DESIGN AND EMBODIMENT OF A NOVEL ADJUSTABLE ACTIVE CARDIAC SUPPORT DEVICE SYSTEM

A Thesis

by

JOHN ALEXANDER MIMS

Submitted to the Office of Graduate Studies of
Texas A&M University
in partial fulfillment of the requirements for the degree of

MASTER OF SCIENCE

August 2009

Major Subject: Biomedical Engineering

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Approved by:

Chair of Committee,	John Criscione
Committee Members,	Michael Johnson
	Duncan Maitland
Head of Department,	Gerard Coté

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ABSTRACT

Design and Embodiment of a Novel
Adjustable Active Cardiac Support Device System. (August 2009)
John Alexander Mims, B.S., The University of Texas at Austin
Chair of Advisory Committee: Dr. John C. Criscione

The American Heart Association estimates that congestive heart failure (CHF) affects over 5 million people in the United States. Recent research indicates that current pharmacological therapies have limitations in their ability to treat end-stage heart failure patients. Device based therapies that provide passive support and active assist through altering the stress environment to reduce end diastolic volume and increase stroke work may be beneficial in overcoming the limitations of simply just increasing the use of pharmacological therapies; however, current devices are inadequate in their design to restore natural heart mechanics. Dr. John C. Criscione of Texas A&M has proposed a minimally invasive adjustable active cardiac support device (AACSD) that promotes natural heart mechanics using passive support and active assist. Design research, using FDA Design Controls, is necessary to supplement prototyping to develop and embody a design for manufacture for continued proof-of-concept studies in ovines.

The design research consists of identifying user needs and functionality of the AACSD for the development of design specifications that drive the design process for the selection of a suitable concept for the AACSD. With a concept selected, geometry and materials of the device are selected to embody a design for manufacture. A parts list, engineering drawings, and assembly instructions allow for the manufacture of the device. Finally, a failure modes and effects analysis allows for evaluation of the design and recommendations for future design research. The design research successfully identified an embodied design for manufacture that will aid in further development of the AACSD as a future therapy for CHF.

DEDICATION

I dedicate this thesis to my mother and father, whose love and support have carried me through every day.

ACKNOWLEDGEMENTS

The research presented in this thesis has been the work of many individuals. I am grateful to all those who have provided me this blessed opportunity to further develop my engineering skills and satisfy my eternal thirst for knowledge in a field that I so love.

First and foremost, I would like to thank my committee chair, Dr. John C. Criscione, for providing me the opportunity to work on such an interesting project with truly wonderful people, and offering his time, assistance, patience, and knowledge throughout the process. I would also like to thank Dr. Duncan Maitland and Dr. Michael Johnson for readily offering support and their invaluable insight throughout the process and sharing their knowledge of medical device design from an industry and academic perspective.

To the entire lab of Dr. Criscione, including Dr. Michael Moreno and Lewis Harrison, thank you for sharing your experience in prototyping the device, and to fellow students Christina Nazzal, Kelly Sheppard, Avni Patel, and Matthew Jackson, thank you for your continued assistance in matters pertaining to the research, and life outside of it. To all faculty and staff of the Texas A&M Biomedical Engineering Department, thank you for providing a welcoming and enlightening environment for my graduate studies. Finally I offer my sincere gratitude to my parents, brother, and friends who have put up with my attempt at a sense of humor while returning their total love and support throughout my time at Texas A&M. These people have brought me to where I am today, and these people are who I will work my hardest to make proud tomorrow as the only true repayment I can offer for their generosity.

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1. INTRODUCTION

Congestive heart failure (CHF) is a serious disease widely prevalent in society. In 2005, CHF affected approximately 5,300,000 adults over the age of 20, and contributed to 284,365 deaths (AHA, 2008). The estimated costs due to CHF in the United States for 2008 are $34.8 billion, with $31.7 billion coming from direct costs of hospitals, nursing homes, physicians, and drugs (AHA, 2008).

In CHF, the heart undergoes changes on the anatomical, cellular, molecular, and genetic scales (Scoote et al., 2006). Anatomical response is present in the form of cardiac remodeling, which results in dilatation of the heart. The dilated heart is associated with increased ventricular geometry towards a more spherical shape and reduced ventricular wall thickness, which adversely affects cardiac function (Scoote et al., 2006). The cardiac output (CO) of the heart is a function of the stretch, or preload, of the muscle fibers before contraction. This stretch is a function of end diastolic pressure (EDP). In response to reduced CO, the heart's intrinsic response is to increase the preloading of the fibers. In normal operation of non-failing hearts, this increased preloading results in increased contractility and increased CO; this is known as the Frank-Starling Law and can be seen in the normal heart curve in Fig. 1 (Nicholson, 2007).

The elevated EDP affects the geometry of the left ventricle. As EDP rises, increased pressure is placed on the ventricular wall, resulting in distention of the ventricle and an increase end diastolic volume (EDV). Chronic distention of the heart results in detrimental cardiac remodeling that permanently dilates the heart; this results in weakening of the heart and decreased cardiac efficiency, as can be seen by the downward shift of the failed heart curve in Fig. 1. This is due to the increase in energy needed to contract the heart due to the higher tensions from the over-stretching of the muscle fibers, known as the Laplace effect (Nicholson, 2007). The process eventually results in inadequate cardiac function, leading to the death of the patient.

This thesis follows the style of the Journal of Biomechanics.

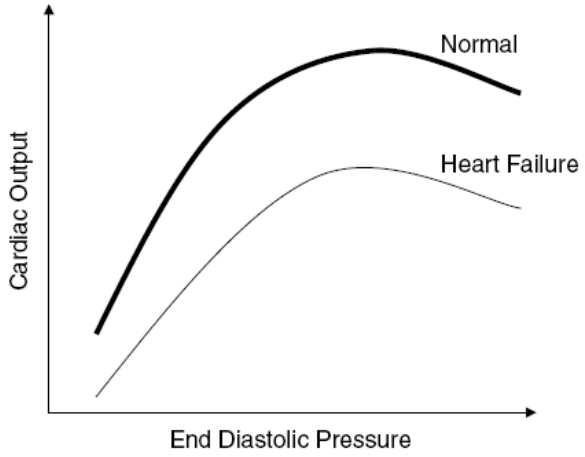


Fig. 1. Relationship between EDP and CO for normal and failing hearts. Figure from Nicholson (2008).

Current CHF therapies are insufficient in reducing cardiac dilatation and restoring natural heart function, creating a significant need for alternative treatment for CHF. The development of an adjustable active cardiac assist device (AACSD) will enable a minimally invasive treatment option for patients with CHF that limits further heart dilatation by applying passive support, and restores natural cardiac motion by offering active assist. The development of such an innovative Class III cardiac device is a lengthy process that requires thorough design research, bench top testing, prototyping, and animal studies before a design can be developed for clinical trials.

The project scope is to perform design research towards the design and embodiment of the implantable components of the AACSD. Implementation of the design process and embodied design proposed allows for the manufacture of a prototype for verification and validation of the design process and the embodied concept with continued proof-of-concept studies. Once implemented, the design process can be applied to future device iterations for continued development of the AACSD.

2. BACKGROUND

2.1 Current Device Therapies for CHF

Pharmacological therapies have been largely unsuccessful in overcoming the progression of CHF. Recent studies have even indicated that increased pharmacological therapies may not be safe or effective (Mancini and Burkhoff, 2005). As the change in stresses in the myocardium has become better understood, the development of device based therapies that target the changed stress environment has increased (Mancini and Burkhoff, 2005). Devices that focus on the application of mechanical forces are classified into blood contacting devices and heart contacting devices, which by nature do not contact the blood. Blood contacting devices present the nontrivial problem of making the device hemo-compatible to limit complications from adverse reactions with the blood. Mechanical devices that contact the blood include left ventricular assist devices and intra-aortic balloon pump counter-pulsation devices.

Heart contacting devices are based on the discovery that wrapping the latissimus dorsi muscle (LDM) around the heart for passive support (known as static cardiomyoplasty), or for assistance through stimulation of the LDM with electrodes (known as dynamic cardiomyoplasty), resulted in opposition to dilatation and systolic augmentation, respectively (Vaynblat et al., 1997). While the benefits of dynamic cardiomyoplasty have shown to be limited, the benefits of static cardiomyoplasty were encouraging due to the "girdling effect" the muscle offered (Power et al., 2003). These benefits have driven the development for heart contacting devices that can be employed in a less invasive manner and composed of a prosthetic material with more suitable mechanical properties (Power et al., 2003).

These devices can further be classified into cardiac support devices (CSDs) and direct cardiac compression devices (DCCDs). CSDs focus on limiting further dilatation of the heart using passive mechanical support to offer resistance to the increased EDP. There are currently no comparable Food & Drug Administration (FDA) approved CSDs on the market; however, two notable CSDs are currently under development, and in

clinical trials that have produced favorable results. These studies indicate CSDs result in the reduction of mechanical wall stress, improved function, and reverse remodeling (Feindt et al., 2005). One such device is Acorn Cardiovascular's CorCap, seen in Fig. 2, which utilizes an inelastic polyester mesh that is wrapped around the heart through an invasive procedure. Previous studies on the CorCap show its use provides a significant increase in left ventricular ejection fraction (Power et al., 2003), and reduced left ventricular volume and sphericity (Starling et al., 2007). Despite its benefits, the CorCap possesses two significant concerns in its design: the invasive procedure needed for its deployment around the heart and the inability of the inelastic mesh to adapt to the reduced heart size to provide adequate passive support. The second prominent CSD in development is Paracor Medical's HeartNet, seen in Fig. 3, which utilizes an elastic nitinol frame deployed around the heart in a minimally invasive procedure. Such a design addresses the concerns of the CorCap (Klodell Jr. et al., 2008); however a new concern of the design is introduced: the inability of the highly compliant nitinol mesh to provide ample resistance to increasing EDPs.

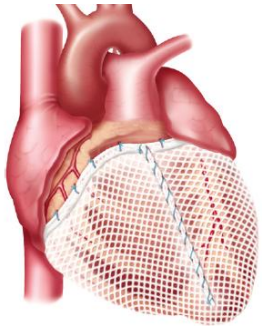


Fig. 2. Depiction of CorCap around the heart. Figure from Power et al. (2003)

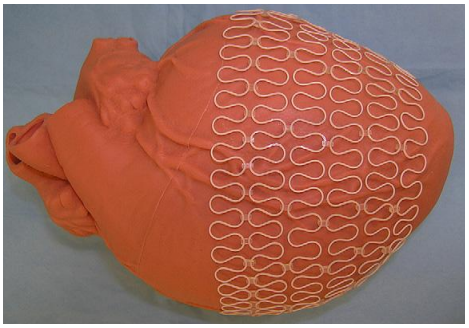


Fig. 3. HeartNet around a model heart. Figure from Klodell Jr. et al (2008)

DCCDs focus on active assist to promote more effective pumping of the heart through active mechanical forces. One notable DCCD is the Anstadt Cup, which is composed of a silicone bladder, as seen in Fig. 4. The bladder is pneumatically filled

and emptied, based on the cardiac cycle, to provide systolic and diastolic augmentation. Studies show the Anstadt cup is effective at improving pump performance (Anstadt et al., 2002); however, a principal concern of the device is that the design further promotes abnormal growth and remodeling of the heart.

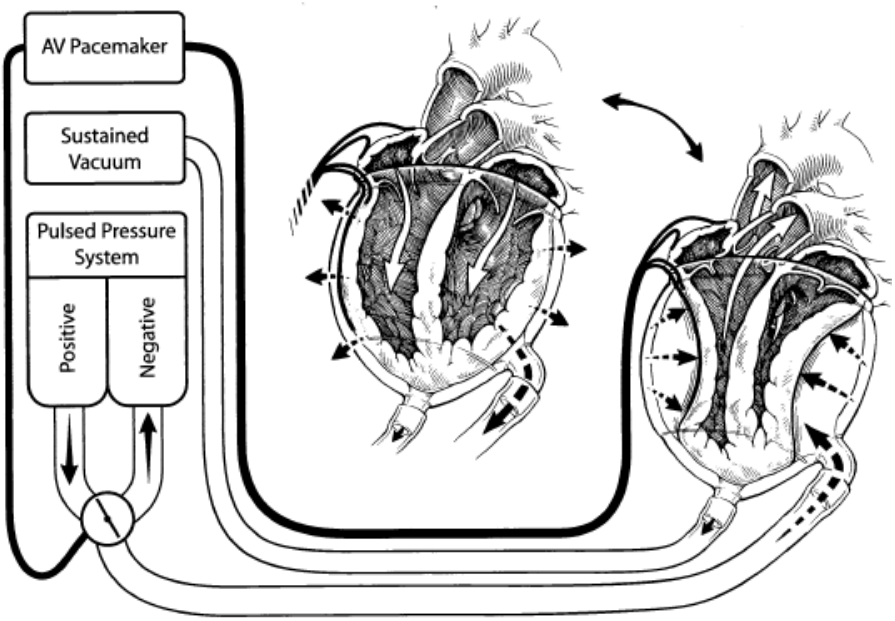


Fig. 4. Depiction of Anstadt cup and drive system. Figure from Anstadt et al. (2002).

2.2 Use of Injection Ports and Transcutaneous Lines in Industry

Subcutaneous injection ports have extensive use with patients requiring long term internal access for the delivery of drugs and withdrawal of blood. While most are utilized to gain venous access, these ports can and are often used for other purposes requiring subcutaneous access; examples of devices that utilize injection ports to fill balloons include tissue expanders and adjustable gastric bands, such as the REALIZE Band and the LAP-BAND.

For instances where continued internal access is needed, the healthcare industry utilizes transcutaneous lines; these include singular devices, such as percutaneous

catheters, and separate devices that utilize these lines, such as left-ventricular assist devices. Examples of percutaneous catheters include central venous catheters (CVCs), peripherally inserted central catheters (PICCs), and midline catheters. Catheters are made for short-term implantation (< 30 days) and long-term implantation (> 30 days). Risk of infection has been a primary concern for long-term percutaneous catheters, and many catheters possess additional features to reduce the risk of infection.

Long-term catheters are made of highly biocompatible materials and may possess a cuff to promote tissue growth as a means for reducing the risk of infection; these catheters are known as tunneled catheters. Non-tunneled catheters account for the largest percentage of catheter related infections (compared to non-transcutaneous catheters and tunneled catheters), while tunneled catheters have a significantly lower risk of infection compared to non-tunneled catheters (CDC&P, 2002). While most catheters generally resemble open tubes, some catheters include an internal valve to prevent unwanted flow of media through the catheter for the purpose of reducing the risk of blood clots and eliminating the need for heparin flushes.

3. RESEARCH AND DEVELOPMENT OF AASCD

3.1 AACSD Architecture

The AACSD system comprises of the following sub-systems: implantable components, delivery components, and external components. The implantable components consist of a novel collapsible cup, a subcutaneous injection port, and a percutaneous drive line. The novel cup comprises of a frame scaffold, bladders for passive support and active assist, and components to provide support for the cup. The delivery components consist of a deployer tube to clear access to the pericardial space and guide the collapsed cup for expansion around the apex of the heart. The external components include a driver for the active system, pumps to fill and remove air from the active bladders, and equipment to monitor the performance of the device and the heart, such as electrocardiogram (ECG) wires and pressure catheters.

The architecture of the implantable sub-system is shown in Fig. 5. The cup is implanted beneath the pericardium and around the dilated heart. The cup's bladders are controlled through two mechanisms, a passive control system and an active control system. Adjustment of volume in the passive bladder, through saline injections into the port, allows the passive system to offer variable support to the heart. Adjustment of the volume of the active bladder allows the active system to offer cyclical assist to the heart. The active bladder volume is adjusted by the pumps that are connected to the external system with a drive line to cycle air in and out of the bladder in sync with the cardiac cycle. When activated, a custom LabVIEW based driver utilizes ECG gating to open and close solenoid valves to control the flow of air to the active bladder. During the onset of systole, air is pumped into the active bladder. After a prescribed period based on the ovine's ECG waveform, the air is cycled out of the active bladder using a trigger relay switch and solenoid valves.

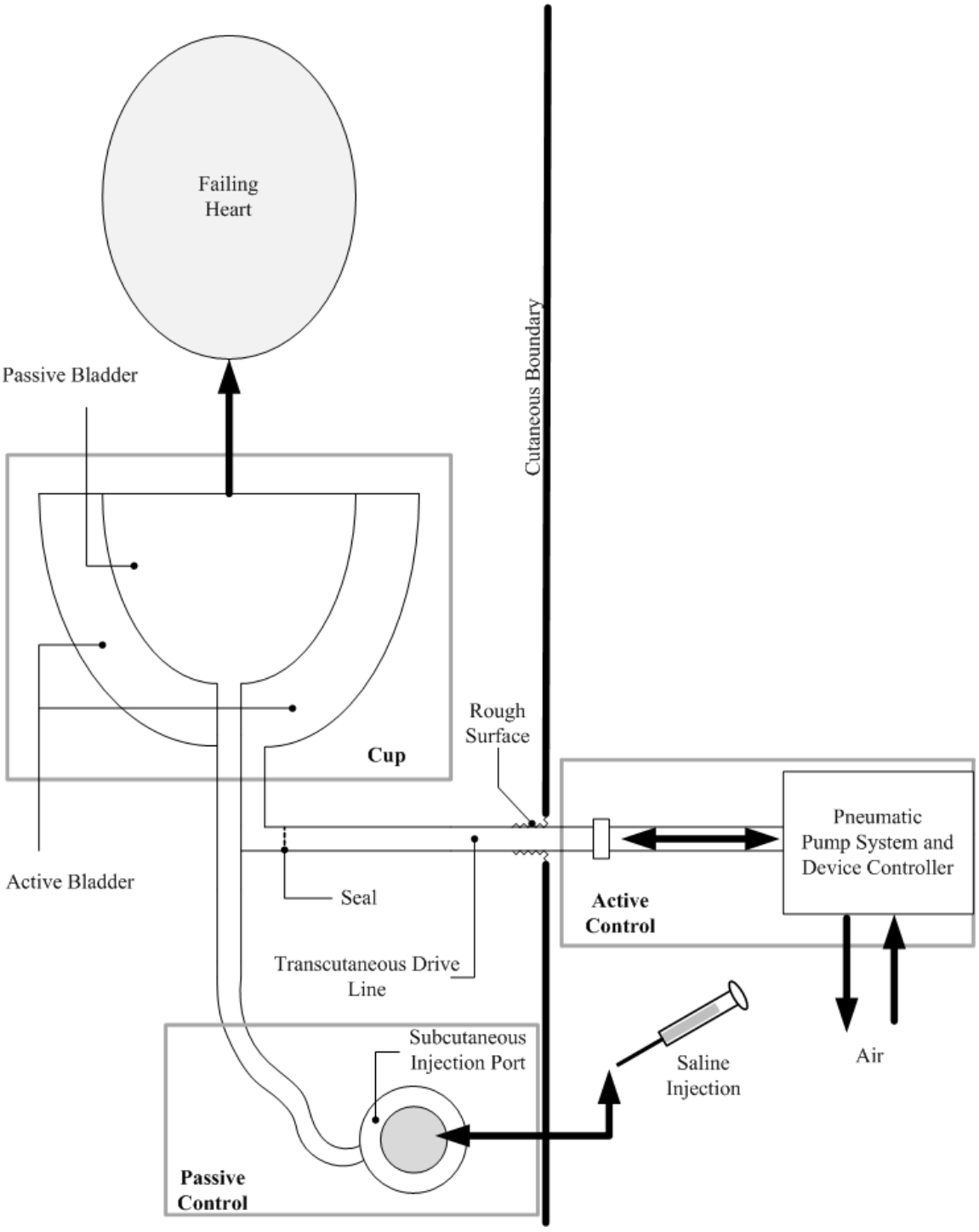


Fig. 5. Device architecture for the implantable components of the AACSD. Interaction with external components to provide the passive support and active assist are also shown.

3.2 Deployment and Operation of the AACSD

Due to their compromised state, CHF patients are not suitable candidates for open-heart surgery; therefore, a minimally invasive implantation method is needed. For implantation, a small incision is made in the chest. The collapsed cup is placed in the terminal end of the deployer tube, and the deployer tube is inserted into the incision. The deployer tube consists of a curved tubular frame that clears the pericardial space to gain access to the heart apex. Upon exiting the deployer tube, the device frame expands the cup from its collapsed state and the cup is guided over the heart. Once all components of the implantable system are in place, the ovine is sewn-up and device operation can begin.

The primary function of the device is to provide passive support. Operation of the passive system occurs for as long as the heart is in need of passive constraint to reduce EDV. Expected duration of passive operation is on the order of weeks, but may vary by the severity the failed heart. If active assist is required, the assist may be employed to supplement the passive support in the most severe cases, when the heart is in need of increased systolic performance to restore blood flow or re-perfuse the kidneys. The active assist will be operated for short durations when needed.

The therapy is intended to gradually wean the heart from the device by reducing heart size and restoring normal heart function. Heart function is restored by promoting normal growth and remodeling in the heart that replaces entire muscle fibers every two weeks. Once active assist is no longer needed, the drive line is removed, and the passive support remains as the sole function of the device. Once passive support is no longer needed, the passive bladder is drained and the device remains implanted around the heart in a dormant state without rigidly constraining the heart or inhibiting cardiac performance.

Unlike other CSDs that offer support through the elasticity of materials, the fluid filled bladders mimic the heart's natural environment – lungs that act as a damper to heart motion. The fluid filled bladders encompass the heart in a similar dampening environment. A vital function of the device is the ability to adjust the volume of the

bladders to conform the cup to the size of the heart, without offering rigid constraint. Feedback for determining appropriate adjustments for the bladder volumes is based on the ovine's central venous pressure (CVP). This feedback system ensures damage to the heart from over inflation of the bladders does not occur. The operating pressures of the device are expected to remain around 20 cm H_2O.

3.3 Prior AACSD Prototypes

Previous prototyping by Dr. Criscione and his lab has focused predominantly on the generation of a variety of different configurations for bench top prototypes to test the kinematics, feasibility, and performance of the design. Some configurations contained passive support and active assist, and others only passive support. Fig. 6 shows a previous prototype with helically shaped passive bladders forming the internal cup. Configurations for improving deployment include the development of internal components to help flare the frame and configurations to better integrate the cup with the deployer tube.

Fig. 6. Helical passive bladders forming the cup interior of a previous prototype.

Prototypes for previous animal studies have been configured for acute studies with invasive deployment, such as in Fig. 7. Prototyping for interfacing with an implantable subcutaneous injection port and transcutaneous drive line has been limited. Instead, prototypes used in ovine proof-of-concept studies consisted of an assembly of tubes, wires, and catheters that connected to the external drive system, as shown in Fig. 8; however, the bulky nature of the assembly of tubes is problematic for preventing infection. Design of a concept for integration with an injection port and drive line must be addressed.

While prototyping has developed a variety of designs for testing, embodiment for manufacture has been limited. The prototypes have been constructed of non-medical grade materials, and concerns for manufacture of a prototype have not been a significant part of the design process. To advance the development of the AACSD, these issues of design embodiment must be addressed.

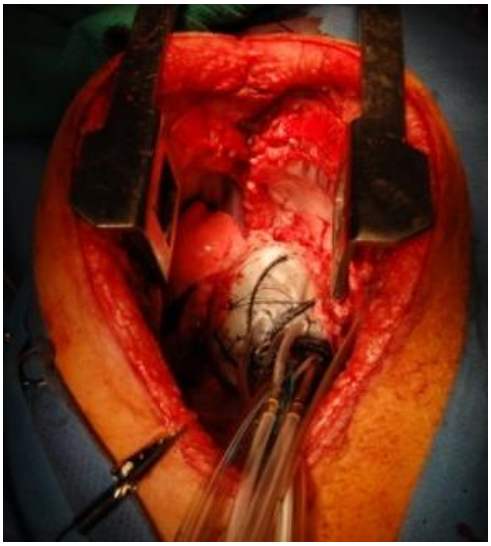


Fig. 7. Previous prototype implanted in an invasive manner during an animal study.

Fig. 8. View of percutaneous lines for inflating the active bladder in a previous prototype.

3.4 Results of Previous Animal Studies

Acute animal studies in ovines have been previously performed by Dr. Criscione and his research group to test the AACSD. When the cup is in use, the increased rigidity of the cup, along with the removal of air in the chest cavity after implantation, draws the heart to the cup to prevent the heart from dislodging. These proof-of-concept studies confirm the hypothesis that the passive support reduces the left ventricle size and active assist, if even for only 10 cardiac cycles, increases stroke work (Criscione, 2008). In addition, when the device was not in use, the non-rigid cup did not interfere with cardiac function; cardiac parameters, such as cardiac output, CVP, wedge pressure, and aortic pressure, were not significantly different when the device was not in use than prior to the implantation (Criscione, 2008). These results compare favorably to results of other CSDs and DCCDs; however the design offers advantages over other CSDs and DCCDs in that the adjustment of bladder volume allows for proper sizing of the device to adequately provide continued end-diastolic support as the heart reduces in size, and the design promotes natural growth and remodeling. While further studies are needed to completely understand the potential of this therapy and optimize a device for treatment, the results of these studies support the continued development of an embodied design to advance the design process.

