MINIMALLY INVASIVE ACCESS

TO THE PERICARDIUM FOR THE

ACTIVE AND ADJUSTABLE CARDIAC SUPPORT DEVICE

A Thesis

by

KELLY DIANNE SHEPPARD

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,	William Hyman
	Matthew Miller
Head of Department,	Gerard Cote

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ABSTRACT

Minimally Invasive Access to the Pericardium for the

Active and Adjustable Cardiac Support Device. (August 2009)

Kelly Dianne Sheppard, B.S., Texas A&M University

Chair of Advisory Committee: Dr. John C. Criscione

According to the American Heart Association, congestive heart failure affected 5.7 million Americans age 20 and older in 2006, and had an estimated direct and indirect cost of $37.2 billion in 2009. Heart assist devices are proving useful in a population where the demand for donor hearts is much greater than the supply. These technologies have successfully improved heart function, but current devices bypass heart pathways, and require invasive surgical methods for placement. Dr. Criscione proposed the Active and Adjustable Cardiac Support Device (AACSD) that allows the heart to maintain some intrinsic motion to restore normal function in the myocytes of a failing heart. Ventricular recovery follows the uniform application of pressure, working on the principle that mechanical stimuli are the key to repairing a mechanical organ. There is a need for a less invasive surgical technique to place the AACSD into the pericardial space. The Pericardial Access and Support System (PASS) is designed to gain access to the pericardium through a 1-2 inch sub-xiphoid incision in ovine models, reducing recovery time, trauma, and costs of the surgery. The design process followed FDA design controls intended to produce a safe and effective device. This includes forming user needs and product function into design input requirements and translating requirements into detailed design specifications. Verification plans were made to confirm that the specifications are consistent with the requirements. Once a physical device is manufactured, validation will ensure that the product satisfies user needs.

DEDICATION

I would like to dedicate this thesis to my father and mother for
their constant support and encouragement throughout my academic career.

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I would like to thank the following people for their contribution to the design prototyping and development:

Dr. John C. Criscione
Dr. William Hyman
Dr. Matthew Miller
Dr. David Nelson
Saurabh Biswas
Lewis Harrison
John Mims
Christina Nazzal
Matt Jackson
Avni Patel

I would like to thank my committee chair, Dr. Criscione, and my committee members, Dr. Hyman, and Dr. Miller, for their guidance and support throughout the course of this research. I also want to extend my gratitude to Dr. Nelson and his staff for their willingness to experiment with device prototypes, and provide feedback on the device design throughout the process. I would like to thank Saurabh Biswas for contributing ideas for the background, and for discussions about the Active and Adjustable Cardiac Support Device (AACSD). I greatly value the involvement of Lewis Harrison in providing design suggestions, checking my design specifications, and retrieving pictures from research and development prototypes. I would like to thank John Mims for his help with SolidWorks, and for helping to maintain compatibility with the AACSD. Finally, I want to recognize Christina Nazzal, Matt Jackson, and Avni Patel for participating in the brainstorming session during concept generation. I appreciate all of the time and effort contributed by everyone during my research design project.

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1. INTRODUCTION

Congestive heart failure (CHF) is a debilitating disease that affected 5.7 million Americans age 20 and older in 2006, and had an estimated direct and indirect cost of $37.2 billion in 2009 (AHA, 2009). In CHF, the pump function of the heart deteriorates as a result of abnormal growth and remodeling. Due to a demand for donor hearts that is greater than the supply, and a selective waiting list, cardiac assist devices and devices that restore normal function in the heart are proving useful. Several cardiac assist devices currently exist that can partially repair damaged hearts, but most require invasive surgical techniques for placement. CorInnova is in the process of developing a mechanical support device to rehabilitate the myocardium in CHF patients. The collapsible device uses mechanical stimuli to restore normal motion in a failing heart. However, the pericardium must be pulled away from the heart apex and stabilized for successful deployment of the cardiac support device. Therefore, a surgical apparatus must be developed and tested to meet this need. The objective of this research was to determine the preferred design methodology for the pericardial access device, and to design a mechanical delivery system for the Active and Adjustable Cardiac Support Device (AACSD). It is hypothesized that accomplishment of these aims will enable the cardiac support device minimally invasive access into the pericardium, which will decrease the risk of infection and reduce recovery time. Once the mechanical delivery system is designed using the most favorable method, the heart can be repaired with a device deployed through a 1-2 inch incision.

The limits of the design scope are to obtain access to the pericardial space for the deployment of the AACSD through the design of a surgical instrument. Safety, technical performance, device quality, user needs, and compatibility with the AACSD were considered throughout the design process. This design research project will not address manufacturing methods or disposal after use.

This thesis follows the style of the Journal of Biomechanics.

2. BACKGROUND

2.1 Congestive Heart Failure

Eighty percent of men and 70 percent of women under age 65 who have heart failure will die within 8 years (AHA, 2009). The shortage of donor hearts, increased cases of CHF, and an aging population necessitate advancements in methods to treat this condition. In CHF, the heart delivers blood to the body inefficiently. The left ventricle changes shape, the heart enlarges, and the walls of the ventricles become thinner. Unnatural growth and remodeling creates a feedback mechanism resulting in weakening functional performance. Heart failure can develop from a loss of function following acute myocardial infarction, as the workload is increased when the elliptical left ventricle becomes abnormally large and nearly spherical (Mann, 2005). The normal motion of the myocytes is disturbed and continues to decline in performance following the initial impairment. Most of the damage caused by a massive myocardial infarction may be attributed to an expansion of the affected boundary due to dyskinesis-the lengthening of myocytes during systole, when cells should contract and shorten to produce a coordinated heart beat (Fossum, 2006). The affected zone must be controlled because the area surrounding the initial damage is not contracting but has oxygen needed for the heart to do work.

Motion is a vital element of work; work is force acting through a differential distance. Thus, the ordered motion of the myocytes is fundamental to maintaining and restoring a functional and efficient heart because work must be done to pump blood through the body. Use of cardiac support devices should stabilize the ventricular radius and reduce wall thinning. Blom et al. illustrated that myocyte length and volumes were reduced by placing a cardiac support device on a heart that recently experienced myocardial infarction, likely because the mechanical driving forces of remodeling were mitigated (Blom et al., 2005). Aside from the potential of devices as a bridge to transplant

for patients awaiting a donor heart, heart assist devices can be used as a bridge to recovery, reversing the effects of CHF and leading to ventricular recovery. They can also improve the quality of life for patients with comorbid conditions, providing permanent mechanical assist as a destination therapy.

2.2 Existing Technologies

The Left Ventricular Assist Device (LVAD) is a classic offloading heart assist device that reduces the work done by the heart by bypassing the organ. It is used as a bridge to transplant to replace or partially replace a failing heart. One end connects to the left ventricle, and the other to the aorta, with a drive tube passing from the device through the skin in most current designs. The mechanical device offloads the heart instead of allowing it to perform its own work, and often requires a power pack and computer control outside of the body (Bryg, 2009). Since it is a blood-contacting device, there are also issues with clotting.

Acorn Cardiovascular created the CorCap™, which is intended to prevent the progression of heart failure by providing circumferential diastolic support to the heart and improving the heart's structure and function. It is a mesh wrap that relieves wall stress to decrease left ventricular volumes and limit infarct expansion. This device was tested on an animal model with dilated cardiomyopathy, and proved that under the influence of Acorn's device, the heart decreased in volume and improved in function, along with reverse remodeling in the ventricular, cellular, and molecular levels of the heart (Acorn, 2005).

The Myotech Circulatory Support System is a method to treat acute and chronic heart failure by restoring blood flow to normal levels through bidirectional compression. The device consists of a flexible polymer cup that takes about 3 minutes to install. The pneumatically-activated liner provides support to both ventricles by attaching via vacuum on the apical end of the heart. The possible applications of this device include short-term cardiac support, rapid resuscitation, and possibly permanent support (Biophan, 2009).

Paracor Medical, Inc. created the HeartNet™, a mesh wrap that is permanently delivered around the ventricles of a heart experiencing dilated cardiomyopathy to reduce the work done per beat. An increase in the potential force of each beat provides for a more efficient cardiac cycle. The Nitinol wrap is available in various sizes that have a pattern similar to that of a stent (Paracor).

Several technologies exist that help the heart recover without transplant, but some require coupled electrical and mechanical support, as well as invasive surgical techniques for implantation. Dr. Criscione's research and testing has shown that his mechanical support device restores regular motion in the myocytes, and encourages a failing heart to deliver blood to the body more competently.

2.3 Active and Adjustable Cardiac Support Device

The laboratory of Dr. Criscione has developed the Active and Adjustable Cardiac Support Device (AACSD) to reduce heart size and restore efficient function in the failing heart. The device works on the principle that in a mechanical organ, mechanical stimuli are the key to restoring normal function (CorInnova, 2007). While the device does not offload the heart in a classical sense, it does so mechanically by application of pressure and decreasing the end-diastolic volume in the heart. This is similar to the heart doing work, which all normal myocytes do during systole. The novel device differs from previous CSDs since it is adjustable, and allows the organ to maintain some of its intrinsic motion. The AACSD is placed within the pericardial sac and directly contacts the heart, creating a vacuum between the device and the organ. The device chamber fills with air, the pneumatic driving force in the chambers, and directly compresses the heart on all sides of the organ in order to restore motion in the myocytes and improve cardiac output. The restoration of normal motion is intended to guide cardiac growth and remodeling, leading to ventricular recovery. The main focus of the AACSD is to limit the decline in pump function by preventing infarct expansion into the borderzone. Thrombosis is not a concern with the AACSD since it does not contact the blood. The

device is a new opportunity to treat CHF and enhance quality of life for patients suffering from the disease. Additionally, the collapsible geometry of the device presents the opportunity for minimally invasive surgery. Figure 1 shows a prototype of the device in two views.

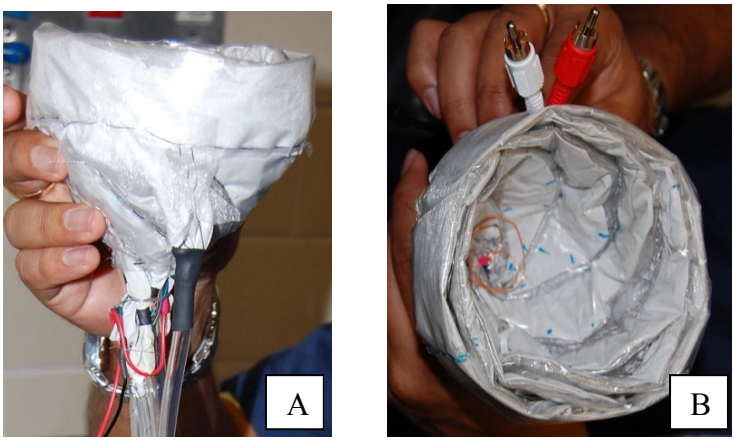

Fig. 1. Active and Adjustable Cardiac Support Device. (A) Side view; (B) top view.

Most patients facing surgical intervention for congestive heart failure will be confronted with an invasive procedure that requires an extended hospital stay for patient monitoring during recovery. Through 2006, the most frequently-used methods to treat cardiovascular diseases included coronary artery bypass grafts, endarterectomies, valve replacements, percutaneous coronary interventions, and implantation of pacemakers and defibrillators (AHA, 2009). Coronary bypass can be performed minimally invasively, but only for cases where no more than two bypasses are needed and the damaged arteries are located at the front of the heart. Valve replacement and repair generally requires surgeons to divide the breastbone, stop the heart, and pass blood through heart-lung machine. However, people can have minimally invasive valve surgery but not if more than one valve needs repair, or there is severe valve damage. Although the procedures for placement of pacemakers and defibrillators are improving in the level of invasiveness, many people still experience open-heart surgery for treatment of severe heart problems.

Surgeons and patients prefer less invasive surgery for implantable devices to reduce trauma, recovery time, and costs.

