:

(Inductive output) – (Photoelectric output) – (wall thickness)

Using this method, a data acquisition program will continuously track and store the sensor readings so that stent position is measured throughout the test cycle.

4.1.3.1 Sensor Verification

Once an inductive displacement sensor was chosen for our measurement method, we needed to verify that it would work in our application. Testing indicated that the bare stent graft is too small of a target to be detected by the inductive sensor. This necessitated the use of a metallic marker that will be placed at the area of interest on the stent graft. We also encountered difficulty because the output of the inductive sensor did not have a linear relationship with the distance being measured. This made it difficult to get accurate distance measurements. Our solution was to choose a more expensive sensor that guarantees a linear output.

The photoelectric sensor was not validated for two primary reasons. First, we needed sponsor approval before purchasing a potential expensive component. Second, the photoelectric sensor will be used in its advertised application and we have high confidence it will perform its function.

4.1.3.2 Selection

The inductive sensor is the 18 mm Eaton AccuProx analog inductive sensor. When we went so select a sensor, we were looking for one with the smallest sensing face while still providing the sensing range that we needed. The problem with inductive sensors is that the larger sensors have a longer range, but require that the object being detected is large too. For this reason, we wanted to minimize the sensor size, so that our metallic marker on the stent graft is smaller. This Eaton sensor also guarantees a linear output signal, so it was the best solution to our need.

Currently, a photoelectric sensor has not been selected due to sponsor complications. The important criteria for these sensors are resolution, cost, and response time. The sensor we use will be the most accurate available that is within our budget.

4.1.3.3 Data Acquisition System

Due to the fact that photoelectric and inductive displacement sensors use voltage outputs, a data acquisition system must be used to track these voltages, convert them to distances using previously defined calibration constants, and provide the location of the stent graft. The system we have selected is the National Instruments USB-6008. It was chosen because it was the lowest cost device that fulfilled the needs of our project. It comes with a student version of the software LabVIEW, but the sponsor may need to purchase a license for use at their facility.

4.1.4 Fixture Components

This section discusses the details of all remaining components that are part of our design.

4.1.4.1 Aorta Model Support

Our supports for the aorta model can be seen below in Figure 6. The fixed base is used at the inlet to the aorta model, and the variable base is used at the aorta outlet. The clevis pins allow the support to be placed in a variety of positions, which allows the aorta model size and geometry to vary. The red hoop in the figure is representative of the hose clamp that will hold the aorta in place, constraining it in both the radial and flow directions.

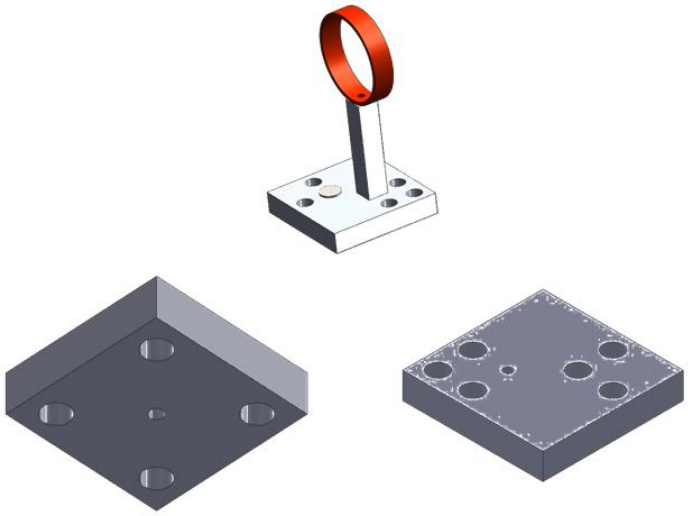


Figure 6 Aorta Model Support Left-Fixed Right-Variable

4.1.4.2 Sensor Support

The sensor support, seen below in Figure 7, is used for positioning the sensors so that their view is normal to the flow in the aorta. This design allows for X-Y translation, as well as rotation. The pins in the base of the support will press fit into the pegboard base.

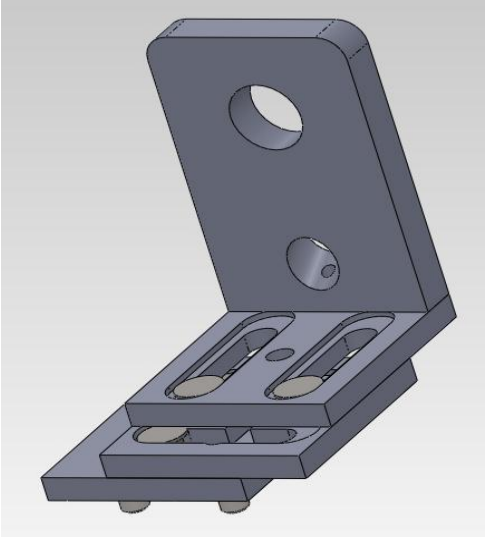


Figure 7 Sensor Support

Both supports will be machined out of Delrin by a 3rd party. We are outsourcing the manufacturing due to the limited hours of Cal Poly machine shops, lack of machining experience among team members, and to lower the workload to a level more appropriate for a two person team.

Delrin is selected for the manufacturing of custom components due to its balance of desirable material properties:

- Machinability
- Good electrical insulating characteristics
- Moisture resistance
- High mechanical strength and rigidity

The cost for Delrin is not desirable in comparison to other plastics, but the effects of this cost are minimized by the small quantity of Delrin required for the design.

4.1.4.3 Auxiliary Tank

In order to introduce fluid into our closed system, we need an auxiliary tank that will act as a reservoir. This tank must be substantial enough to support a wall mounted heating element that Medtronic is providing. The specific dimensions of this tank can be found in its part drawing in Appendix B. We are still searching for a company to fabricate this custom tank. As a backup plan, we will have sheets of polycarbonate cut to size and will glue them together ourselves.

4.1.4.4 Pegboard Base

Since versatility and ease of transport were important aspects of project, we decided to use a pegboard as our base. This allows components to be anchored while still being portable. It also leaves room for integration with future models/measurement systems. We will use a 18”x12” section of polypropylene pegboard to satisfy our need.

4.1.4.5 Assorted purchased components

Our final design uses pressure fittings for connections between the pump, reservoir, and aorta model. All fittings that we have specified have data sheets located in Appendix B, and will be purchased from McMaster-Carr. They all are rated to pressures that far exceed our application.

The design uses PVC tubing and hose clamps to complete the loop between components. The PVC piping was chosen as the most cost effective product that was strong and flexible enough for our needs. The specific information about these components can be found in their data sheets in Appendix B.

4.2 Cost Analysis

A prospective cost analysis is detailed below. It should be noted that cells highlighted in light blue are estimate costs. Both pertain to uncertainty in the manufacturing of each part, as these costs have not yet been determined. Dashed lines in the total price column indicate that the part corresponding to the dashed line will be acquired in another purchase, and therefore should not be factored into the total cost.

Table 2. Bill of Materials/Cost

Part #	Component Name	Part Name	Supplier	Quantity Desired	Price/Pkg	Total Price
111	Aorta	Model	Local	1	200.00	200.00
112		Pressure fitting	http://www.mcmaster.com	2	4.61	9.22
211	Pegboard	Board	http://www.mcmaster.com	1	40.72	40.72
212		Feet	http://www.mcmaster.com	6	11.16	11.16
221	Aorta support	Base	http://www.mcmaster.com	1.5"x1.5"x.375"	40.95	40.95
222		High-res base	http://www.mcmaster.com	2"x2"x.375"	40.95	-
223		Column	http://www.mcmaster.com	.375"x.375"x1.75"	40.95	-
224		Sliding pin	http://www.mcmaster.com	6	7.07	7.07
225		Stationary pin	http://www.mcmaster.com	4	7.19	7.19
226		Aorta clamp	http://www.mcmaster.com	2	11.71	11.71
231	Aorta-tank coupling line	Tube	http://www.mcmaster.com	2ft	3.28	6.56
232		Clamp	http://www.mcmaster.com	2	5.34	5.34
233		Pressure fitting	http://www.mcmaster.com	2	9.63	19.26
241	Tank-basin coupling line	Tube	http://www.mcmaster.com	2ft	3.28	6.56
242		Clamp	http://www.mcmaster.com	2	5.34	5.34
243		Pressure fitting	http://www.mcmaster.com	1	9.14	9.14
251	Basin-aorta coupling line	Tube	http://www.mcmaster.com	2ft	3.28	6.56
252		Clamp	http://www.mcmaster.com	2	5.34	-
253		Pressure fitting	http://www.mcmaster.com	1	9.63	9.63
261	Auxiliary tank	Tank	http://aggsons.com/default.aspx	1	100.00	100.00
262		Through-wall fitting	http://www.mcmaster.com	2	18.67	37.34
263		Plug fitting	http://www.mcmaster.com	2	4.68	9.36
311	Sensor	Stent	http://www.mcmaster.com	1	267.00	267.00
312		Aorta wall	http://www.mcmaster.com	1	0 - 1162.00	0 - 1162.00
321	Sensor stand	Lower base plate	http://www.mcmaster.com	2"x2"x.25"	7.22	7.22
322		Mid base plate	http://www.mcmaster.com	2"x2"x.25"	7.22	-
323		Upper base plate	http://www.mcmaster.com	2"x2.25"x.25"	7.22	-
324		Head	http://www.mcmaster.com	2"x3"x.375"	40.95	-

Part #	Component Name	Part Name	Supplier	Quantity Desired	Price/Pkg	Total Price
325		Set screw	http://www.mcmaster.com	1	2.15	2.15
326		Positioning pin	http://www.mcmaster.com	1	7.07	-
327		Base pin	http://www.mcmaster.com	1	7.19	-
331	DAQ	Module	http://www.ni.com/	1	169.00	169.00
				Total Cost		998.48-2150.48

The total cost is presented as range due to the variability in aorta wall sensor cost. The sensors vary in cost from $0.00, where Medtronic provides a sensor, to $1162.00, where we purchase a high resolution sensor. We are currently awaiting sponsor feedback to define our decision path, and select a photoelectric sensor to measure aorta wall displacement. It should be noted that the projected cost range is low because it does not account for aorta support and sensor stand manufacturing. Manufacturers will be evaluated and selected following design approval from Medtronic.

4.3 Safety

Due to the nature of this project, safety is not of great concern. The pressure fittings and hose clamps have been over specified so the possibility of a burst connection is highly unlikely. The auxiliary tank is utilized so that we were able to isolate the sensors' electrical components from the water, so chance of electric shock is very low. As long as pump pressure is kept in the desired operating range, 0-120 mmHg, there are no safety risks.

4.4 Repair/Maintenance

Since the vast majority of project components are purchased, it should be easy for any replacement parts to be ordered. The custom supports are subjected to very limited loads, and are expected to last much longer than most components. The only component that is not easily replaced is the aorta model. However, it is predicted that Medtronic will fabricate future aorta models and integrate them with our measurement method.