4. DESIGN PLAN FOR COMPLETING AIM I AND AIM II

The design plan utilized for the embodiment of the AACSD, shown in Fig. 9, follows the use of design controls as recommended by the FDA in their guidance document "Design Control Guidance for Medical Device Manufacturers". Due to the novelty of the cup, this design plan model is needed for maintaining a quality system. Unlike the novel cup, the availability of FDA approved subcutaneous injection ports and transcutaneous lines allow for the use of an approved port and drive line to be interfaced with the cup, rather than the design of a custom port and drive line. Utilizing components for the AACSD system that have prior FDA approval allows for the focus to remain on the novel cup design and its interfacing with the port and drive line.

This plan utilizes a waterfall approach; the outputs of one phase are also the inputs for the subsequent phase. Modeling the design plan of the research after this plan possesses two significant benefits. The first is the design plan has been proven to set up a structure for verifying the design output maps to the design input, and validating the medical device maps to the user needs. Secondly, the model allows for the design plan to be easily translated to future iterations of the design as different features are tested and evaluated later on.

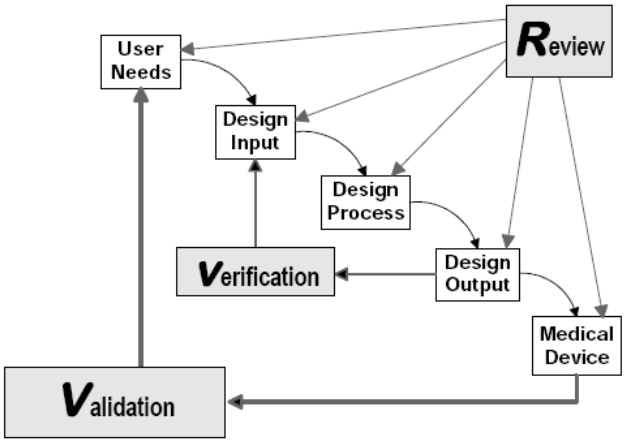


Fig. 9. FDA Design Control process. Figure from FDA (1997).

5. AIM I: PROBLEM STATEMENT

The first specific aim is to develop a concept of a novel AACSD system for use towards the development of a manufactured prototype. The design control process will be used in completing Aim I. The initial phase is identifying and classifying the user needs. Defining the user needs accurately is vital for ensuring the end product is something the user will desire. The vagueness and subjectivity of user needs make them insufficient as criteria for developing a quality design; therefore a more explicit and objective criteria is needed. To obtain these criteria, the classified user needs are used to develop the design inputs. The purpose of the design input phase is to establish design requirements for the design process phase that will map to user needs. In addition, this phase is the basis for verification that the product meets the original design requirements. Inputs into the design input phase are the user needs, and the outputs are the design requirements. The design process phase consists of concept generation for each implantable component, and the selection of the best concept based on the design specification criteria generated.

The deliverables for Aim I include a design specification sheet for the AACSD cup, selection criteria for identifying suitable port and drive line candidates, and generating concepts for consideration. Finally, the selection of the best cup concept, port, and driveline for integration into the AACSD implantable sub-system is performed based on the design input criteria.

This design research supplements the prototyping research also being performed by Dr. Criscione and his lab. The primary focus of the design research is to obtain a cup concept, port, and drive line by going through the design process; however verification of the design input criteria must be done through prototyping research and is not the focus of the design research.

6. USER NEEDS

6.1 Interactions between the User and the AACSD

To analyze the user needs based on product-user interaction, an activity diagram was created, seen in Fig. 10. Activity diagrams identify customer needs by examining customer and product interaction, and characterize the needs into categorized specific needs (Otto and Wood, 2001). The activity diagram begins with user's first interaction with the product, and ends with removal of the device from the ovine. The activity diagram can be broken into five stages: preparation, implantation, operation, dormancy, and explantation. From the diagram it is seen that the surgeon is the direct user of the device and the patient is an indirect user. Target patients for this device are end-stage heart failure patients that are not eligible for a heart transplant list, so a therapy such as the one proposed is a last resort. The importance of user-device interaction on user needs is evident; particularly so during the implantation stage and the operation stage. The surgeon's need for ease of user interaction during device implantation and operation is vital for meeting the needs of the patient, safety and proper performance. Finally, product quality is important to ensure each of the functions in the operation stage can be performed as required. The following categories for classifying user needs are identified: product performance, patient safety, ease of user interaction, and product quality.

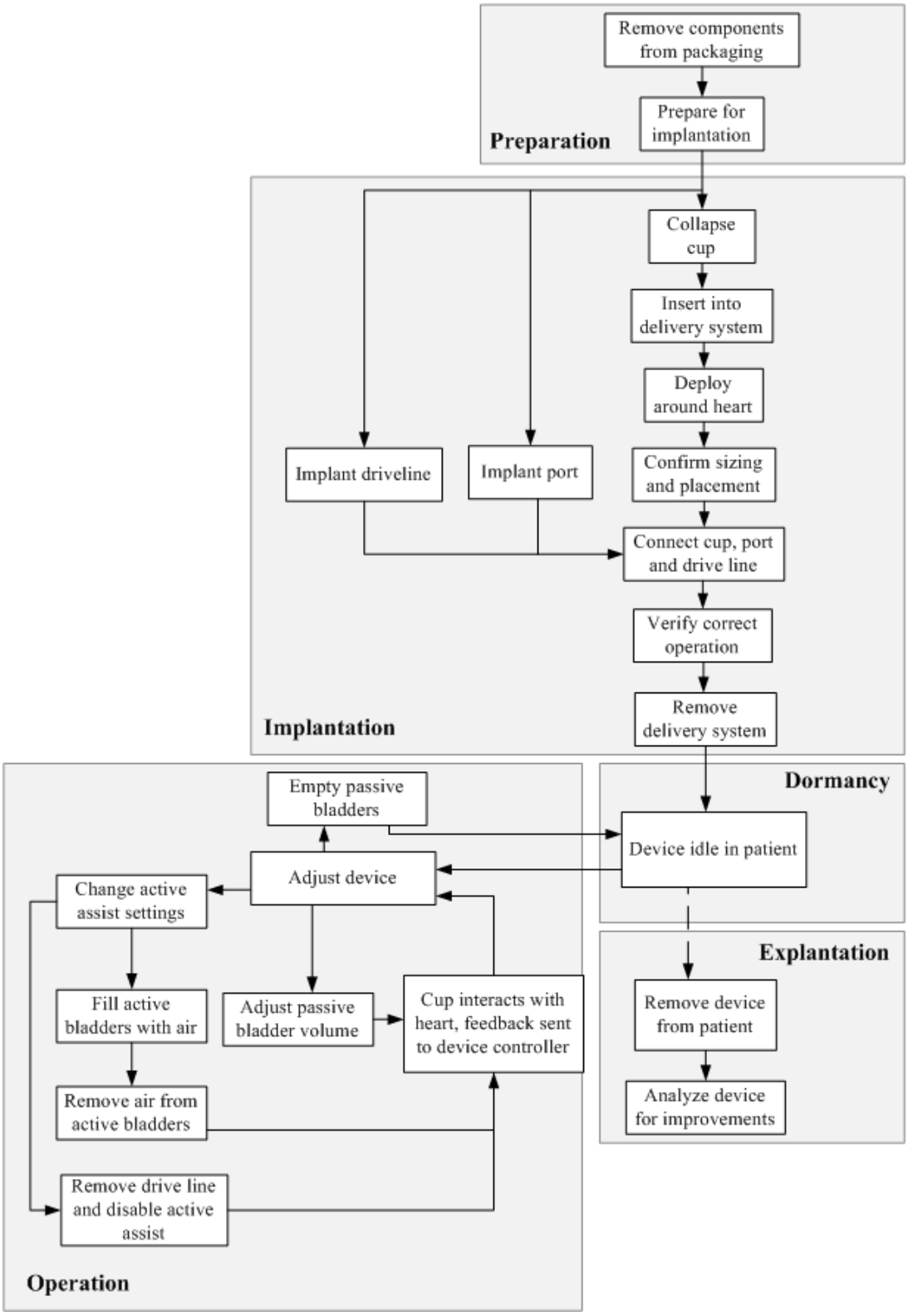


Fig. 10. Activity diagram for the AACSD.

6.2 Interpreted User Needs

To identify specific user needs based on the categories identified by the activity diagram, a customer needs assessment (CNA) was performed. A CNA is a researched based technique for determining user needs in the context of the product application, product environment, and customer characteristics. The CNA, shown in Appendix A in Table 27, was completed through background research of previous methods of heart failure treatment, FDA regulations, and results of previous prototyping. Combining the derived user needs from the CNA and the interfacing needs from the activity diagram produces a concise and thorough listing of interpreted user needs, shown in Table 1. The user needs in the product performance category address what the device must do, and concerns the patient as the user. The patient safety category outlines the importance of reducing device related risks and risks from implantation. The ease of user interaction category addresses needs with the physician as the user, to allow the physician to successfully implant, access, and adjust the device. Finally, product quality is necessary to maintain a quality system.

Table 1
Categorized interpreted customer needs

Category	Interpreted Need
Product Performance	reduce heart size
	restore natural heart function / increase cardiac performance
	restore natural heart motion
Patient Safety	reduce risks of implantation
	not detrimental to heart when dormant
	reduce risks of infection
Ease of User Interaction	ease of monitoring device
	ease of operation
	ease of access to device
Product Quality	minimize risk of device failure
	design process follows FDA regulations
	device adequately stored
	adequate product lifetime

7. DESIGN INPUTS

7.1 Functional Models

Ensuring product functionality meets the user needs is an important part of the design control process; therefore the interpreted user needs were mapped to product functionality using functional modeling. Functional models break down the product into sub-functions needed to transform product inputs into product outputs that meet the user needs. The initial function model is a black box model, shown in Fig. 11. The black box depicts "what" the device must do, rather than "how" it will do so, and consists of defining the main function of the device along with the inputs and outputs necessary to achieve this function. The inputs and outputs are classified into three domains: energy, materials, and information**.**

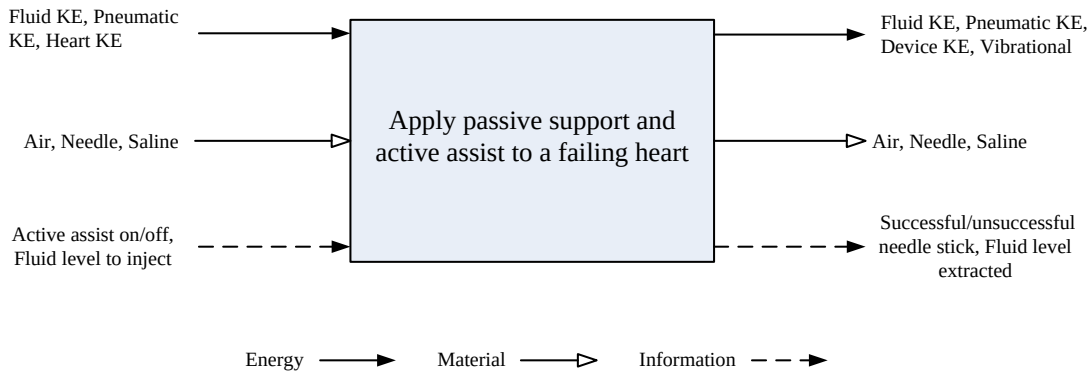


Fig. 11. Black box model of AACSD system.

The main function of the product, apply passive support and active assist to a failing heart, is derived from the user needs. The energy inputs reflect the driving force for filling the passive and active systems, and the hearts own kinetic energy to the device. The energy outputs reflect the device imposes its own energy on the heart, and the driving force for emptying the passive and active bladders, along with vibration

energy that is generated in the process. The material inputs and outputs reflect that all materials that are input into the device must be recoverable and leave the device as outputs. The information inputs and outputs indicate user feedback entering and leaving the device.

For identifying the sub-functions, a function structure was created, shown in Fig. 12. The function structure provides a systematic method of transferring user needs to product function, allowing verification and validation to later be performed. Each of the inputs and outputs appearing in the black box are shown as inputs and outputs on the function structure, along with sub-functions the product must perform to obtain the outputs from the inputs. The injection port is responsible for taking in the injection needle and saline, and transferring the saline to the passive bladder. The driving force is the kinetic energy of the saline. The drive line transfers air to the active bladders with the driving force of pneumatic kinetic energy. Once imported, saline and air are distributed to their appropriate bladders and stored, where they act on the heart to perform their primary function of providing energy to the device to provide passive support and active assist to the failed heart. Once no longer needed the fluids are distributed out of the bladders and transferred back to the injection port and drive line for removal from the system. These sub-functions will be a focus for generating the design specifications for the device.

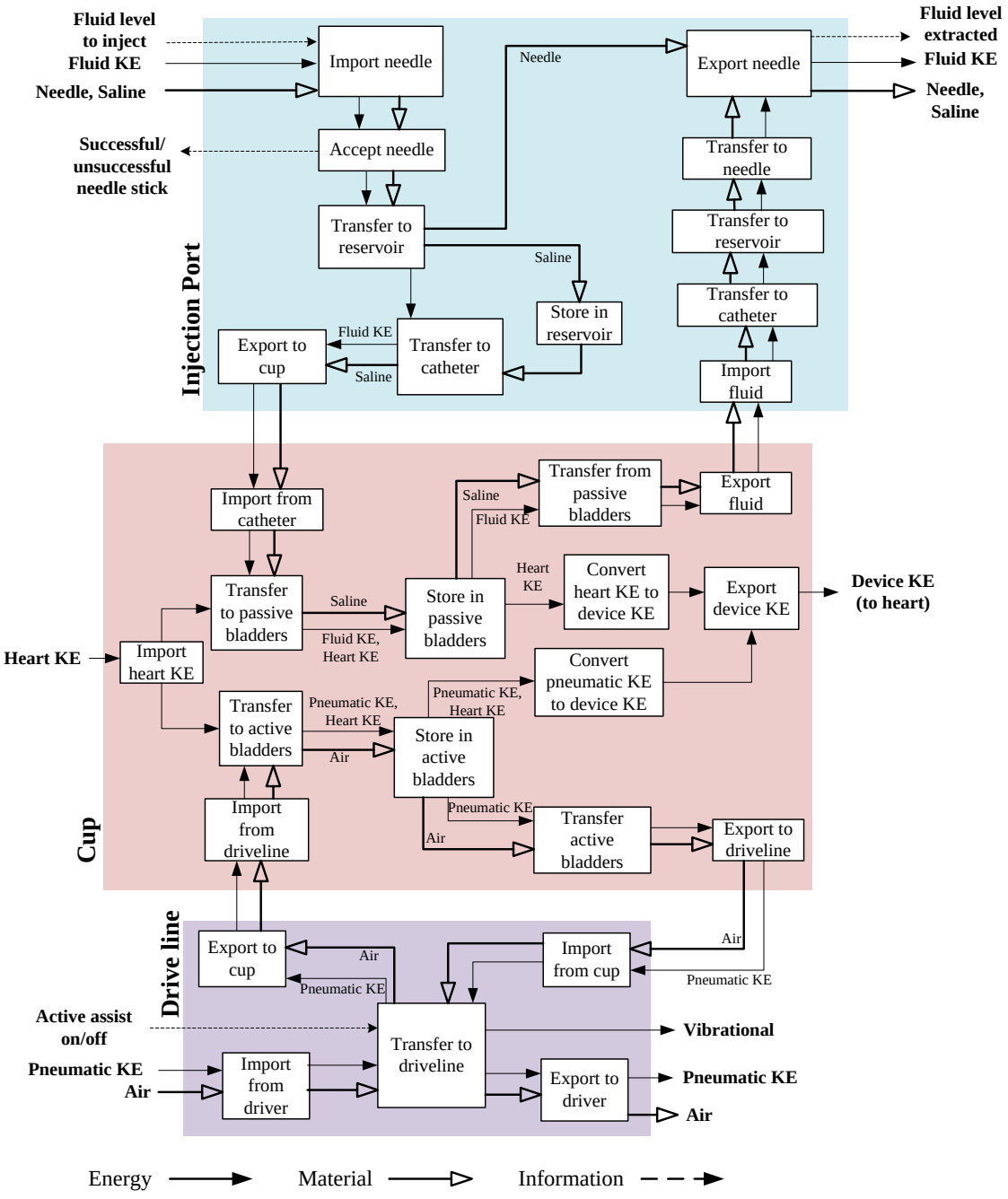


Fig. 12. Function structure of the device for operation.

7.2 Cup Design Specifications

The design requirements consist of functional requirements, interface requirements, and performance requirements. Functional requirements dictate 'what' the device should do, interface requirements dictate how the device must interface with its environment, and design constraints dictate 'how' the device must perform (FDA, 1997). Once compiled, the design requirements will be the design specifications for the device. Due to the novelty of the cup, a specification sheet is required for concept generation. The design specification sheet for the cup is shown in Table 2. Functional requirements are listed first, and interface requirements and performance requirements are listed together as constraints. Each requirement indicates whether the specification is a demand (D) or a wish (W), and the method of verification. Some verification methods are easily tested with the development of bench top models; other specifications require the manufacture of a prototype for testing.

The functional requirements must be met to achieve adequate device performance, prevent the device from damaging the heart, and allow minimally invasive deployment. The constraints list specifications concerning geometry, kinematics, materials, and production. Geometric specifications are essential to ensure proper sizing of the device so it will take up minimal space in the pericardium, while still conforming to the patient's heart properly. Kinematic specifications are needed to ensure proper operation and prevent obliteration of the heart cavity. Material specifications ensure acceptable performance of the device in the presence of heavy cyclic loading from natural heart motion and the varying volumes of the passive and active bladders, and ensure the cup fibroses to the heart and can be sterilized. Production specifications ensure the device will not damage the heart due to sharp corners or wires, and the ability to manufacture prototypes on the scale desired.

Table 2
AACSD cup design specification sheet

#	D/W	Requirement	Verification Method
		Functional Requirements	
1	D	Adjustable girdle providing passive support by allowing for nearly 50% reduction of cavity from deflated state to maximum inflated passive state	Fill cavity of prototype with liquid at maximum and minimum volumes and measure to ensure $V_{min}/V_{max} \approx 0.5$
2	D	Change in cardiac output < 3% when passive constraint is null	Verify with cardiac output data from PV loops during animal studies
3	D	Device is collapsible for deployment in a 1 ¼" diameter cylindrical tube	Measure maximum cross-section dimension of collapsed prototype and verify it is < 1 ¼"
4	D	Device flares to 75% of natural diameter upon leaving deployer tube	Measure diameter of prototype exiting deployer to ensure is > 75% of max
		Constraints	
5	D	Maximum deflated device volume is < 1% of EDV	Verify with dimensional check on engineering drawings to calculate deflated cup volume to verify is less than 1% EDV
6	W	Cup conforms to patient's heart within a 5% volume basis when device is deflated	Perform dimensional check of engineering drawings to calculate deflated cup volume, calculate heart volume from imaging, and compare to ensure the cup volume is within 5% of heart volume
7	D	When activated, residual cavity volume is > 50% of cavity volume when not inactive	Fill prototype with fluid at passive and active states and measure cavity volume to ensure $V_{active}/V_{inactive} < 0.5$
8	D	All materials used are legacy implant grade biomaterials	Verify all materials have previous and acceptable use in FDA approved devices
9	D	Fluid impermeable pockets, tubing, and connections	Verify with long term bench top testing of prototype at 20 cm H_2O
10	D	Tissue contacting materials chosen fribrose to the heart	Verify with extended prototype testing of device/tissue interactions
11	W	Device does not completely fibrose to heart	Verify with extended prototype testing of device/tissue interactions that portions of cup are not fibrosing to heart
12	D	Mechanical failure must not occur for 200 million heart cycles (≈ 5 yrs at 76 BPM)	Perform accelerated cyclic stress/fatigue tests at 0→20 cm H_2O with simulated heart loading
13	W	Mechanical failure must not occur for 1 billion heart cycles (≈ 25 yrs at 76 BPM)	Perform accelerated cyclic stress/fatigue tests at 0→20 cm H2O with simulated heart loading
14	D	Mechanical failure must not occur after 110 thousand cycles of active assist (≈ 24 hrs at 76 BPM)	Perform accelerated cyclic stress tests from 0→20 cm H_2O with active assist
15	D	Bladders have a bursting strength of > 20 cm H_2O	Verify with prototype test by filling bladders with saline to > 20 cm H_2O
16	D	Consists of no sharp corners or wires	Verify with engineering drawings
17	D	Production capacity ≈ 100	Verify that materials and parts are available for small scale production
18	D	Materials can be sterilized and packed using current sterilization methods	Verify with material literature

7.3 Selection Criteria for the Injection Port

Since the injection port is not designed, functional requirements, interface requirements, and performance requirements will not be needed for the design of the port, but rather for developing a list of acceptable candidate ports for integration into the device. The selection criteria are shown in Table 3 in a similar format to the design specification sheet for the cup. Unlike for the cup, the verification methods for the injection port will not be tests done for verifying the design, rather they are verification methods for verifying compatibility of the injection port. Thus, the verification methods will not be experiments but rather they will be research driven, such as verifying the candidate port meets the requirement by analyzing manufacturer specifications for the candidate port.

The functional requirements concern needs for the use of the port, and the constraints discuss the specifications regarding geometry, materials, and regulations. Geometric constraints for the injection port include site of implantation and use of a small sized port catheter, since rate of fluid flow is not a primary concern, to reduce risks of infection. Force and energy specifications require the port to be capable of filling the passive bladders to a pressure of 20 cm H_2O. Material specifications concern the duration that the port may be implanted and biocompatibility, which is important as the injection port will be implanted for long term access.

Table 3
Injection port selection criteria

#	D/W	Requirement	Verification Method
		Functional Requirements	
1	D	Deliver fluid to and from external injection needle and passive bladder	Verify with device literature and ensure compatibility in connections for interfacing
2	D	Self-sealing membrane from syringe punctures for at least 100 injections	Verify with device literature and specifications that maximum number of injections is > 100
3	W	Maximum dimension of port < 1 ½"	Verify in device literature and specifications that maximum cross-section dimension of port is < 1 ½"
		Constraints	
4	D	Injection Port can be placed securely in chest	Verify device literature supports implantation in chest
5	W	Maximum OD of tubing connecting to passive bladder is 3.2 mm	Verify with port specifications
6	D	Port capable of withstanding internal pressure of at least 20 cm H_2O	Verify with device literature and specifications
7	D	Port is designed for long-term implantation (> 30 days)	Verify with device literature and specifications
9	D	Tube's distal end is open	Verify with device literature
10	D	Current FDA approval	Verify with FDA
11	D	Have ≈ 100 available for order	Verify with manufacturer that port selected meets volume goal
12	W	Port has detachable attachment	Verify with device literature and specifications

7.4 Selection Criteria for Drive Line

Similar to the injection port, selection criteria are needed for developing a list of acceptable drive line candidates for integration in the device, shown in Table 4. The functional requirements discuss specifications needed to fill and empty the active bladders and provide a seal to the environment capable of holding up to 20 cm H_2O. The constraints concern kinematic, geometric, material, and regulatory concerns. Geometry constraints illustrate a design conflict. The outer diameter of the drive line should be minimized to reduce the risks of infection; however, the inner diameter should be maximized to allow for more flow of air to be cycled in and out during active assist. Other geometric constraints include the line being long enough to extend out of the ovine at a distance to minimize movement at the exit site when the proximal end is being

adjusted by the physician, and the internal seal being located away from the exit site to minimize movement of the line at the exit site. Force and energy specifications require the line to be capable of filling the passive bladders to a pressure of 20 cm H_2O. Material constraints are important for minimizing the risk of infection and for holding up to the cyclic loading.

Table 4
Drive line selection criteria

#	D/W	Requirement	Verification Method
		Functional Requirements	
1	D	Deliver air to active assist bladders	Prototype test verifying the active bladders can fill to 20 cm H_2O
2	D	Remove air from active assist bladders	Prototype test verifying the active bladders can be deflated
3	D	Provides seal to external environment when active assist is not in use, capable of holding up to 20 cm H_2O	Prototype test with the active bladders that seal holds up to 20 cm H_2O
		Constraints	
4	D	Maximum OD of 0.25 inches	Verify with dimensional check on engineering drawings
5	D	Tube extends out of patient at least 6 inches from dermal boundary	Verify with device literature and specifications
6	D	Tube is non-rigid	Verify with device literature
7	D	Inner seal can hold at pressure of 20 cm H_2O	Verify with device literature and specifications
8	D	Tube capable of withstanding pressures up to 20 cm H_2O	Verify with device literature and specifications
9	D	Tubing is designed for long-term implantation	Verify with device literature and specifications
10	D	Seal is internal and > 2 inches away from the dermal boundary	Verify with dimensional check on engineering drawings
11	D	Promotes tissue growth at dermal boundary	Verify with device literature
12	D	Lifetime of 110 thousand active cycles (≈ 24 hrs at 76 BPM)	Perform accelerated fatigue tests
13	D	Production capacity ≈ 100	Verify with manufacturer that design selected meets volume goal

8. DESIGN PROCESS

8.1 Concept Generation of the AACSD Cup

The first stage of the concept generation process for the AACSD cup involved individual and group brainstorming. Between four and eight concepts variants each were generated for bladder shape and arrangement, interface between the active and passive bladders, frame design, and base components of the cup needed for support. These concepts were then evaluated based on the design criteria and their ability to provide the functions needed from the function structure. All sub-group concepts and their evaluation are discussed in Appendix B.