In order to gain access to the pericardial space, cardiac surgeons use sutures to pull the sac away from the heart apex. In a limited working space, a stabilizing device would provide a clear passageway for improved visibility for the surgeon, decreased surgical time, and systematic placement of the AACSD. A complementary apparatus must be developed and tested that limits the level of invasiveness that the AACSD requires upon installation, and provides a viewing window for the surgeon. CorInnova, a company founded by Dr. Criscione to bring this technology to the market place, is in the process of developing the pericardial access and support system (PASS) for the delivery and deployment of the AACSD into the pericardial space. With this device, a 1-2 inch sub-xiphoid incision is possible in ovine models, and a small, left-lateral thoracotomy is projected when the device is implemented in humans. The midline location of the heart apex in ovines allows easy access to the heart for deployment of the device. Previous access devices currently exist to restrain the pericardium for entry into the space surrounding the heart.

2.4 Previous Access Devices

The HeartNet™ is delivered during a minimally invasive mini-thoracotomy via a single-use delivery system. The device is placed onto the epicardial surface of the heart after it is pre-loaded into the syringe-like system (Paracor).

Medtronic has designed the single-use Octopus® Tissue Stabilizer to position, stabilize, and access various spaces during beating heart surgery. The Octopus® provides clear visibility for the surgeon and has a single, flexible tube leading to the device head to decrease any possible obstruction that could result in tissue damage. The system mounts onto other surgical devices for use in coronary artery bypass grafting. The Urchin™ and Starfish™ are heart stabilizing devices used in conjunction with the Octopus via suction to the heart (Medtronic, 2008).

Comedicus Incorporated's PerDUCER® is a passive device that captures the pericardial tissue via suction at the tip of a needle enclosed in a tube. The product cuts the pericardium and gives access to the space surrounding the heart for placement of a guidewire for diagnostic and therapeutic purposes. The device is intended for temporary surgical use and does not provide a viewing window for the surgeon, who must use a fluoroscope (Hou & March, 2003).

3. AIM I PROBLEM STATEMENT

To accomplish the goals of a successful pericardial assist device for the AACSD, the process was broken down into determining the preferred design methodology for the pericardial access device, and designing a mechanical delivery system for the AACSD into the pericardial space. It was the goal of the research presented here to design the PASS using design methods that would allow a smooth progression from development of the PASS to market.

The first objective was to determine the design methodology for the pericardial access device. The Food and Drug Administration ensures the safety and effectiveness of all medical devices in the United States by requiring clearance or approval before most devices can be placed on American markets. The Quality System Regulation (QSR) states that manufacturers must have a quality system in place for the design and production of medical devices (U.S. FDA, 2009). Compliance with QSR design controls in the design and development phases of the instrument helps ensure that the device performs its intended function and meets user needs. The aim of the research was to convert user needs and product function to design input. Using design control methods, a delivery system was designed for the AACSD to enter a 1-2 inch sub-xiphoid incision. As a result, the device will satisfy the Federal Food, Drug, and Cosmetic Act.

The primary goals of Aim I in the design of the PASS are:

- User needs must be made into design requirements.
- Design specifications should be comprehensive and clearly defined.
- Develop concepts for the device design.
- Develop distinct design criteria.
- Select concept for PASS using design criteria.

4. DESIGN PROCESS

A design builds upon decisions, deliverables, and progress of the previous design phase. Design output for one phase becomes the design input for the next step. The design should maintain functional performance based on user needs as a verified and validated device throughout the product life cycle. Verification ensures that the design specifications developed as a result of the design input are met; and validation tests that the produced device fulfills the design requirements, intended uses, and user needs. Careful review at all levels of the process is critical to good design and quality assurance. Reviews can identify design inconsistencies and defects early in the design cycle, saving money and time. The natural feedback mechanisms in the design process are discussed in the FDA design controls, which is the framework used for designing the PASS. The following diagram, figure 2, illustrates the iterative nature of the design process.

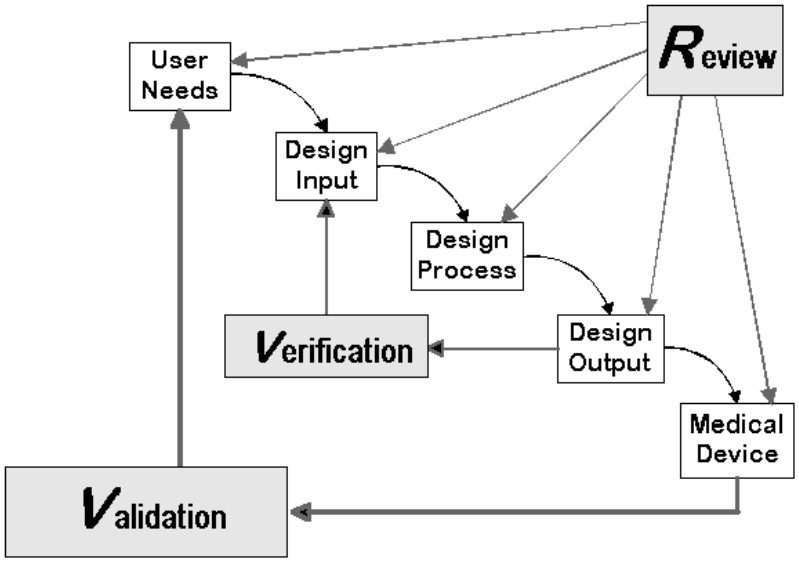

Fig. 2. Waterfall design process (U.S. FDA, 1997).

A quality product is more easily generated when the design process is followed diligently, and a quality system is introduced. Assessing user needs and expectations is the most fundamental and critical component for the design team. The developers should elicit customer input to ensure the design is focused on user needs, which are the basis for product specifications. Translating user needs into manageable requirements is the first step in the design process. Device specifications are a dynamic set of functional requirements and constraints that the device must satisfy. After the initial specifications become the first design output, they feed into the next step as design input, and the process continues.

Elements and ideas for this project were obtained from research and development, prior work in access devices, brainstorming sessions, and contact with a surgeon and AACSD developers. Each design concept considered in the final concept selection process fulfilled the functional requirements. Design criteria were developed without bias towards any of the alternatives. Mandatory criteria were established that the device must meet for a design concept to be considered for the final design. Other characteristics that would benefit device function or ease of use factored into the selection of a design concept as design goals.

The design and development plan laid out what would be developed, with a task breakdown, deliverables and a timeline. Regardless of the creation of a design plan, the design process is not successful without executing the goals and objectives set in a timely manner. The design and development plan for the PASS is discussed below.

5. DESIGN AND DEVELOPMENT PLAN

The pericardial access device will be designed using FDA Design Controls to meet pre-determined design requirements. After alternate designs are created, the three design concepts considered to best meet the criteria will be further developed and illustrated in SolidWorks for final consideration. The final concept will be chosen using a Pugh chart based on durability, effectiveness, safety, efficiency, and ease of use for the introduction and deployment of the AACSD into the pericardial space. Re-use is not a necessary design consideration since the pericardial access device will be a single-use device. The selected device will proceed to the manufacturing phase with CorInnova staff. Table 1 depicts the design and development plan for the PASS.

All design processes in the development plan are subject to QSR requirements. The major tasks include creating design specifications based on the user needs and design requirements, developing design concepts, choosing a concept, and creating Computer-Aided Design (CAD) documents of the final concept. A change in the SolidWorks drawings demanded an additional week to be added to this task. The projected completion dates set for each task were met, and all deliverables were produced.

Table 1
Design and development plan for the PASS.

	Design Tasks	Prerequisite Information	Duration (wks)	Projected Date of Completion	Personnel Required	Deliverable	Constraints
AIM I	Outline design process	QSR	1	Aug-08	GSI	Design and development plan	QSR
	Develop design inputs	QSR	2	Oct-08	GSI	Design inputs	QSR
	Develop design outputs	QSR	4	Feb-09	GSI	Design outputs	QSR
AIM II	Research previous devices	None	4	Oct-08	GSI	Device summaries	QSR
	Review R&D prototypes	Notes from efficacy studies	4	Nov-08	GSI	R&D Summary	QSR
	Define user needs	Surgeon input and general anatomy	1	Dec-08	GSI, Dr. Criscione	User needs	QSR
	Define functional requirements and constraints	AACSD dimensions, user needs, research	2	Dec-08	GSI, Dr. Crisione, John Mims	Functional requirements and constraints	QSR
	Translate requirements into intial specifications	Requirements	3	Jan-09	GSI, Dr. Criscione	Design Specifications	QSR
	Verify that specifications meet requirements	Design specifications	2	Feb-09	GSI	Verification	QSR
	Develop Concepts	User needs, R&D, specifications	4	Mar-09	GSI	Concepts	QSR
	Develop design criteria	Initial design input	2	Mar-09	GSI	Design criteria	QSR
	Concept Selection	Design criteria	1	Apr-09	GSI, Dr. Criscione	Final concept	QSR
	Determination of materials	Research materials in previous devices	2	May-09	GSI, Dr. Hyman, Dr. Criscione	Materials selected	QSR
	SolidWorks drawings with dimensions	Design specifications	4	May-09	GSI	Drawings	QSR
	Method of Sterilization	Research successful sterilizatio methods	1	May-09	GSI	Sterilization method selected	QSR
	Verify that final specifications meet requirements	Final specifications, device requirements	2	Future work	CorInnova Staff	Verification	QSR
	FMEA	Types of failure modes	2	May-09	GSI	FMEA spreadsheet	QSR
	Design History File	All documents and drawings	5	Jul-09	GSI	DHF	QSR
	Validation of device prototype	Initial production unit, user needs, requirements	10	Future work	CorInnova Staff	Validated Device	QSR
	Final Design Review	Validation	1	Future Work	CorInnova Staff	Completion	QSR

The work of this design research project was completed after the verification methods were laid out for the final verification. Once the final design is converted into a physical prototype meeting all specifications and materials chosen, verification will take place through benchtop studies and ovine efficacy studies. A design history file was

compiled to document the design, including design assessment meeting agendas and action items, all schematics and device sketches, and documents that led to the design development.

6. DESIGN INPUT

Device design begins with evaluating user needs, device requirements, and constraints. The surgeon is the primary user, so his/her preferences are highly regarded, and any suggestions or criticisms he/she offers are valuable. In addition, the developers should consider the design scope, desirable and undesirable features, and any compatibility issues that they may face in the design process.

According to the FDA, design input includes the physical, functional, and safety requirements (U.S. FDA, 2009). The desired and required properties of the instrument must be determined either quantitatively or qualitatively. In device design, it is important to establish sufficient requirements as a foundation for a safe and effective product as early as possible. The input requirements are converted to more detailed design specifications that reflect customer needs. These specifications represent the first design output of the design process. Design output, section 820.30 (d) of the QSR, is a documented product of each design phase and the final design process with acceptance criteria to illustrate that the output meets the input requirements of safety and function for the device (U.S. FDA, 2009). The specifications are considered to be a design output because they are continuously updated and modified throughout the design process. Before a project advances to the next phase, it is essential for the design output to meet the design input.

The design will focus on technical performance, risk management and human factors. The device must be capable of accessing the pericardial space without unintended consequences. It should be designed to assure that the user is able to achieve the device purpose consistently, safely, and with relative ease. It is the responsibility of the designer to protect the patient and the surgeon against preventable errors. Close communication with a surgeon was maintained throughout device development to increase efficiency and concentrate on user and patient needs. The device must be sterilized initially prior to placement in the pericardium. The product must be constructed at a reasonable cost with

considerable quality control; however determination of manufacturing procedures does not fit into the scope of this project.

The device will be used in a hospital environment at approximately standard room temperature and in low humidity. The device must be compatible with the AACSD for deployment. The design input requirements were reviewed and approved by Dr. Criscione in March 2009. Preliminary design specifications were reviewed by Lewis Harrison, CorInnova Engineer, and Dr. Criscione.

6.1 Quality System Regulation Requirements

According to the Design Controls in the Quality System Regulations, Section 820.30(c), design input should be "appropriate and address the intended use of the device, including the needs of the user and patient" (U.S. FDA, 2009). The first design inputs are the design requirements constraining the device. More specifically, they are the foundation of the device, covering the device purpose, device operation, device compatibility requirements, research and development work, and the device life cycle. Comprehensive requirements ensure that all assumptions, problems, and other considerations are exposed upfront to save time and money on the design efforts. These requirements launch the design and development plan, and make the designer aware of the goal of the design process. Design input is a continuous process beginning with the feasibility phase and continuing to the physical design stage (U.S. FDA, 2009). Although design input usually includes labeling, packaging, manufacturing, installation, maintenance, and servicing requirements, these processes are not contained within the scope for this project.