Chapter 5: Product Realization

This section documents the aorta molding process as well as any component changes that differ from the final design. It also contains an explanation of sensor calibration and details regarding the measurement method. The aorta model and measurement components of our project can be seen below in Figure 8.

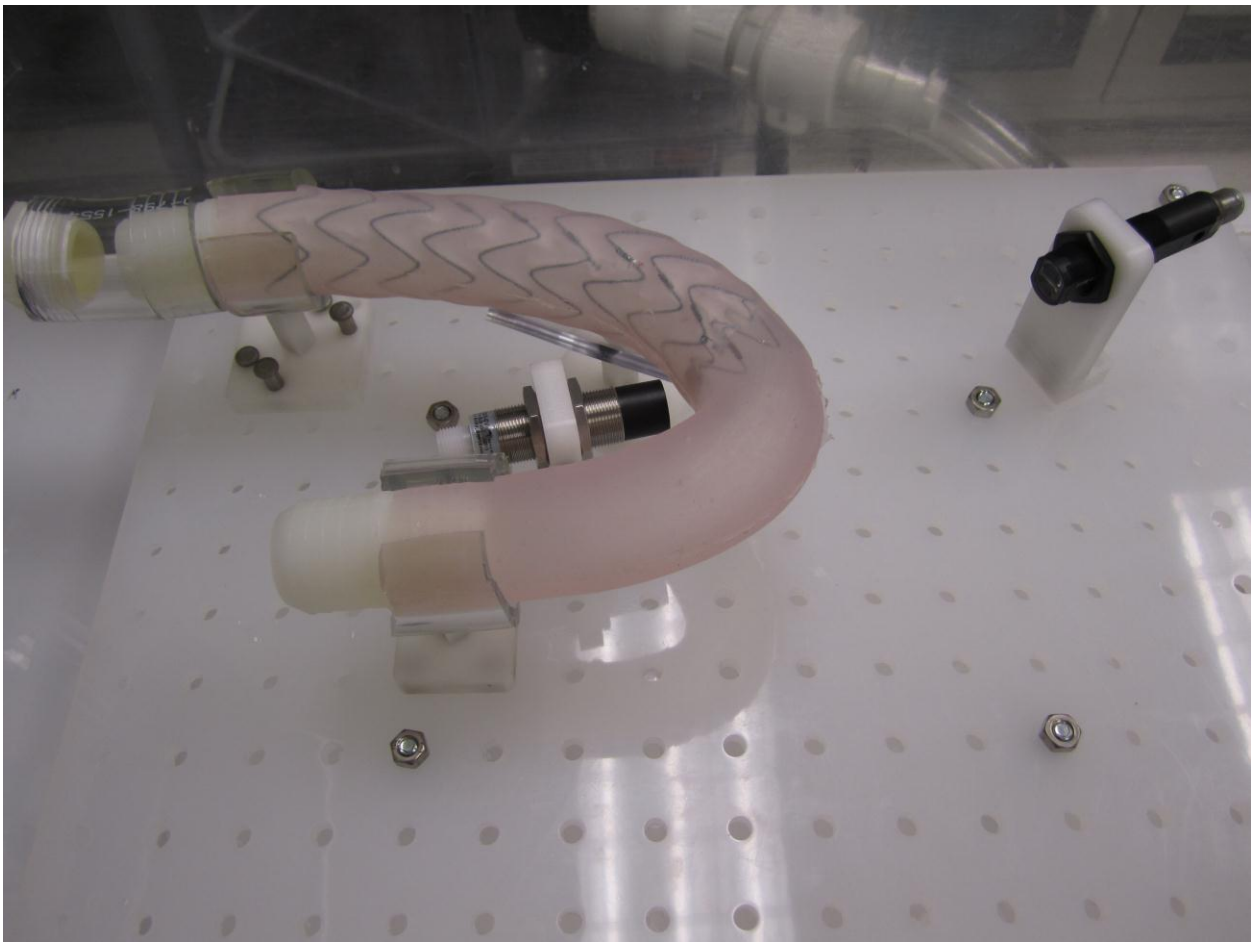


Figure 8. Aorta, stands, and sensors

5.1 Aorta Molding

The aorta manufacturing process began with manufacturing the mold sets used to cast the aorta. Two mold sets were involved: (1) the core mold and (2) the aorta mold as shown in Figures 9 and 10, respectively.

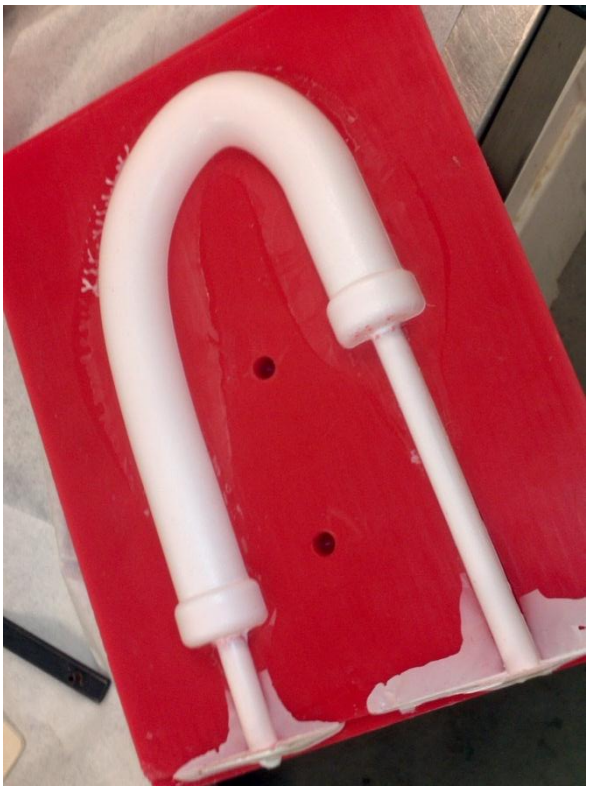


Figure 9. Core mold half with molded core

Figure 10. Aorta mold half with inserted core

The core mold defines the inner surface of the aorta, while the aorta mold defines the outer surface of the wall. The molds were cut in a 3-axis CNC Haas mill from machinable wax blocks. The core was then cast with Smooth-on Smooth Cast 300Q molding compound. With the core installed in the aorta mold, the aorta mold was poured with Smooth-on Sorta Clear 18, and then placed in a vacuum chamber, at 29mmHg for 5 minutes. This molding run was unsuccessful due to the air bubble present in the aorta wall, as shown in Figure 11.

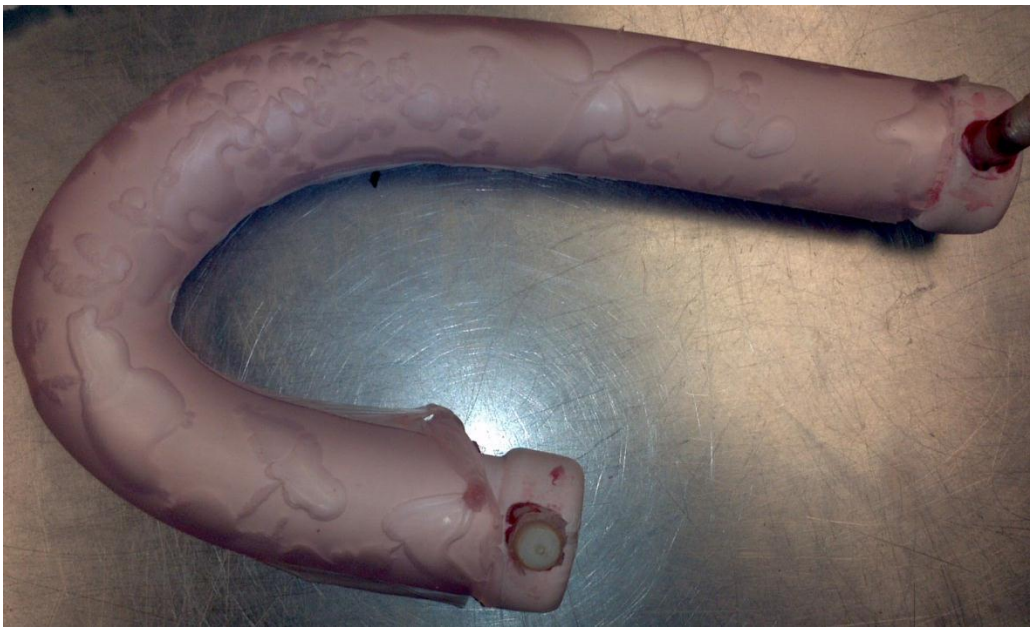


Figure 9. Aorta model with air bubbles.

The presence of bubbles is due to the high viscosity of the Sorta Clear 18 compound, coupled with the small inlets of the mold. The high material viscosity traps air in the mold, while the small mold inlets provide a high resistance to fluid flow, and therefore to air exiting the mold. In response to these problems, the molding process was iterated on several times before developing a reliable solution. Changes made to the process, some successful, and others not, are listed below:

- Replacing the solid core with a dissolvable plaster core
- Changing the material to Smooth-On Clear Flex 50
- Replacing the solid core with a crushable abs core
- Adding a gating system
- Injecting the material, Sorta Clear 18, into the mold under pressure
- Adding indexing pins to the core
- Modifying the lengths of time that the molds are vacuumed
- Modifying the number of times that the molds are vacuumed

Through these iterations, a successful molding process was developed. The process involves the original, solid core and the previously selected Sorta Clear 18 silicone rubber, and requires the following materials:

1. Solid, non dissolvable core cast from Smooth Cast 300Q
2. Aorta mold set
3. Vacuum chamber and pump
4. Pneumatic grease gun, continuous operation
5. Smooth On Sorta Clear 18

An overview of the process is outlined below:

1. Mix Sorta Clear 18 molding compound according to Smooth On provided instructions
2. Pour mixed compound into grease gun cartridge
3. Place cartridge into vacuum chamber
4. Vacuum cartridge at 29mmHg for 7 minutes, or until most bubbles are ejected

5. Attach cartridge to grease gun
6. Interface grease gun with aorta mold set
7. Actuate grease gun to inject Sorta Clear 18 into aorta mold
8. Detach grease gun from aorta mold
9. Place aorta mold on level surface
10. Leave aorta mold for 24 hour cure time
11. Demold aorta

This process allows for reliable casting of a flexible aorta model. A result of this process is pictured in Figures 12 and 13.