After evaluation, the leading concepts were included for consideration in an overall cup design. For the passive and active bladders, the advantage of using a single global bladder include providing less restriction of fluid flow, especially in the active bladder, and easier method of assembly and manufacture. For the bladder interface design, a 2-layer design is suggested for its ability to form the cup shape, while minimizing the passive bladder and active bladder adversely affecting the operation of each other. However, an integrated concept possessed many advantages (along with the many disadvantages) over the 2-layer concept, so the integrated concept will be studied further. The frame design suggested is an offset petal design due to its ability to better allow for rotation; however, the petal design will also be analyzed further due to its simplicity. The cup base design suggests the benefits of a rotating base. Such a design is naturally suited for pairing with the offset petal, however a regular base will also be considered due to its simplicity.

Three overall cup design concepts were generated. Table 5 shows the breakdown of each the overall cup concepts based on their individual sub-groups. The three concepts chosen reflect an effort to piece together compatible concepts from different sub-groups, while maintaining a diverse range of cup concepts for consideration. The first concept is a compilation of the sub-groups suggested from the concept generation. The second concept is a more conservative and simple concept that also utilizes two

layers of bladders, but minimizes the need for a more elaborate base. The third concept is an integrated bladder concept with a single global bladder to perform both the passive and active roles and a regular base that will minimize the volume of the device. Sketches of each of these concepts are shown in Fig. 13.

Table 5
Overall cup concepts

	Overall Cup Concepts		
	1	2	3
Category	Rotating	Petal	Integrated
Passive Bladder	Global	Global	Global
Active Bladder	Global	Global	Global
Bladder Interface	2-Layer	2-Layer	Integrated
Frame Design	Offset Petal	Petal	Petal
Base Interface	Rotating	Regular	Regular

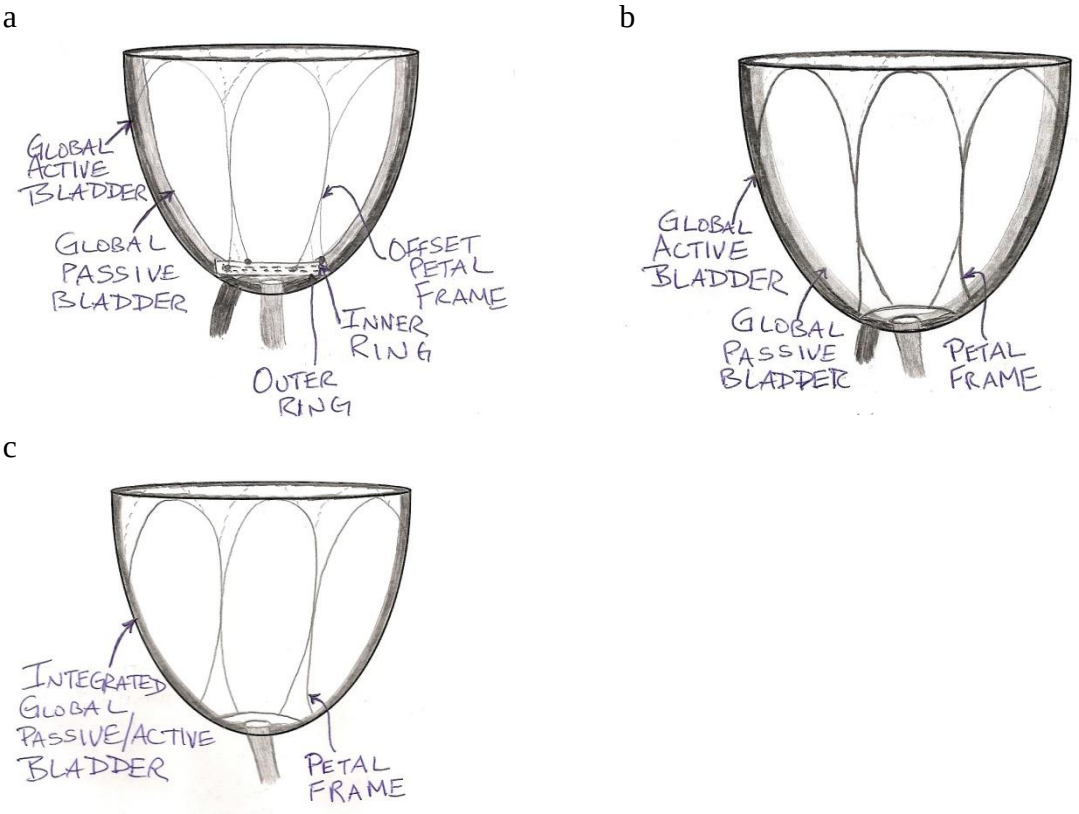


Fig. 13. Overall cup concepts generated for further consideration. These concepts include (a) rotating concept, (b) petal concept, and (c) integrated concept.

8.2 Port Candidates

To gather a list of candidate ports to be considered for interfacing with the cup, thorough research was done on current injection ports on the market using the FDA's Registration and Listing Database. Next, the list was trimmed of any ports that were not suitable for future consideration due to improper sizing, recent recalls, and the inclusion of unnecessary technology not needed for the basic functions described in the function structure. Once completed, the process generated seven port candidates for consideration. The port candidates and their manufacturers are shown in Table 6. For the seven candidate ports, select specifications are shown in Appendix C in Table 33.

Table 6
Ports selected for consideration

Company	Port Manufactured
Angiodynamics	Infuse-A-Port
	TitanPort
Bard Access Systems	M.R.I. Hard-Base Port
	Titanium Dome Port
	Titanium Port
	M.R.I. Port
Covidien	Chemosite Infusion Port

8.3 Concept Generation of Drive Line

The initial step of the concept generation process for the drive line looked closer at the design requirements for the active system. From the function structure it is clear the driveline must perform the following functions: provide external access to the active bladders for inflation and deflation, maintain mechanical integrity, and ward off infection that is common with percutaneous access.

The results from the concept generation are two different design concepts. The first uses a percutaneous tube with an internal seal, shown in Fig. 14 (a), and the second uses a valved catheter with the valve internal to the active bladder, shown in Fig. 14 (b). The difference between the two concepts is the first must be designed for use in the cup,

while the second concept uses a current FDA approved product, therefore only the interface must be designed. In each case, a one tube design is preferred because it takes up less space and therefore reduces the risk of infection. At the exit site, additional measures are needed to promote tissue growth to secure the line in the patient and to prevent infection. To minimize tube movement at the exit site and prevent infection, the seal would ideally be located internal to the patient and away from the exit site.

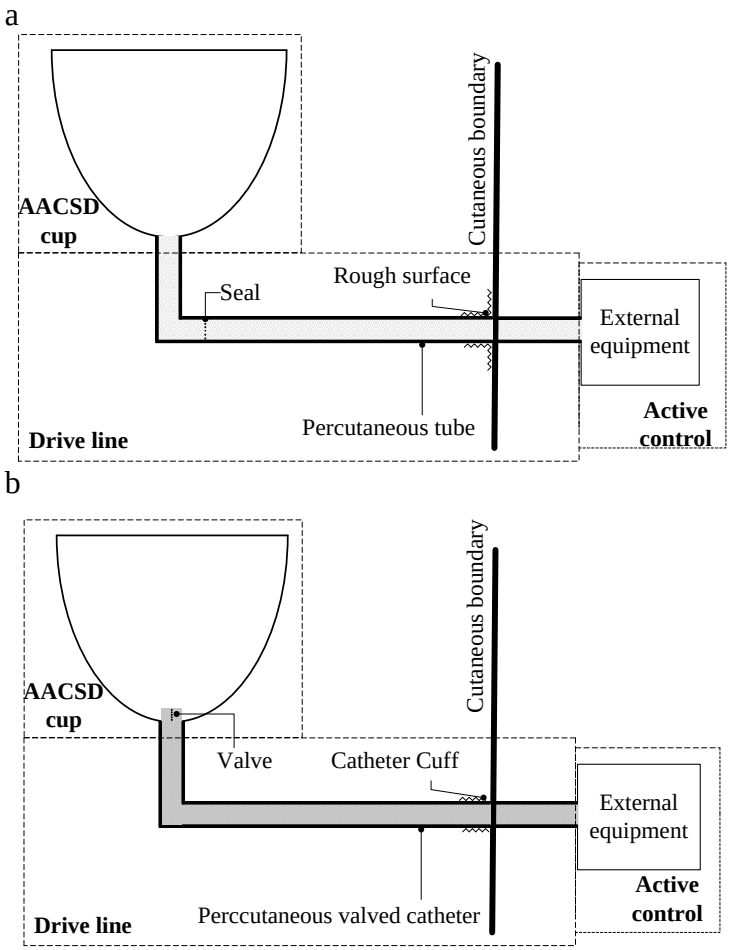


Fig. 14. Concepts generated for drive line. Concepts include a percutaneous tube with internal seal (a), and a valved percutaneous catheter (b).

9. CONCEPT EVALUATION

9.1 Concept Selection of AACSD Cup

The next step of the design process for the AACSD cup is to evaluate the overall cup concepts from concept generation using concept selection. To aid in concept selection, a common design technique, known as a Pugh chart, is employed. Pugh charts are used in comparing multiple candidate methods to a list of criteria to determine the optimum candidate. The criteria are taken directly from the specification sheet, to ensure the design outputs map to the design inputs. In a Pugh chart, candidates are rated against a datum candidate based on the design criteria. If the candidate satisfies criteria more favorably than the datum, the candidate receives a "+1". For less favorable satisfaction of the criteria the candidate receives a "-1", and for comparable satisfaction the candidate receives a "0". The highest score indicates the concept that best satisfies the design criteria. For each Pugh chart, the datum was selected based on the most simple solution or solution that had been previously prototyped by the lab. While Pugh charts have extensive use in industry, assumptions of the method include that the criteria are weighted with equal importance, and that a limited ranking scale with three options to rank each candidate is sufficient; however, at this stage in the development process these assumptions are acceptable as the process is aiming to develop a design for further testing. Once further prototype testing has developed a more final design towards the end of the development process, these considerations should be taken into account during the selection process.

These overall cup concepts were evaluated using the Pugh chart in Table 7. The design criteria are taken from the design specifications. The top rated design of the cup was the rotating concept. This design provides passive support and active assist with two separate global bladders. With concerns of proper filling and emptying of bladders and maintaining a desired pressure, the global bladder assembly is able to accomplish each of these most easily. The passive bladder is located on the inside of the cup and the active bladder is located on the outside of the cup. An offset petal frame that resides

internal to the passive bladder, provides support for the cup shape, allows for the device to be collapsed and flare upon leaving the deployer tube, accommodates rotation of the heart, and prevents the active bladder from obliterating the cavity. The cup takes up minimal volume that will allow it to fit in the pericardial space, and requires only a limited amount of tubing.

Table 7
Pugh chart of overall cup concepts

		Candidate Concepts		
Criteria		Rotating	Petal	Integrated
Doesn't interfere with cardiac output when not in use		0	0	0
Collapsibility		0	0	1
Ability to flare around heart during deployment		0	0	0
Ability to conform to heart		0	-1	-1
Ability to obtain desired pressure		0	0	-1
Adequate lifetime of design		0	0	-1
Ease of deployment		0	-1	-1
Ease of manufacture and assembly/costs		0	0	1
Amount of material needed/cost		0	1	1
Fit in pericardial space/overall volume		0	1	1
Ability to handle rotation		0	-1	-1
Ease of filling bladders		0	0	-1
Ease of emptying bladders		0	0	-1
Amount of tubing needed		0	0	1
Avoid cavity obliteration		0	0	0
Support for cup shape		0	0	0
Reduces coupling of cup and tubing from rotation		0	-1	-1
	Σ	0	-2	-3

While the other designs had certain individual aspects that made them favorable, the petal concept is not as effective as handling rotation of the heart and the integrated concept had too many concerns on the difficulty of operating a device that utilizes a single bladder for passive support and active assist. The overall design of the rotating concept lends itself to simplicity, favoring concept embodiment and manufacture.

9.2 Concept Selection of Port

For the port, selecting a candidate from the seven under consideration was done using a Pugh chart. The criteria from the Pugh chart, shown in Table 8, come from the Port Selection Criteria. To rate each candidate port, specifications from the manufacturer were used. For a reference point, the Bard Access M.R.I. Port was used as the datum. The Pugh chart indicates that the candidate ports were very close in their ability to meet the selection criteria. The Bard Access M.R.I. Port and the Angiodynamics Infuse-A-Port both compared similarly based on their product specifications. However, due to the unknowns of the Infuse-A-Port, and because the Bard Access M.R.I. Port was chosen as the datum, the recommendation is for selection of the Bard Access M.R.I. Port. Research of the port reveals that there is no recent history with complications with the FDA regarding the manufacture or marketing of the port, such as product recalls, and the port is manufactured by a reputable company with a longstanding reputation. Fig. 15 shows the selected port.

Table 8
Pugh chart of candidate injection ports

	Candidate Ports						
Criteria	Bard Access M.R.I. Port	Angiodynamics Infuse-A-Port®	Angiodynamics TitanPort™	Bard Access M.R.I. Hard-Base Port	Bard Access Titanium Dome Port	Bard Access Titanium Port	Covidien Chemosite™ Infusion Port Products Standard
Max injections at least 100	0	0	0	0	0	0	-
Largest dimension < 1 ¼"	0	0	0	-1	0	-1	0
Available for chest placement	0	0	0	0	0	0	0
Catheter sizes available	0	0	0	0	0	0	0
Legacy product	0	0	0	0	0	0	-1
FDA approved/recent issues	0	0	0	0	0	0	0
Catheter pre-attached	0	0	0	-1	-1	0	0
Weight of Port	0	-	-	0	0	-1	0
Height of port	0	-	-	0	0	0	0
Septum diameter	0	-	-	0	0	0	-
Port body material	0	0	-1	0	-1	-1	0
Catheter material	0	0	0	0	0	0	0
MRI compatibility	0	0	0	0	0	0	0
Σ	0	0	-1	-2	-2	-3	-1

Fig. 15. Bard Access M.R.I. Port. Figure from Bard Access Systems (Bard Ports, 2009).

9.3 Concept Selection of Drive Line

With concepts generated, the next step of the design process for the active system is concept selection. The resulting Pugh chart is shown in Table 9. The Pugh chart indicates that the design that best accomplishes the needed criteria is the valved catheter. The concept entails the insertion of the valved catheter into the active bladder, with the valved portion of the catheter contained in the active bladder and bladder sealed around the catheter.

Table 9
Pugh chart for active interface concepts

		Candidate Concepts	
Criteria		Percutaneous Tube with Seal	Valved Percutaneous Catheter
Ease of filling active bladders		0	0
Ease of emptying active bladders		0	0
Provides seal to external environment when active assist is not in use, capable of holding up to 20 cm H_2O		0	0
Infection concerns		0	0
Fit in pericardial space		0	0
Interfacing with Cup		0	-1
Total Volume		0	0
Ease of deployment		0	0
Ease of Operation		0	1
Amount of material needed/Cost		0	1
Difficultly of manufacture and assembly		0	1
Amount of tubing needed		0	0
Kink-resistance in system		0	0
Availability/Choices available		0	-1
Prior use in other implants		0	1
	Σ	0	2

Here the previously mentioned design tradeoff becomes issue: for patient safety and reducing infection risk, a smaller diameter catheter is desired; however, to aid in the filling and emptying of the active bladders a larger inner diameter is desired, which also requires a larger outer diameter. With catheter advancements in reducing the risks of infection, and with no resolution available for increasing the efficiency in filling the bladders without increasing the size of the catheter, the design tradeoff can be resolved by using larger catheters that have features to prevent infection.

Identifying valved catheter candidates was done in a similar manner as the injection ports. Catheters are available with different numbers of lumens; typically catheters have one lumen, although some have as many as four lumens or more in a catheter. However, the addition of internal walls needed to separate lumens within the catheter decreases the cross-sectional area available for airflow, thereby reducing the efficiency of filling and emptying the active bladder. For this reason, only single lumen catheters were considered for the percutaneous drive line. Three catheters are available for consideration, shown in Table 10. While the technologies of these are similar, the method of accomplishing the valve seal is different in each case. The Bard catheter utilizes a single valve at the distal end. The Angiodynamics catheter uses two valves at the distal end to achieve this same operation. The Navilyst catheter uses a valve located on the proximal end. Table 34 in Appendix C lists the specifications for each valved catheter candidate.

Table 10
Valved catheter selected for consideration

Company	Catheter Manufactured
Angiodynamics	CVC with LifeValve
Bard Access Systems	Groshong
Navilyst	PICC with PasV

A Pugh chart was done to evaluate the valved catheters based on Drive Line Selection Criteria. The Pugh chart of valved catheters, shown in Table 11, indicates that

the best valved catheter for use in the device is the Bard Groshong valved catheter. The Groshong catheter is preferred because of its superior features to prevent infection to enable a larger catheter size, a valve at the distal end, a single valve to design around for interfacing, and a solid reputation. The particular catheter chosen of the Groshong is the largest sized catheter available; all available catheter options are shown in Appendix B in Table 35.

A Groshong catheter is shown in Fig. 16. Each of the catheters possesses two cuffs to help prevent infection. The first cuff is a VitaCuff Antimicrobial Cuff that is designed to secure the placement of the catheter and prevent migration of microorganisms. In the figure, this is the more distal cuff. The second is a cuff made of Dacron whose main responsibility is to promote tissue growth to ensure implantation of the catheter, but also acts to prevent migration of microorganisms to prevent catheter related infections.

Table 11
Pugh chart of valved catheters

	Candidate Concepts		
Criteria	Bard CVC Groshong Catheter	Angiodynamics LifeValve CVC	Navilyst PICC with PasV
Provides seal to external environment when active assist is not in use, capable of holding up to 20 cm H_2O	0	0	0
Min ID of filling tube	0	1	-1
Max OD of filling tube	0	-1	0
Catheter capable of withstanding pressures up to 20 cm H_2O	0	0	0
Legacy implant biomaterials	0	0	0
Infection concerns	0	-1	-1
Fit in pericardial space	0	0	0
Interfacing with cup	0	-1	1
Ease of deployment	0	0	0
Ease of operation	0	0	0
Kink-resistance in system	0	0	0
Location of valve	0	0	-1
Length	0	0	0
Σ	0	-2	-2

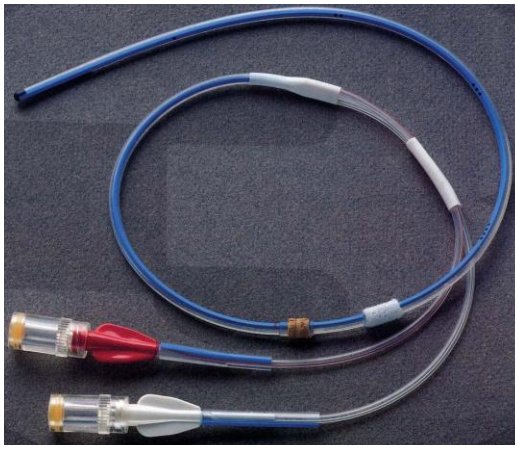


Fig. 16. Dual lumen Bard Access Groshong CVC. The proposed design uses only a single lumen. Figure from Bard Access Systems (Bard Groshong CVC, 2009).

10. AIM I FUTURE CONSIDERATIONS

A limitation of the selected concepts is that they have not yet been verified. The verification methods listed in the design specification sheet must be performed with a prototype. Future studies and prototypes will likely change some of the design criteria and present a more optimal concept based on the design criteria. However, the design process is made to accommodate these design changes; each of the design inputs (black box model, function structure, design specification sheet) are meant to be fluid documents that are updated throughout the design process once new information becomes available. This allows for the process to be transferrable to future iterations of the device.

If desired, less reputable but cheaper ports are available as original equipment manufacturer (OEM) parts. These OEM ports may be desirable for studies in the short term, however, for long term applications a more reputable port like the Bard Access M.R.I. Port will aid in allowing the focus future studies to remain on the novel components of the AACSD.

Previous studies have indicated that there is some concern of the ability to remove air from the active bladders. To help promote fluid flow, a single global active bladder was proposed for the device. To reduce the novel components of the device, a valved catheter was proposed for use as the percutaneous drive line over a designed percutaneous tube with an internal seal. However, if the valve is not able to allow for enough air to pass through during the time frame, then the designed percutaneous tube concept may need to be revisited. In this case, a larger diameter line with an internal seal must be designed. This can be accomplished using a larger non-valved catheter, such as any CVC, or a simple silicone or polyurethane tube. Finally, future iterations of the drive line may further integrate the external components by allowing for integration of monitoring devices within the drive line. Devices that dictate the active assist parameters, such as ECG wires and pressure catheters for monitoring pressure within the bladder, may be included in the percutaneous line.

11. AIM II: PROBLEM STATEMENT

The second specific aim is to embody the selected concept of the AACSD system, consisting of an FDA approved subcutaneous injection port, an FDA approved percutaneous drive line, and the novel design of the AACSD cup developed in Aim 1. The results of the design process phase from Aim I were then used to develop the design outputs. Design outputs are any work product or deliverable item of any design task in the overall design plan (FDA, 1997).

The design embodiment consists of sizing of the device for fit around an ovine heart and the selection of properties for each of the components of the AACSD; this includes dimensions, quantity of components, materials, and methods of assembly. Once each of these is defined, evaluation of the embodied design was done using a failure modes and effects analysis (FMEA) to evaluate potential concerns for device failure, and provide recommendations for future iterations of prototypes.

The design outputs will be the deliverables of the research, and include design embodiment methods, a parts list, engineering drawings of the selected concept, and the FMEA. As mentioned previously, the design research supplements the prototyping research performed by Dr. Criscione and his lab. As part of the design controls, the results of the design output phase are used to map to the design input phase for verification that the design outputs adequately fulfill the design inputs; this verification must be performed through additional prototyping research as part of maintaining a quality system.

12. SIZING AND ASSEMBLY OF THE AACSD

12.1 Sizing of Cup

With a design concept selected, embodiment of the concept begins with determining necessary sizing of the cup for the manufacture of a prototype. Since focus of this research is for continued development of the AACSD cup for ovine proof-of-concept studies, the sizing proposed herein will be for ovine hearts. As the ovine heart dilates and begins to fail, the left ventricle becomes more spherical. The spherical-like cross-section allows for modeling of the heart as a prolate ellipsoid, with defining dimensions of radius R (corresponding to the approximate radius of the heart at its maximum cross-section) and length L (corresponding to the length of the heart from the maximum cross-section to the heart apex). It is important that the heart dimensions used for modeling the cup be measureable with non-invasive standard hospital imaging equipment to ensure the cup is the correct size. To complement the heart model, the cup will be modeled as a semi-prolate ellipsoid, with the defining dimensions R and L mentioned previously. A depiction of the shape of the cup overlaying an ovine heart is shown in Fig. 17.

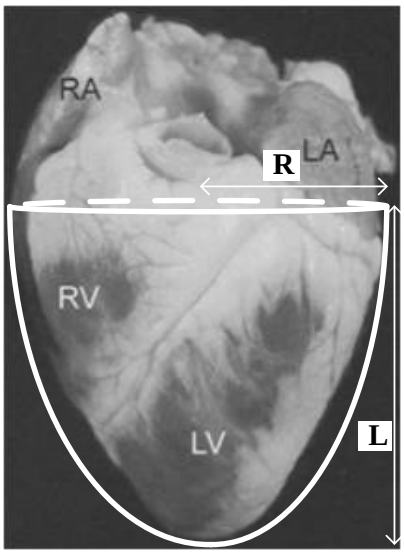


Fig. 17. Depiction of the semi-prolate ellipsoid AACSD cup shape over an ovine heart. Figure modified from Hill and Iaizzo (2005).

Dr. Criscione and his lab have developed castings of excised ovine hearts from previous studies for sizing of prototypes. From these hearts, a standard size has been developed by the lab for the construction of bench top prototypes. To coincide with the prototyping process, the same size is used for the embodiment of the cup of the selected design. The embodied device has an upper perimeter of 12 inches (therefore $R \approx 1.91$ inches) and a length L of approximately 4 inches. The sphericity of the design can be defined by dividing the transverse axis of the ellipsoid (R) by the longitudinal axis (L). A perfect sphere will have a value of 1, while a prolate ellipsoid that deviates further from a sphere will have a value that approaches 0. The sphericity of this model is 0.55.