Thorough review ensures that the requirements are complete and not repetitive before final approval and documentation. Design evaluation meetings were held to assure device reliability, and to assess the compatibility of the pericardial access device with the cardiac support device. These discussions allowed early recognition of issues and ensured that the requirements of the device were met in its current form. In most cases, the "reviews"

were informal assessments of the design. Design concerns were presented to reviewers for corrections, requirements and constraints were evaluated and approved, and action items were managed by the Graduate Student Investigator (GSI). These materials were distributed to Lewis Harrison via email due to his location for suggestions and approval. Meetings were held periodically with Dr. Criscione for approval of the design at the appropriate design phases. When vital design issues arose as a result of the meetings, Dr. Criscione and the GSI identified necessary corrective actions to follow, such as updating specifications, researching options, or making design changes. Design assessment meetings were documented in the design history file to track modifications and the evolution of the design for future reference.

6.2 Device Life Cycle

After device production, packaging, and sterilization, the PASS is ready to use. The PASS and AACSD must be removed from their separate packaging directly before use. Then, the AACSD suture loops should be placed over the PASS scaffold guide wires with the AACSD concave cup surface facing upward, as it will approach the heart apex. The AACSD should be collapsed inside of the shaft of the pericardial access device prior to entry into the incision. In order to fit into the 1-2 inch sub-xiphoid incision, the deployment guide wires should be held together at their tips to prevent any tissue damage. The ends of the guides should be placed into the incision, and the PASS should advance into the pericardial space until the shaft flare is enclosed by the pericardium. The guide wires should be released so they stabilize and support the pericardium, pulling it away from the heart. Next, the suture loops should be slipped off of the guide wires of the PASS so that the AACSD deploys around the heart. Once proper placement of the AACSD has been achieved, the PASS can be removed slowly, ensuring no damage to the body. As a single-use device, the device must be discarded after removal from the pericardium. The diagram below, figure 3, depicts the steps of the device life cycle.

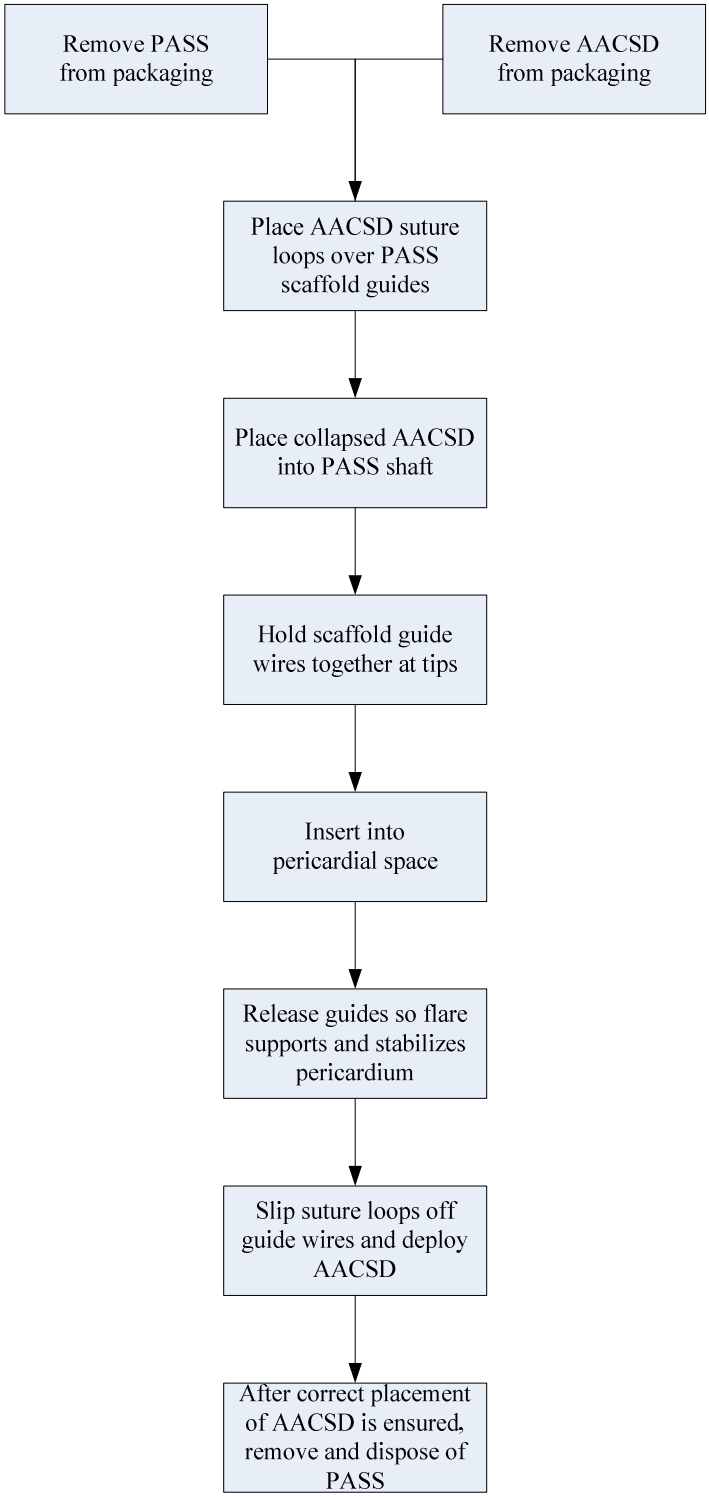

Fig. 3. Device life cycle of PASS.

6.3 User Needs

Before concept generation begins, user needs were analyzed to lay out the design requirements. The developer must interpret the user needs in terms of the capabilities of the device to decide what must be achieved, and how to approach the objective. The designer must consider the patient on the operating table as well as the surgeon using the device for access to the pericardium for placement of a cardiac support device. The PASS must accommodate the surgeon needs and preferences as the primary user by making a simplified surgery possible with a product that will be beneficial. If the implant mechanism appears to be an obstacle rather than an aid, the desire to use the product diminishes.

The pericardium is not rigid enough to maintain the desired position away from the heart once the incision is made. Thus, the current procedure requires that the surgeon use sutures in combination with the PASS to manipulate the flexible pericardium away from the heart. The device designed aims to provide an easier surgery, but it is yet to be determined if suturing the pericardium can be removed from surgical tasks. The objective is to design a device that is capable of providing a sufficient viewing window for the cardiac surgeon, and supporting the pericardium well enough to maintain a distance from the heart for the AACSD to fit around the organ. The benefit of using a pericardial access device is less complicated entry of the AACSD into the sub-xiphoid incision that will reduce surgery and recovery time for the surgical team and the patient. Table 2 below lays out the user needs for the PASS.

Table 2
Practical application of user needs in design of PASS.

Category	Need
Technical Performance	Delivers and deploys AACSD
	Minimally-invasive
	Must withstand forces of deployment
	Does not interfere with AACSD function
Patient Safety	Sterilized device
	Biocompatible materials
	Prevents abrasion to cardiac tissue
Ease of Use	Accessibility to pericardial space
	Simple operation
	Provides fast, smooth deployment
	Allows unobstructed view of heart
Quality Assurance	Follows QSR design controls
	Manufactured to specifications

The PASS must be designed for technical performance and lack of unintended consequences. The device is intended for the minimally-invasive delivery and deployment of the AACSD, and should not interfere with the placement or function of the AACSD in repairing heart motion. The stabilization system must be durable enough to withstand the forces exerted on it by the surgeon during entry into the incision and deployment of the AACSD without deformation.

Patient safety is a major concern for any medical device design team. The PASS must be capable of entering the pericardial space without abrasion to the surfaces of the pericardium or the heart. Although it is intended as a temporary delivery system, it must also be comprised of biocompatible materials and sterilized prior to use. A quality device will be designed by following the design process laid out in the FDA Quality System Regulations. Manufacturing processes will adhere to the design specifications.

Aesthetically, the device must not appear too complicated. That is, the user should preferably be able to look at the device and have an idea of its purpose and how it couples with the AACSD for device delivery and deployment to the heart apex inside of the pericardium. The PASS must be designed so that the user is confident and capable of using the device consistently and safely for its intent without recurring error. Ease of entry into the pericardial space is an important instrument in convincing the surgeon to use the device, because one prefers a mechanism that does not obstruct the necessary surgical space or add to patient time on the operating table. In order to aid the surgeon in placement of the cardiac support device for an easier operation, the device should allow the surgeon to maintain a clear view of the anatomy and AACSD.

6.4 Research and Development Summary

The original design concept was motivated by clinical need and through research and development. The PASS has improved rapidly through extensive prototyping to provide easier access to the pericardial space. The delivery and deployment of the AACSD began with suction, advanced to sutures, and most recently has become a rigid tunnel with Nitinol guides to stabilize the pericardium away from the heart. The process has been a collaborative effort with John Mims and the CorInnova staff to develop ideas and manufacture mechanical devices based on these ideas.

The necessary device dimensions for the pericardial access device were obtained by using the previous PVC tube introducer that was inserted into the sub-xiphoid incision during the first ovine efficacy trials. This testing is demonstrates the safety of the device, and for proof of concept. The tube was inserted into the incision until it reached the apex of the heart, and the points were measured from apex to surface of the incision. The depth of the tube was 4.5 inches, with a 1.6-inch inner diameter, and a 1.9-inch outer diameter. Thus, these are the upper limits of the PASS since the PVC tube was a snug fit into the surface incision.

PASS Prototype 1

The 2006 device (see Figure 4) consisted of 12 rigid polyethylene tubes connected to 12 hypodermic metal tubes glued to a ¼-inch thick brass ring with a 1.5-inch outer diameter. The countersink holes in the brass ring were intended to attach to the pericardium via suction. The middle 6-inch diameter ring and the top 10-inch diameter ring were connected to the rest of the device with T-connectors and tubing. A 45-degree angle of flare created a significant viewing window for the surgeon from the brass ring to the 6-inch diameter ring, while remaining within the boundaries of the 2-inch incision. The piece of the device that contacts the pericardium at the heart apex was large enough for the collapsible AACSD to fit into the pericardial space. The brass ring proved too rigid to maintain the suction between the heart and the device, so the device only maintained contact with the organ during diastole-when the heart is most deformable. A compliant material and increased surface area of suction on the base would enhance the device efficiency.

Fig. 4. PASS prototype 1. Picture shows how the device appears looking down at the heart apex from the surgeon's viewpoint during use.

PASS Prototype 2

In June 2007, a thin wall PVC tube with a flared base was used to provide a surface to support the pericardium and pull the thin tissue away from the heart (shown in Figure 5). A 1 ¼-inch inner diameter tube was attached to a 1 ½-inch tube with PVC solvent, and the

joint was sanded down to create a smooth surface and prevent tissue damage. The flare was produced with a lathe, and eight pairs of holes were drilled at 45-degree angles just above the joint for sutures to enter and exit the tube from the pericardium. The angle was selected to prevent the PVC from cutting or wearing the sutures. Application of the device revealed that the flared surface could not hold the sac away from the heart sufficiently. Also, the suture weaving method was more of an obstacle than an aid, as it added unnecessary time and work for the surgeon.

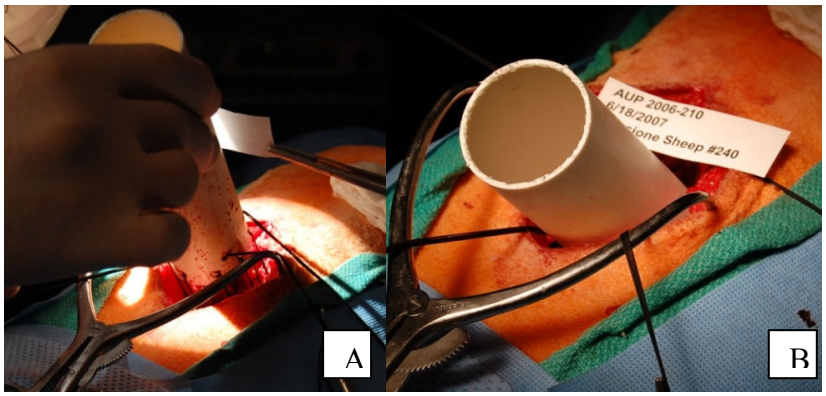

Fig. 5. PASS prototype 2. (A) Suture holes shown in delivery process in ovine efficacy study; (B) fully inserted into pericardial space with sutures laced.