Figure 12. Successful, demolded aorta model

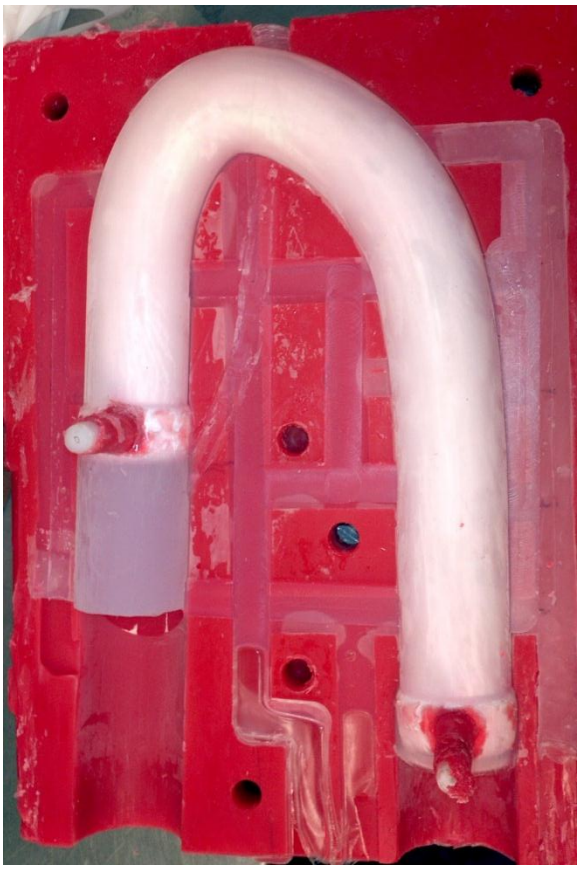


Figure 10. Successful aorta in gated mold, with core intact.

This procedure, however, could be easily improved with a bit more time and money. Suggestions for these improvements are outlined in the conclusion section.

5.2 Component Changes

Alterations were made to the fixturing components during implementation. These changes were found to be more practical, lower cost, and improve the performance of the fixture as a whole.

The aorta stands were originally designed to utilize snap grip hose clamps, to secure the aorta to the column of the stand. These hose clamps were replaced with sections of tubing. The hose clamps were found to be too skinny for the application. And, while the tube sections solved this issue, they were also a more versatile solution, as they were more customizable in terms of length, diameter, and material.

An additional aorta stand was implemented to account for the weight, making a total of three stands. Due to the flexibility of the aorta, the load of the water flowing inside caused it to deflect toward the ground, requiring a third stand located at the arch portion of the model.

The sensor stand was originally designed to hold both the photoelectric and inductive sensor. This design was changed to support a single sensor on each stand. Therefore the fixture assembly utilizes two stands. Both stands are physically identical. This design is more versatile in terms of positioning the sensors, and better fits the selected sensor models themselves. The selected sensors vary greatly in their advertised ranges: the inductive 0-15mm, and the photoelectric 5-10cm. Therefore, it was more convenient to allow for the sensors to be moved to two different distances from the aorta model, requiring that they be supported by separate stands. Implementing two stands as opposed to one, however, does introduce the assumption that the aorta deflects equally at both measured portions of the cross section. The finite element simulation performed validates this assumption.

5.3 Measurement System

The correct implementation of the measurement method requires finding the calibration equation for each sensor. The calibration equation is determined by placing a target in the sensor's view at various distances, and recording distance and voltage at each point. A linear curve is then fit to the data, which yields an equation that converts sensor voltage to a distance. The inductive sensor must be calibrated for the specific marker it is sensing, because its equation is dependent on marker area and thickness. It was also found that the presence of the aorta model between sensor and marker changed the calibration equation. This is best fixed by placing a section of aorta material in front of the marker during calibration. The final marker was a square section of stainless steel foil with side length 1 cm.

Once both sensors are calibrated correctly, the distances are fed into a formula in LabVIEW that calculates the conformability measurement. In order to utilize this equation, the inductive and photoelectric sensors must be set up on opposite sides of the aorta section of interest. The inductive sensor must be close enough to the aorta so that the stent graft is never out of range (15mm). The photoelectric sensor must be placed on the other side of the aorta, and be collinear with the inductive sensor. Refer to Figure 8 for a visualization of this setup. For the specific photoelectric sensor used, it must be placed at least 5 cm and no more than 10 cm from the aorta. Finally, the formula operates on the assumption that the aorta dilates equally on both sides of the aorta.

The formula below determines the location of the inner aorta wall where the metallic marker should be making contact. The difference between the inductive sensor output and the formula output is the conformability measurement.

$$X_{Inner\ Wall} = L - 2\delta_o - D + t + \delta$$

where: L= Distance between the two sensor faces (mm)

δ_o= Static photoelectric reading (mm)

δ= Dynamic photoelectric reading (mm)

D= Aorta diameter (mm)

t= Aorta wall thickness (mm)

$$X_{Conformability} = X_{Inductive} - X_{Inner\ Wall}$$

Chapter 6: Testing

On May 19th, 2012, the team traveled to Santa Rosa, CA, to perform testing using Medtronic's pulsatile pump. The first task was to hook up the system and test the aorta for leaks and dilation. The plastic hose clamps that we planned to use did not provide enough clamping force to prevent leaks. The leaks were stopped though the use of metal hose clamps and cable ties. Once the system was free from leaks, we were able to increase the pressure from the pump. The entire test setup, except for inductive sensor, is pictured below in Figure 14.

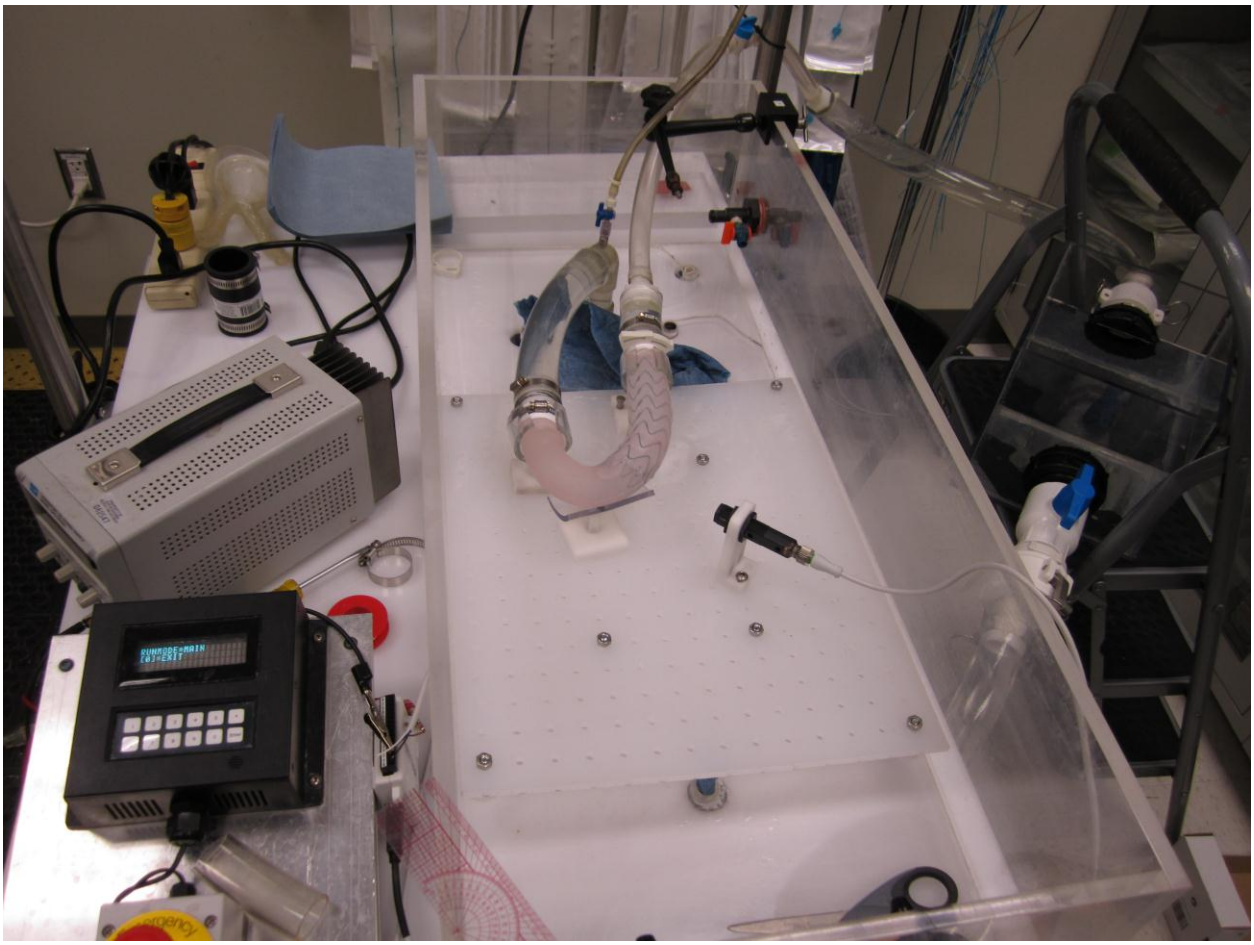


Figure 11. Aorta and photoelectric sensor test assembly

The desired dilation of the aorta model was achieved at approximately 40 mmHg systolic pressure. This differed significantly from our expectations of dilation occurring at 160 mmHg.

The next step was to implement the photoelectric sensor to measure the dilation of the aorta. However, the readings from the sensor were incorrect when sensing the position of the aorta. This error has been attributed to three possible causes:

1) Sensor is measuring a curved surface
2) Surface finish of the aorta
3) Low quality sensor

It is unclear at this point if all photoelectric sensors would have a problem with this application, or if the problem was sensor quality. Future testing should examine integration of a higher quality photoelectric sensor.

The final step was to test the inductive sensor. A metal marker was glued to the outer aorta, as we were still trying to measure dilation while the pulsatile pump was running. This sensor produced exceptional data that was both accurate and free from noise. If it was determined that photoelectric sensors are inappropriate for this application, a 2nd inductive sensor could easily be adapted to measure aorta position. Due to the failure of the photoelectric sensor, a conformability measurement could not be obtained. The results of our testing are organized below in Table 3.