AACSD Design Specification #5 dictates that "maximum deflated device volume is <1% of EDV". EDV is the summation of EDV of the left ventricle and right ventricle. While EDV varies for each heart, an approximation of 200 mL for EDV is acceptable. Using this approximation, the maximum deflated device volume is 2 mL (or 2,000 mm^3). The volume of a semi-prolate ellipsoid is shown in Equation (1).

$$V = \frac{2}{3}\pi R^2 L \tag{1}$$

Using this calculation, an approximation for the maximum device thickness, *t*, can be obtained using the R and L previously defined above. For calculating the volume, the volume of the wires is not taken into account, therefore this calculation is effective in calculating the maximum thickness of the bladders. The thickness can be found by Equation 2, where V_{cup} is 2000 mm^3, and V_{outer} and V_{inner} can be calculated by Equation 3 and Equation 4, respectively.

$$V_{cup} = V_{outer} - V_{inner} \tag{2}$$

$$V_{outer} = \frac{2}{3}\pi(R+t)^2(L+t) \tag{3}$$

$$V_{inner} = \frac{2}{3}\pi R^2 L \tag{4}$$

The calculated maximum thickness for the bladders is approximately 0.087 mm; therefore a thin film must be used to create the bladders. Due to the variability in heart size, a range of cup sizes will eventually be needed to sufficiently fit the device over the range of heart sizes. Further research will need to be performed on the development of different sizes of the heart; however, the focus for the research is on the embodiment of a single design for verification testing. Once verification testing has been performed the development of different cup sizes may be performed in the future.

12.2 Design Embodiment of Port

The product details and specifications of the Bard Access M.R.I. Port are shown in Table 12. This table shows the relevant port dimensions such as the diameter of the port base, port height, and septum diameter. Also shown are other properties of the port such as weight and reservoir volume, catheter properties, and materials of the port and catheter. The attachment method refers to if the port catheter is pre-attached or attachable by the physician. Different catheter options are available on the selected Bard Access M.R.I. Port, including both silicone and polyurethane catheters. The specifications for these catheters are shown in Appendix C in Table 35, and include the dimensions of the catheter and the type of end on the catheter. Standard dimensioning for the outer diameter are given French size (Fr.) units; to convert to millimeters the French size is divided by 3.

Due to the excellent mechanical properties of polyurethane, catheters composed of polyurethane possess thinner walls than silicone catheters. However, since the pressures the catheter will be experiencing are relatively low during operation compared to the pressures the catheters are manufactured to withstand, the more expensive polyurethane catheters are not required for this application. A valved catheter is also not needed for this application since the port, catheter, and passive bladder will form a closed system internal to the patient. The selected catheter is the 9.6 Fr. radiopaque silicone catheter. To aid in adjusting the device, an attachable catheter is recommended for integration with the port body. This catheter meets the selection criteria and adequately performs the functions needed by the function structure.

Table 12
Specifications of Bard Access M.R.I. Port (Bard Ports, 2009).

Base diameter	31.5	mm
Height	15.3	mm
Septum diameter	12.5	mm
Reservoir volume	0.6	mL
Weight	8.9	g
Base material	Plastic	
Septum material	Silicone	
Implant location	Chest	
Catheter material	Radiopaque silicone	
Lumen OD	9.6	Fr.
Lumen ID	1.6	mm
Catheter length	76	cm
Catheter attachment	Attachable	
MRI compatible	Y	
Maximum number of injections	2000 with 20 Gauge Needle 1000 with 19 Gauge Needle	

12.3 Design Embodiment of Drive Line

The product details and specifications of the Bard Access Groshong catheter are shown in Table 13. This table shows the relevant catheter dimensions such as the outer diameter, inner diameter, length, and placement of the valve. The distal end of the catheter composes of a single valve that is designed for 3-way use, as shown in Fig. 18.

The operating pressures of the valve are shown in Table 14. At normal CVPs, the valve remains closed. When negative pressure is applied inside the lumen, the valve opens inward to allow fluid to be withdrawn. When positive pressure is applied inside the lumen the valve opens outward to allow fluid to be injected. The maximum expected pressure in the active system is on the order of 20 cm H_2O (or 14.7 mm Hg), well within the operating range of the valved catheter. When the active bladders are filled, the pumps create a positive pressure in the catheter that will open the valve to the active bladder and allows the bladder to be filled. When the pump terminates operation of filling the active bladder, the valve will close and create a seal that holds the pressure of the active bladder. After the prescribed delay, the pump system shuttles air out of the active bladder by creating a negative pressure that opens the valve inward to allow air to be removed out of the active bladder. When the pump system terminates vacuuming air,

the valve closes at the neutral pressure, and the active assist cycle is ready to be repeated.

Table 13
Chosen drive line specifications from manufacturer specifications (Bard Groshong Brochure, 2009).

Catheter Material	Silicone	
Lumen OD	2.7	mm
Lumen ID	1.5	mm
Length	65	cm
Valve Type	1-valve	
Valve Location	Distal	
FDA Approval	Y	
Recent FDA Issues	N	

Fig. 18. Operation of the 3-way valve on the Groshong catheter. Figure from Bard Access Systems (Bard Groshong CVC, 2009).

Table 14
Valve operating pressures (Bard Groshong IFU, 2009)

Valve Status	Internal Pressure	External Pressure
Opens Inward	Negative Pressure	P > 80 mm Hg
Opens Outward	Positive Pressure	P < -7 mm Hg
Neutral (Closed)	Neutral Pressure	-7 < P < 80 mm Hg

12.4 The Embodied Design of the Device

For embodiment, engineering drawings for each component were created, along with an assembly drawing showing the entire AACSD embodied design. Each of the drawings indicates the dimensions and layout of each component. The assembly and dimensioning were determined based on the sizing of the cup, results of previous prototyping, and the constraints of the other components of the system to allow for interfacing.

The passive bladder and its assembly are shown in Fig. 19. The passive bladder begins as a single rectangular film. Adhesive is used for folding the passive bladder onto itself along the bottom of the film to create a smaller dimension for the base, shown in grey in Fig. 19 (a). The passive bladder is folded along each of the vertical fold lines in the adhesive area and allowed to set. This results in a crenellated trapezoidal sheet as seen in Fig. 19 (b). Crenellations are desired to allow the bladder to fill more effectively once the inner film fibroses to the heart; this can be seen in Fig. 20. Next the bladder is folded in the hoop direction and bonded to create a circumferential film assembly, where the larger diameter at the top corresponds with the upper perimeter of the cup. Further dimensions of the passive bladder were determined by Dr. Criscione and his lab from prototyping; these passive bladder dimensions are shown in Appendix D in Fig. 35. Next the film is folded over along the horizontal fold line to create the bladder pocket where the saline, frame, and internal components reside. Later in the assembly process the bladder pocket will be sealed around the base of the cup and the port catheter to seal the bladder to hold the saline in a water tight fashion.

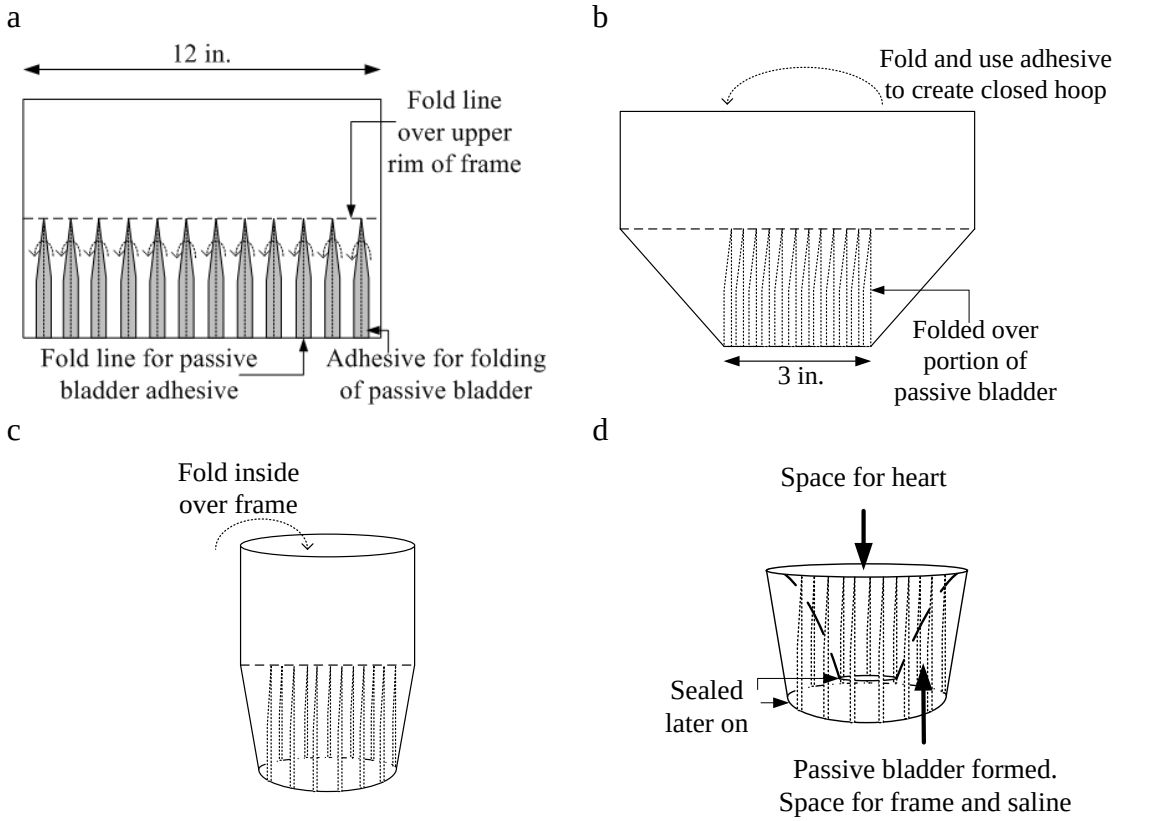


Fig. 19. Passive bladder assembly. The assembly begins as a film sheet (a). The film is folded over on itself using adhesive to create a smaller base diameter (b), and then folded and bonded to itself to make a circumferential shape (c). Finally the top half is folded down to form the bladder shape (d). Sealing of the open sections of the bladder will take place later on in the assembly process.

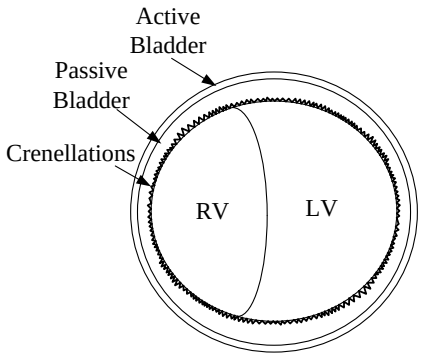


Fig. 20. Passive bladder crenellation at heart interface.

The active bladder is a single film of the same material that is slightly longer in length. The active bladder is assembled in a similar process as the passive bladder. The active bladder film is folded to fit around the passive bladder and attaches to the passive bladder along the top of the cup and around the base of the cup using a film welding process. The shape of the film allows for the film to be attached to the passive bladder in this manner. Fig. 21 shows the assembly of the film and its attachment external to the passive bladder. Further dimensions of the active bladder were determined by Dr. Criscione and his lab from prototyping; these active bladder dimensions are shown in Appendix D in Fig. 36. Later on in the assembly process the active bladder will be sealed around the base of the cup and the valved catheter to seal the bladder to hold the air for active assist. The thickness of the deflated device is then equivalent to four times the thickness of the film. To comply with the design a specification, a 20μm film thickness is suggested.

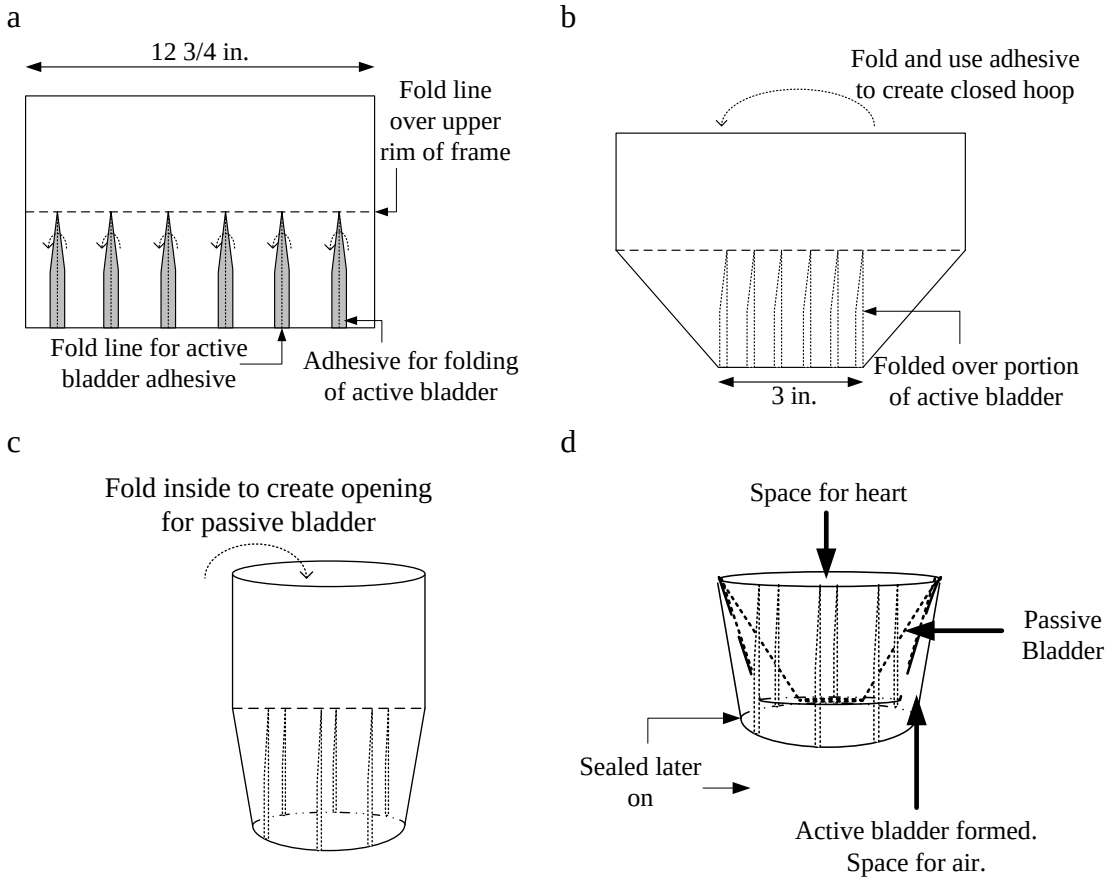


Fig. 21. Active bladder assembly. The active bladder begins as a film sheet (a). The film is folded over on itself using adhesive to create a smaller base diameter (b), and then folded and bonded to itself to make a circumferential shape (c). Finally the top half is folded down to form the bladder shape that fits around the already assembled passive bladder (d). Sealing of the open sections of the bladder will take place later on in the assembly process.

One of the shaped wires and the entire frame of the wires configured into the frame shape are shown in Fig. 22. The frame is composed of twelve identical wires spaced equally in the hoop direction to form the cup shape. The wire is pre-bent to form and set the shape of the upper tip of each loop. Each individual wire has one section that forms the outer frame and another section that forms the inner frame; the section of wire that makes up the inner frame is longer than the outer part of the loop to accommodate for the rotation of the heart.

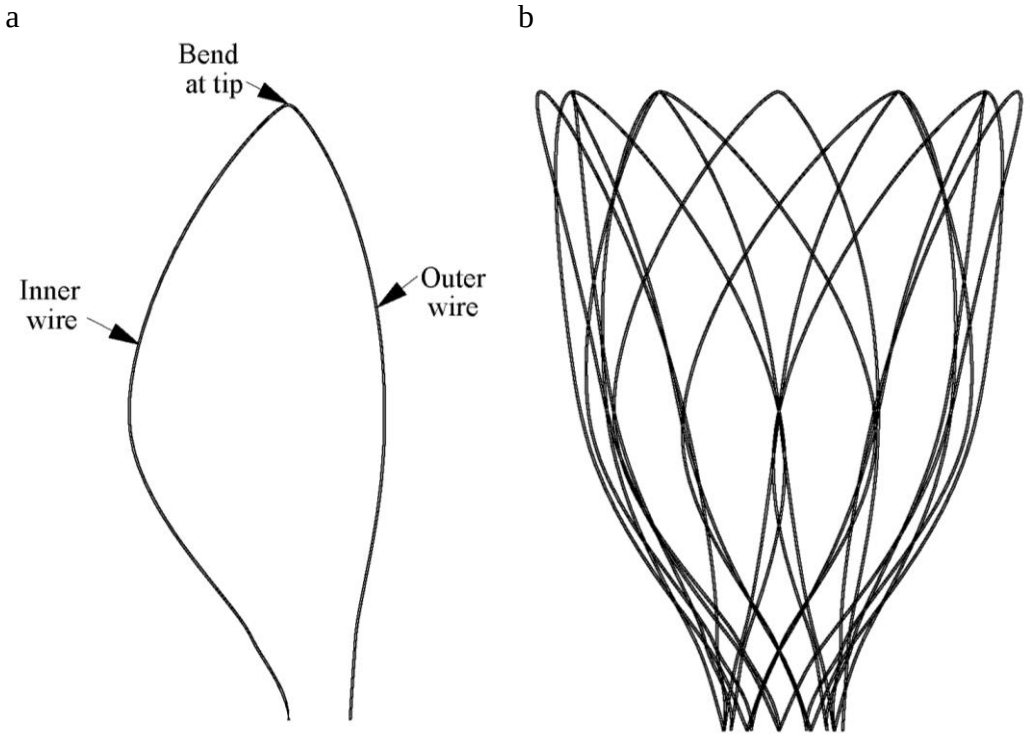


Fig. 22. Wire and frame. Shape of a wire for the frame assembly (a). The shorter section of wire forms the outer frame, and the longer section forms the inner frame. The frame is composed of twelve of these wires to form a cup shape (b).

The inner wires of each loop of the frame are secured to the inner hub. The inner hub is a ring that fits at the base of the cup, below the heart. The hub consists of a plastic ring with twelve holes to allow attachment for each individual wire of the

scaffold. Fig. 23 shows the inner hub. The frame will first be attached to the inner hub by looping the wire through the hole and fixing the looped wire to the inner hub with adhesive and sutures. Further dimensions of the inner hub are shown in Appendix D in Fig. 37.

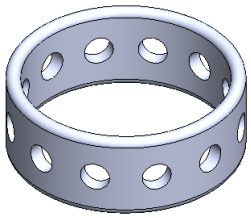
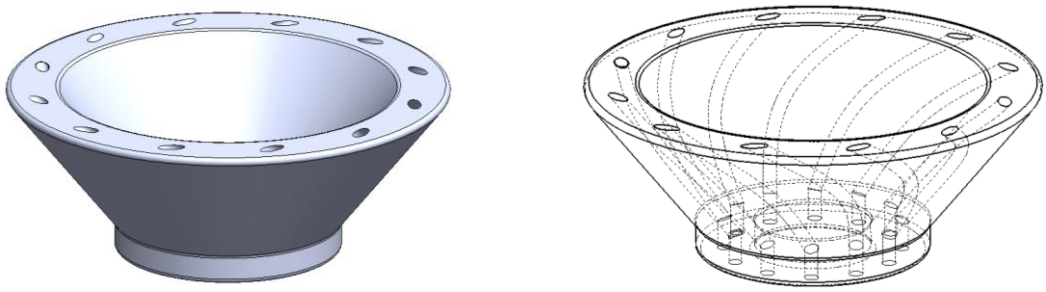


Fig. 23. Inner hub. The hub is used to anchor each of the twelve inner wires of the frame.

In addition to the components described in the selected concept, previous prototyping indicates that to aid in flaring the wire for deployment, another internal component was beneficial. This component is a sliding hub. The sliding hub possesses channels that set the angle of flaring of the wire for deployment. The hub resides between the inner hub and the upper tips of the frame and is free to slide along the inner wire. Once each of the twelve wires is attached to the inner hub, the other ends of the wires are passed through each of the channels in the sliding hub.

The sliding hub design is a ring design that is conical in shape to help match the shape of the heart apex. The sliding hub is shown in Fig. 24. Further dimensions of the sliding hub are shown in Appendix D in Fig. 38. The sliding hub is used for deploying the device around the heart. When the device is in its collapsed state, the sliding hub is at the top of the frame assembly to hold the wires compactly. Upon deployment, the sliding hub rests on the heart apex and the wires are pushed through the sliding hub channels to expand the frame for deployment around the heart.



(a) (b)

Fig. 24. Sliding hub. The hub is designed to accommodate heart apex shape and flare frame during deployment. Solid model shown in (a), and sketch depicting the channels that the inner frame wire passes through shown in (b).

Once the inner part of the wire frame has passed through the sliding hub, the outer part of the frame is attached to the outer hub in a similar manner as the inner hub. The outer hub is similar to the inner hub, except the outer hub has a larger diameter so that the outer hub may slide over the inner hub. The two hubs are concentric and free to move relative to each other with minimal friction from rubbing against each other, and create the offset shape of the frame by having one end of each wire on the inner hub and the other on the outer hub. The outer hub is showed in Fig. 25. Further dimensions of the outer hub are shown in Appendix D in Fig, 39.

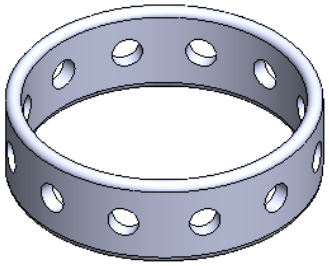


Fig. 25. Outer hub. The hub is used to anchor each of the twelve outer wires of the frame.

With the wires secured to the hubs, the rest of the frame assembly is assembled to prepare for the attachment of the passive bladder to encompass the scaffold. A suture is run in a saw-tooth pattern around the hoop direction along each of the wire loops towards the upper tips to define the loop shape and secure the loops to each other. Then a hoop suture is run around the upper perimeter of the cup to set the circumference of frame. This suture can vary in length to help shape the frame to the size and shape of the ovine heart. The sutures are passed over each tip in multiple loops before continuing on to the next frame loop. Next adhesive strips are attached to each wire loop along the line of the saw-tooth suture. The strips align in a uniform direction around the frame and act to secure the loops and provide a foundation for the attachment of the passive bladder. Finally, double-sided adhesive strips are attached to the single-sided adhesive allowing for a side of the adhesive to be exposed. The frame assembly is shown in Fig. 26.

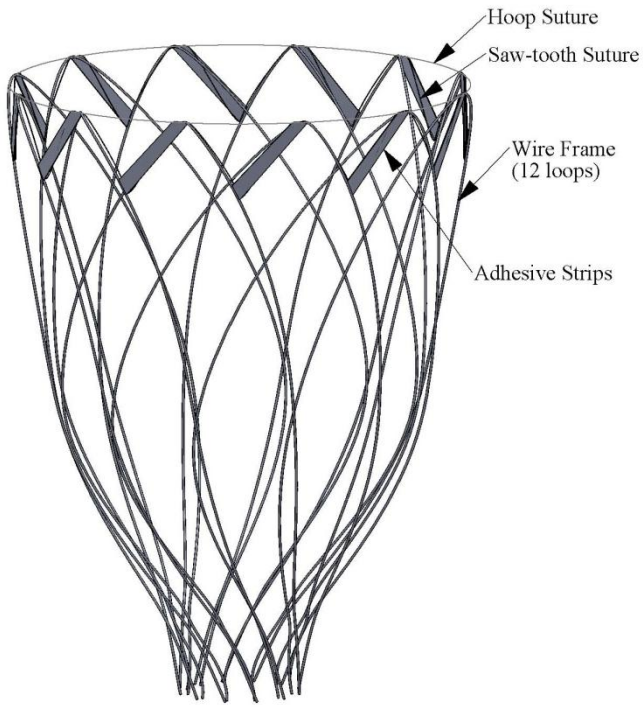


Fig. 26. Frame assembly. The assembly is composed of the twelve wires, a hoop suture to define the upper perimeter, a saw-tooth suture to connect each of the wires, and adhesive strips that fit over the saw-tooth suture that provide a foundation for attachment of the passive bladder later on in assembly.

Fig. 27 shows the M.R.I. port. Since the injection port was selected and not designed, complete engineering drawings were not needed of the port. Dimensions of the port are shown in Appendix D in Fig. 40. Shown are the major overall dimensions of the port (base diameter, height, septum diameter) and of the port catheter (French size, internal lumen diameter, and length) that are needed to display the port in an assembled drawing. The port catheter is truncated in the drawing to allow for better visibility of the complete drawing. The dimensions explicitly shown in the port drawing are exact, however the rest of the dimensions needed to create the port are approximate, as such detailed information was not available from the manufacturer, nor required for the project.

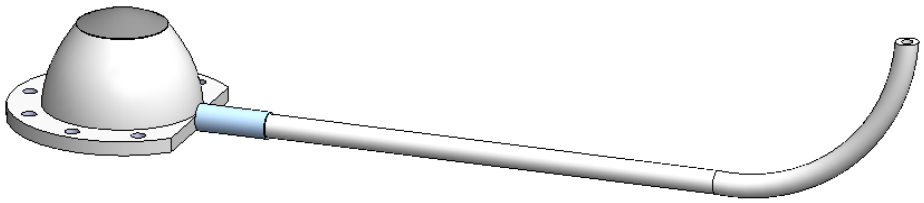


Fig. 27. Bard Access M.R.I. Port and port catheter.