PASS Prototype 3

A new device was tested in January 2008 and is shown in Figure 6. It was constructed of soldered brass and 1 ½-inch Teflon (PTFE) tubes. The length was maintained from the last study to allow the surgeon to access the pericardial space with enough excess length to remain outside of the sheep's cavity. The device body consisted of 6 brass struts curved into a brass ring that entered the pericardial space at the heart apex. The Nitinol wires curved to avoid bending since the struts guiding the wire were perpendicular to the brass ring at the bottom of the device. A Teflon ring at the top of the pericardial access apparatus reinforced the struts. Nitinol wire is laced through the struts with enough additional wire at the top of the device for grips to direct the 6 loops into the pericardial space. To use, the

device operator pushes the Nitinol wire from the top of the apparatus to force the wire through the struts and form the 6 loops to stabilize the pericardium.

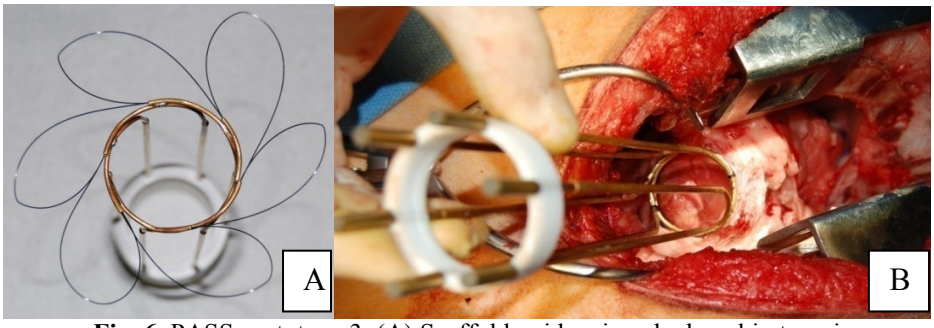

Fig. 6. PASS prototype 3. (A) Scaffold guide wires deployed in top view; (B) surgeon's view of device during placement into the pericardial space

PASS Prototype 4

In May 2008, a similar device was tested, which is depicted in Figure 7. The supports guiding the device to the heart apex ring were the same material, and the manufacturing method used was identical. However, the struts were bowed so that the surgeon could position the device under the sternum and direct it to the heart apex. With a 15-inch radius of curvature, the device can access the heart apex on the sheep, which faces away from the spine and slightly downwards towards the pelvis. Upon application, the curve of the device fit into the incision better, and gave less-obstructive access to the pericardial space. The curve on the shaft of the device made it more difficult for the Nitinol wires to slide inside of the brass, so the surgeon had to use more force to push the handles downwards. Improvements can be made by placing a solid cylinder inside the device shaft so that the cardiac support device is not stopped by any of the brass struts, and the CSD will not enter one of the spaces between brass columns.

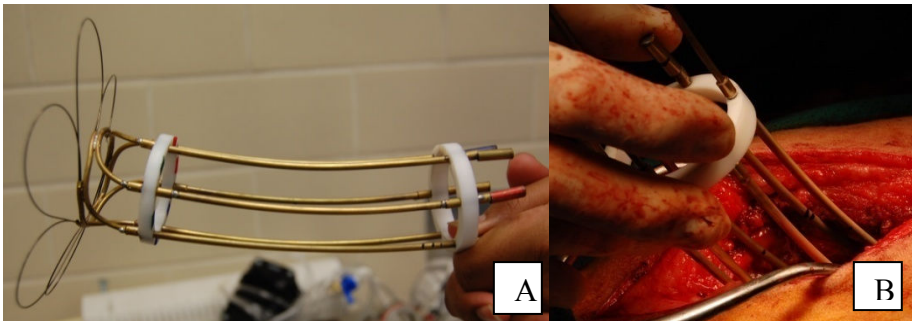

Fig. 7. PASS prototype 4. (A) Full view of prototype with guide wires deployed; (B) device during placement into pericardial space at May 2008 ovine efficacy study.

PASS Prototype 5

In the same May sheep study, a pericardial access device without the curvature of the previous instrument was tried. A flared, foam piece that resembled a suction cup was attached to the end of the device to replace the 6 stays and provide the contact surface at the heart apex. This device offered a clear view of the heart apex for the cardiac surgeon, but required a larger incision. Without a larger opening into the body, the device can cut or rip the tissue at the incision, which would create a disordered cut that takes longer to heal. See Figure 8.

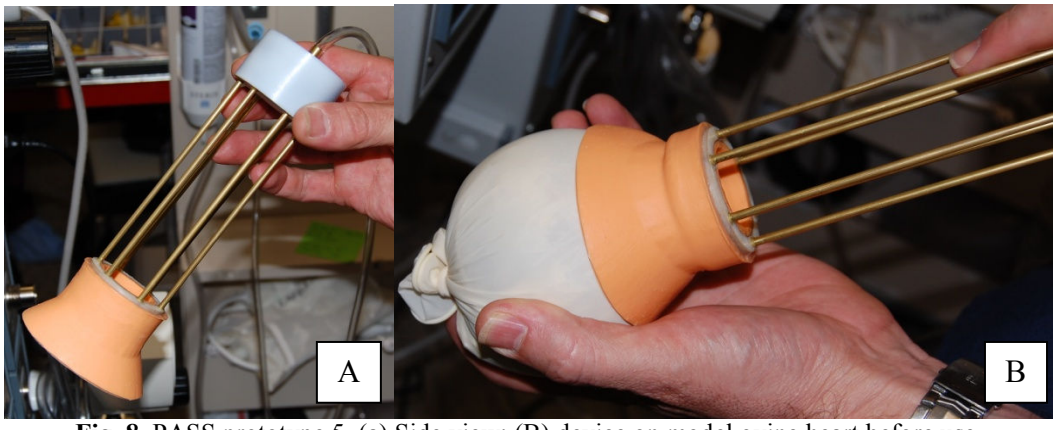

Fig. 8. PASS prototype 5. (a) Side view; (B) device on model ovine heart before use.

PASS Prototype 6

Figure 9 illustrates the device used in the November 13 trial, which maintained the curvature of prototype 4, but curved only at the heart-contacting end of the device. This change was made to provide the surgeon with a better view of the heart apex and pericardial space while preserving the same approach into the space. The design returned to the Nitinol wire guide wires at the heart apex, as this method stabilized the pericardium better than any previous technique. The shaft of this version was 1.5-inches in diameter and 7 inches long when deployed. A new method of cardiac support delivery was employed. The cardiac support device was attached to a deployment instrument to fit into the pericardial access mechanism. The deployment system had 6 longer Nitinol loops that were threaded into the corner of the guide wires of the cardiac support device. The devices were much more difficult for the surgeon to operate. Entry through the sternum into the pericardial space was challenging with the curvature isolated to the end of the device. Finally, the two devices for delivery of the AACSD interacted negatively. The deployment stays wove themselves into the rounder guide wires of the access device, and were unable to retract. Prototype 4 was used during this trial when prototype 6 was too large.

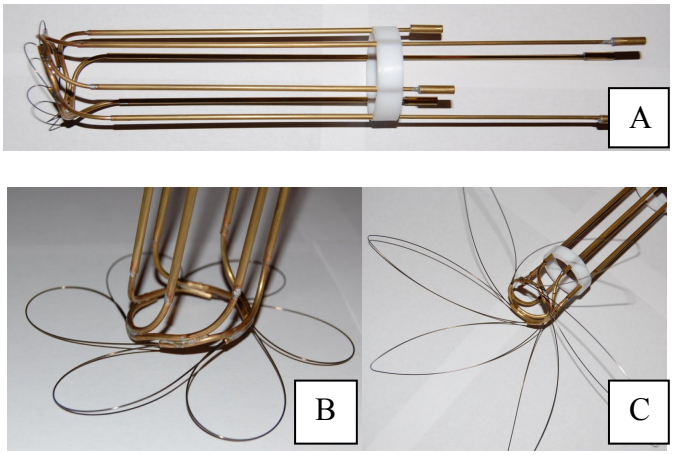

Fig. 9. PASS prototype 6. (A) Full view;
(B) extended scaffold guides; (C) deployment device.

PASS Prototype 7

A combined stabilizer and deployment jig was studied on November 14, 2008 to provide a less intricate mechanism of placing the cardiac support device into the pericardial space. Nitinol wires were woven together to make 6 stays, reinforced with Nylon thread on a PVC tube, and adhered to the PVC with electrical tape. Suture loops were sewn on the 6 chambers of the AACSD to secure the CSD to the stabilizer stays. To deploy the device, the surgeon pushed the stays to a single point, the support device collapsed inside the access jig, and the sutures attached the pericardium were pulled away from the heart apex to open the space. Once the point of the deployment apparatus had fully entered the pericardial space, the Nitinol wires were released to open the space around the heart. Finally, the cardiac support device was pushed away from the stabilizer and onto the heart apex with an aluminum tube. Dr. Nelson, the cardiac surgeon on the project, reported that the combined device was a faster and easier method to place the cardiac support device on the heart. The device could be improved with less pointed tips because there was a concern with the abrasion on the heart and pericardium. Figure 10 depicts the device from a top and side view with flared guides.

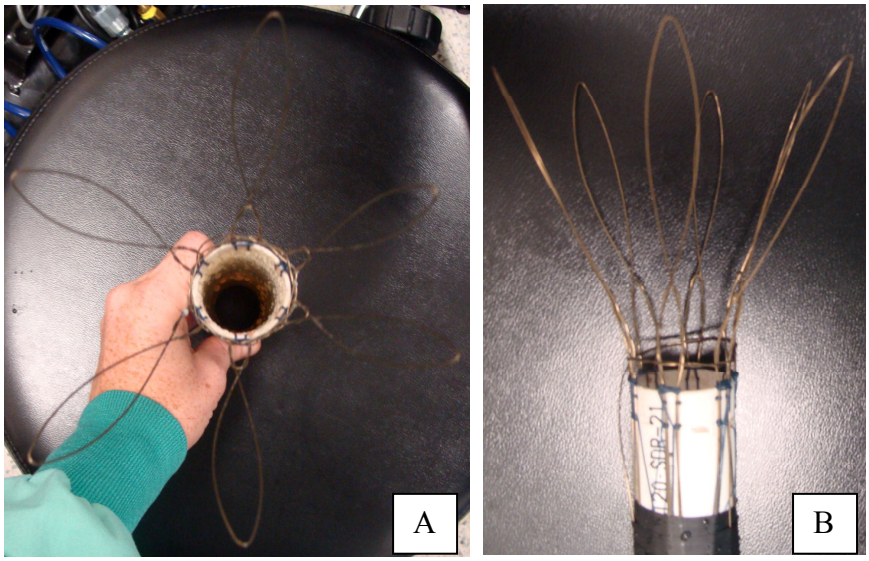

Fig. 10. PASS prototype 7. (A) Top view; (B) side view of flared guides.

7. DESIGN SPECIFICATIONS

There are two types of requirements to consider when designing and engineering a device: functional requirements, or what the device has to do, and constraints, or how the device will perform its function. Functions are satisfied by subsets of the product through operation, and constraints are satisfied by properties of the entire product (Otto & Wood, 2000). For the PASS, the requirements were established during the initial design input phase to lay the groundwork for concepts developed to meet these requirements. The ovine studies tested the prototypes during the research and development phases, which helped in the conversion of the requirements into specific design specifications. As changes were made to the cardiac support device during the studies, ideas for the PASS evolved to maintain compatibility with the device geometry and size. Also, Dr. Nelson, the surgeon who performed the operations using the prototypes, provided suggestions that helped the PASS developer create a device that is easier to use, and reduces deployment time, while preserving aspects of the device that allow a minimally invasive surgery.