Report Date	6/1/2012	Sponsor	Medtronic					Component/Assembly		REPORTING I	Kendall
TEST PLAN								**TEST REPORT**			

Item No	Specification or Clause Reference	Test Description	Acceptance Criteria	Test Responsibility	Test Stage	SAMPLES		TIMING		TEST RESULTS			NOTES
						Quantity	Type	Start date	Finish date	Test Result	Quantity Pass	Quantity Fail	
1	Inductive Sensor	Take measurements at different distances	Linear relationship and sufficient sensing range	Kendall	PV	1	B	1/5/2012	1/5/2012	Fail	0	1	30 mm
						1	B	2/28/2012	2/28/2012	Pass	1	0	18 mm Eaton
2	Photoelectric Sensor	Test for accuracy and range	Manufacturer Specs	Kendall	PV	1	B	2/28/2012	2/28/2012	Pass	1	0	Eaton Intelliview
3	Aorta Material	Mold tubular sections and observe properties	Transparent, strong, and flexible	Dylan	PV	1	B	2/17/2012	2/17/2012	Fail	0	1	"Encapso-K"
					PV	1	B	2/24/2012	2/24/2012	Pass	1	0	"Dragon Skin"
					PV	1	B	2/27/2012	2/27/2012	Pass	1	0	"Sorta-Clear 18"
4	Weight	Place assembly on scale	<25 lbs	Kendall	DV	1	C	4/1/2012	5/19/2012	Pass	1	0	
5	Temperature	Place thermometer in aux	37 ±3 deg	Kendall	DV	1	C	4/1/2012	5/19/2012	Pass	1	0	
6	Stent Deployment	Add/remove stent graft	<10 min	Dylan	DV	1	C	4/1/2012	5/19/2012	Pass	1	0	
7	Elasticity	Measure max and min aorta	>10% dilation	Dylan	DV	5	C	4/1/2012	5/19/2012	Pass	5	0	
8	Surface finish	Feel inside of aorta model	Smooth	Lauren	DV	1	C	4/1/2012	5/19/2012	Pass	1	0	
9	Aorta Length	Measure descending aorta	>250 mm	Kendall	DV	1	C	4/1/2012	5/19/2012	Pass	1	0	
10	Flow rate	Use flowmeter	2.7± 1 Lpm	Dylan	DV	1	C	4/1/2012	5/19/2012	N/A	-	-	
11	Pressure	Measure pressure	160± 5 mmHg	Kendall	DV	1	C	4/1/2012	5/19/2012	Fail	0	1	

Table 3. DVP&R testing report

Chapter 7: Conclusion/Recommendations

While we were unable to collect any useful data with this version of the design, this was due to the failure of one component that is easily remedied. If this project is continued, the following are changes that should be implemented:

AORTA MOLDING

The current molding process utilizes molds manufactured from machinable wax. This material was advantageous for the prototyping stage due to its low durometer, and machining repeatability. These properties allowed the molds to be cut at high speeds, and machining blanks to be melted and reformed as the CNC code was being developed. However, the disadvantage of the wax is the molding repeatability – the low durometer amplifies the wear that results from each molding iteration. Now that a reliable procedure has been developed, and therefore the geometries finalized, the molds should be manufactured from a harder material. A metal, such as aluminum or steel, would produce the desired smooth surface finish, and hardness for molding repeatability. Although these molds would take considerably more time to machine, this drawback would negligible when producing multiple aortas.

SENSORS

As stated earlier, the photoelectric sensor failed to perform its function and must be replaced. It is unclear whether the poor sensor readings were a result of the surface being measured, or the sensor quality. The curvature and surface finish of the aorta could have caused the poor sensor readings. If this is the case, an inductive sensor and second metallic marker should replace the photoelectric sensor. However, it is possible that a higher quality photoelectric sensor would accurately measure the aorta position. This is the preferred solution since it is more versatile and user friendly than the inductive-marker combination.

SENSOR STANDS

The current sensor stand configuration was advantageous for validating the measurement system. However, it has disadvantages in its ease of use and mobility: it is tedious to adjust the position of the sensors, and not possible to adjust the orientation of each sensor relative to its stand. In addition, these disadvantages limit the user to the allowable measurement locations around the aorta. The sensor stands should be redesigned to remedy these disadvantages.

One possible solution would be to implement a system where the sensors are supported from a hanger type device, so the sensors are suspended above the aorta. Each sensor would be directly connected to a ball joint, allowing for a 360° rotation of the sensor, and each ball joint connected to a rail positioned above the aorta. The ball joint connection to the rail would allow for translation along the rail. Implementation of a solution of this type would greatly increase the range of motion of each sensor, and ease of adjustment.

FIXTURE COMPONENTS

The final change that should be implemented is a downsizing of the fittings and tubing used. The initial design specified fittings and tubing at pressure ratings that far exceeded our system, which meant components that were unnecessarily bulky. The ID of the tubing and wall thickness can be reduced, which will allow greater flexibility and less weight.

This project revealed that conformability is a difficult parameter to quantify. While a 1-D measurement at one point in the aorta is a start, it is still a very simplistic measurement. However, given the scope and resources of this project, our method is a good way to measure conformability at a point while the aorta undergoes dynamic, clinical conditions.

Appendix A: QFD, Decision Matrices

▲ Larger is Better
O Nominal is Best
▼ Smaller is Better

Customer Description:
1 = Medtronic
2 = R&D Engineers

Customer Requirements (Whats)	Item No.	Importance	O Fluid temperature	O Fluid pressure	O Flow rate	O Arch radius of curvature	O Constant circular x-section	O Material durometer/elasticity	O Material surface finish	▲ Withstands vertical drop	▼ Fixture size	▼ Total weight	▼ Stent addition/removal time	O Measures stent distance from model wall	▲ Descending aorta length		
			Specifications (Hows)														
			A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
Replicates thoracic aortic flow environment	1	**5**	**9**	**9**	**9**			**1**	**1**								
Sized to common/average thoracic aorta	2	**5**				**9**	**3**				**1**				**3**		
Replicates thoracic aortic wall material properties	3	**3**	**1**	**1**	**1**			**9**	**9**					**1**			
Accomodates range of stent lengths	4	**2**				**3**	**1**								**9**		
Durable	5	**2**								**9**							
Benchtop model	6	**3**									**9**	**1**					
Easy to use	7	**3**											**9**	**3**			
Portable	8	**3**										**9**					
Tests stent graft conformability to model wall	9	**5**	**1**	**1**	**1**	**1**	**1**	**1**	**1**				**1**	**9**	**1**		
Targets			**37°C**	**160(max)/80(min) mmHg (systole/diastole)**	**2.7±1 Lpm**	**Tight**		**Allows for 10% diametral dilation**	**Smooth**	**4ft**	**≤2ftx3ft rectangular area**	**<25 lbs**	**<10 mins**	**±1mm**	**≥250 mm**		
Weighted Importance			53	53	53	50	20	37	37	18	32	30	32	57	38		
% Importance			0.10	0.10	0.10	0.10	##	0.07	0.07	##	##	##	##	0.11	0.07		

Relationship Strength:
Strong - 9
Medium-3
Weak - 1

Manufacturer Decision Matrix:

		Model Production Options			
Characteristic	Weight	DialAct	Syndaver	Arterial Solutions	Medtronic
"Learn by doing" factor	5	0	0	1	0
Design Time	5	1	1	-1	0
Cost	4	-1	-1	0	0
Accuracy	3	0.5	1	1	0
Customizability	3	-0.5	-1	1	0
Production Time	2	1	1	-1	0
Shipping Time	1	-0.5	-1	0	0
Repeatability	1	1	1	0	0
Total		3.5	3	4	0

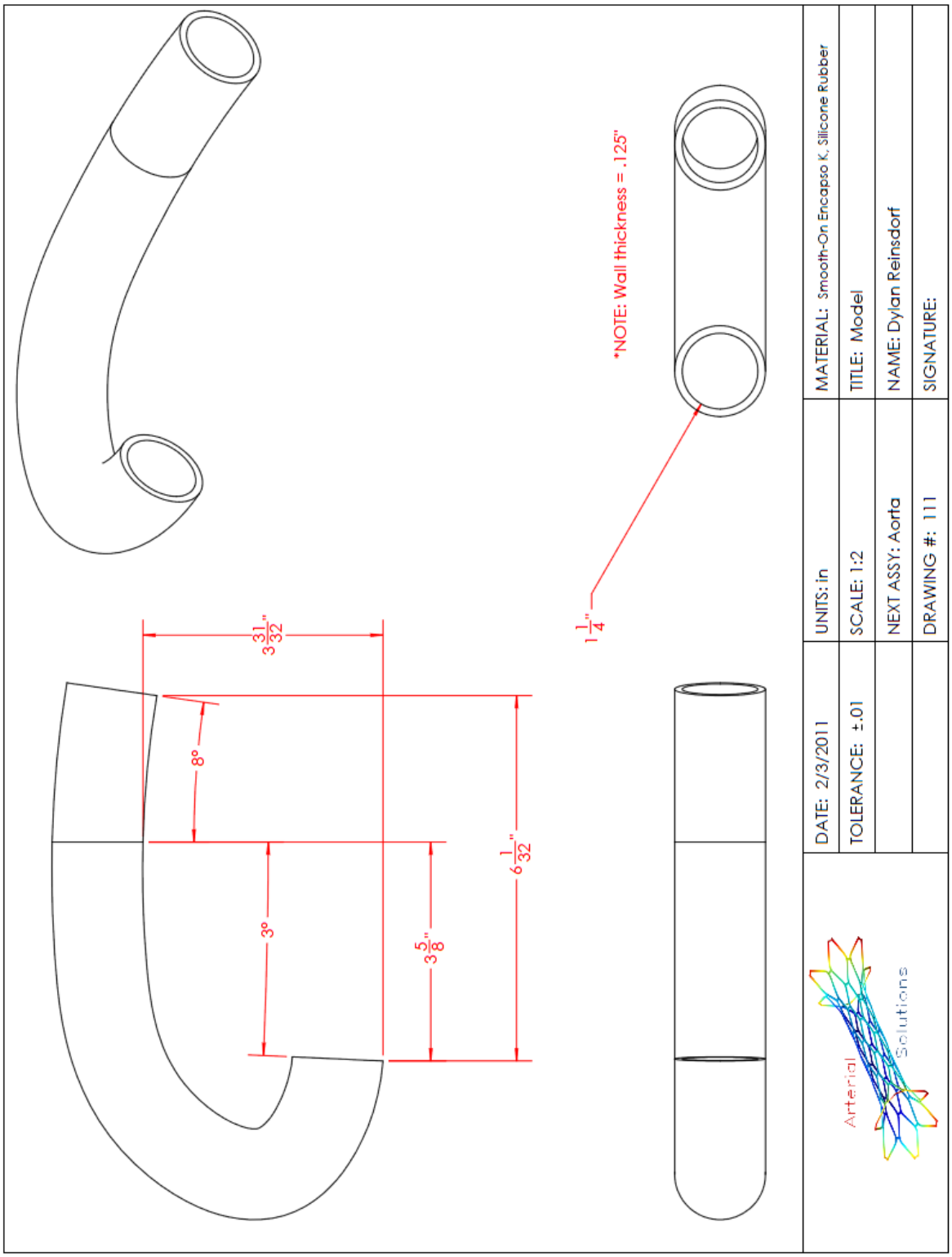
Measurement Method Decision Matrix:

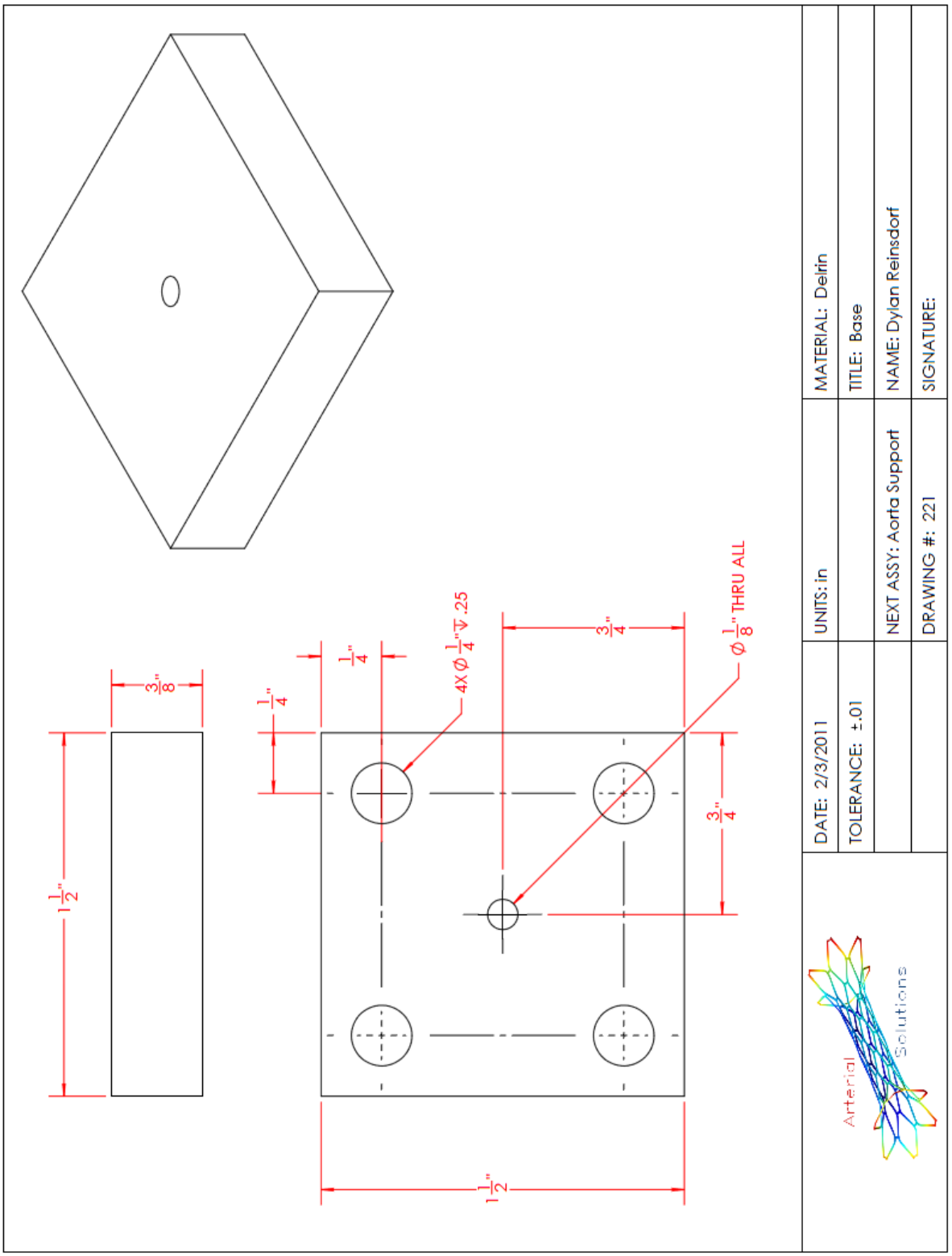
		Conformability Test Method				
Characteristic	Weight	Pressure	Flow Rate	Displacement Sensor	Color Wall	Camera + Computer
Quantifies radial distance	5	-1	-1	1	-1	0
Numerical 3D measurement	4	0	0	1	0	0
Accuracy (sensitivity)	4	-1	-1	1	-1	0
Quantifies w/ wall contact	3	1	-1	0	0	0
Ease of model integration	3	-1	0	0	-1	0
Maintenance (calibration,cleaning, etc)	2	-1	-1	-1	-1	0
Cost	1	0	0	-1	1	0
Ease of specification	1	-1	-1	-1	-1	0
Total		-12	-15	9	-14	0

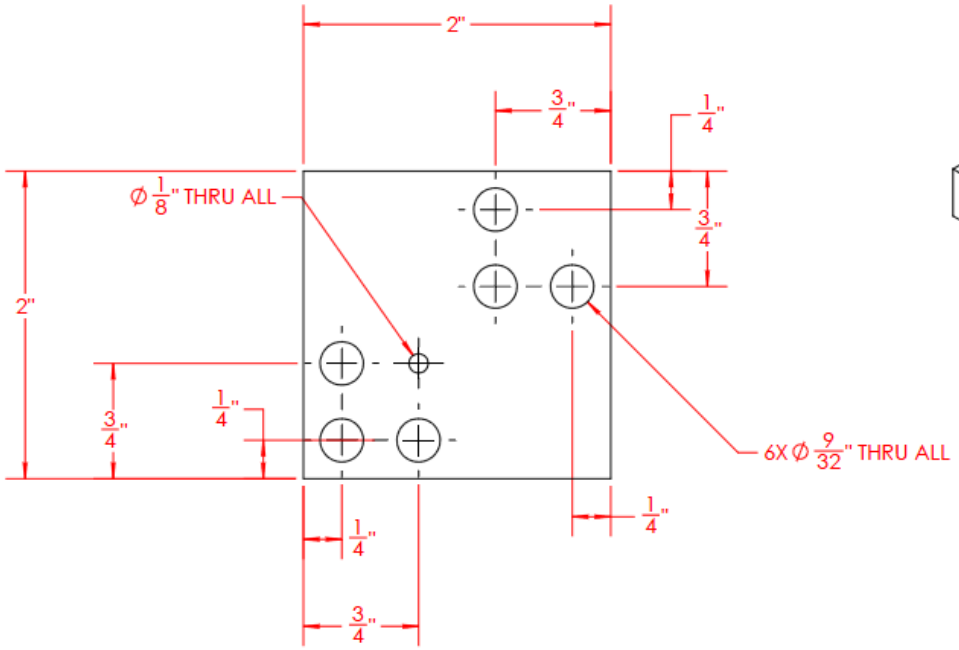
Appendix B: Bill of Materials, list of vendors, contact info and pricing

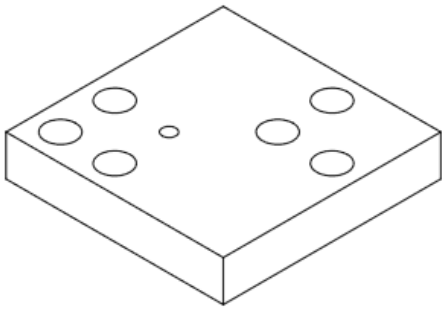
Part #	Component Name	Part Name	Supplier	Quantity Desired	Price/Pkg	Total Price
111	Aorta	Model	Local	1	200.00	200.00
112		Pressure fitting	http://www.mcmaster.com	2	4.61	9.22
211	Pegboard	Board	http://www.mcmaster.com	1	40.72	40.72
212		Feet	http://www.mcmaster.com	6	11.16	11.16
221	Aorta support	Base	http://www.mcmaster.com	1.5"x1.5"x.375"	40.95	40.95
222		High-res base	http://www.mcmaster.com	2"x2"x.375"	40.95	-
223		Column	http://www.mcmaster.com	.375"x.375"x1.75"	40.95	-
224		Sliding pin	http://www.mcmaster.com	6	7.07	7.07
225		Stationary pin	http://www.mcmaster.com	4	7.19	7.19
226		Aorta clamp	http://www.mcmaster.com	2	11.71	11.71
231	Aorta-tank coupling line	Tube	http://www.mcmaster.com	2ft	3.28	6.56
232		Clamp	http://www.mcmaster.com	2	5.34	5.34
233		Pressure fitting	http://www.mcmaster.com	2	9.63	19.26
241	Tank-basin coupling line	Tube	http://www.mcmaster.com	2ft	3.28	6.56
242		Clamp	http://www.mcmaster.com	2	5.34	5.34
243		Pressure fitting	http://www.mcmaster.com	1	9.14	9.14
251	Basin-aorta coupling line	Tube	http://www.mcmaster.com	2ft	3.28	6.56
252		Clamp	http://www.mcmaster.com	2	5.34	-
253		Pressure fitting	http://www.mcmaster.com	1	9.63	9.63
261	Auxiliary tank	Tank	http://aggsons.com/default.aspx	1	100.00	100.00
262		Through-wall fitting	http://www.mcmaster.com	2	18.67	37.34
263		Plug fitting	http://www.mcmaster.com	2	4.68	9.36
311	Sensor	Stent	http://www.mcmaster.com	1	267.00	267.00
312		Aorta wall	http://www.mcmaster.com	1	0 - 1162.00	0 - 1162.00
321	Sensor stand	Lower base plate	http://www.mcmaster.com	2"x2"x.25"	7.22	7.22
322		Mid base plate	http://www.mcmaster.com	2"x2"x.25"	7.22	-
323		Upper base plate	http://www.mcmaster.com	2"x2.25"x.25"	7.22	-
324		Head	http://www.mcmaster.com	2"x3"x.375"	40.95	-
325		Set screw	http://www.mcmaster.com	1	2.15	2.15
326		Positioning pin	http://www.mcmaster.com	1	7.07	-
327		Base pin	http://www.mcmaster.com	1	7.19	-
331	DAQ	Module	http://www.ni.com/	1	169.00	169.00
				Total Cost		998.48-2150.48