The Groshong valved catheter engineering drawing is shown in Fig. 28. Like the injection port, complete engineering drawings were not needed for use in the design. Dimensions of the valved catheter are shown in Appendix D in Fig. 41. Necessary dimensions such as catheter length, internal diameter, and outer diameter are dimensioned. All other dimensions were approximated. The drawing also includes the tissue cuff, anti-microbial cuff, and the valve.

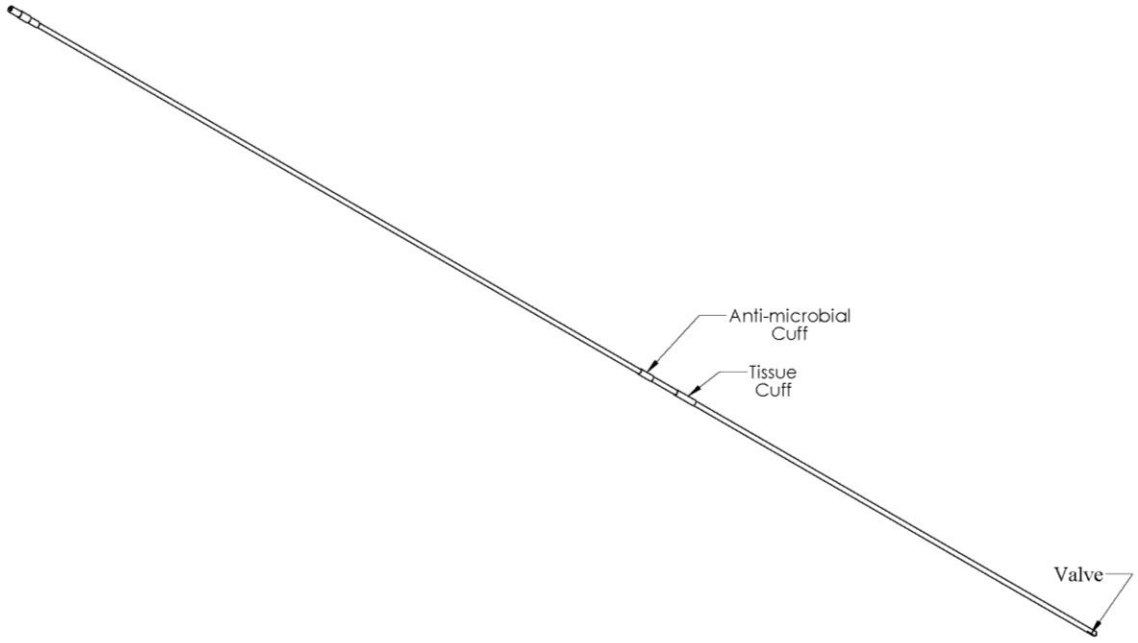


Fig. 28. Bard Access Groshong valved catheter. The distal end houses the 3-way valve, and the middle possesses two cuffs that reduce risk of infection.

With the frame and hubs completely assembled, the bladders can now be attached to the frame assembly. Fig. 29 shows an exploded assembly of all the components prior to attaching the bladders. The passive bladder film is ran external to the frame and then folded over the frame to encompass the frame. Once in position, the film is pressed onto the adhesive strips to affix the film to the frame. The looped hoop suture around each frame tip provides a buffer between the frame loop and the bladders along the upper rim of the cup. The outer film is run down the cup frame and over the rest of the internal hub components. An exploded view of the assembly with the passive bladder only is shown in Fig. 30(a). The passive bladder is shown in a cross-section view for easier viewing. As can be seen, the frame and hubs reside internal to the passive bladder. Fig. 30(b) shows an exploded drawing of the complete bladder assembly in a cross sectional view with the active bladder assembled around the passive bladder.

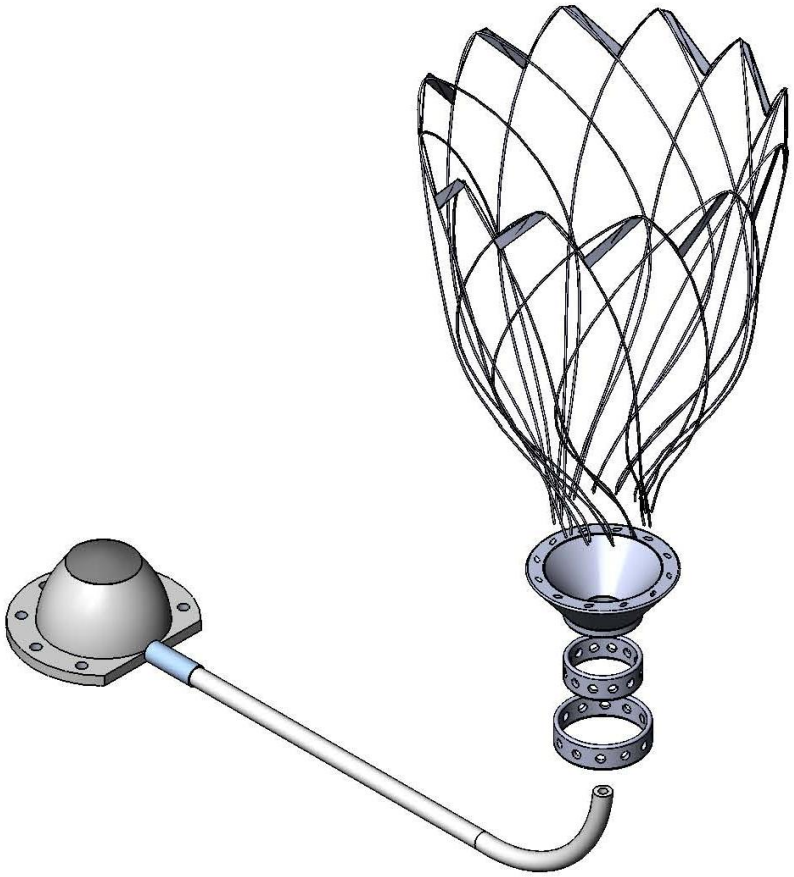


Fig. 29. Exploded view of the AACSD components prior to bladder assembly.

a b

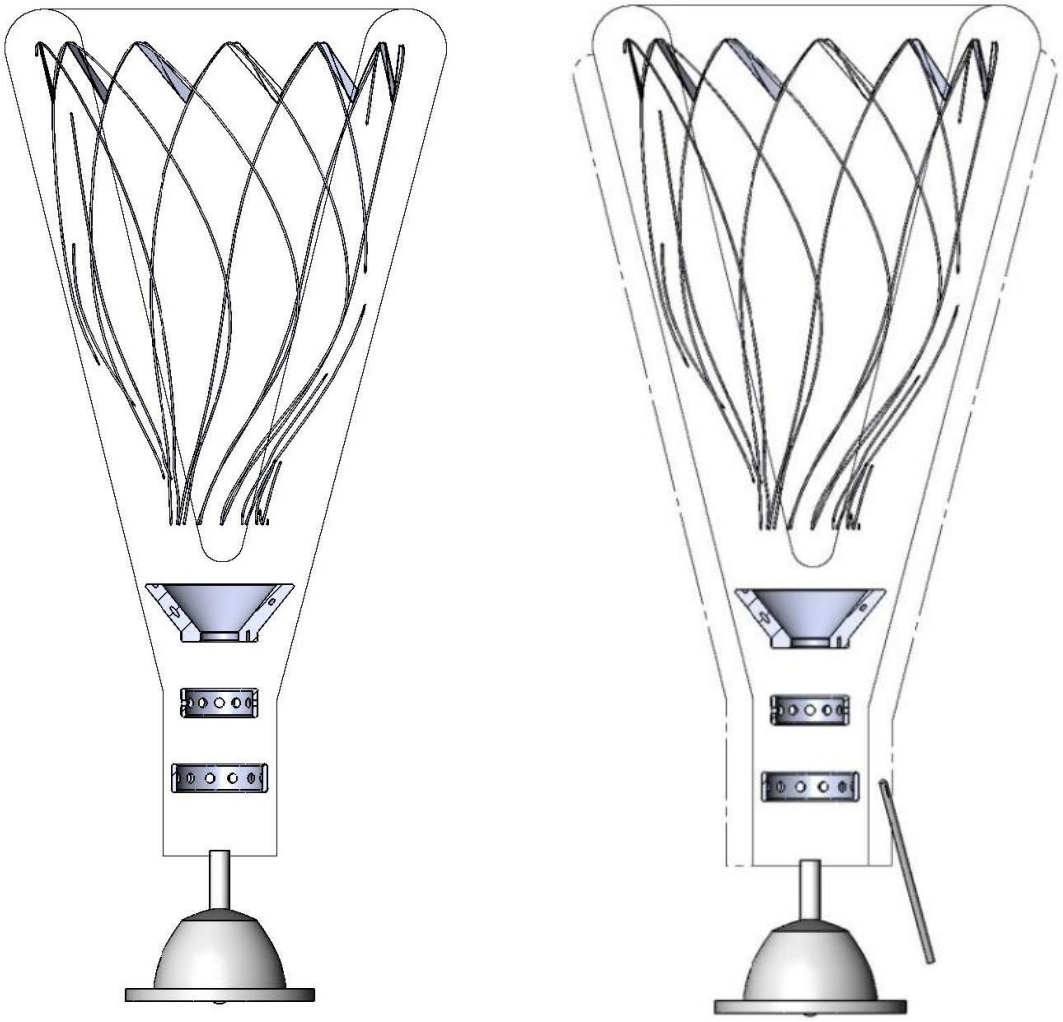


Fig. 30. Exploded cross-section with bladders. The completed passive assembly is shown in (a), and the assembly with active and passive is shown in (b). The active assembly shows the insertion of the valved catheter into the active bladder.

13. MATERIAL SELECTION OF THE AACSD

13.1 Passive and Active Bladder Materials

Due to its innovation, the AACSD's path to market would be significantly more complicated using materials that are also innovative, as additional testing would be required to validate their safety. Therefore, as stated in the design specifications, all materials must be legacy biomaterials. Legacy materials have the benefit of being available in current devices, which serve to validate their safety and effectiveness. Materials are chosen based on the sub-functions the component must perform and on the design specifications. Materials that contact the heart or pericardium must be implant grade materials and offer the required mechanical properties to accomplish each of the functions in the function structure, while materials housed internal to the bladders face less stringent biocompatibility requirements.

The passive bladders will be contacting the heart; therefore a highly biocompatible material that is not abrasive is needed to prevent scarring of the heart. The material will be under a varying internal pressure from the saline; however, the pressures are relatively small. In addition, the ability to form films of small thicknesses is needed to minimize the volume of the device to reduce its profile in the pericardium.

There are many films that are used in a balloon concept similar to the application here. Balloons are common in devices for balloon angioplasty, intra-aortic balloons, and tissue expanders. Selection of materials for these balloons is made based on the mechanical properties needed and concerns of biocompatibility. Some balloon catheters utilize a stiffer balloon material, such as polyester, that must be resistant to external forces in blood vessels. Other balloons are designed to be more compliant, such as tissue expanders, which are typically made of silicone that is extremely flexible. Other common materials available for medical films include polyurethanes and polyether block amides; both of these families are highly versatile in their properties and applications

based on their characterization and method of manufacture. Common properties and applications of each of these materials are shown in Table 15.

Table 15
Properties and uses of common material films for medical applications
a: (Teoh, Tang, and Hastings, 1998), b: (Helmus and Hubbell, 1993), c: (Martins, 2004), d: (Kucklick, 2006), e: (Batich and Leamy, 2002), f: (Bhat, 2002), g: (Pebax Medical, 2009)

	Properties	Applications
Polyurethane	high elongation at break, high flexibility, low permanent deformation on static and dynamic loading, favorable friction and abrasion performance [a], high versatility	catheters, artificial heart bladders [b], percutaneous leads, intraaortic balloons, tubing [c]
Silicone	very stable, inert [d], flexible, low mechanical strength [e]	tubing, heart valve poppets [b], catheters, membranes [f], breast implants, tissue expanders
Polyester	can be made into thin films, noncompliant, achieve desired shapes [d]	high-pressure angioplasty balloons [d]
Polyether block amides	highly versatile, easy to bond with, ease of secondary operations [d], waterproof, low coefficient of friction, flexibility, can be made into thin films, and high versatility [g]	catheter extrusion, medical textiles [d]

The primary properties of the passive bladder require a flexible material with excellent mechanical properties that can be manufactured into thin films, while maintaining a water tight environment to contain the saline. Due to the level of non-rigidity needed for the passive bladder and the low-pressure application, a non-rigid elastomer is preferred for the design embodiment; therefore a more rigid film such as polyester is not preferred. While the flexibility and biocompatibility of silicone is beneficial, the material possesses weak mechanical properties that do not make it a good choice due to the loading and unloading of the material from the heart and adjustment of bladder size, especially in thin films. The polyurethane and polyether block amide families each offer excellent biocompatibility, strong mechanical properties, low coefficients of friction, and flexibility. Polyurethane has extensive use in the medical balloon industry; however, its ability to be fashioned into thin films and maintain a

watertight environment is a concern. Polyether block amides however can be processed into very thin films while still maintaining a water tight environment.

With favorable biocompatibility and mechanical properties, and the ability to use very thin films to minimize volume of the device, a polyether block amide is suggested for use in the device. One member of this family that has extensive use in the medical industry is Pebax. Pebax is a thermoplastic elastomer used for coating for dental floss, medical textiles, and films (Pebax Medical, 2009). Pebax is capable of being extruded using a cast or blown film process down to a thickness of 10μm (Pebax Processing, 2009), which is well within the maximum specified thickness of the films. The properties of Pebax are highly versatile; one particular film suitable for this purpose is Pebax MV 3000 SA 01. Table 16 shows some properties of this film.

Table 16
Select properties of Pebax MV 3000 SA 01
a: (Pebax MV 3000, 2009), b: (Pebax Medical, 2009)

Tensile Stress at Break [a]	35	MPa
Tensile Strain at Break [a]	500	%
Flexural Modulus [a]	45	MPa
Hardness [a]	35	Shore D
Melting Point [a]	158	°C
Biocompatibility [b]	USP class IV, free of additives and plasticizers	
Sterilization [b]	Ethylene oxide process, steam, gamma radiation	

It is beneficial to use the same type of material for the active bladder as the passive bladder to minimize any unfavorable material interactions between the bladders. The material should be elastic to preserve the integrity of the bladder over the range of operating stresses and should have sufficient fatigue strength to handle the cyclic inflation and deflation. Like the passive bladder, biocompatibility, good mechanical properties, and the ability to be made into thin films are primary concerns; therefore Pebax is also suggested as the material for the active bladder. The active bladder must be attached to the passive bladder along the upper rim and the base; this can be done

using an adhesive to bond the bladders together or through thin film welding techniques, such as high frequency welding (Pebax Welding, 2009).

13.2 Frame Materials

The frame consists of a metal wire scaffold. Since the entire frame is contained within the passive bladder, biocompatibility of the material is not a primary concern; the primary concern of the frame is mechanical properties of the material needed to achieve its main functions: flaring the cup from its collapsed state, providing structure for the cup, and adapting the cup to the changing shape of the heart. Unlike the bladders, which must be custom manufactured, metal wires for assembling the frame are available for purchase as standard parts in industry.

Metal wires for medical applications are typically either stainless steel 316L or nitinol. Of the two materials, nitinol possesses many unique mechanical characteristics that make it a suitable choice for the frame. Nitinol is a shape memory alloy that allows for the variability of many of its mechanical properties based on the material composition and the manufacturing process. The principal concern of the frame is ensuring it flares the cup for deployment from its collapsed state. Unlike stainless steel 316L, which may be readily deformed, nitinol can be made into a super elastic alloy that possesses excellent resistance to deformation and can spring-back to its original shape.

Nitinol can be made into different phases by adjusting the transformation temperature of the alloy. For super elasticity, deformation slightly above its transformation temperature results in stress-induced changes in the material microstructure. Once the stress is removed, the material microstructure returns to its original microstructure, resulting in the metal returning to its original shape. This process gives the nitinol excellent kink resistance, strain recovery, and flexibility. For this application, the nitinol used should possess a transformation temperature below room temperature to ensure that it possesses these super elastic properties for operation at normal body temperature. The super elastic nitinol prevents plastic deformation from collapsing the device for implantation and springs the device open for deployment

around the heart. Given the elasticity needed for deploying the device and for adapting to the heart's motion, nitinol is selected for use in the frame. Table 17 shows the composition of super elastic nitinol, and Table 18 shows select mechanical properties of super elastic nitinol.

Table 17
Composition of super elastic nitinol (MatWeb, 2009)

Carbon	≤ 0.05	%
Iron	≤ 0.05	%
Nickel	55.3-56.3	%
Oxygen	≤ 0.05	%
Titanium	43.55-44.7	%

Table 18
Select mechanical properties of super elastic nitinol (MatWeb, 2009)

Tensile Strength, Ultimate	155	ksi
Tensile Strength, Yield	118	ksi
Elongation at Break	8	%
Lower super elastic plateau stress	20	ksi
Upper super elastic plateau stress	55	ksi

13.3 Internal Components Materials

The internal components consist of the following: outer hub, inner hub, and sliding hub. Due to their location within the passive bladder biocompatibility is not a primary concern, and since the components will not be under high stress, mechanical properties are also not a significant concern. It is beneficial that these components be composed of similar materials to avoid unfavorable interactions between dissimilar materials. The geometries of these components are simple and the parts themselves are small in size. Advanced manufacturing processes, such as injection molding have heavy up-front costs that makes the process suitable for large scale production, but not for small scale production. Since the number of parts needed to be produced is on the order of 100, such advanced manufacturing processes are not feasible for the manufacture of the internal components for further prototyping and animal studies.

A feasible process for obtaining parts of this nature for small scale production is rapid-prototyping (RP). RP is a process used by many small companies and researchers to develop parts of precise geometries with low cost and quick turnaround. The development of expensive molds is not necessary. Instead, many RP techniques can

manufacture components straight from 3-D drawings. One popular RP process that can be used for the development of the inner hub, outer hub, and sliding hub is stereolithograpy (SLA). SLA uses a layer building process to construct the part. A laser cures an ultraviolet light sensitive polymer of the desired cross-section one layer at a time. After the layers have finished building on top of each other, the part is post-processed to set the shape and remove any unwanted resin. SLA is capable of producing rigid polymers with high tolerances and good surface finishes. While materials used for SLA do not possess the same mechanical properties as engineering plastics, the hubs will not be undergoing large stresses and therefore are suitable for SLA design.

13.4 Assembly Components Materials

For assembly, original equipment manufacturer (OEM) adhesives and sutures can be utilized. Nylon sutures can be used in the assembly; they are prevalent in the medical field and provide excellent tensile strength, ability to knot, resistance from fraying, and resistance to elongation. Adhesives are needed for use internal to the passive bladder to attach the wires to the hubs, to assemble the passive and active bladders, and to attach the passive bladder to the frame. Since these adhesives will be internal to the passive bladder, medical grade adhesives are not needed. For attaching the nitinol wires to hubs, an adhesive such as cyanoacrylate can be used to bond the nitinol to the hubs, or suture can be used to mechanically join the wire and hubs. For the attachment of the passive bladder to the frame, commercial quality adhesive melt strips can be used. The adhesive can be melted in its desired location and upon drying the adhesive effectively bonds the bladder together. Prototyping has validated its ability to create a sufficiently strong bond and hold in the presence of saline. This is preferred over two part adhesives or light curing adhesives due to its ease of construction. For creating the seal of the passive bladder to the port catheter and active bladder to the valved catheter, a medical grade adhesive is needed since it is not internal in the device. Typically ultraviolet light cure adhesives are used in similar catheter assembly processes (Kucklick, 2006), and these adhesives can be to assemble the bladders and catheters.

14. DESIGN OUTPUTS AND DESIGN EVALUATION

14.1 Parts List

With the design and materials for embodying the design selected, a parts list can be generated for the design output stage. The parts list details each component of the design, and includes the number of parts needed, part material, dimensions, a description of the part, and functions of the part. The Parts List for the AACSD is shown in Table 19. The parts list is broken into separate sections. The first contains the passive and active bladders. These may be manufactured through extrusion processes such as blown film extrusion. This process is commonly used for creating thin plastic films for a wide variety of applications, including medical device packaging. The nitinol wire, sutures, and adhesives are available as OEM products. The internal hubs can be manufactured using RP. Finally, the port, port catheter, and valve catheter are available from Bard Access Systems. For complete dimensions refer to the engineering drawings in Appendix D.

14.2 Failure Modes and Effects Analysis

The final production specification generated is an FMEA. This is an evaluation tool for the embodied design to provide a look at the weaknesses of the concept design described herein and is useful for future studies to identify possible failure modes of the design to provide recommendations for future prototype iterations. Failure modes of the port and catheters were included; however failure in these components is unlikely due to their high level of manufacturing and their extensive use already on the market.

Table 19
Parts List

Part#	Sub-component	Qty.	Material	Dimensions	Description	Function
1	Passive Bladder	1	Pebax MV 3000 SA 01	12" length, 14" height, 20 μm thickness	Thin film which folds over frame to form bladder	Form passive bladder, provide barrier between device and heart
2	Active Bladder	1	Pebax MV 3000 SA 01	12.75" length, 14" height, 20 μm thickness	Thin film attaches to top and base of cup around passive bladder	Form active bladder, provide barrier between device and pericardium
3	Frame	12	Super elastic nitinol	0.025" OD 8.25" wire lengths - 3.75" outer and 4.5" inner lengths	Wire proximal end at inner hub and distal end at outer hub	Flare cup around heart during deployment, provide cup structure, promote proper kinematics of device
4	Frame Suture	vary	Nylon	Vary upon use	Medical Suture	Secure frame wires to hubs
5	Frame Adhesive (single-sided)	12	Plastic melt adhesive	0.5" length 0.125" width	Single-sided plastic melt adhesive strips fashioned to upper portion of outer nitinol wire	Mate individual wires to allow for collapsibility of device but limit expansion in hoop direction, provide attachment area for active bladder
6	Frame Adhesive (double-sided)	12	Plastic melt adhesive	Length 0.5" Width 0.125"	Double-sided plastic melt adhesive strips	Mate frame and passive bladder by covering single-sided frame adhesive strips to provide attachment area for inner layer of passive bladder
7	Saw-tooth Suture	1	Nylon	≈ 16" length, vary based on assembly	Medical suture	Provide firm connection between individual wires in frame with saw-tooth pattern along frame adhesive strips
8	Hoop Suture	1	Nylon	12" length	Medical suture	Provide barrier between frame and passive bladder at tips, set frame upper diameter
9	Wire Adhesive	vary	Cyanoacrylate	Vary upon use	Non-medical adhesive	Bonding nitinol wire and hubs
10	Passive Bladder Adhesive	12	Plastic melt adhesive	0.75" width by ≈ 7" length wedges	Plastic melt adhesive cut into wedges	Reduce size of bottom circumference of bladder, help create crenellation of bladder

Table 19 Continued

Part#	Sub-component	Qty.	Material	Dimensions	Description	Function
11	Active Bladder Adhesive	6	Plastic melt adhesive	1.625" width by ≈ 7" length wedges	Plastic melt adhesive cut into wedges	Reduce size of bottom circumference of bladder, help create crenellation of bladder
12	Sliding Hub	1	Rapid Prototype Resin (vary by supplier)	Bottom OD: 0.5", Bottom ID: 0.25" Top OD: 1", Top ID: 0.75" Height: 0.375" Channel Radius of Curvature: 0.25" Channel Diameter 0.031"	Conically shaped shell that contains a channel for each inner nitinol wire	Aid in deployment by matching with apex and promoting flare of frame
13	Inner Hub	1	Rapid Prototype Resin (vary by supplier)	OD: 0.5", ID: 0.438" Height: 0.188" Hole Diameter: 0.063"	Cylindrically shaped ring that contains 12 holes for the nitinol wires and suture	Base connection for inner nitinol inner
14	Outer Hub	1	Rapid Prototype Resin (vary by supplier)	OD: 0.625", ID: 0.563" Height: 0.188" Hole Diameter: 0.063"	Cylindrically shaped ring that contains 12 holes for the nitinol wires and suture	Base connection for outer nitinol wire
15	Port	1	Base: Plastic Septum: Silicone	Base Diameter: 31.5mm Septum Diameter: 12.5mm Height: 15.3mm	FDA approved, M.R.I. compatible, up to 1000 injections with 19 Gauge Needle	Delivering and removing saline subcutaneously
16	Port Catheter	1	Silicone	OD: 3.2 mm (9.6 Fr.), ID: 1.6mm Length: 76cm	FDA approved, open-ended	Transfer saline to and from port and passive bladder
17	Valved Catheter	1	Silicone	OD: 2.7 mm (8.0 Fr.), ID: 1.5mm Length: 50cm	FDA approved, 3-way valve on distal end	Transfer air to and from external pump system and active bladder, seal air in bladders

The FMEA lists the functions and potential failure modes of each part. For each failure mode, three categories are examined. The first is the potential effects of the failure. The severity of these effects is rated and given a number based on the scale shown in Table 20. The second category is potential causes for the failure. The likelihood of occurrence of the causes generating the failure is rated and given a number based on the scale shown in Table 21. The third category is current controls in place to prevent or detect the failure from occurring beforehand. The likelihood of detection is rated and given a number based on the scale shown in Table 22.