The specifications are a dynamic collection that transforms to become a detailed and quantifiable file that the design must be verified to meet. The necessary specifications are prioritized over the desired specifications, but all should be met and verified by the design. The verification status is documented as proposed, confirmed, modified, satisfied, or verified as the design process proceeds. The verification methods shown in the specification table below are representative of the intended use of the PASS. When design input requirements are finalized and accepted in engineering terms as piece of the device master record, they become the product specification (U.S. FDA, 2009). Table 3 shows the design specifications established for the PASS.

Table 3
Design Specifications.

#	Necessary (N) Desired (D)	Requirement	Verification Method
		Functional Requirements	
1	Necessary (N)	Provide non-interfering path for Active Adjustable Cardiac Support Device into pericardial space	Develop prototype of AACSD and PASS and test compatibility and interface in efficacy study
2	Necessary (N)	Must not alter shape or function of cardiac support device	Develop prototype of AACSD and PASS and test compatibility and interface in efficacy study
3	Desired (D)	Should not require surgical attachment from device to sheep anatomy (i.e. via sutures)	Create stand alone design and manufacture prototype for efficacy tests
		Constraints	
4	Necessary (N)	Fit into 1-2 inch sub-xiphoid incision and pericardial incision at heart apex	Verify with engineering drawings
5	Necessary (N)	Approximately same diameter as deflated cardiac support device (maximum deflated support device volume is <1% end diastolic volume)	Develop prototype of AACSD and PASS and test in benchtop study
6	Necessary (N)	Length should be at least and not much greater than distance from heart apex to sub-xiphoid incision (to outside of sheep anatomy)	Research distance in average ovine in literature and confirm with PASS engineering drawings
7	Necessary (N)	Must smoothly move into and out of the pericardial space	Develop prototype of PASS and test in efficacy study
8	Necessary (N)	Must withstand forces exerted by pericardium elastically	Develop prototype of PASS and test in efficacy study
9	Necessary (N)	Must withstand force applied by cardiac surgeon to open device into pericardial space	Develop prototype of PASS and test in efficacy study
10	Necessary (N)	All materials used are legacy grade implant materials	Documented FDA approval and previous biomedical use without major issues
11	Necessary (N)	Materials chosen should not be abrasive or increase healing time at incision (alter anatomy)-surface roughness	Check with medical device literature
12	Necessary (N)	Mechanical failure must not occur during use; device is not to be re-used	Manufacture final design prototype and test in benchtop study until failure
13	Necessary (N)	Meets FDA and CDRH requirements	FDA documentation
14	Necessary (N)	Shelf life meets FDA and packaging requirements	QSR
15	Desired (D)	Scaffold length 1:1 aspect ratio with shaft diameter; should not extend length of heart from apex to base	Verify with engineering drawings
16	Necessary (N)	Shaft < 1/16" thickness	Verify with engineering drawings

The PASS and AACSD developers worked together to maintain consistency with the specifications required by the AACSD, which fall mostly under the functional requirements. The interaction between the two devices was evaluated before specifications were established, because the two devices must coordinate efforts to rehabilitate the heart. As the mandatory specifications state, the device must provide an unobstructed passageway for the AACSD into the pericardial space without altering the shape or performance of the assist device. This includes the restriction of a shaft thickness of less than 1/16" to allow as much space as possible inside of the tube for the collapsed AACSD. The inner diameter of the PASS should be approximately the same diameter, or larger than the deflated AACSD, which has a maximum deflated volume of <1% of end diastolic volume. It is preferred that the PASS not entail attachment to the ovine anatomy to function, because it is ideal that the device will minimize the work required of the surgeon.

The geometric device constraints were developed for the pericardial access device by placing a PVC tube into the incision and taking measurements. The device must fit into a 1-2 inch sub-xiphoid incision, and a 1-2 inch pericardial incision at the heart apex. The shaft should be long enough to reach from the heart apex to the outside of the sub-xiphoid incision, but must not extend so far as to interfere with the procedure. It is a desirable trait for the length of the deployment guides to maintain a 1:1 aspect ratio with the outer diameter of the shaft. The guide wires should not span the length of the heart from apex to base. The size and shape limits of the device should aid in smooth movement into and out of the confined surgical area to prevent tissue damage.

Mechanical failure testing will be completed during verification to ensure that the PASS does not fail during use. The pericardial access device must withstand forces applied by the surgeon and the ovine anatomy. The magnitude of the force varies with the strength of the surgeon, as well as how well the operator adapts to using the device. Finally, the device must be easy to use and well understood with minimal reading of a manual or requiring further explanation beyond initial training.

8. CONCEPT GENERATION

Innovative concepts must be created and sketched to meet the customer needs. Before a concept can be selected, all aspects of the design must be understood, and various competing alternatives should be drafted. All ideas should be produced on the front end of the design process as possible solutions for the need, and eventually narrowed down to concepts from which to choose the final design. Initial consideration of a wide array of ideas prevents design changes later that would force the developer to incur additional costs. The design of a surgical instrument should be kept simple and unnecessary features or accessories should be avoided.

8.1 Foundation for Concept Development

The ideas were generated based on the design input, particularly the research and development results. Extensive research and development and device versions were tested in efficacy studies in animals. The research and development phase revealed various advantages and disadvantages of options for each part, as well as potential problems with the device.

The central component of the device is the shaft. The shape determines the effort required by the surgeon to place the PASS through the incision under the sternum. It must be large enough to permit entry by the cardiac support device without demanding more invasive surgery that would defeat the device purpose. The ideal radius of curvature for the prototype apparatus was established by considering the anatomy of the sheep, the ability of the surgeon to examine his work throughout the procedure, and the difficulty required to direct the device to the heart apex. Distributing the curve throughout the shaft of the device proved challenging, because it was more difficult to manufacture, and extensive curvature could interfere with surgical observation. On the other hand, the curved shaft simplified entry into the sheep by allowing the surgeon to get under the bone

without excessive force. The view of the heart through the device is important because the surgeon must locate the apex before placing the cardiac support device. A straight cylinder provides a direct view of the anatomy and makes the path of the support device through the tube easier. However, it is not as easy to maneuver to the heart. The brass supports that form the shaft in certain iterations of the device allow the user to identify precisely where the support device sits at all times, but the AACSD could enter the passages between the supports. The tunnel-like view through the PVC tube was adequate as long as the cardiac support device can be placed at the end of the tunnel before the access device enters the body. At one point, the PASS included separate stabilizer and deployment mechanisms used together to place the AACSD, but this method was abandoned because of the difficulty Dr. Nelson had with placement and the time it added to the process. The most recent design combined delivery and deployment, and also did not require that the AACSD travel the length of the PASS shaft. The design that advances to prototype manufacturing will feature this combined system, because the surgeon reported that it was much easier to use. Furthermore, the system will not have multiple pieces that must enter the pericardial space and potentially interfere with the progress of the surgery.

The thin and adaptable tissue of the pericardium is easy to pull away from the heart, but must be held in place once the desired position is found. Several of the previous efficacy studies demonstrated that a flared end on the device was effective in providing an additional method of maintaining control of the pericardium and opening the heart space. It has also been demonstrated that more contact with the inside of the pericardium provides a more stabile system that does not have to be periodically corrected during surgery. This can be seen when comparing the results of the flared PVC tube to the Nitinol stays. The looped stays have a larger surface area than the PVC and the pericardium remained separated from the heart without much trouble. The angle of flare also was increased with the Nitinol, so space for the AACSD to enter the pericardium was much greater. Different guide lengths will be tested to pinpoint the one that will engage properly with the pericardial sac. The retractable deployment guides introduced

with the Nitinol made the device much easier for the surgeon to direct into the pericardial space. A movable guiding system provides increased user control of the instrument, and allows for gradually opening and flaring. On the other hand, moving parts add to the potential of mechanical failure and could increase deployment time.

In order to gain new perspective for device concepts, a brainstorming session was held with members of the development and construction team for the AACSD. All contributors previously observed efficacy studies using PASS prototypes, but were not involved in the creation of these prototypes. The procedure at the meeting was for each of the five attendees to create original ideas with knowledge of the device intent and research and development work. After 10 minutes to sketch and annotate drawings, each person passed their sketch to the next person for comments and additions, and this task was repeated until each person had the paper they started with. The process was beneficial in concept generation because it offered original ideas to contemplate that otherwise would not have surfaced with a limited design team. The collaborative effort also raised compatibility issues between the PASS and AACSD that needed to be recognized and overcome early in the design process to prevent unnecessary costs. The results of the meeting are in the design history file for the PASS.

Another facet of concept generation was analysis of similar access devices used in the medical setting. This was advantageous in development of the PASS design, because the products have been used in the field, and it is possible to combine previous ideas with one's own to create a successful product. A combination of ideas from brainstorming sessions, research and development, precedent devices, and frequent interaction with the lead user contributed to concept generation for the PASS design.

8.2 Design Concepts

The concepts were sketched after dividing the device into its separate functions and their requirements. With this method, various combinations could be made with the ideas to carry out each function, provided there are not compatibility issues. Also, if

multiple functions can be carried out by a single part solution without compromising performance or safety of the product, more concepts are possible for consideration. The PASS must enter the sub-xiphoid incision and be moved to the heart apex without damaging any tissue along the way. It also must enter the pericardial space and stabilize the sac away from the heart to allow space for AACSD entry. Finally, it must successfully deploy the AACSD for placement around the heart.

Original drawings from the first rounds of concept generation are shown in Appendix A. Sketches became more refined with each iteration as the generation process advanced. Three concepts were eventually drafted to advance to concept selection. The ideas incorporated previously accepted models throughout the research phase of the process. The first design concept has a solid, curved shaft with a 1.5” outer diameter at the end that does not contact the heart (the bottom), and a flared top. The scaffold guide wires are in their deployment position set on the flared tip of the device shaft. There are six guides in an approximate oval shape that come to a rounded tip. The guides are fixed on the device shaft, and must be held together by the surgeon to enter the pericardium. The device will hold the collapsed AACSD inside of the shaft, with suture loops extending over the guides to maintain control of the placement of the cardiac support device prior to deployment. Concept 1 is shown in figure 11 below.

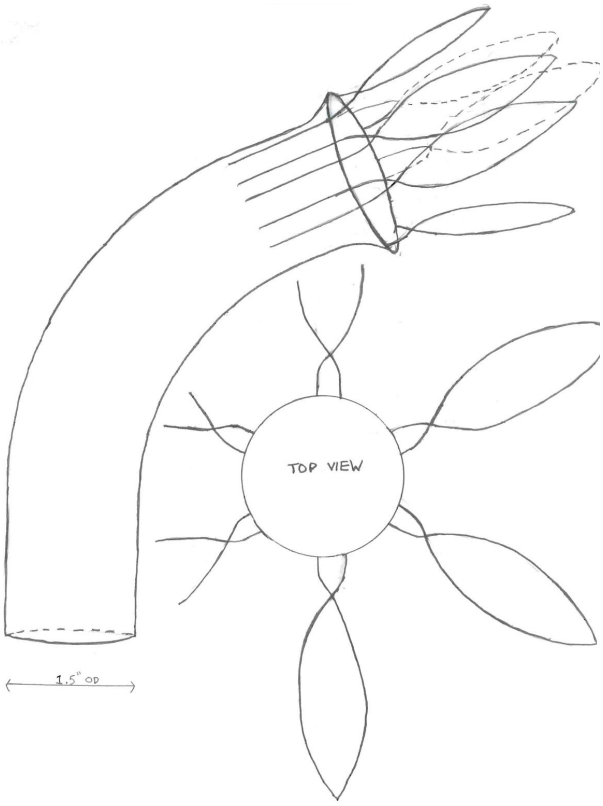

Fig. 11. Design concept 1.

The second idea has a solid, straight shaft with a 1.5” outer diameter at the bottom to maintain classification as a minimally-invasive device. The end of the shaft has a short flare where the six guide wires are attached. The guides are more rounded than the previous design, forming an almost parabolic shape at the ends. When the device is delivered inside the pericardial space, the guides must be held together by the surgeon for deployment of the AACSD. The cardiac support device will be positioned in the top end of the PASS, temporarily connected to the guides as they pass through the incision. Design concept 2 is shown below in figure 12.