Appendix C: Part Drawings

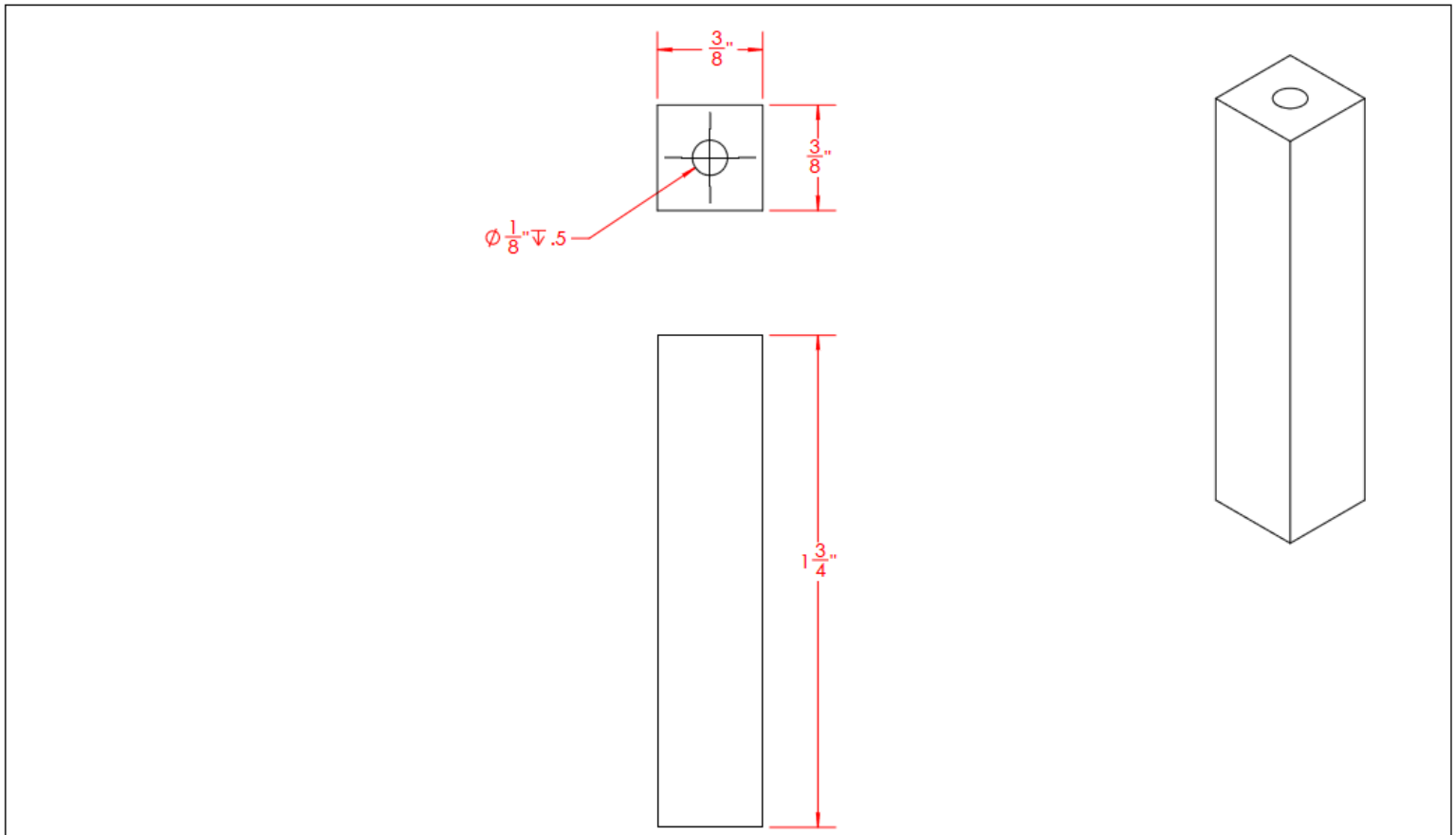



3/8"
1 1/2"
1/4"
1/4"
4X Ø 1/4"↧ .25
3/4"
Ø 1/8" THRU ALL
3/4"
1 1/2"
DATE: 2/3/2011
UNITS: in
MATERIAL: Delrin
TOLERANCE: ±.01
TITLE: Base
NEXT ASSY: Aorta Support
NAME: Dylan Reinsdorf
DRAWING #: 221
SIGNATURE:
Arterial
Solutions

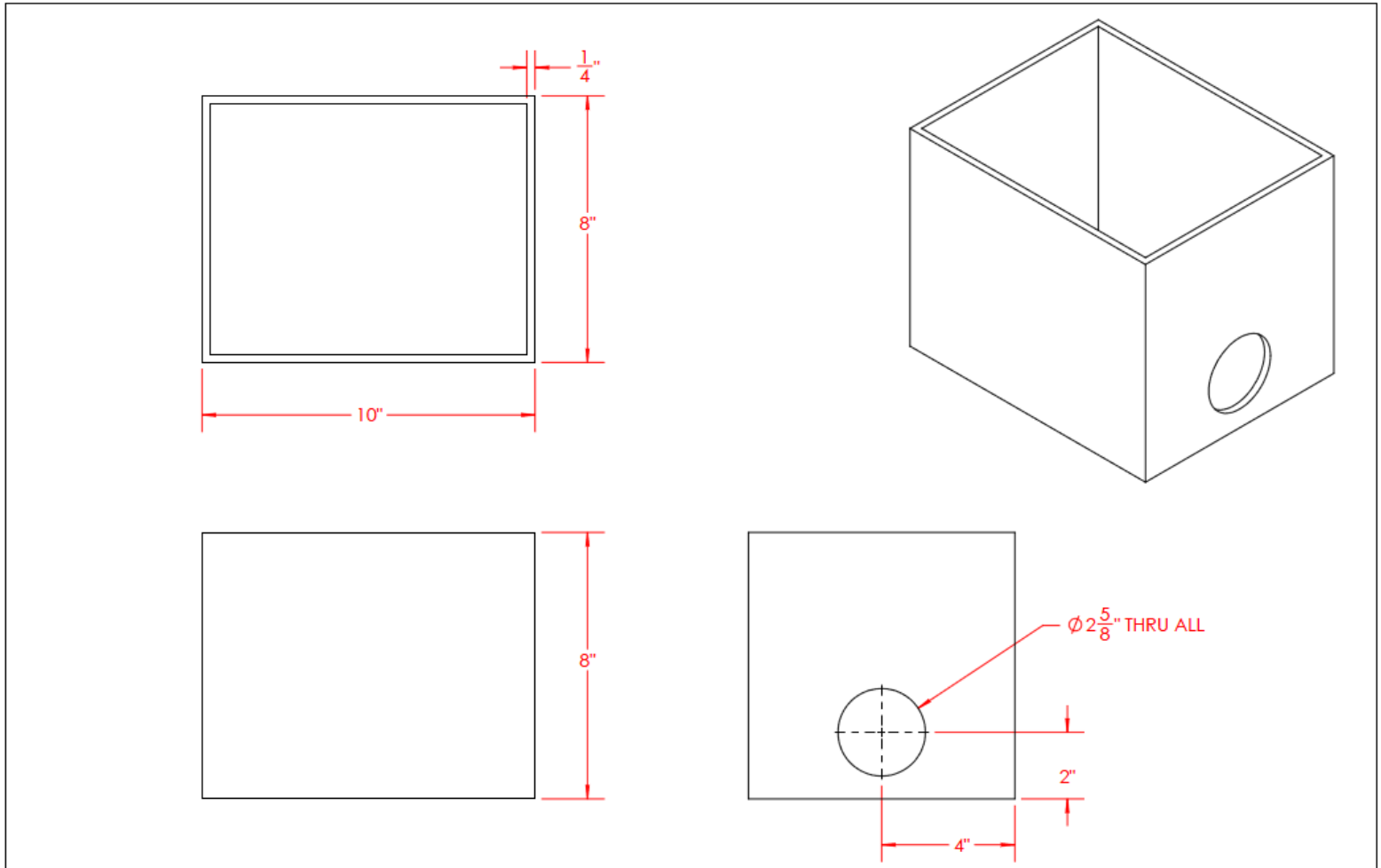




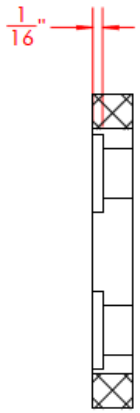
Arterial Solutions	DATE: 2/3/2011	UNITS: in	MATERIAL: Delrin
	TOLERANCE: ±.01	SCALE: 1:1	TITLE: High-res base
		NEXT ASSY: Aorta support high res	NAME: Dylan Reinsdorf
		DRAWING #: 222	SIGNATURE:



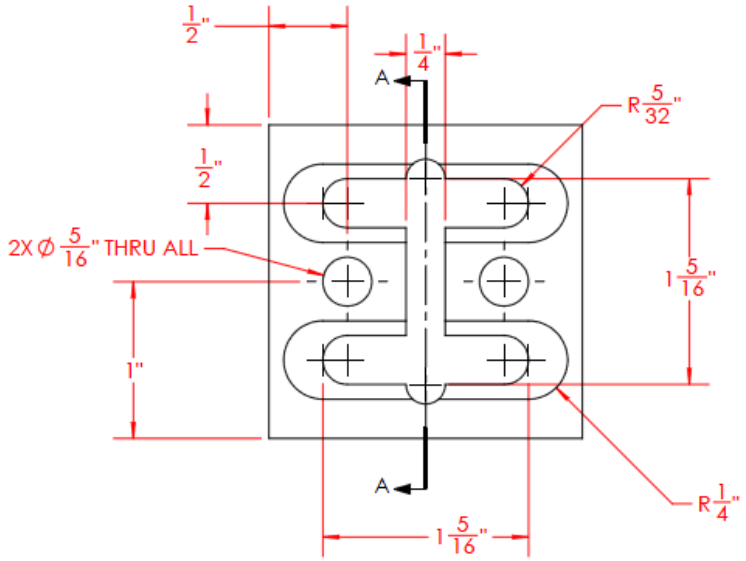
Arterial Solutions	DATE: 2/3/2011	UNITS: in	MATERIAL: Delrin
	TOLERANCE: ±.01	SCALE: 2:1	TITLE: Column
		NEXT ASSY: Aorta support	NAME: Dylan Reinsdorf
		DRAWING #: 223	SIGNATURE:

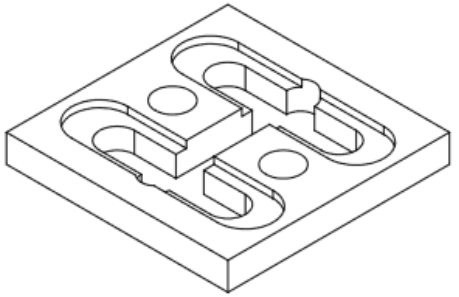


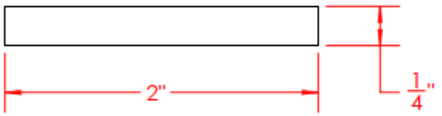
Arterial Solutions	DATE: 2/3/2011	UNITS: in	MATERIAL: Polycarbonate
	TOLERANCE: ±.01	SCALE: 1:4	TITLE: Tank
		NEXT ASSY: Auxiliary tank	NAME: Dylan Reinsdorf
		DRAWING #: 261	SIGNATURE:



SECTION A-A

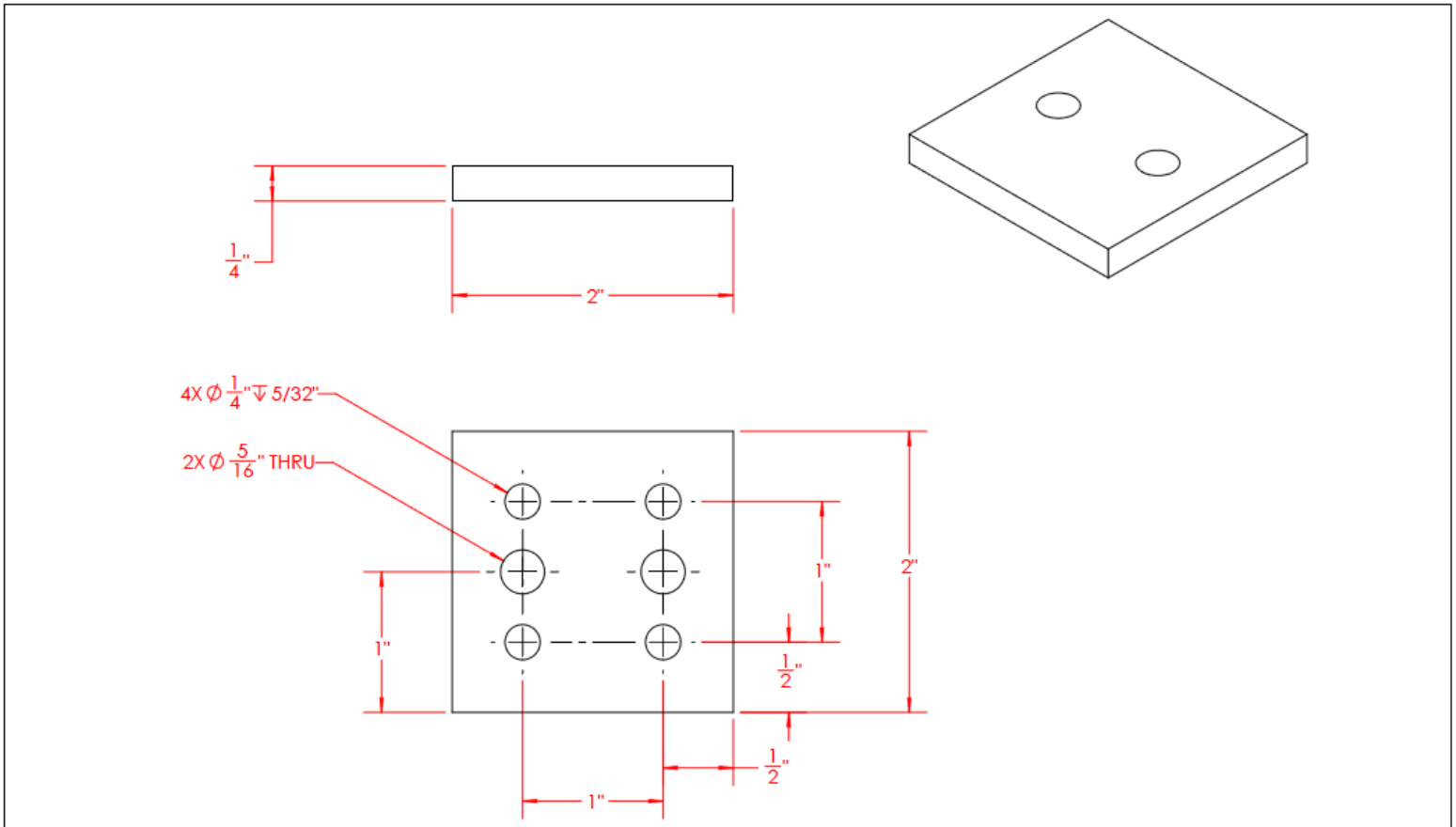




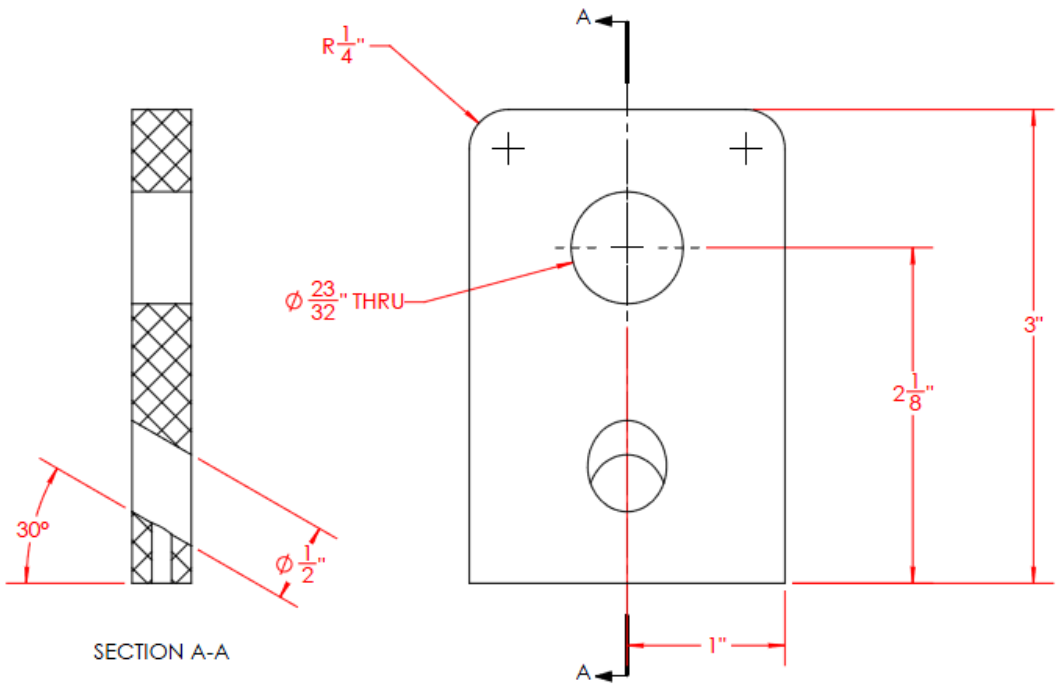


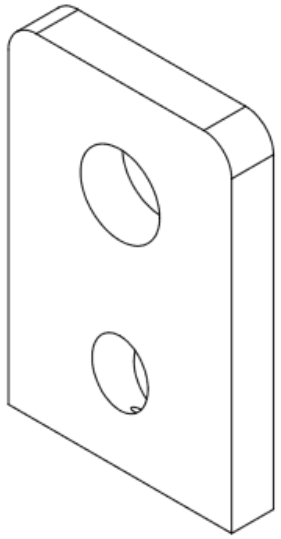
*NOTE: Slot dimensions are equal

Arterial Solutions	DATE: 2/3/2011	UNITS: in	MATERIAL: Delrin
	TOLERANCE: ±.01	SCALE: 1:1	TITLE: Mid base plate
		NEXT ASSY: Sensor stand	NAME: Dylan Reinsdorf
		DRAWING #: 322	SIGNATURE:

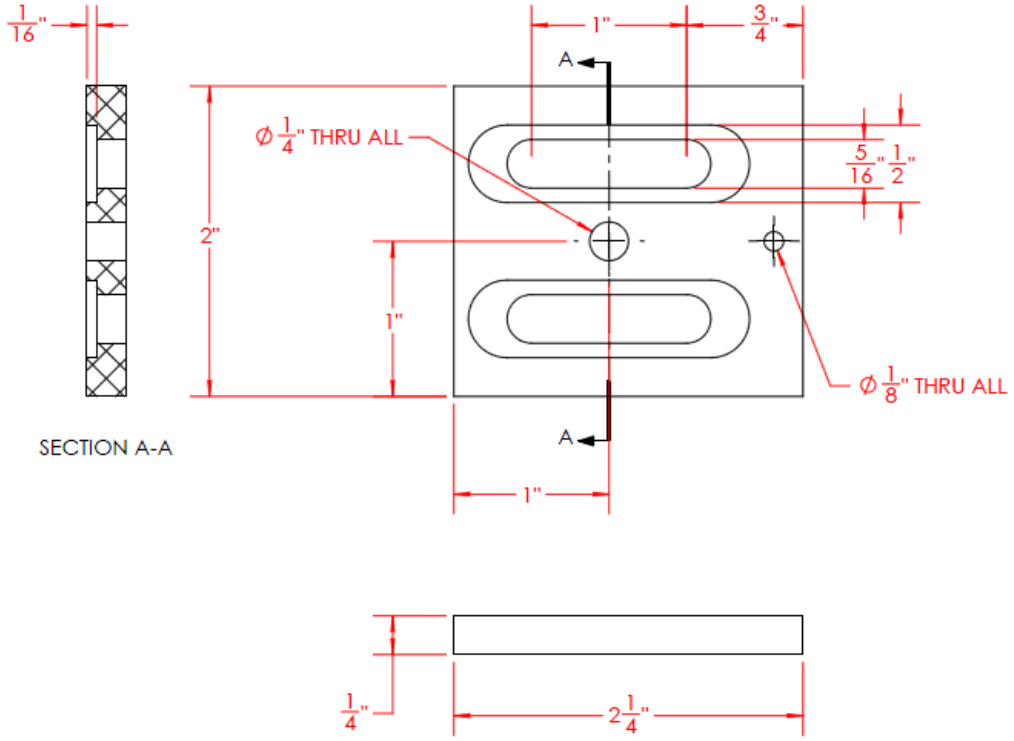


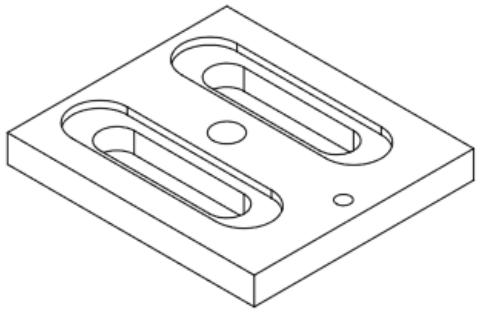
Arterial Solutions	DATE: 2/3/2011	UNITS: in	MATERIAL: Delrin
	TOLERANCE: ±.01	SCALE: 1:1	TITLE: Lower base plate
		NEXT ASSY: Sensor support	NAME: Dylan Reinsdorf
		DRAWING #: 321	SIGNATURE:





Arterial Solutions	DATE: 2/3/2011	UNITS: in	MATERIAL: Delrin
	TOLERANCE: ±.01	SCALE: 1:1	TITLE: Head
		NEXT ASSY: Sensor Stand	NAME: Dylan Reinsdorf
		DRAWING #: 324	SIGNATURE:





*NOTE: Slot dimensions are equal

Arterial Solutions	DATE: 2/3/2011	UNITS: in	MATERIAL: Delrin
	TOLERANCE: ±.01	SCALE: 1:1	TITLE: Upper base plate
		NEXT ASSY: Sensor stand	NAME: Dylan Reinsdorf
		DRAWING #: 323	SIGNATURE:

Appendix D: Vendor component spec sheets

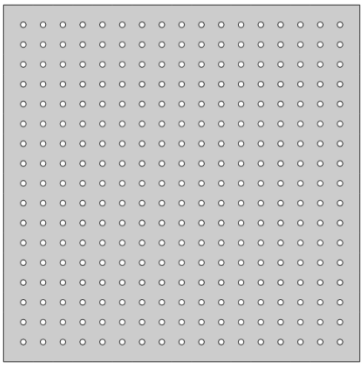
100 SERIES

Component, Part: Aorta, Pressure fitting
Part#: 112

Supplier: McMaster-Carr
Description: Plastic cam-and-groove hose coupling, plug with hose barb connection
Item#: 91105K751
Material: FDA/NSF Polypropylene
Coupling Size: 1.5in
For Hose ID: 1.25in
Max. press. @ 72°F: 100psi
Price: $4.61