Table 20
Scale for potential severity (S) (Otto and Wood, 2001)

Scale for Potential Severity (S)	
1	No effect
2	Very minor (only noticed by discriminating customer)
3	Minor (affects very little of the system; noticed by average customer)
4/5/6	Moderate (most customers are annoyed)
7/8	High (causes a loss of primary function; customers are dissatisfied)
9/10	Very high and hazardous (product becomes inoperative; customers are angered; the failure may result unsafe operation and possible injury)

Table 21
Scale for likelihood of occurrence (O) (Otto and Wood, 2001)

Scale for Likelihood of Occurrence (O)	
1	No effect
2/3	Low (relatively few failures)
4/5/6	Moderate (occasional failures)
7/8	High (repeated failures)
9/10	Very high (failure is almost inevitable)

Table 22
Scale of likelihood of detection beforehand (D) (Otto and Wood, 2001)

Scale of Likelihood of Detecting Beforehand (D)	
1	Almost Certain
2	High
3	Moderate
4/5/6	Moderate - most customers are annoyed
7/8	Low
9/10	Very remote to absolute uncertainty

Next the Risk Priority Number (RPN) is calculated by Equation 5,

$$RPN = (S) \times (O) \times (D) \tag{5}$$

The range of the RPN is 1-1000, with the higher the numbers indicating increased concern for failure. It should be noted that the scale is not linear. Ratings above 100 are defined as being likely to occur and should be revisited to reduce the risk of failure (Otto and Wood, 2001). Ratings below 30 are typical for products and are reasonable (Otto and Wood, 2001). Based on the RPN, recommended actions are suggested for revisiting the part in order to reduce the risk of failure, if applicable. The FMEA is shown in Table 23.

Table 23
FMEA for components of AACSD

Part	Function	Potential Failure Mode	Potential Effect(s) of Failure	S	Potential Cause(s) of Failure	O	Current Controls - Prevention & Detection	D	RPN	Recommended Action
Passive Bladder	Store Saline, Import Saline, Export Saline	Degradation	weakening of bladder	3	biological environment	3	use of legacy biomaterials	4	36	animal study to test
		Material yield	improper bladder inflation	4	over inflation, over use	2	use material with strong mechanical properties	2	16	animal study to test
		Fatigue	weakening of bladder	5	cyclic loads from volume changes and from heart	3	use material with strong mechanical properties	4	60	animal study to test
		Creep	weakening of bladder	5	prolonged stresses from inflation	4	use material with strong mechanical properties	5	100	animal study to test
		Unstable	cavity obliteration	10	over inflation	3	in short term care taken not to over inflate, in long term bladder fibroses to heart	4	120	careful monitoring during initial use; animal study to test
		Tear	put hole in bladder	8	inadequate deployment	2	use material with strong mechanical properties, smooth walls of deployer tube	1	16	develop procedure for collapsing, bench top testing of deployment
		Bonding failure	detachment of catheter, leaking and loss of pressure	8	insufficient contact area	3	use of standard methods of heat bonding	2	48	animal study to test
Active Bladder	Store Air, Import Air, Export Air	Degradation	weakening of bladder	3	biological environment	4	use of legacy biomaterials	4	48	animal study to test
		Material yield	improper bladder inflation	4	over inflation, over use	3	use material with strong mechanical properties	2	24	animal study to test
		Fatigue	weakening of bladder	5	cyclic loads from volume changes and from heart	6	use material with strong mechanical properties	4	120	animal study to test
		Creep	weakening of bladder	5	prolonged stresses from inflation	2	use material with strong mechanical properties	5	50	animal study to test
		Unstable	pericardial sac obliteration	10	over inflation, insufficient material properties	3	use of a stiffer material to promote direction of inflation inward	3	90	animal study to test
		Tear	put hole in bladder	8	inadequate deployment	3	use material with strong mechanical properties, smooth walls of deployer tube	1	24	develop procedure for collapsing, bench top testing of deployment
		Bonding failure	detachment of catheter, leaking and loss of pressure	8	insufficient contact area	3	use of standard methods of heat bonding	2	48	animal study to test

Table 23 Continued

Part	Function	Potential Failure Mode	Potential Effect(s) of Failure	S	Potential Cause(s) of Failure	O	Current Controls - Prevention & Detection	D	RPN	Recommended Action
Frame / Wire adhesive	Flare device, Shape device to heart, provide cup structure / Secure wires to hubs	Material Yield	deformed scaffold, improper deployment	3	inadequate material selected	1	use of super elastic nitinol, allow for degree of freedom at connections	3	9	bench top testing of operation
		Buckling	deformed frame, improper frame motion	4	improper assembly	2	allow for degrees of freedom at connections	4	32	bench top testing of operation
		Fatigue	weakened frame	4	varying loads from heart and bladders	3	use material with strong mechanical properties	3	36	bench top testing of operation
		Misalignment	improper frame movement	3	improper assembly	2	use of sutures and adhesives to help define frame shape	1	6	prototype testing of assembly
		Creep	weakened frame	4	prolonged stress from bending	3	use material with strong mechanical properties	4	48	bench top testing of operation
		Scratching	wears hole through bladder	8	abrasive ends or surface	2	bladder will be filled to act as a buffer, smooth material is used, knots lift passive bladder off frame	2	32	bench top testing of operation
		Bonding failure	detachment of wire from hubs, loose wire could damage bladder	8	inadequate amount of adhesive used, insufficient contact area of adhesive	3	use of legacy adhesive compatible with frame and hub materials, and use of sutures	4	96	develop a mechanical attachment
Sliding Hub	Flare nitinol scaffold	Corrosion	weakening of hub	3	saline solution damages surface	3	use of material resistant to saline	2	18	bench top testing of operation
		Fracture	frame becomes detached	9	improper deployment	2	use of a mechanically strong polymer	2	36	bench top testing of deployment
		Misalignment	improper frame orientation	3	improper assembly	2	use a symmetrical design	1	6	prototype testing of assembly
		Cracking	frame becomes detached	4	excessive loads from frame, improper deployment	2	use of a mechanically strong polymer	2	16	bench top testing of deployment and operation
		Scratching	wears hole through bladder	8	abrasive surface	4	selection of a manufacturing process capable of smooth surfaces	2	64	bench top testing of operation
		Wear	weakening of hub, abrasive particles in bladder	4	rubbing with other hubs	3	sizing specifications to minimize rubbing	3	36	bench top testing of operation

Table 23 Continued

Part	Function	Potential Failure Mode	Potential Effect(s) of Failure	S	Potential Cause(s) of Failure	O	Current Controls - Prevention & Detection	D	RPN	Recommended Action
Inner Hub	Secure inner nitinol scaffold	Corrosion	weakening of hub	3	saline solution damages surface	3	use of material resistant to saline	2	18	bench top testing of operation
		Fracture	frame becomes detached	9	improper deployment	2	use of a mechanically strong polymer	2	36	bench top testing of deployment
		Misalignment	improper frame orientation	3	improper assembly	2	use a symmetrical design	1	6	prototype testing of assembly
		Cracking	frame becomes detached	4	excessive loads from frame, improper deployment	2	use of a mechanically strong polymer	2	16	bench top testing of deployment and operation
		Scratching	wears hole through bladder	8	abrasive surface	2	selection of a manufacturing process capable of smooth surfaces	3	48	bench top testing of operation
		Wear	weakening of hub, abrasive particles in bladder	4	rubbing with other hubs	4	sizing specifications to minimize rubbing	3	48	bench top testing of operation
Outer Hub	Secure outer nitinol scaffold	Corrosion	weakening of hub	3	saline solution damages surface	3	use of material resistant to saline	2	18	bench top testing of operation
		Fracture	frame becomes detached	9	improper deployment	2	use of a mechanically strong polymer	2	36	bench top testing of deployment
		Misalignment	improper frame orientation	3	improper assembly	2	use a symmetrical design	1	6	prototype testing of assembly
		Cracking	frame becomes detached	4	excessive loads from frame, improper deployment	2	use of a mechanically strong polymer	2	16	bench top testing of deployment and operation
		Scratching	wears hole through bladder	8	abrasive surface	3	selection of a manufacturing process capable of smooth surfaces	3	72	bench top testing of operation
		Wear	weakening of hub, abrasive particles in bladder	4	rubbing with other hubs	4	sizing specifications to minimize rubbing	3	48	bench top testing of operation
Sutures (Frame / Hoop / Saw-tooth)	Attach frame to hubs / Define nitinol scaffold shape, buffer for bladder / Secure frame	Fatigue	weakening of suture, break in suture	2	overstressed	3	use of a medical grade suture	2	12	animal study to test
		Misalignment	improper frame orientation	4	improper assembly	2	use of a medical grade suture	3	24	animal study to test
		Loosening	detachment of suture	3	overstressed, improper assembly	3	use of a medical grade suture	3	27	animal study to test

Table 23 Continued

Part	Function	Potential Failure Mode	Potential Effect(s) of Failure	S	Potential Cause(s) of Failure	O	Current Controls - Prevention & Detection	D	RPN	Recommended Action
Adhesive (Frame / Bladder)	Secure passive bladder material to frame / Form passive and active bladder shape	Bonding failure	detachment of materials	8	inadequate amount of adhesive used, insufficient contact area of adhesive,	3	use of legacy adhesive compatible with frame and bladder materials	2	48	bench top testing of operation
		Corrosion	weakening of adhesive	3	saline solution environment	3	use of legacy adhesive compatible with frame and bladder materials	3	27	bench top testing of operation
		Misalignment	improper bladder orientation	4	improper assembly	4	use a symmetrical design	3	48	prototype testing of assembly
		Wear	loss of adhesive to weaken bond	3	rubbing between components	2	use of legacy adhesive compatible with frame and bladder materials	3	18	bench top testing of operation
Port Body	Accept Needle, Store Saline, Transfer to catheter	Fatigue	compromised membrane allowing leaks	7	over injection, overfill	1	selection of port made for operation within pressure range	2	14	bench top testing of operation
		Cracking	infection, leak of fluid	7	inadequate injection procedures	1	selection of port made for long term use	2	14	bench top testing of operation
		Leaking	loss of fluid	7	inadequate manufacture	1	selection of port made for long term use and with good reputation	1	7	bench top testing of operation
		Corrosion	infection	5	inadequate material selected	1	selection of port for long term use	2	10	animal study to test
		Misalignment	kink in line, difficulty in injection	3	inadequate implantation	2	selection of port made for chest cavity and with established reputation	2	12	prototype testing of assembly
		Loose fittings	leak, detachment of catheter	5	inadequate implantation or manufacture	1	selection of port with secure attachment	1	5	animal study to test
Port Catheter	Transfer to passive bladder	Fatigue	leak of fluid	6	overstress	1	selection of catheter made for operation within pressure range	2	12	bench top testing of operation
		Cracking	infection, leak of fluid	7	overstress, improper implantation	1	selection of catheter with established reputation	2	14	bench top testing of operation
		Misalignment	kink in line	3	improper implantation	2	selection of catheter with established reputation	2	12	prototype testing of assembly

Table 23 Continued

Part	Function	Potential Failure Mode	Potential Effect(s) of Failure	S	Potential Cause(s) of Failure	O	Current Controls - Prevention & Detection	D	RPN	Recommended Action
Drive Line	Transfer to active bladder, Prevent Infection	Material yield	valve no longer functions in normal operating range	5	over stress, flow rate too high	3	selection of catheter and valve made for operation within pressure range	3	45	bench top testing of operation
		Misalignment	kink in line, valve doesn't open to bladder	8	improper assembly or implantation	5	selection of catheter with established reputation	3	120	prototype testing of assembly
		Vibrations	infection, unwanted movement of line and or cup	7	inadequate implantation	4	have seal within bladder, use of tunneled catheter	3	84	animal study to test
		Cracking	infection, leak of fluid	7	overstress, improper implantation	1	selection of catheter with established reputation and made for long term use	2	14	bench top testing of operation
		Inefficient	can't empty or fill bladder in required time frame	8	inadequate catheter diameter	7	selection of largest ID valved catheter in line	2	112	bench top testing of filling bladder
		Wear	infection	6	biological environment	2	selection of catheter with established reputation and made for long term use	2	24	animal study to test
		Fatigue	leak of fluid, valve no longer works in normal operating range	7	too many cycles	5	selection of long term catheter and valve made for operation within pressure range	3	105	bench top testing of operation

For the passive bladder, the largest concerns are the threat of cavity obliteration and creep. The frame protects the active bladder from obliterating the cavity, but care must be taken while filling the passive bladder to prevent cavity obliteration; however, the relatively static nature of the passive bladder limits its ability to obliterate the cavity. Long term studies to test the effects of creep on the passive bladders are needed; however Pebax possesses good mechanical properties, so creep is not expected to be a significant concern. Bonding failure is also a concern since it has not been previously looked at during prototyping; however, Pebax bonds easily and many medical grade adhesives are used in high-pressure applications. For the active bladder, the largest concerns for failure are fatigue, creep, and pericardial sac obliteration. Further fatigue testing is needed; however, the good mechanical properties of Pebax along with the limited duration needed for active assist and the absence of high pressures give promise to the design proposed.

For the frame the primary concerns are bonding failure; however cyanoacrylates have prior use bonding to nitinol and sutures may also be used to secure the wires. The smooth surface of nitinol is beneficial to reduce the risks of scratching. In addition, the passive bladder will be inflated for most of its use, causing the bladder to inflate away from the frame and reduce the risk of scratching. The primary concern of the hubs is abrasive scratching to create a hole in the bladder. This risk is reduced by creating hubs of a smooth surface finish and inflating the passive bladder so that the material is inflated away from the hubs. The sutures did not exhibit any large concerns as their failure is not likely to be very severe. The adhesive failures are similar to the concerns of the bonding failure in the bladders. The concern for failure of the port or port catheter is minimal due to their FDA approval for higher pressure applications. The innovative use of the valved catheter to shuttle air and out of the active bladder dictates that additional testing is needed to ensure the seal will not yield over the course of its operation, and that the catheter is sufficient to remove and add air to the active bladder in the limited time frame. Additional concerns for ensuring the valve is not blocked or misaligned and the effects of vibrations in the line must also be tested.

15. AIM II FUTURE CONSIDERATIONS

15.1 Verification of the Embodied Design

The design plan for the AACSD proposed herein provides a model for the design of future prototypes and follows the design control process. For future iterations, steps of this design plan should be reviewed to assure that all steps are applicable, and revisions made where needed. For example, it may come to light that the design specifications may need revision upon further testing. This would involve appropriately adjusting the design specification and then making adjustments to the design plan as necessary. The plan proposed herein also allows for a framework of verifying that the design output meets the design input, before continuing onto the medical device phase of the design process.

15.2 Development of Multiple Sizes of the Device

The development of a sizing algorithm for the manufacture of multiple sizes of the device will be needed to have an appropriately sized device due to the variability of the heart shapes and sizes. Due to the wide range of sizes, continued studies must be performed to develop a product line for the device. Overall heart geometry is attainable for each ovine prior to implantation in a non-invasive manner using imaging, such as echocardiography. Other CSDs also have multiple sizes to account for this difference; for example the HeartNet is available in 16 different sizes for human heart use (Klodell et al, 2008), while the CorCap is available in the 6 different sizes for human heart use shown in Table 24 (Acorn, 2009). The inability of current CSDs to adapt to the shape of the heart is the reason why so many of these sizes are needed. Conversely, the Anstadt Cup DCCD uses three different models, based on the ventricular length to adapt to varying human heart (Anstadt, 1992). One model is used for lengths less than 7.5cm, a second for lengths between 7.5-14cm, and a third for lengths greater than 14cm (Anstadt, 1992). The lengths between the CorCap and the Anstadt cup do not

necessarily use the same references, so care must be taken when comparing dimensions between the two devices.

Table 24
Six different sizes of Acorn Cardiovascular's CorCap (Acorn, 2009)

Length (cm)	Circumference (cm)
11.5	32
12	37
13.5	39
15.5	41
17	44
19	46

The Anstadt Cup is in need of significantly less device sizes than the CorCap or HeartNet because the inflatable nature of the Anstadt Cup does not require a precise fit as is required for the CSDs. From this information it is hypothesized that the number of sizes needed for the AACSD for meeting the range of heart sizes expected is between three and six. To determine the number of sizes needed for the AACSD additional testing of the embodied design would be required. Testing must be done on a manufactured prototype to determine the effective range of heart sizes that a prototype can effectively provide adequate support and assist. From this information, the appropriate number of models and sizing of each model to cover the entire range of hearts can be determined.

Manufacturing of different sizes of the device is expected to be relatively straightforward, as the design embodiment process is readily transferable towards the development of multiple sizes in the product line. The same methods of assembly and manufacture can be used for the development of each device size; only dimensions of the components must be varied. For the passive bladder and the active bladder, the height and length of the films will need to be adjusted. For the frame, the wire lengths must be varied. The diameters of the internal hub components may not need to be adjusted as their vertical location within the passive bladder can be varied to achieve

different frame shapes close to the hubs; however if variable diameters of the hubs are needed then they can be readily manufactured in different sizes. A benefit of manufacturing these hub components using RP is that the development of different sizes can be easily completed in a fraction of the time and cost in comparison to advanced manufacturing processes, like injection molding. The assembly components can also be adjusted as needed. For example, the hoop suture length may need to be adjusted to fit the new cup diameter. Finally, the same port, port catheter, and valved catheter can be used for all of the cup configurations.

15.3 Use of Engineering Plastics for the Hubs

While the frame and bladder are made of durable engineering materials, the hubs were suggested to be made of resin that could be made through SLA. If the development of a more durable rigid strong plastic with high fatigue strength properties is desired, then conventional manufacturing of engineering plastics is necessary. Possible plastics for consideration include polyacetal and polysulfone. Properties and applications of each of these plastics are shown in Table 25.

Table 25
Properties and applications of material candidates for internal components
a: (Teoh, Tang, and Hastings, 1998), b: (Kucklick, 2006), c: (Helmus and Hubbell, 1993)

	Properties	Applications
Polyacetal	Outstanding creep and fatigue resistance, good toughness and impact resistance, excellent strength [a], low coefficient of friction, difficult to bond to, chemical resistance, sensitive to sterilization [b]	Heart valve structures[c], injection port bodies
Polysulfone	Good rigidity, creep resistant, tough [a], high resistance to salt solutions, high strength [b]	Heart valve and artificial heart structures[c], injection port bodies

Both plastics have extensive and validated use in the medical device industry. Due to the low loads that the inner hubs will be experiencing, the excellent mechanical properties of each thermoplastic polymer are sufficient for the application. However, the difficulty of bonding to polyacetal is well documented, and the need for the ability to bond the nitinol wire to the hubs makes this a significant concern. For this reason polysulfone is the recommended material for the inner hub, outer hub, and sliding hub. Another important property of polysulfone is its high resistance to salt solutions, which is important since it will be housed internal to the saline filled passive bladder. One available polysulfone is UDEL. Select mechanical properties of UDEL polysulfone are shown in Table 26.

Table 26
Select mechanical properties of UDEL Polysulfone (Park and Lakes, 2007)

Tensile strength	70	MPa
Tensile modulus	2.52	GPa
Elongation	50-100	%
Water adsorption	0.3	%, 24 h

16. SUMMARY

The design research performed is aimed toward the development of an AACSD concept suitable for a novel cup that can perform passive support and active assist on the heart and be deployed in a minimally invasive manner to meet the needs of CHF patients, and toward the embodiment for a manufactured design for further proof-of-concept studies. The AACSD is designed to encourage natural growth and remodeling of the heart that results in reduced EDV and increased stroke work, while weaning the heart off the device. The research was successful in identifying a design for embodiment through classifying user needs, mapping user needs to design specifications for the device, using the design specifications for the generation of design concepts, and ultimately concept selection. The research was also successful in identifying methods for embodying the design for manufacture. Included are dimensions of the device, selection of a port and drive line for integration in the device, selection of materials for the device, a parts list, engineering drawings, and a FMEA for evaluation of the device.

Further studies with the design will inevitably result in new criteria needed for the device and the identification of better techniques for accomplishing the criteria. However, the research provided herein uses a design process that encourages such iterative designing to ensure a quality system is maintained. As changes are made to the design, the design process can be adapted and translated as needed to the new design. While changes are inevitable, it should be noted that the development of such a design plan for the design and embodiment of iterative designs is essential for verification and validation down the road to ensure the device has been thoroughly tested for performance and safety, and meets the needs of the user to provide a safer, more effective, and more natural CHF therapy.

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APPENDIX A

There are numerous methods available for determining the user needs of the market. Methods available include direct methods that utilize user interaction, such as customer surveys or product demonstrations, while other methods are indirect and focus on research of the product and market. Direct methods are most useful for consumer products and have the advantage of direct user feedback for determining the user needs; however such methods require extensive time, and often money, in contacting numerous users to gain an understanding of the user needs of the entire market and avoiding bias of a subset of the market. Indirect methods lack the direct user interaction that is often desired for determining the user needs of consumer products; however indirect methods have the advantage of providing an objective and thorough analysis of the user needs without the need of contacting numerous users directly.

One indirect method of determining user needs is to perform a contextual needs assessment (CNA). A CNA consists of a listing of context factors that categorize user concerns of the product. The response to the concerns is determined through research of unmet user needs from current therapies on the market, results of previous prototypes of the device, and animal studies. The response to the concerns is then translated into the respective needs of the user for each particular context. The CNA for determining the corresponding user needs for the device is shown in Table 27. The particular template was adapted for specific use for this research from (Linsey, 2008). The corresponding needs are used as the basis for the interpreted needs.

Table 27

Customer needs assessment. Indicates contexts and needs for Product Application, Product Environment, and Customer Characteristics.

#	Context Factor	Concerns	Response to Concerns	Corresponding Needs
			Application	
1	AACSD application	What is the purpose of the AACSD?	Limit the progression of congestive heart failure while promoting natural mechanics.	reduce heart size, restore natural heart function
2	AACSD function	What functions should the AACSD provide?	Provide passive support and active assist to a failing heart in a minimally invasive manner.	reduce risks of implantation, restore natural heart function
3	AACSD quality	What quality of function is needed?	High quality is needed to ensure that device does not damage heart or endanger patient.	minimize risk of device failure, reduce risks of implantation, not detrimental to heart
4	AACSD process	What are the current therapies? How will the AACSD differ?	Current options include other invasive procedures that do not provide a natural recovery. The product allows for a minimally invasive treatment for a more natural recovery.	reduce risks of implantation, reduce heart size, restore natural heart motion
5	AACSD frequency	How often will the AACSD be used?	Use will vary based on heart condition. Passive support will be used continuously to gradually wean heart off device and active assist will be used only as needed in short intervals.	adequate product lifetime, ease of access to device, ease of monitoring device, minimize risk of device failure
6	AACSD duration	How long will the AACSD be in use?	Passive support will be used on the order of weeks. Active assist will be used on the order of minutes in short intervals as needed.	adequate product lifetime, minimize risk of device failure, ease of monitoring device
7	AACSD performance	How will performance be measured?	A statistically significant increase in cardiac output and reduction in overall heart volume.	reduce heart size, increase cardiac performance
8	AACSD ruggedness	How roughly will product be handled?	Device will be methodically collapsed prior to implantation.	reduce risks of implantation, minimize risk of device failure
9	User Condition	What is the condition of the user?	Patient is in a compromised state, and can only perform basic limited tasks.	increase cardiac performance
10	Sterilization	How and where might the product be sterilized?	Device will be sterilized prior to packaging.	device adequately stored

Table 27 Continued

#	Context Factor	Concerns	Response to Concerns	Corresponding Needs
			Environment	
11	AACSD surroundings	Where and in what type of surroundings will product be used?	Device will be implanted in a surgical environment. Once implanted, will be subject to the environment of the patient's body.	reduce risk of infection, reduce risks of implantation
12	Interactions with surroundings	What objects will the AACSD interact with?	Device will interact with delivery system and external components.	ease of operation
13	Available space	How much space is available for the AACSD?	Device must fit in pericardial sac.	ease of access to device
14	Storage	How will the AACSD be stored?	AACSD will be stored in sterile packaging until needed.	device adequately stored
15	Adjustments and monitoring	How will adjustments and monitoring of the AACSD be done?	Adjustments and monitoring will be performed by physician.	ease of access to device, ease of monitoring, ease of operation
16	Energy availability	What is the availability of possible energy sources?	Availability of fluid, pneumatic, and electric energy is readily available.	ease of operation
			Customer Characteristics	
17	AACSD user	Who will use the AACSD? What user characteristics affect what the AACSD must be like?	Physicians will choose to obtain for use by the patient. Device implantation and monitoring must be straightforward.	ease of operation, ease of monitoring, reduce risks of implantation
18	User experience level	How skilled is the user with the task?	The users will be experienced physicians.	ease of implantation, ease of operation
19	User tolerance for complexity	What complexity level is allowed?	Users are comfortable operating complex products, but concern is needed to make process as straightforward as possible to reduce patient risk.	reduce risks of implantation
20	Regulatory Concerns	What regulations must the AACSD meet?	Must meet FDA regulations.	FDA approved
21	Cost expectations	What are the financial concerns for the AACSD?	Due to limited options available to the patient and the availability of health insurance, cost is not a primary concern.	FDA approved
22	Time expectations: implantation & operation	How much time is the physician willing to spend implanting product? To operate this product?	Implantation time should be minimized as much as possible. Length of operation times are not a primary concern.	ease of implantation, adequate lifetime
23	Safety and Risks	What safety concerns does the patient have regarding the AACSD?	Safety concerns are of the utmost importance. The device should not inhibit cardiac function when not in use. Adverse material interactions and infections need to be minimized.	not detrimental to heart, reduce risks of infection, adequate lifetime, minimize risk of device failure
24	AACSD lifetime	What is the expected life of the AACSD?	Device should last at least as long as the life expectancy of an end-stage heart patient, therefore, on the order of years.	adequate product lifetime, minimize risk of device failure
25	Selection for Use	How will AACSD be selected for use?	Physicians will take into account patient characteristics when deciding if the device is right for the patient.	FDA approved

APPENDIX B

The first category is concepts for the passive and active bladders, as shown in Fig. 31**.** These concepts describe possible bladder arrangements and alignments of the cup for both the active bladder and the passive bladder. The vertical, curved, and helical concepts are composed of separate bladders that are circumferentially joined to create the cup shape. The global bladder consists of a single bladder in the shape of the cup. The pocket bladder is sort of a hybrid, consisting of little bladders connected by a single network of channels in the cup. The chamber concept is composed of four bladders, one over each heart chamber to allow for adjustments to be made on each individual bladder based on the chamber that the bladder is interacting with.