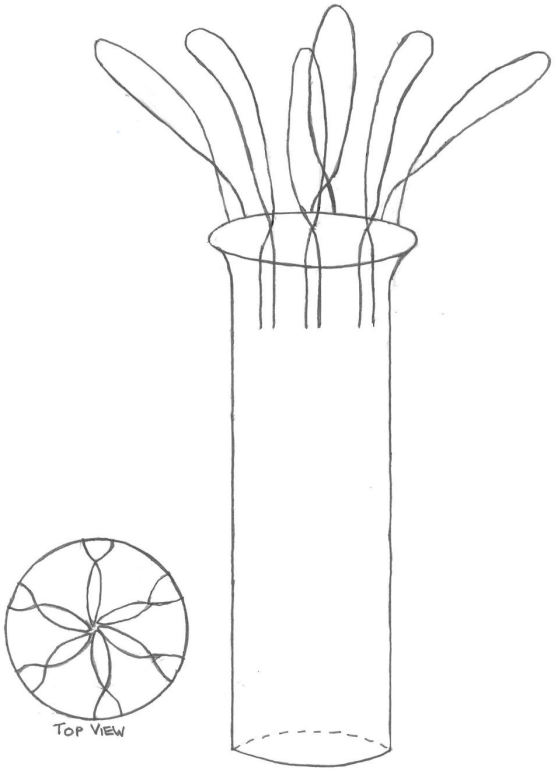

Fig. 12. Design concept 2.

The third device concept has six metal struts with guides inside of them that will open and flare after pericardial entry. The guides are directed by small cylindrical knobs at the opposite end of the struts. There is a solid ring bracing the struts that runs parallel to the ends of the instrument before the struts begin to curve. The curve of the struts is a safety feature to prevent abrasion and allow a smoother entry into the pericardial space for the PASS as the guides are pushed out to support the pericardium. Also, since the end of the device shaft does not flare, the curve allows the guides to extend away from the heart. The guides are shorter than the previous concepts but fully line the inner wall of the pericardium in what looks like a rounded pinwheel form. The AACSD will require a separate deployment instrument to travel through the straight shaft of the PASS for the concept because there is no attachment mechanism. The surgeon will push the AACSD

through the center of the PASS for placement after the pericardium has been stabilized with the rounded guides. The third idea is shown in figure 13 below.

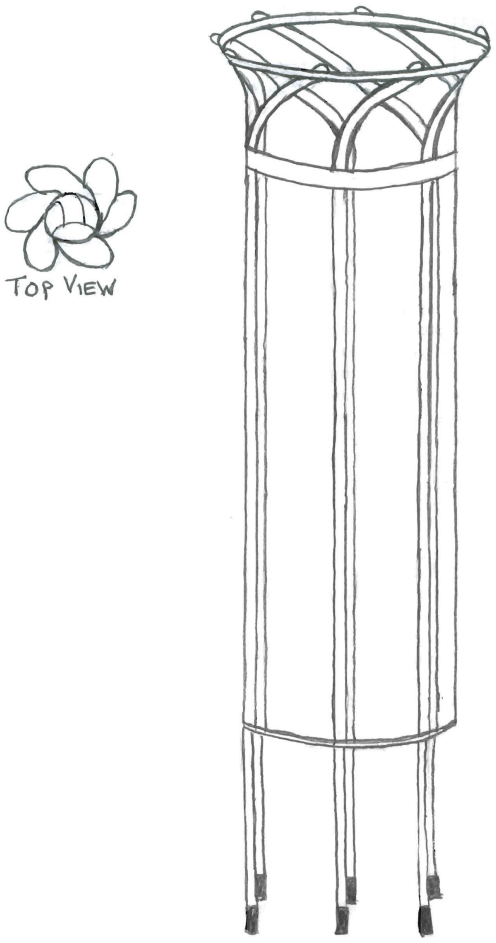

Fig. 13. Design concept 3.

9. CONCEPT SELECTION

9.1 Concept Selection

A systematic evaluation of the concepts was needed to narrow down the ideas to one final design. This prevented unnecessary bias from entering the picture and allowed the most effective idea to surface. The engineering and manufacturing required for each alternative was considered before evaluation. It was important for everyone involved in the decision-making process to agree on the design criteria upon which the concepts were rated. To select the concept, consensus criteria was developed without any uncertainties, the three ideas were understood well and to the extent of detail permitted at this stage of the design process, and the concepts were ranked based on the criteria.

9.2 Design Criteria

The design criteria are based on the ability to meet user needs, manufacturing capability of the design, compatibility with the total system, safety, and technical performance. More specifically, the design criteria for the PASS cover the needs of the patient and surgeon, production, and the limits of the less-invasive surgery. Some criterion is more important than others to the success of the device, but all criteria will distinguish the proposed ideas from one another. A drafted list of the criteria was made based on the engineering specifications as the first design output, and all of the design inputs. Modifications to the list were made to prevent overlapping criteria, and to ensure that all necessary items were taken into account.

An important factor in choosing the most favorable model is the surgeon's needs. The device must allow the surgeon to see his/her work as he/she places the PASS and deploys the AACSD. As the device approaches the heart, it is important that the surgeon maintain a field of view through the device shaft to avoid hitting the heart apex. This is

an important criterion in the selection process, because a less-invasive surgery gives the surgeon a smaller area to work with, so he/she must not be further limited by the device. Also, all parts of the device must be strong enough to withstand forces exerted by the surgeon. Serious problems could arise if the device failed during the delivery and deployment process, so the PASS must be strong enough to be maneuvered upon entry into the sub-xiphoid incision. Device functionality is covered by the ability of the scaffold guide wires and the shaft to enter the pericardial space easily and without extra force from the surgeon. The PASS must deploy the AACSD faster and better than the surgeon could do on his/her own. A device with moving parts, or one that requires twisting and working with the anatomy too much is not appealing as an instrument.

The PASS must be compatible with the AACSD geometry when collapsed. It must also provide smooth deployment of the cardiac support device around the heart by pulling the pericardium away from the heart. The level of support that the pericardium receives is essential to successful AACSD deployment, because the pericardial sac must be held away from the heart. The inner surface of the shaft must not have any pieces that could cut through the outer membrane of the AACSD, or in other way inhibit device performance.

Criteria concerning safety of the device include rounding all corners of the deployment guides, and ensuring that the outside of the shaft has a smooth finish. Also, the shaft must be sturdy enough so that it does not buckle, causing failed deployment or tissue damage. Finally, as a medical instrument, the materials used must be short-term biocompatible.

The design criteria cover user needs, compatibility, safety, and functionality. This reflects the design input. It is also important to consider the manufacturing process for the PASS. Manufacturability must be honestly looked upon during the selection process, because cost and the ability of the parts to come together to form a device is what allows the concept to advance to practical use.

9.3 Pugh Chart

Each of the three design concepts had advantages and disadvantages in durability, feasibility of implementation, effectiveness, ease of use, and size. An isometric view of each alternative was drawn to scale, and the most effective design was chosen based on criteria developed by the GSI. Each criterion was considered for all concepts before the next criterion was visited, to allow consistent definition of the criteria. Criteria must be prioritized if two alternatives have close outcomes on the Pugh chart.

The first alternative was selected as the datum for the Pugh chart. This means that it received "0" for every design criterion. This idea was chosen for the datum above the others because it was predicted to be the best design. Next, if the design variant was deemed worse than the datum for the criteria, it received a negative value, and alternatives that performed better than the datum received a positive value. The Pugh chart for the design selection is shown in Table 4 below.

Once the datum was selected as the final concept based on the design criteria, the device was evaluated for design refinement. Also, the negative rankings were looked into further for the concepts that would not be pursued to establish what feature of the ideas earned them the poor rating. Though there are design trade-offs, positive aspects of other devices can be combined with the chosen alternative to create an improved concept.

Table 4
Pugh chart for concept selection.

Design Criteria	1 Curved shaft, fixed scaffold	2 Straight shaft, fixed scaffold	3 Straight shaft, retractable scaffold
Ease of shaft entry into pericardial space	0	-1	-1
Ease of scaffold entry into pericardial space	0	0	-1
Amount of moving parts	0	0	-1
Buckle-resistant scaffold	0	0	0
Ease of AACSD deployment from PASS	0	0	-1
Field of vision for surgeon	0	1	1
Deployment time	0	-1	-2
Support level for pericardium	0	0	-1
Roundness of scaffold tip (scaffold safety)	0	0	0
Ease of manufacturing	0	0	-1
Tube width for entry into sub-xiphoid incision	0	0	1
Compatibility with AACSD geometry	0	0	0
Smoothness of shaft inner surface	0	0	-1
Smoothness of shaft outer surface	0	0	-1
Ability to withstand forces exerted by surgeon	0	0	0
Biocompatibility	0	0	0
∑	0	-1	-8

During the research and development process, the curved shaft proved to be more effective than the straight tube, because it entered the incision and advanced to the heart more normally. Thus, a curved shaft is beneficial in the design because it requires less work for the surgeon, and is less harsh than moving through the anatomy toward the heart with a straight tube. The straight shaft on the second and third design variants makes the devices harder for the surgeon to manipulate into the pericardial space, so it was decided that they performed worse than the datum for that criteria. The straight shaft of the second concept also increases delivery time to the pericardium because it is more difficult for the surgeon, and does not slide in as smoothly as the curved shaft does. The two alternatives achieve a better field of vision for the surgeon because the straight shaft provides an unobstructed view.

The third alternative has a retractable scaffold that makes entry of the guides into the pericardial space more difficult, creates a problem when deploying the AACSD

unattached through the shaft, and increases deployment time greatly. The retractable deployment guides controlled by the handles on the opposite end contribute to the complexity of the device. It was thought that this extra control for the surgeon would prevent him/her from having to hold the scaffold together at the end when it enters the pericardium. With the guides built into the struts, and no flare at the shaft end, the shaft has a smaller maximum outer diameter for entry into the sub-xiphoid incision, making the surgery less invasive. However, the moving parts make failure modes more likely to occur, and also increase the difficulty of manufacturing the concept into a practical device. The struts create additional problems with device compatibility with the body and the AACSD, because their surface is not as smooth, and could harm the patient or puncture the AACSD active bladder.

The support level of the pericardium is determined by the flare of the scaffold guides and the presence of a flared end of the device shaft. The device flare ensures stabilization of the pericardium where the incision is made once the PASS is in place. Stabilization of the pericardium is the main function of the PASS, and the third concept received a negative here because its features do not maintain contact with the pericardium as well as the other two variants. The following sections cover the device embodiment, where the size, arrangement of parts relative to one another, and materials were established.

10. AIM I FUTURE CONSIDERATIONS

Section 820.30(f) of the QSR states that verification is to "confirm that the design output meets the design input requirements" (U.S. FDA, 2009). Each design specification also has a planned verification method to demonstrate that the input requirements were met. Methods were devised as acceptance criteria to verify that the instrument meets these specifications, and to confirm that the manufacturing process does not alter the safety or effectiveness of the device. The verification methods include ovine efficacy studies and benchtop tests with a prototype for performance, compatibility, and mechanical properties. Safety specifications, such as the shelf-life and biocompatibility of materials will refer to the FDA for standards. The verification and validation processes will be performed with the constructed access mechanism in ovine studies, as the current model was designed for this animal heart size and surgical access point. Once performed, documentation of the verification and validation results and methods will be found in the design history file.

In order to complete the design process following FDA regulations, all of the results from the design assessment meetings go into the DHF to document decision making and activities within the project. All sketches, procedures and design control records for the pericardial access device will be made accessible in the DHF to maintain quality standards and device competency. A Device Master Record (DMR) for the PASS will contain all specifications and procedures for the device, including drawings of every component and a description of device composition. Device records become a reference instrument for the manufacturer once the product is transferred to production.