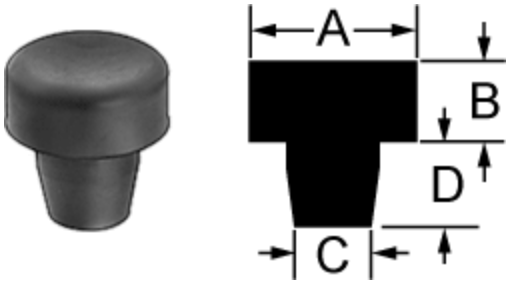
200 SERIES

Component, Part: Pegboard, Board
Part#: 211



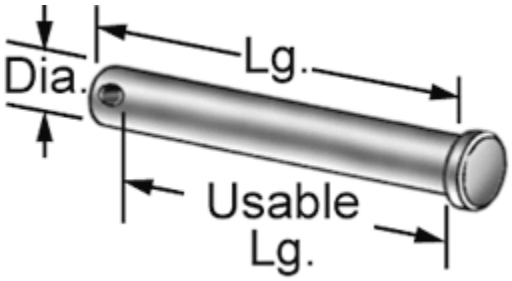
Supplier: McMaster-Carr
Description: Unframed pegboard
Item#: 18615A22
Material: Polypropylene
Length: 36in
Width: 24in
Thickness: .25in
Price: $40.72

Component, Part: Pegboard, Feet
Part#: 212



Supplier: McMaster-Carr
Description: Push-in bumper
Item#: 1638K3
Material: Hard thermoplastic elastomer
Durometer: 75A
A: 7/16in
B: 3/16in
C: 9/32in
D: 1/4in
Price: $11.16

Component, Part: Aorta support, Sliding pin
Part#: 224



Supplier: McMaster-Carr
Description: Clevis pin, w/o cotter pin
Item#: 98306A156
Material: Plain steel
Usable Length: 3/8in
Length: 5/8in
Price: $7.07

Component, Part: Aorta support, Stationary pin
Part#: 225

Supplier: McMaster-Carr
Description: Dowel pin
Item#: 98385A237
Material: Plain steel
Length: 1/2in
Price: $7.13

Component, Part: Aorta support, Aorta clamp
Part#: 226

Supplier: McMaster-Carr
Description: Snap-grip hose and tube clamp
Item#: 5246K74
Material: Nylon
Clamp ID range: 1.25-1.4375in
Price: $11.71

Component, Part: Aorta-tank coupling line, Tube
Part#: 231

Supplier: McMaster-Carr
Description: Plastic cam-and-groove hose coupling, socket with hose barb connection
Item#: 5233K74
Material: PVC
OD: 1.625in
ID: 1.25in
Wall thickness: .1875in
For use with: Air, beverage, food, water
Color: Clear
Specifications met: FDA
Price: $3.28/ft

Component, Part: Aorta-tank coupling line, Clamp
Part#: 232

Supplier: McMaster-Carr
Description: Corrosion-resistant nylon worm drive hose and tube clamp
Item#: 5471K1
Material: Nylon
Clamp ID range: .625-3.5in
Price: $5.34

Component, Part: Aorta-tank coupling line, Pressure fitting
Part#: 233

Supplier:	McMaster-Carr
Description:	Plastic cam-and-groove hose coupling, socket with hose barb connection
Item#:	91105K641
Material:	FDA/NSF Polypropylene
Coupling Size:	1.5in
For Hose ID:	1.25in
Max. press. @ 72°F:	100psi
Price:	$9.63

Component, Part: Tank-basin coupling line, Tube
Part#: 241

Supplier:	McMaster-Carr
Description:	Plastic cam-and-groove hose coupling, socket with hose barb connection
Item#:	5233K74
Material:	PVC
OD:	1.625in
ID:	1.25in
Wall thickness:	.1875in
For use with:	Air, beverage, food, water
Color:	Clear
Specifications met:	FDA

Price: $3.28/ft

Component, Part: Tank-basin coupling line, Clamp
Part#: 242

Supplier: McMaster-Carr
Description: Corrosion-resistant nylon worm drive hose and tube clamp
Item#: 5471K1
Material: Nylon
Clamp ID range: .625-3.5in
Price: $5.34

Component, Part: Tank-basin coupling line, Pressure fitting
Part#: 243

Supplier: McMaster-Carr
Description: Plastic cam-and-groove hose coupling, socket with hose barb connection
Item#: 91105K641
Material: FDA/NSF Polypropylene
Coupling Size: 1.5in
For Hose ID: 1.25in

Component, Part: Basin-aorta coupling line, Tube
Part#: 251

Supplier: McMaster-Carr
Description: Plastic cam-and-groove hose coupling, socket with hose barb connection
Item#: 5233K74
Material: PVC
OD: 1.625in
ID: 1.25in
Wall thickness: .1875in
For use with: Air, beverage, food, water
Color: Clear
Specifications met: FDA
Price: $3.28/ft

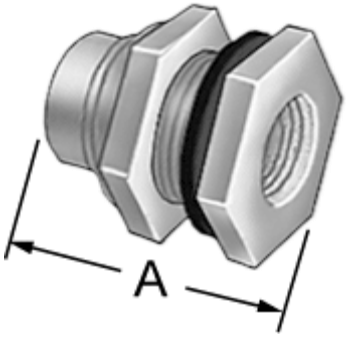
Component, Part: Basin-aorta coupling line, Clamp
Part#: 252

Supplier: McMaster-Carr
Description: Corrosion-resistant nylon worm drive hose and tube clamp
Item#: 5471K1
Material: Nylon
Clamp ID range: .625-3.5in
Price: $5.34

Component, Part: Basin-aorta coupling line, Pressure fitting
Part#: 253

Supplier: McMaster-Carr
Description: Plastic cam-and-groove hose coupling, socket with hose barb connection
Item#: 91105K641
Material: FDA/NSF Polypropylene
Coupling Size: 1.5in
For Hose ID: 1.25in

Component, Part: Auxiliary tank, Through-wall fitting
Part#: 262



Supplier: McMaster-Carr
Description: Through-wall fitting, threaded female x threaded female connection
Item#: 3736K5
Material: Polyethylene
A: 1.75in
Pipe size: 1.25in
Required wall hole size: 2.625in
Max press. @ 72°F: 150psi
For Hose ID: 1.25in
Price: $18.67

Component, Part: Auxiliary tank, Plug fitting
Part#: 263

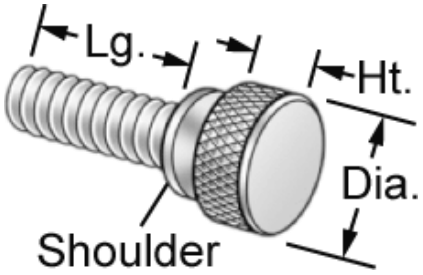
Supplier: McMaster-Carr
Description: Plastic cam-and-groove hose coupling, plug with NPT male threaded connection
Item#: 91105K811
Material: FDA/NSF Polypropylene
Coupling Size: 1.5in
For Hose ID: 1.25in
Max. press. @ 72°F: 100psi
Price: $4.68

300 SERIES

Component, Part: Sensor, Stent
Part#: 311

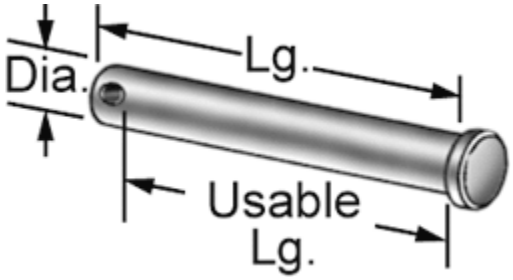
Supplier: Eaton
Description: Inductive, AccuProx analog sensor
Item#: E59-A18C115C02-CV
Size: 18mm OD
Range: 1-15mm
Operating Voltage: 15-30VDC
Price: $267.00

Component, Part: Sensor stand, Set screw
Part#: 325



Supplier: McMaster-Carr
Description: Small diameter knurled-head thumb screw w/ shoulder
Item#: 94567A570
Length: .75in
Head height: .25in
Head diameter: .5in
Price: $2.21

Component, Part: Sensor stand, Positioning pin
Part#: 326



Supplier: McMaster-Carr
Description: Clevis pin, w/o cotter pin
Item#: 98306A156
Material: Plain steel
Usable Length: 3/8in
Length: 5/8in
Price: $7.07

Component, Part: Sensor stand, base pin
Part#: 327

Supplier: McMaster-Carr
Description: Dowel pin
Item#: 98385A237
Material: Plain steel
Length: 1/2in
Price: $7.13

Component, Part: DAQ, Module
Part#: 331

Supplier: National Instruments
Description: Multifunction USB DAQ
Item#: USB-6008
Inputs: 8 analog inputs (12-bit, 10 kS/s)
Outputs: 2 analog outputs (12-bit, 150 S/s); 12 digital I/O; 32-bit counter
Measurement type: Voltage
Voltage range: -10v to 10v
Software Compatibility: LabView
Price: $169.00

Appendix E: Detailed support analysis

Initial Conditions

Geometry

$ID = 30$ [mm] Inner diameter during diastole

Material Properties

$S = 20$ [A] Shore hardness

$\nu = 0.5$ Poisson's ratio

Load

$p_d = 80 \cdot 0.01934$ [psi] Diastolic pressure

$p_s = 160 \cdot 0.01934$ [psi] Systolic pressure

$D_d = 10$ [%] Diametral dialation

Analysis

Geometry

$$a = \frac{ID}{2 \cdot 25.4}$$ Radius during diastole

Material Properties

$E = 10^{(0.0235 \cdot S - 0.6404)} \cdot 145$ [psi] Elastic modulus - valid for 20<S<80

Load

$$r_d = \frac{D_d}{2 \cdot 100}$$ Radial dialation

$p_{net} = p_s - p_d$

Displacement - Thin Wall

$$u_{a,s,thin} = p_{net} \cdot \frac{a^2}{E \cdot t}$$ Inner surface radial displacement during systole

$u_{a,s,thin} = (1 + r_d) \cdot a - a$

Check Thin Wall Assumption: a/t > 10

$$Check_{thin} = \frac{a}{t}$$

Displacement - Thick Wall

$u_{a,s,thick} = (1 + r_d) \cdot a - a$

$$u_{a,s,thick} = a \cdot \frac{p_{net}}{E} \cdot \left[\frac{a^2 + b^2}{b^2 - a^2} + \nu \right]$$ Inner surface radial displacement during systole

Results

$t_{thin} = t \cdot 25.4$ Required thickness assuming a thin walled presure vessel

$t_{thick} = (b - a) \cdot 25.4$ Required thickness assuming a thick walled presure vessel

Listed below in Tables and are the wall thickness calculation results.

Wall thickness determination for 120/80 mmHg, 10% diametral dilation

Inner Diameter (mm)	Shore Hardness (A)	Wall Thickness (mm)
20	20	1.89
	40	0.57
	50	0.31
25	20	2.36
	40	0.67
	50	0.39
30	20	2.84
	40	0.80
	50	0.47
35	20	3.31
	40	0.94
	50	0.55

Wall thickness determination for 160/80 mmHg, 10% diametral dilation

Inner Diameter (mm)	Shore Hardness (A)	Wall Thickness (mm)
20	20	4.84
	40	1.20
	50	0.62
25	20	6.05
	40	1.50
	50	0.78
30	20	7.25
	40	1.80
	50	1.00
35	20	8.46
	40	2.11
	50	1.09

Appendix F: Gantt chart