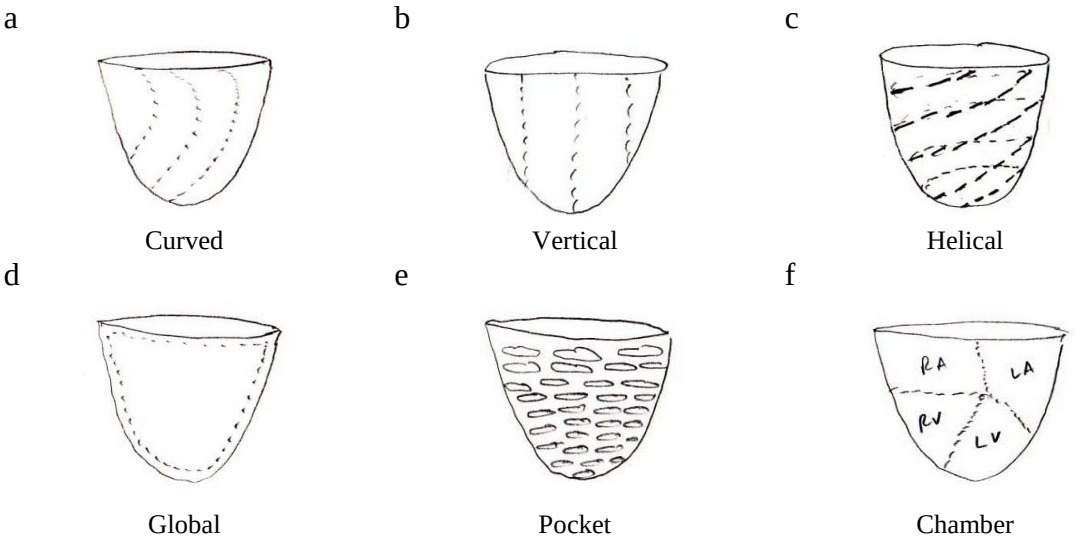


Fig. 31. Concepts generated for passive bladders and active bladders. Concepts include: (a) Curved, (b) Vertical, (c) Helical, (d) Global, (e) Pocket, and (f) Chamber.

The next category is the interface between the passive and active bladders. This is shown in Fig. 32. The bladders may be arranged in one layer to form a single component of the cup, or two layers to form inner and outer components of the cup.

Another method uses complete integration of the passive and active bladders. This approach uses a single layer of bladders that perform both passive support and active assist. The final concept is a detachable active bladder that can be removed from the patient when no longer needed. Since the active assist is only needed initially this allows for reducing volume of the device in the patient; however another surgery might be required.

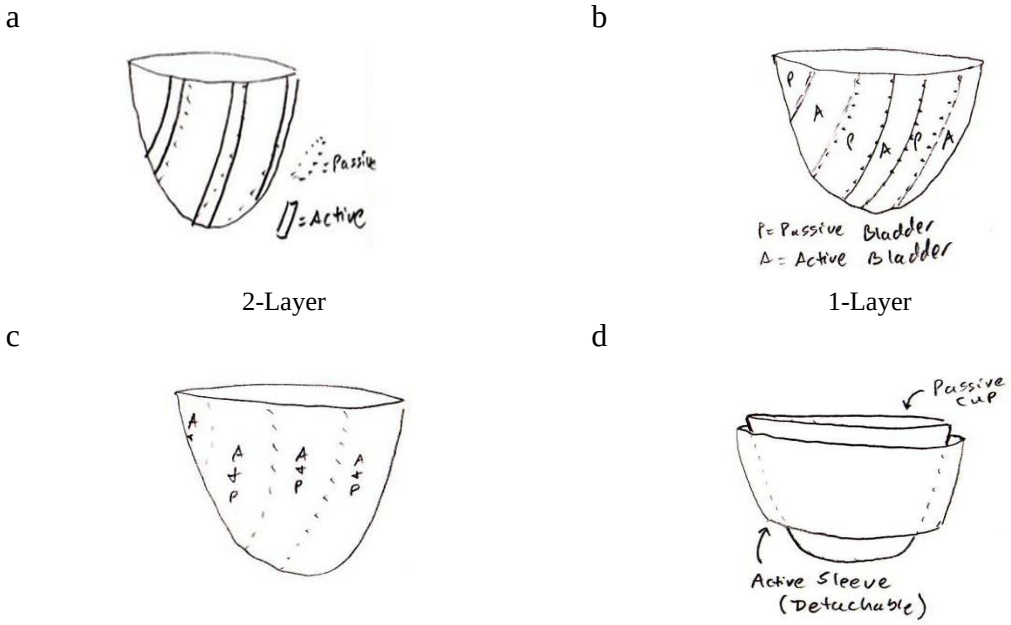


Fig. 32. Concepts generated for interface of passive and active bladders. Concepts include: (a) 2-Layer, (b) 1-Layer, (c) Integrated, and (d) Active Detachable.

The next category, shown in Fig. 33, is concepts for the frame. The frame is responsible for giving support to the device, expanding the device for deployment around the heart, and promoting proper kinematics of the cup in response to the applied loads of the heart. The frame will be composed of metal wire. The first concept is a petal frame. The second is an offset petal frame that is similar to the petal frame, but the petals are tilted to change the direction of motion of the petal. Next is a concept of using

braided wire to support the frame. The net mesh concept consists of a wire array as a mesh to form the cup, similar to the Paracor HeartNet. The modified petal consists of two sections; the lower section provides support while the upper section allows for the frame petals to rotate at a higher pivot point. As the heart reduces in size, this allows for the frame to better envelope around the heart due the higher location of the pivot points. The helical frame consists of a wire rotating around the cup. The branch concept uses multiple wires that come up from the base to the apex and then double back over themselves to terminate back at the base. The final concept is a circumferential frame is composed of wires forming loops around the cup but is connected to each other around the cup, rather than just at the base as seen in the petal design.

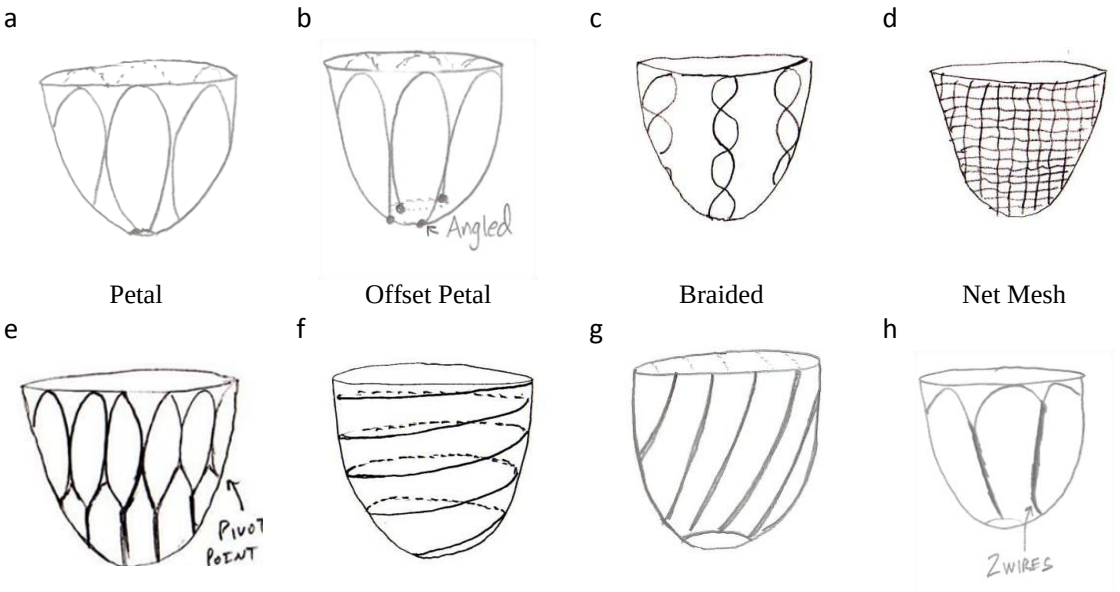


Fig. 33. Concepts generated for the frame. Concepts include: (a) Petal, (b) Offset Petal, (c) Braided, (d) Net Mesh, (e) Modified Petal, (f) Helical, (g) Branch, and (h) Circumferential.

The next category is the cup base, as shown in Fig. 34. The regular frame base concept is composed of using the selected frame as the base, with no additional components. The polymer ring base concept uses a polymer ring at the base that can

handle rotation, and is elastic to return the device to its original position. The rotating base concept uses an inner ring and an outer ring that are free to rotate relative to each other. The next two concepts focus on reducing loads in line with the cup by dampening the loads from the tubing. The first uses a fluid bladder at the cup base to act as a shock absorber, and the second uses a material damper to absorb the energy. The material damper is also extendable to allow for motion outward from the cup by any tubes.

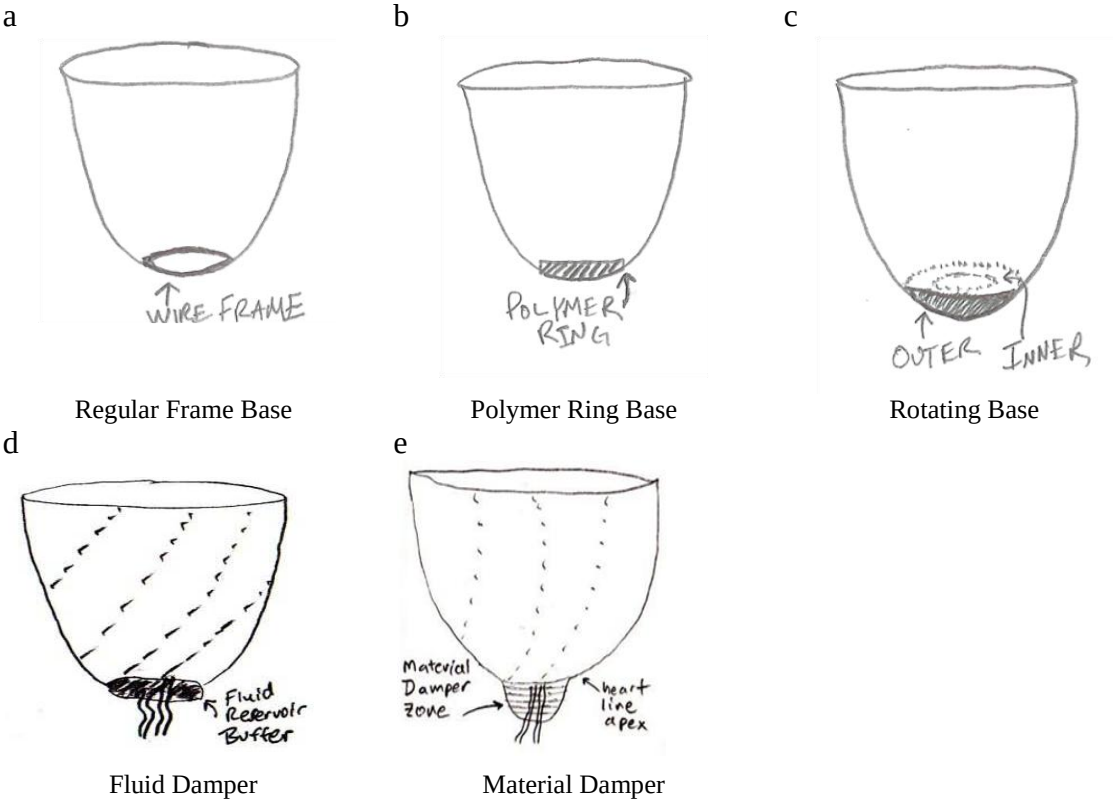


Fig. 34. Concepts generated for the cup base. Concepts include: (a) Regular Frame Base, (b) Polymer Ring Base, (c) Rotating Base, (d) Fluid Damper, and (e) Material Damper.

The next step in the design process phase is to evaluate the concepts using a Pugh chart based on the design requirements previously determined. The first Pugh chart is for the passive bladder, shown in Table 28. The curved bladder was used as the datum for the Pugh chart. Due to the similarities between the vertical and curved bladders, the

Pugh chart indicates that the two meet the criteria in a comparable manner. The helical concept fared slightly better than the datum based on the helical shape of the bladders being able to handle the rotation of the cup more favorably. The pocket bladders proved to be a poor concept variant and met the criteria worse than the datum in several categories due to its difficulty to manufacture and operate based on the level of intricacy needed for the concept. The chamber concept likewise performed unfavorably compared to the datum. With the ability to control each chamber bladder separately, the level of difficulty in making such a bladder and the tubing needed to implement such a bladder are too much. The effect of the usefulness of this idea is negated by the passive bladder being a steady-state system, and in order to vary each bladder individually multiple ports would be needed. The Pugh chart indicates the best concept is the global bladder. The simplicity makes the design easier to manufacture, assemble, and operate. However, concern must be taken that the passive bladder does not obliterate the cavity.

Table 28
Passive bladder Pugh chart

		Candidate Concepts					
Criteria		Curved	Vertical	Helical	Global	Pocket	Chamber
Ease in filling passive bladder		0	0	0	0	-1	0
Ease in emptying passive bladder		0	0	0	0	-1	0
Ability to obtain uniform pressure		0	0	0	1	0	0
Ability to handle rotation		0	0	1	0	-1	0
Amount of tubing needed		0	0	0	1	0	-1
Avoid cavity obliteration		0	0	0	-1	1	0
Manufacture and assembly		0	0	0	1	-1	-1
Ease of deployment		0	0	0	0	0	0
Amount of material/cost		0	0	0	0	-1	0
	Σ	0	0	1	2	-4	-2

The next Pugh chart, Table 29, shows the results for the active bladder. The selection criteria for the active bladder is the same as for the passive bladder, however the rapid cycling of the active system can affect the concept variant's ability to satisfy the criteria differently than for the passive system. Similar to the passive bladder, the curved, vertical, helical, and chamber concepts were comparable to the passive bladder scores. The pocket configuration scored even less due to the rapid cycling needed to fill

and empty the bladders with each heart cycle and the pocket assembly inhibiting this rapid cycle. The clear winner was again a global bladder. In addition to its advantages discussed previously, the global bladder allows for less interference of air flow between separate bladders so that the filling and emptying can be performed more efficiently.

Table 29
Active bladder Pugh chart

	Candidate Concepts					
Criteria	Curved	Vertical	Helical	Global	Pocket	Chamber
Ease in filling active bladder	0	0	0	1	-1	0
Ease in emptying active bladder	0	0	0	1	-1	0
Ability to obtain uniform pressure	0	0	0	1	-1	0
Ability to handle rotation	0	0	1	0	-1	0
Amount of tubing needed	0	0	0	1	0	-1
Avoid cavity obliteration	0	0	0	-1	1	0
Manufacture and assembly	0	0	0	1	-1	-1
Ease of deployment	0	0	0	0	0	0
Amount of material/Cost	0	0	0	0	-1	0
Σ	0	0	1	4	-5	-2

The passive and active bladder interface Pugh chart is shown in Table 30. The 2-layer concept was used as the datum. The 1-layer concept compared favorably over the 2-layer in that the device requires less volume and material, however this advantage is negated by the bladders potentially interfering with each other. For example, an active bladder surrounded by passive bladders on either side may encounter too much resistance in filling. Likewise the integrated concept provided advantages of reducing the volume and materials of the device; however the operation of a single integrated passive and active system is much more complex. While the active detachable concept provides the benefit of removing part of the device once no longer needed, the ability to make such a design is much more difficult and the need for a second surgery to remove the cup is not worth the benefits. Therefore, the selected concept of the passive and active interface is the 2-layer approach, with the passive bladder and active bladder each forming separate layers of the cup.

Table 30
Passive and active bladder interface Pugh chart

	Candidate Concepts			
Criteria	2-Layer	1-Layer	Integrated	Active Detachable
Interference on each other	0	-1	-1	0
Ease of assembly and manufacture	0	1	1	-1
Obtaining uniform pressures	0	-1	0	0
Ease of deployment	0	0	0	-1
Ease of filling bladders	0	-1	-1	0
Ease of emptying bladders	0	-1	-1	0
Amount of material/cost	0	1	1	-1
Σ	0	-2	-1	-3

The Pugh chart for selecting the frame concept is shown in Table 31. The petal concept was used as the datum. The braided design did not offer much advantage, and would be more difficult to assemble. The net mesh frame had several benefits in providing a mesh support that could adapt to the size of the heart; however the amount of wire needed in the design and concerns of it restricting the bladders outweighed the advantages. The modified petal offered several benefits due to its ability to adapt to the heart, however the design is much more difficult to manufacture. The helical design provides excellent structure for the cup; however, its structure is too constricting and would likely affect the performance of the cup. The branched design is similar to the helical in that it is more favorable towards rotation; however, the design of the branches does not provide the same type of cup structure. The circumferential frame had concerns with collapsibility and manufacture. The offset petal scored favorably for its ability to handle the rotation of the heart and conform to the heart more favorably than the regular petal design, and is the selected design for the frame.

Table 31
Frame Pugh chart

Criteria	Candidate Concepts							
	Petal	Offset Petal	Braided	Net Mesh	Modified Petal	Helical	Branch	Circumferential
Collapsibility	0	0	0	-1	-1	-1	0	-1
Ability to flare	0	0	0	-1	1	-1	0	0
Provide shape	0	0	0	1	1	1	-1	1
Material and cost	0	-1	0	-1	-1	0	0	0
Handle Rotation	0	1	0	0	0	1	1	0
Damage to heart	0	0	0	0	0	0	0	0
Conform to heart	0	1	-1	0	1	-1	0	0
Manufacture and assembly	0	0	-1	-1	-1	0	-1	-1
Σ	0	1	-2	-3	0	-1	-1	-1

The cup base Pugh chart is shown in Table 32. The regular wire frame base is used as the datum. The polymer ring scored lower than the datum due its added cost and manufacturing concerns. Also of concern is fatigue of the ring and it possibly restricting the motion of the cup, thereby placing unwanted loads on the heart that counteract the heart's natural rotation. The fluid damper presented many problems that outweighed the risks of it dampening any motion of tubes in line with the cup. The material damper likewise took up too much space and provided difficulty in designing and manufacturing. The rotating base is the suggested design for the cup base due to its ability to handle the hearts rotation and for its simplicity in design.

Table 32
Cup base Pugh chart

Criteria	Candidate Concepts				
	Regular Base	Polymer ring base	Rotating base	Fluid damper	Material damper
Amount of material needed/cost	0	-1	-1	-1	-1
Space taken up	0	0	0	-1	-1
Reduces damage to heart	0	0	1	1	1
Reduces coupling	0	0	1	0	1
Ease of operation	0	0	0	-1	0
Ease of deployment	0	0	0	0	0
Ability to handle rotation	0	1	1	0	0
Manufacture and assembly	0	-1	0	-1	-1
Impact when null	0	0	0	0	0
Collapsibility	0	0	0	0	0
Σ	0	-1	2	-3	-1

APPENDIX C

Table 33

Select manufacturer specifications for candidate ports.

a: (Angiodynamics Infuse Brochure, 2009), (Angiodynamics Ports Info, 2009), (Angiodynamics Titan Brochure, 2009), (Angiodynamics Port IFU, 2009). b: (Bard Ports, 2009). c: (Covidien, 2009)

Device Name	Needle Gauge / Max. Injections	Base Diameter / Height (mm)	Port Materials	Septum Diameter (mm)	Catheter Attachment	Catheter Options	Cath. ID (mm)	Cath. Length (cm)
Angiodynamics Infuse-A-Port	22/2000	≈ 20-30	Acetal plastic, Silicone Septum	-	Pre-attached or attachable	7.5 Fr. Silicone 9.6 Fr. Silicone 6.0 Fr. Silicone	-	-
Angiodyncamis TitanPort	22/2000	≈ 20-30	Titanium, Silicone Septum	-	Pre-attached or attachable	7.2 Fr. Silicone 9.6 Fr. Silicone	-	-
Bard Access M.R.I. Hard-Base Port	22/2000 19/1000	32/13.5	Plastic	12.5	Attachable	8 Fr. Silicone (valved) 9.6 Fr. Silicone 6.6 Fr. Silicone 8 Fr. Polyurethane	1.5 1.6 1.0 1.6	50 76 75 61
Bard Access Titanium Dome Port	22/2000 19/1000	27.2/15	Titanium	12.7	Attachable	8 Fr. Silicone (valved) 9.6 Silicone	1.5 1.6	50 76
Bard Access Titanium Port	22/2000 19/1000	31.7/14.5	Titanium & Silicone	12.7	Pre-attached or attachable	8 Fr. Silicone (valved) 9.6 Fr. Silicone 6.6 Fr. Silicone 6.1 Fr. Silicone 14.3 Fr. Silicone 8 Fr. Polyurethane 6 Fr. Polyurethane	1.5 1.6 1.0 0.5 2.6 1.6 1.3	50 76 75 61 50 61 75
Bard Access M.R.I. Port	22/2000 19/1000	31.5/15.3	Plastic & Silicone	12.5	Pre-attached or attachable	8 Fr. Silicone (valved) 9.6 Fr. Silicone 6.6 Fr. Silicone 6.1 Fr. Silicone 14.3 Fr. Silicone 8 Fr. Polyurethane 6 Fr. Polyurethane	1.5 1.6 1.0 0.5 2.6 1.6 1.3	50 76 75 61 50 61 75
Covidien Chemosite Infusion Port	-	26/13.2	Titanium interior, Polysulfone exterior, Silicone septum	-	Pre-attached or attachable	7 Fr. Polyurethane 9 Fr. Silicone 9 Fr. Polyurethane	-	-

Table 34
Specifications of valved catheter candidates.
a: (Angiodynamics CVC, 2009), b: (Bard Groshong Brochure, 2009), c: (Navilyst, 2009)

Company	Catheter	Lumen OD (mm)	Lumen ID (mm)	Length (cm)	Valve Type	Valve Location
Angiodynamics[a]	CVC with LifeValve	2.2, 3.27	1, 1.7	85	2-valves	Distal
Bard Access[b]	Groshong CVC	1.17, 1.84, 2.3, 2.7	0.7, 1.1, 1.3, 1.5	35, 40, 50, 65	1-valve	Distal
Navilyst[c]	PICC with PasV	1.33, 1.67	1.067, 1.28	adjustable	1 valve	Proximal

Table 35
Catheter options for the Bard Access M.R.I. Port (Bard Ports, 2009).