11. AIM II PROBLEM STATEMENT

The second objective of the GSI was to design a mechanical delivery system for the AACSD into the pericardial space. Since the heart is a mechanical organ and mechanical factors influence its growth and remodeling, it is important that the AACSD contacts the myocardium directly to modulate the strain and restore normal motion to the heart. The pericardium is thin and flaccid, so it forms around the heart and maintains close contact through the pericardial fluid, which creates a challenge when trying to pull the pericardium away from the heart apex. In fact, the pericardium and the pericardial fluid act as a barrier between the heart and the rest of the body, so the heart would not be able to feel the full pressure applied by the device if it were placed outside the pericardium. Thus, access to the pericardial space surrounding the heart must first be obtained in order for the cardiac support device to be successfully deployed around the damaged heart. The mechanism for this action is a device placed in the pericardial incision that allows placement of the CSD between the heart and the pericardium. The PASS is needed to deliver the collapsible AACSD to the heart, and to deploy the support device into the heart space so that a failing heart can be mechanically repaired. The research and development prototypes have proved useful in access of the pericardial space and deployment of the AACSD without creating obstacles for the surgeon. Unlike previous devices, this pericardial access method is purely mechanical, does not require suction, and gives the surgeon a viewing window of the heart for introduction of the CSD and use of surgical instruments. The PASS also permits a minimally invasive surgery to reduce trauma, time, and costs associated with heart surgery.

It is hypothesized that the PASS will reduce the time and effort required by the surgeon to deliver and deploy the AACSD into the heart space. The initial design characteristics for the PASS were that it includes a rigid, hollow tube as a viewing window to allow the surgeon to maintain clear sight of the heart and AACSD, and a supportive, but adjustable scaffold to enter the pericardial space and support the

pericardium. The tube must not collapse under the forces applied by the surgeon or ovine anatomy because it would then not be able to deploy the AACSD in this state.

Although the device is intended as a single-use device, it must be biocompatible and sterilized before that use. With functionality as the primary concern, the primary goals of the second objective are:

- The PASS should be able to withstand, without plastic deformation, the forces applied by the surgeon in placement of the AACSD.
- The scaffold must adjust to the needs of the surgeon, but be strong enough to hold the pericardium away from the heart.
- The AACSD must be positioned inside of the PASS shaft, and be deployed through the guides by suture attachment to the scaffold.
- The final design should be refined and described with full dimensions in SolidWorks to meet specifications.
- A method must be chosen that makes the device biocompatible and sterilized before use.
- Risk analysis and device evaluation through failure modes and effects analysis must be performed.
- Scope does not include on labeling, packing, shipping, service/maintenance.

12. MATERIAL SELECTION

All materials that will be considered for the design of the PASS are legacy biomaterials used in FDA-approved and FDA-cleared devices on the market. Within this domain, materials are anatomical site specific and device specific, so the material choice is driven by the application. With biomedical devices that require access through the skin, thrombosis can become a problem. Since the PASS is intended for temporary use during surgery to place the AACSD, clotting is not a concern for the design.

Materials can dictate design because of the interactions involved with the device, the patient, and the surgical team. In some cases, patient characteristics and compliance with doctor instructions factor into the success of the device. The biomaterial mass, surface conditions, and physical form, as well as the location, application, and the individual receiving the care with the device all effect how the device and patient react to the use of the biomedical device. Doctor preference over the type of materials used can factor into whether they would feel comfortable using a device. Also, the surgeon's technical skill and handling of the device can alter device performance. Finally, at the device level, material properties, device design and fabrication all work together to form the final properties and function of the device. For the PASS, patient compliance with restricted activity is not an issue, but the necessary material integrity depends upon surgeon and staff use of equipment, overall design of parts and compatibility of parts, material selection, and quality control.

The PASS is a design that is durable, relatively light-weight, and safe for use in ovine models. There is a rigid metal shaft with a metal scaffold to enter the pericardial space. In order to determine the best material, biomedical applications of materials were researched and each was rated against the other for the particular application. The device does not have to be sterilized multiple times since the PASS is a single-use device, but the materials considered must be capable of maintaining form through one sterilization process.

12.1 Material Considerations

Degradation can lead to the unintended loss of properties and performance depending on the level the material degrades. Polymer degradation can result in bond changes, changes in cross-linking, loss of additives, and adsorption, all of which lead to alterations in chemical properties and function. The combination of mechanical and chemical degradation is called mechanochemical degradation. Corrosion-accelerated fatigue occurs once stress foci are created. Wear-accelerated corrosion is a concern if the metal is dependent on surface finish, such as stainless steel. However, the tube will not require surface treatment since the device is only inside of the body cavity for approximately 10 minutes.

The size and geometry of the device, as well as the type of material used in manufacturing effect the possibility of deformation. In ovine efficacy tests, forces applied to the materials are minimal, but material properties are an important topic of discussion in this context. Manufacturability, cost, and availability of materials are other practical considerations in production of a device on its way to market.

The ultimate strength, yield strength, and stiffness of the material are important mechanical properties of interest in consideration of a material for device delivery and deployment into the pericardial space. Stiffness is a function of modulus and geometry. The ratio of uniaxial stress to uniaxial strain, also known as the modulus of elasticity or Young's modulus, applies in the elastic range of the material before the material reaches yield strength. A material with a high modulus of elasticity is said to be stiff. Yield strength is the stress where the material reaches plastic deformation. Ultimate strength is a measure of the stress at fracture of a material under an applied load.

12.2 Materials Alternatives

Metal Tube

Although polyvinyl chloride and brass were used for the shaft in research and development, a biocompatible material is needed that allows for the correct device geometry. Plastics would have to be made with thicker walls than is desired for the device, so metals will be compared for practical use. Metals can be cast in a mold, or wrought. Machining is less expensive than having a mold created for a particular part, so if a component can be wrought, it is preferred over casting. Material properties are in part a function of how the component is made. The instrument will be outsourced for manufacturing.

ASTM standard F 138 is a standardized orthopedic stainless steel made of the elements in table 5. Mechanical properties, illustrated in table 6, are best with cold-worked stainless steel.

Table 5.
ASTM F 138 Composition. The requirement should meet:
% Cr + 3.3 x % Mo ≥ 26.0. As from MatWeb (ASTM F 138, 2008).

Element	Composition (%)
Carbon	0.030 max
Manganese	2.00 max
Phosphorous	0.025 max
Sulfur	0.01 max
Silicon	0.75 max
Chromium	17.00-19.00
Nickel	13.00-15.00
Molybdenum	2.25-3.00
Nitrogen	0.10 max
Copper	0.50 max
Iron	balance

Table 6
The mechanical properties of F 138 stainless steel. Taken from ASTM Standards (ASTM F 138, 2008).

Property	Value
Ultimate Tensile Strength, min, psi (Mpa)	125000 (860)
Yield Strength (0.2% offset), min, psi (Mpa)	100000 (690)
Elongation, min, %	12

Since titanium alloys are lighter than most other biocompatible metals, they are widely used in joint replacements, and other medical devices. Titanium alloy has much higher ultimate and yield strengths than stainless steel. The modulus of elasticity for titanium alloy is substantially lower than that of stainless steel, i.e. it is less stiff. This means that under the same applied load, stainless steel would change its shape less than titanium. The device shaft should maintain its shape while the surgeon pushes it through the incision so that it is stabile as a delivery and deployment apparatus.

In order to maximize the working space within the device shaft, a metal that can be manufactured with a thin wall is necessary. The desired property is a wall thickness of less than 1/16” for a larger surgeon viewing window, and more space for the collapsed AACSD. This increased degrees of freedom between the AACSD and PASS will provide for better deployment. This is the primary reason F138 stainless steel was chosen over any titanium alloy.

The moderate yield stress of stainless steel gives it an ability to bend, which is a mandatory trait for the tube of the PASS when entering and exiting the sub-xiphoid incision around delicate organs. The metal is ductile and easily manufactured as well. Corrosion is common with stainless steel, causing a major reduction in the use of the metal in joint repair, now solely for fracture repair instead of joint replacement. If the metal is scratched, one part becomes anodic and loses ions, leading to corrosion. It does have a history of corrosion in vivo, which can be prevented by surface treatment, design, and minimizing handling. The transient use of the surgical instrument limits corrosion as a concern for the design of the PASS.

Scaffold Guide Wires

Scaffold guide wires should be flexible and elastic so that when the surgeon presses the guides together for entry into the pericardial space and releases them; they will spring back to their flared position and hold the pericardium away from the heart. ASTM standard stainless steel 316L is easy to deform, which is not a desirable characteristic for the flare of the PASS. It would be preferable to have a material that is flexible and springs back to shape.

ASTM F2063 is a wrought nickel-titanium alloy used for medical devices and surgical implants in orthopedics and dentistry, such as self-expanding stents. Nickel titanium, more commonly known as Nitinol, is a shape memory alloy. Mechanical working and heat treatment can drastically change the properties of Nitinol. One of the unique properties of this particular choice is a transition temperature below room temperature that will allow it to work inside of the body. The shape of the wire is set upon cooling. Above the transition temperature, super-elastic properties are exhibited, and the metal will recover its previous shape after being bent and twisted. Flexibility is about 20 times greater in Nitinol than in stainless steel (Duerig, Pelton, & Stockel, 1997). The Nitinol used during research and development of the PASS has the ability to be strained 8-10 times more than spring steel without plastic deformation (Small Parts, 2008). This flexibility and resistance to permanent deformation will allow for more durable scaffold guide wires to maintain the initial flare and hold the pericardium away from the heart for deployment of the AACSD. An example of a positioning and deployment device using Nitinol is Mitek's Homer Mammalok, which is used to mark the location of a breast tumor. The Nitinol wire hook in the Mammalock allows a much smaller radius of curvature at a larger wire diameter than stainless steel, and returns to its original configuration after experiencing approximately 8% strain inside the stainless steel cannula (Duerig, Pelton, & Stockel, 1997). With the limited space available inside the body for a minimally invasive surgery, such elasticity is invaluable. Finally, placement of the AACSD in animal efficacy studies illustrated a clear fluoroscopy image

with Nitinol, so a more precise deployment is possible. The typical composition of Nitinol is shown in table 7.

Table 7
ASTM F 2063 Composition. Taken from ASTM Standards (ASTM F 2063, 2008).

Element	Composition (%)
Nickel	54.5-57.0
Carbon	0.050 max
Cobalt	0.050 max
Copper	0.010 max
Chromium	0.010 max
Hydrogen	0.005 max
Iron	0.050 max
Niobium	0.025 max
Nitrogen plus Oxygen	0.050 max
Titanium	balance

The mechanical properties for super elastic Nitinol are in table 8 below.

Table 8
The mechanical properties for F 2063 Super Elastic Nitinol. Taken from MatWeb Material Properties (MatWeb F2063).

Property	Value
Ultimate Tensile Strength, psi (Mpa)	155000 (1070)
Yield Strength (after transition), psi (Mpa)	118000 (814)
Elongation at Break, %	8

Securing Ring

For the ring to secure the Nitinol wires onto the stainless steel tube, a rigid plastic is desired. Plastic is preferred over metal here to allow more degrees of freedom for the Nitinol guidewires. A stabilizer can be added to limit cross-linking that might be caused

by radiation sterilization. Cross-linking increases modulus, ultimate strength and yield strength, changing the properties of the material.

Polysulfone, ASTM F702-98a, has good radiation stability that is 200 times that of polypropylene, almost 700 times that of polyacetals, and 10 times polycarbonate (Sterigenics, 2009). It is often used to replace polycarbonate, but is more expensive. Polyacetal was briefly researched for use as the ring material, but it was discarded due to low radiation tolerance and the likelihood of embrittlement after sterilization (Sterigenics, 2009). Polypropylene has a superior fatigue life when compared to other biomedical polymers. The material is used in intravenous drip chambers and syringes. Also, the flex of the material allows wide biomedical use as a hinge in clamps. A stabilizer must be added when gamma irradiation is used for sterilization to limit degradation because the polymer becomes brittle (Sterigenics, 2009). The high mold shrinkage and water absorption found with polypropylene made it unappealing for the ring as accurate dimensions are needed for a precise fit on the guide wires (MatWeb polypropylene). PEEK (polyetheretherketone) was researched and is used for more involved engineering applications than a ring with grooves would require. The Young's modulus for PEEK is substantially higher than polycarbonate, and such a degree of stiffness is not a desired property for a ring passing through the pericardium.