Material	OD (Fr.)	ID (mm)	Length (cm)	Attachment	End Type
Radiopaque Silicone	9.6	1.6	76	Both	Open
Radiopaque Silicone	6.6	1	75	Both	Open
Radiopaque Silicone (Groshong)	8	1.5	50	Attachable	Valved
Radiopaque ChronoFlex Polyurethane	8	1.6	61	Attachable	Open
Radiopaque ChronoFlex Polyurethane	6	1.3	75	Attachable	Open

APPENDIX D

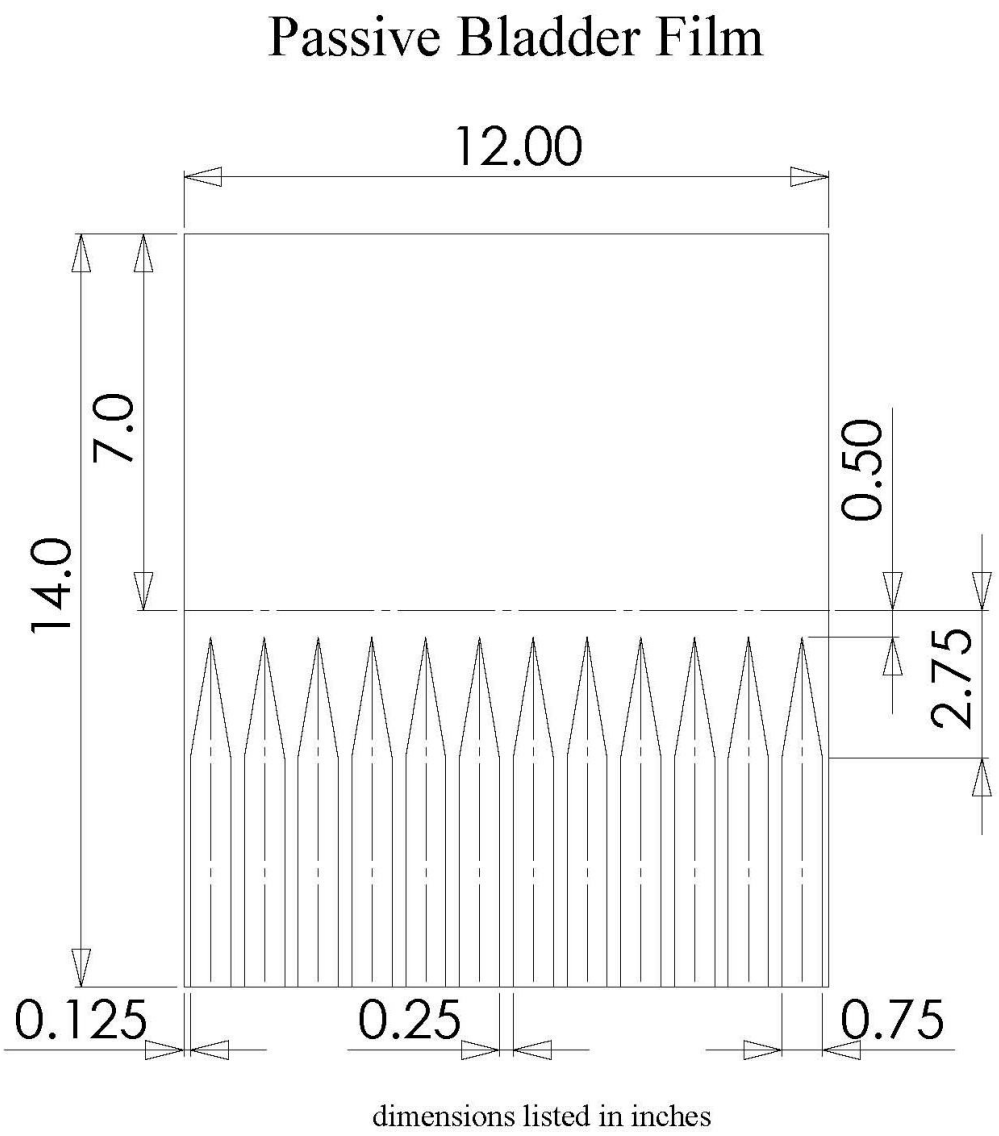


Fig. 35. Passive bladder film before assembly, with dimensions.

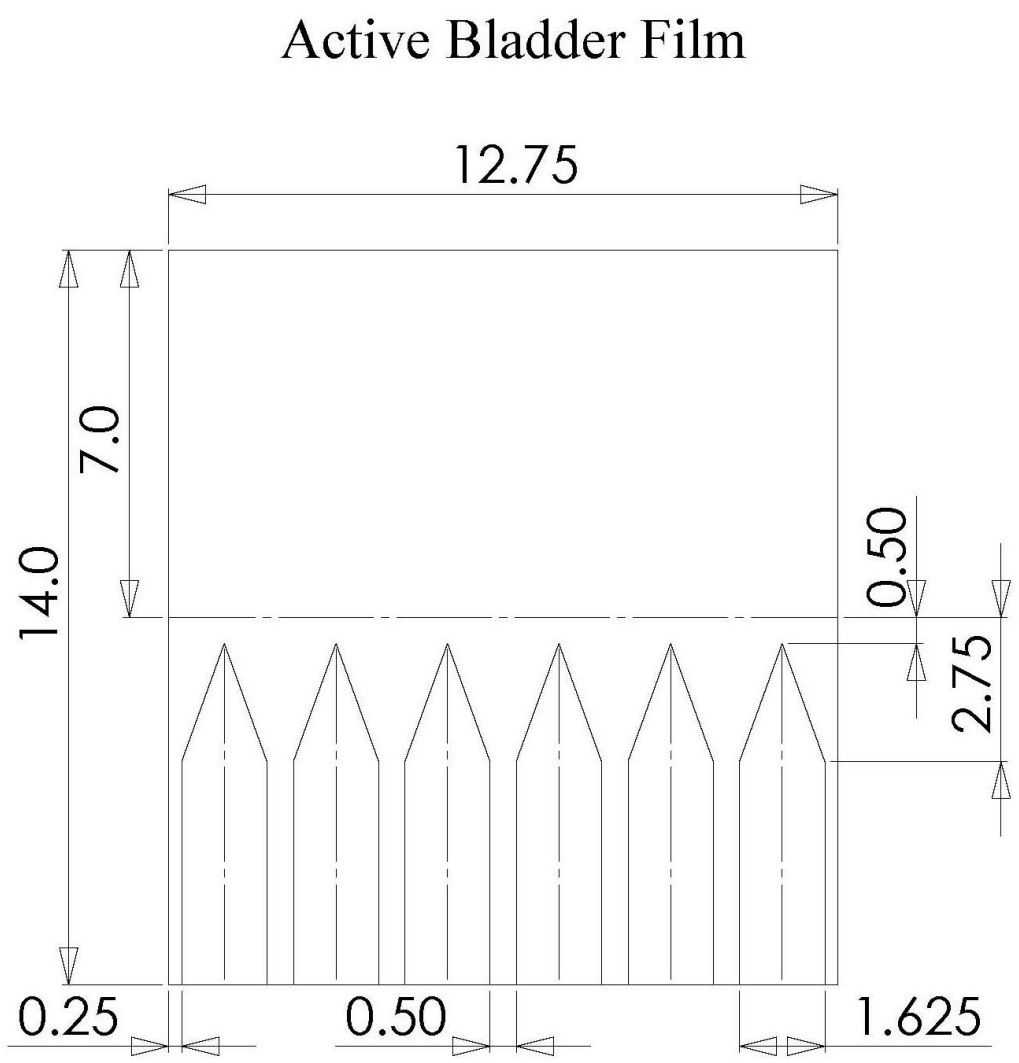


Fig. 36. Active bladder film before assembly, with dimensions.

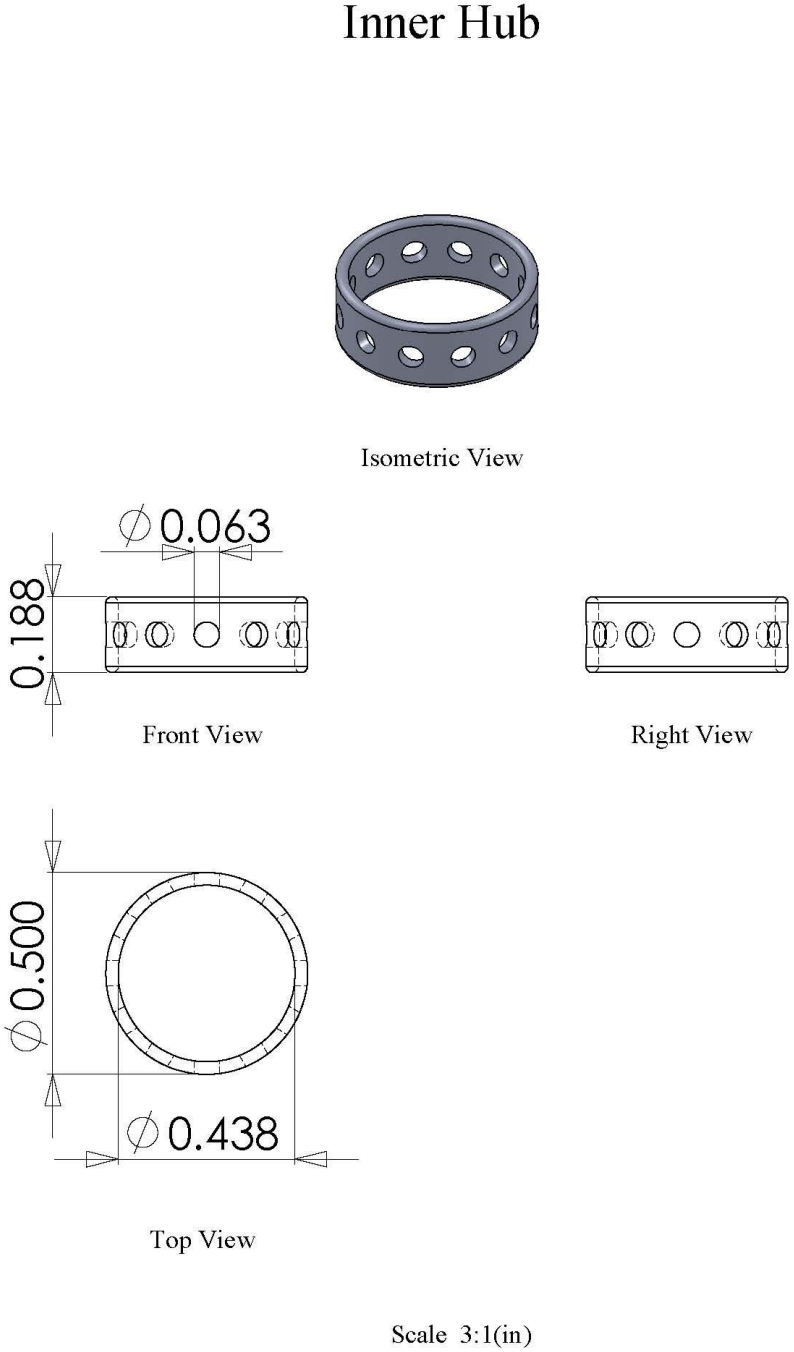


Fig. 37. Inner hub, with dimensions.

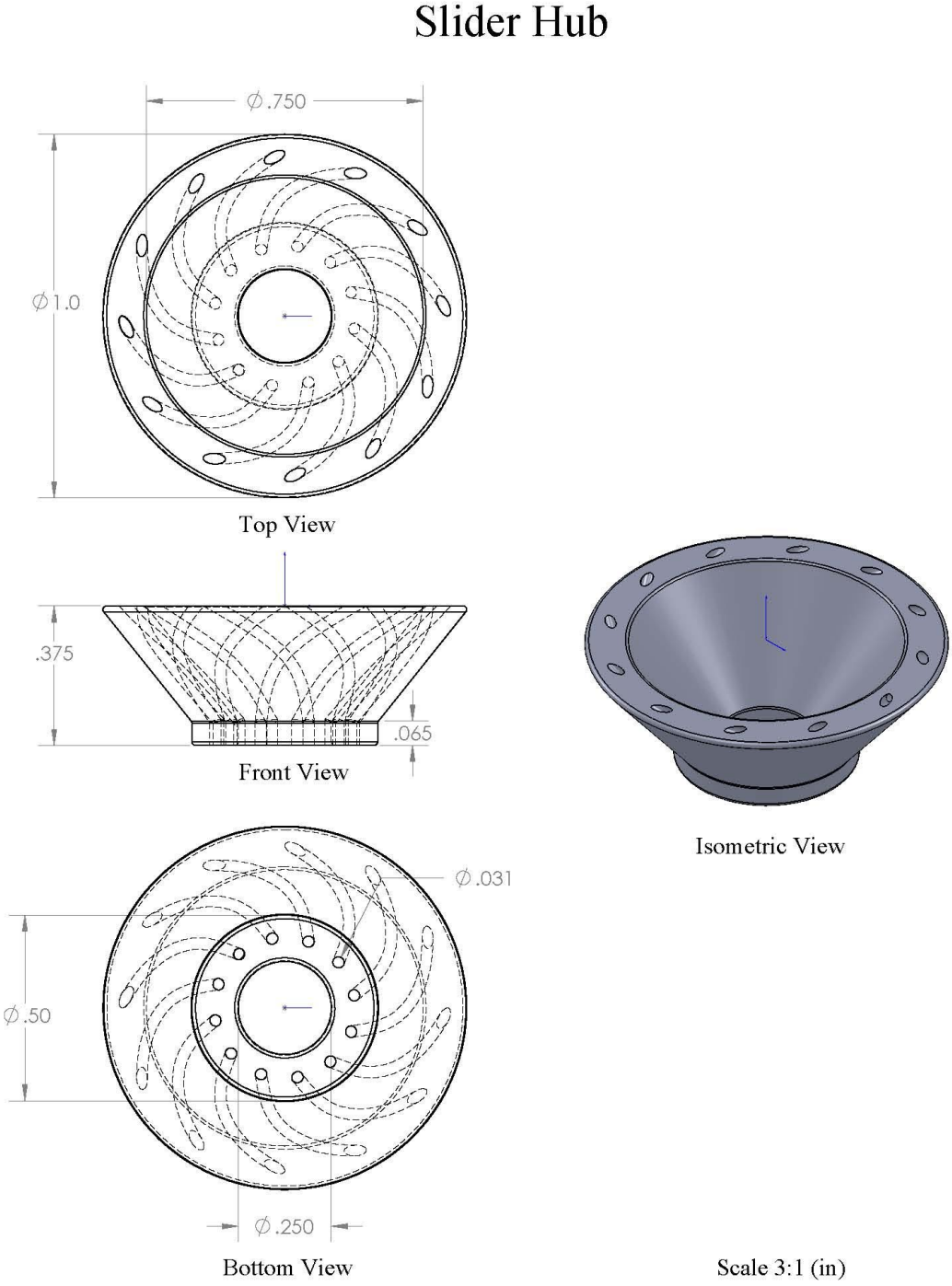
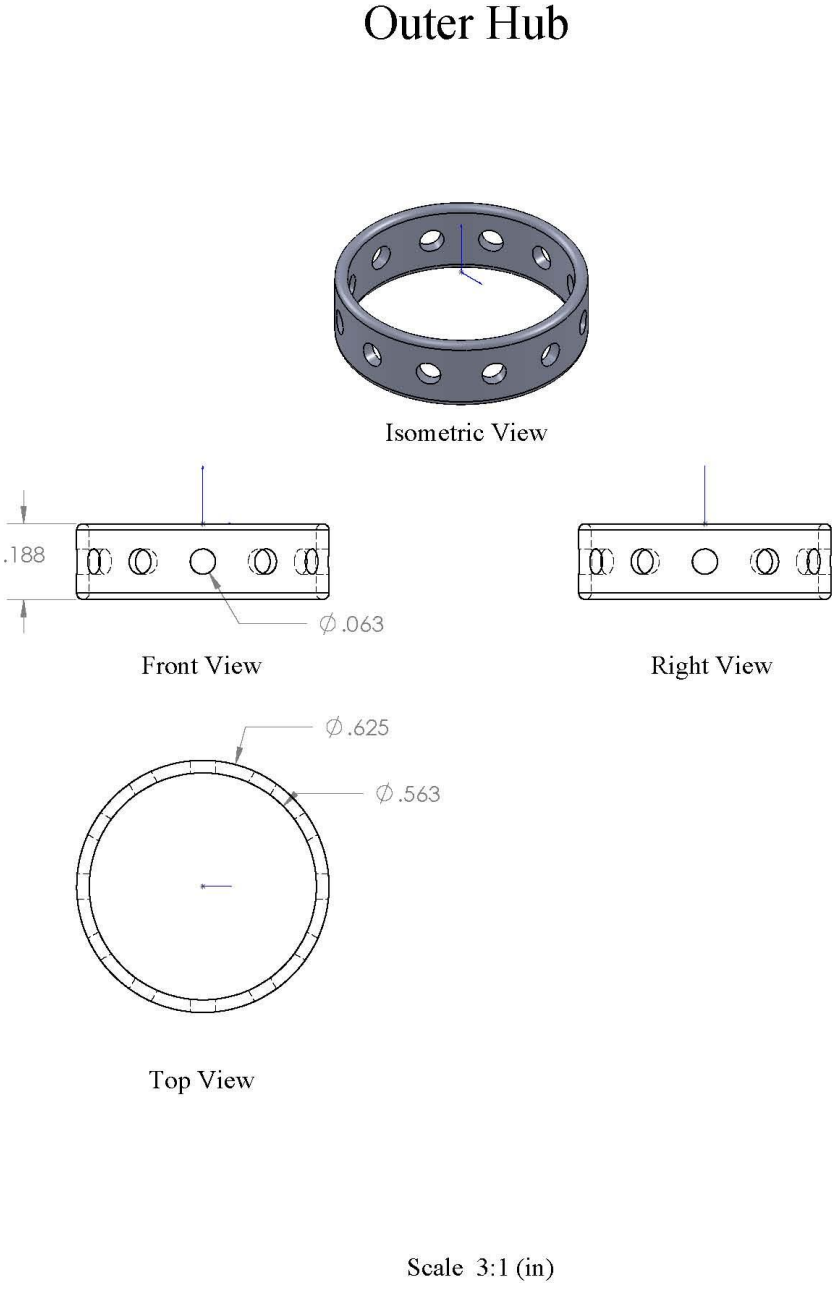


Fig. 38. Sliding hub, with dimensions.



Fig, 39. Outer hub, with dimensions.

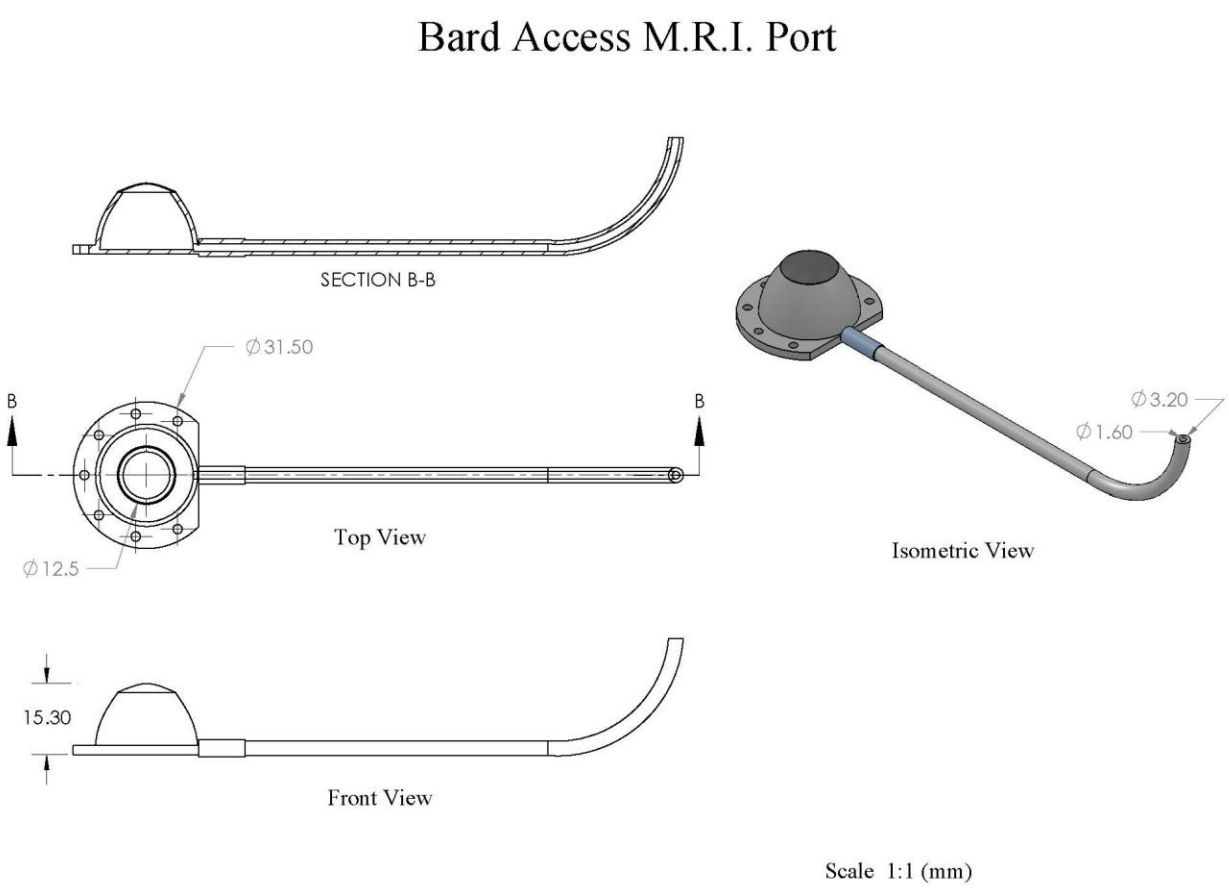


Fig. 40. Bard Access M.R.I. Port, with dimensions.

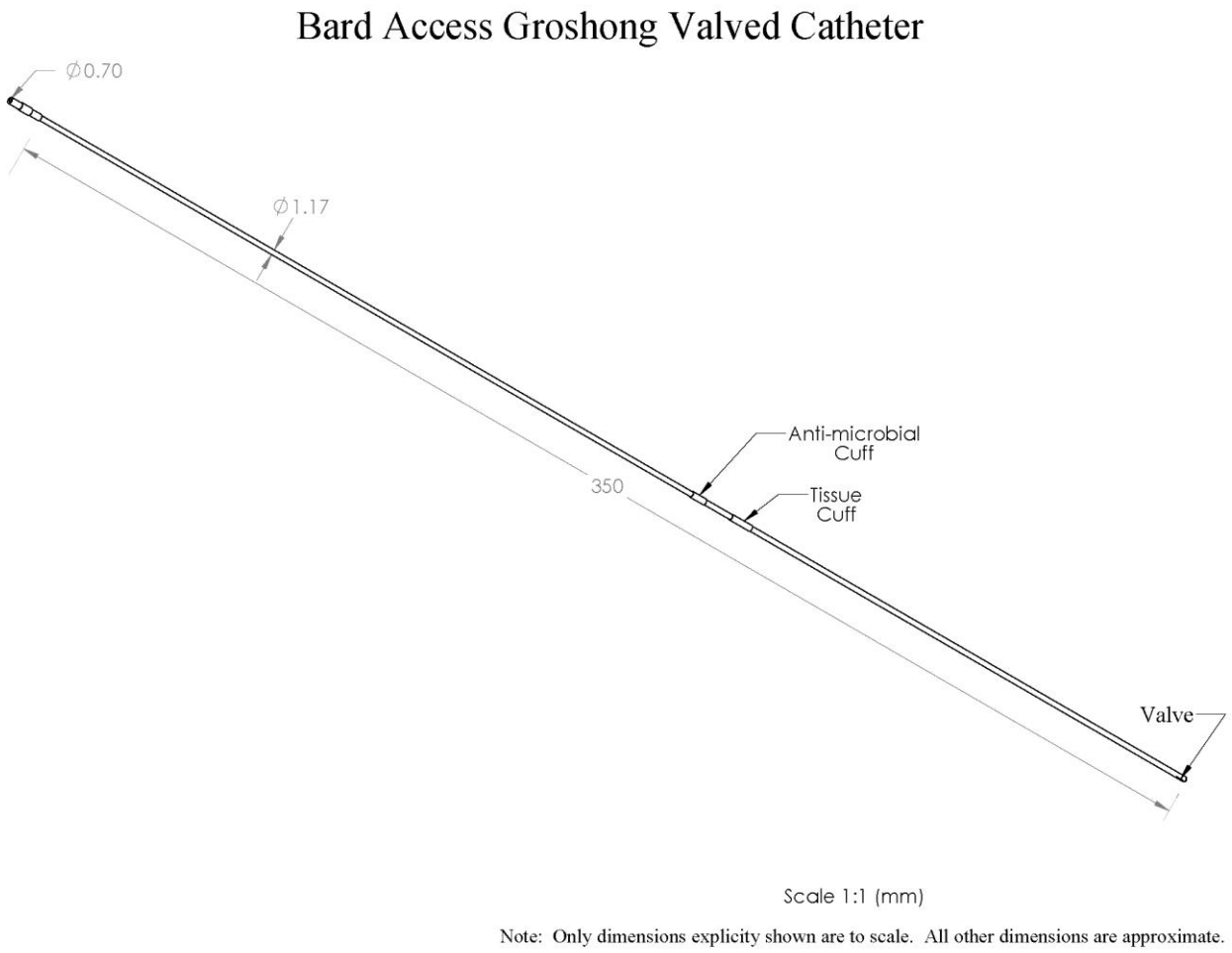


Fig. 41. Bard Access Groshong valved catheter, with dimensions.

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