Polycarbonate (F 997-98a) has less mold shrinkage than polysulfone and is cheaper, which was the basis for choosing this thermoplastic. It is a more effective material option for a single-use device. It is also easy to machine, has good strength and stiffness. Since water absorption is low for polycarbonate, it can provide high dimensional accuracy, which is important in securing the Nitinol guide wires. The polycarbonate will be molded to create the grooves on the inner surface of the ring. Table 9 shows the mechanical properties for gamma radiation-resistant polycarbonate.

Table 9
The mechanical properties for F 997-98a Gamma Radiation Resistant Polycarbonate. Properties were found on MatWeb (MatWeb F 997-98a).

Property	Value
Ultimate Tensile Strength, psi (Mpa)	7250-18000 (50-124)
Yield Strength, psi (Mpa)	5370-27700 (37-191)
Elongation at Break, avg., %	79.4
Modulus of Elasticity, ksi (Gpa)	261-1100 (1.8-7.58)
Water Absorption, avg., %	0.227
Linear Mold Shrinkage, avg., cm/cm	0.00583

Heat-Shrink Tubing

The heat shrink tubing is Teflon®, a form of polytetrafluoroethylene (PTFE) commonly used for fabric vascular grafts. This PTFE thin-walled tubing is ASTM standard D 3295. It has a 2:1 shrink ratio, and in order to fit the 1/8" tubing, a ¼" outer diameter tube will be used. The tubes will slide over each of the six guides to envelope the wires. They have a high operating temperature, so when heat is applied, they will shrink to half of their size, forming a tight fit around the guides. The tubes will provide a smoother entry for the guides inside the pericardium because of the low coefficient of friction of PTFE. Table 10 below illustrates the material properties of D 3295 PTFE tubing.

Table 10
The mechanical properties for D 3295 PTFE tubing. Taken from Lenntech (Lenntech, 2008).

Property	Value
Ultimate Tensile Strength, psi (Mpa)	34000 (23)
Elongation, %	325
Flexural modulus, ksi (Gpa)	85000 (600)
Upper Service Temperature °C (°F)	204 (400)

13. FINAL DESIGN AND PART DESCRIPTION

13.1 Description

The shaft must extend outside of the body cavity where the sub-xiphoid incision is made, but must also be short enough so that the curvature does not block the view of the AACSD for the surgeon. The shaft curvature was optimized during research and design at a 15-in. radius of curvature to maintain a viewing window for the surgeon while conforming to the ovine anatomy as well as possible.

The flare of the device shaft provides better support for the pericardium than the scaffold alone, because the material of the shaft is more rigid than the scaffold material. Also, a flared end encourages and accommodates the AACSD to flare around the heart upon deployment. The angle of flare was calculated using a circle of the same diameter as the outer diameter of the bottom of the shaft, which is 1.5 inches. A cone was made by cutting a 90° sector out of this circle and folding the edges of the remaining parts of the circle into a cone. The perpendicular height of the right circular-based cone was controlled by the maximum outer diameter of the top of the shaft that would first enter the sub-xiphoid incision in the ovine model. To remain below the 1.9-inch outer diameter constraint of the tube, the flare diameter was set to 1.8 inches. This left 0.15 inches for the radius of the base of the cone, with the shaft flare starting at the 1.5 inch diameter of the remaining shaft. The calculation of the perpendicular height of the cone, using the angle of flare is shown in Appendix B. These dimensions were needed to convert the design sketch into a 3-dimensional SolidWorks design. The collapsed AACSD will fit well within the limits of the 6-inch tube.

The desired aspect ratio between the shaft outer diameter and the length of the scaffold extension past the shaft is 1:1. The scaffold pieces should be equally spaced to support the pericardium around the heart. To determine the width of the pieces, the AACSD suture loop size and the circumference of the shaft flare top were taken into

account. The circumference is 5.7 inches, which allows 0.95 inches for each of the 6 scaffold guides. The scaffold guide wires extend straight up from the flared shaft end 1.5” and are 1/8” wide, until the rounded top, which has a 1/16” radius of curvature. The sutures used to slide the AACSD on the guide wires are 3/16” long before being sewn into loops to go over the scaffold ends. Although the guide wires are thinner than those used in the efficacy study prototypes, the strength of the scaffold guides coupled with the shaft flare extending into the pericardial space will provide sufficient support of the pericardium. Figure 14 below shows the device presented in SolidWorks.

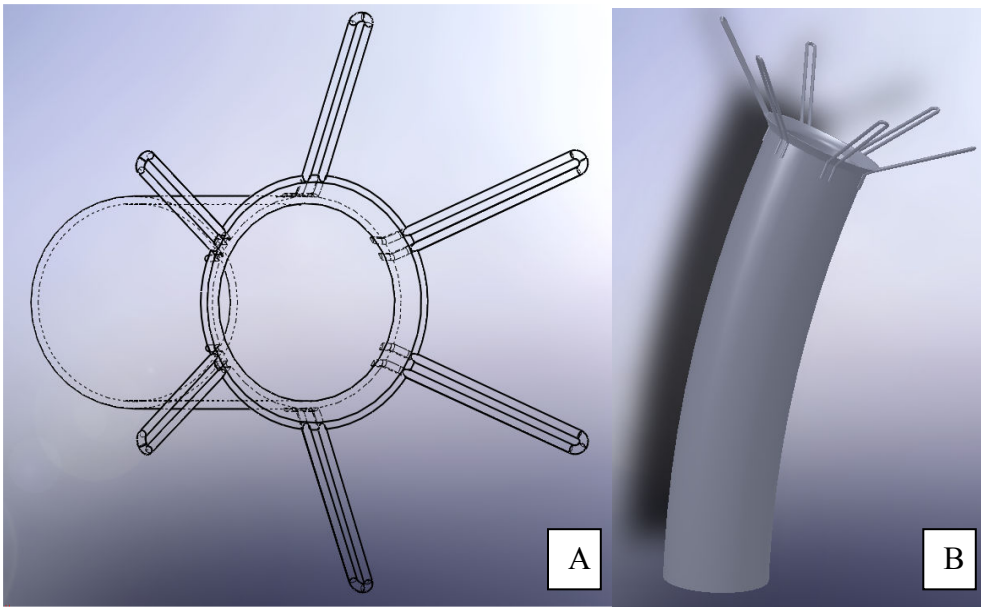

Fig. 14. PASS design in SolidWorks. (A) Top view; (B) isometric view.

Once the device is placed, it sets the path for the cardiac support device, but does not have the ability to change in form or size. The device is not capable of flexible movement around the site, but this is not necessary for the specific application with the cardiac support device. Upon entry into the pericardial space, the scaffold guide wires will be manually held together so they do not snag the pericardium, and released once they completely clear the pericardial sac. The stabilizing apparatus opens into the space

when the scaffold is released, forming a cup around the heart apex. Then the surgeon can pull the pericardium away from the heart and the suture loops will slide off of the scaffold guide wires for the deployment of the AACSD.

13.2 Refinements

At this point in the design process, the concept sketch depicted maximum dimensions of the device for clearance into the incision, the deployment path of the AACSD through the shaft, and the layout of the components relative to each other. Ranges of the variables of shaft length, flare angle, scaffold length, and materials were listed before each parameter was precisely established to work best together. Any simplifications that could be made to the device while meeting functional requirements and constraints were made.

Once a final design was chosen, the GSI consulted Dr. Criscione, the creator of the AACSD and CEO of CorInnova for necessary design refinements. The ends of the scaffold guides were rounded further to prevent abrasion to the heart and pericardium, and to provide for smoother entry into the pericardial space. All edges were filleted to prevent abrasion as well. Also, a securing ring was added to attain increased bonding between the scaffold wires and the device shaft outer surface. The ring will slide over the shaft at an angle to reduce the cross-sectional area of the shaft entering the incision so that the additional piece does not require a more invasive entry. This way, the diameter of the shaft will only be the outer diameter plus one thickness of the ring, instead of two, which would be the case if the ring were parallel to the top of the shaft. Of course, the flare at the top of the device will be of larger diameter than any other part of the PASS, so the securing ring remains less than the diameter of the top of the flare.

To prevent tangling of the AACSD Nitinol frame and the PASS Nitinol guide wires upon deployment, heat-shrink tubing was placed over the guide wires and activated to create a 1.35” long thin film between the guides on each of the six scaffold pieces. This way, if the AACSD frame hits the PASS deployment guides, it will deflect off

instead of interlacing. Teflon® heat-shrink tubing will further prevent abrasion to the heart. Further discussion and illustrations for the design change can be found in Appendix C. Figure 15 below shows how the tubing fits over the Nitinol guide wires.

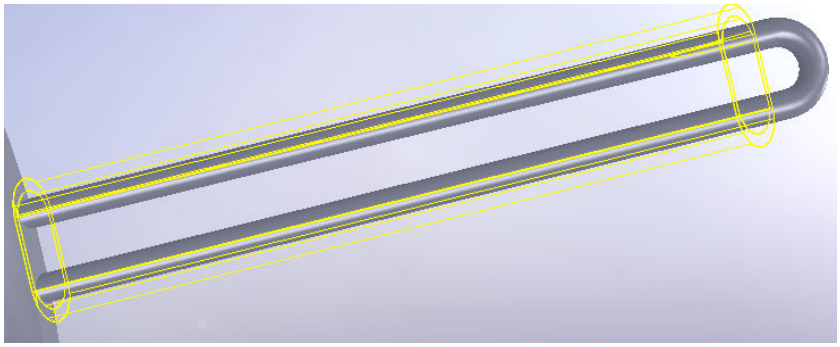

Fig. 15. Scaffold of device in SolidWorks. Heat-shrink tubing fits over a single guide.

13.3 Bill of Materials and Assembly

Table 11 below is the bill of materials with all parts, their function, materials, and dimensions.

Table 11
Bill of materials

Part #		Part Name	QTY	Function	Material	Dimensions
1	1.1	Shaft	1	Provide viewing tunnel for surgeon and pathway for AACSD into pericardial space	F 138 Stainless Steel	1.5" OD, 1.4" ID, 15-in radius of curvature, 6" long
	1.2	Shaft flare	1	Aid in holding pericardial sac open and away from the heart	F 138 Stainless Steel	0.12" height, 1.8" OD, 1.7" ID
2	2.1	Scaffold guide wires	6	Stabilize pericardium away from heart; open heart space for AACSD entry	F 2063 Nitinol	0.025" Diameter, 1.5" above tube for 1:1 aspect ratio with tube diameter, 1/8" width, equal spacing (every 60 degrees)
3	3.1	Heat-shrink tubing	1	Cover gap between guide wires to prevent entanglement; better stabilization of pericardium	D 3295 Teflon	1/4" Diameter, 1.35" length
4	4.1	Securing Ring	1	Secure scaffold pieces to tube	F 997-98a Polycarbonate	1.5" ID, 1.6" OD, 0.9" height, 0.025-in radius on 12 groove arcs corresponding to scaffold guides

If the shaft of the tube were straight and did not have a radius of curvature, a lathe could be used for machining the part because of the rotational axis of symmetry. A lathe will allow accurate dimensions to be attained, and smoothing of the inner and outer surfaces of the device. However, a wall thickness of 1/16” is needed for the shaft, so machining the part this way would waste material. Also, the curvature of the shaft makes it more difficult to machine, so it will likely be outsourced for production. Once the part is gradually curved to meet specifications for the radius of curvature, all edges will be rounded for safety. The polycarbonate securing ring will be injection molded for a close tolerance and a tight fit to prevent the deployment guides from slipping or dislodging during the procedure. The angle of the securing ring, the curvature of the shaft, and the grooves in the ring make molding a better option than machining the part. The temperature will be closely monitored during the molding process to prevent decline in mechanical properties of the polycarbonate. Once the part is created, it slides onto the shaft at the base, fitting just below where the flare begins. Nitinol wire will be heated and shaped in a small tube to obtain the correct curvature and length. Once the six deployment guides are made, they will fit securely into the ring grooves, flaring outward and upward from the center of the tube. Heat-shrink tubing will be pulled over the each deployment guide to the top of the shaft flare, and activated to form sleeves over the guides.

The device was finalized with dimensions, as illustrated in figure 16 below.

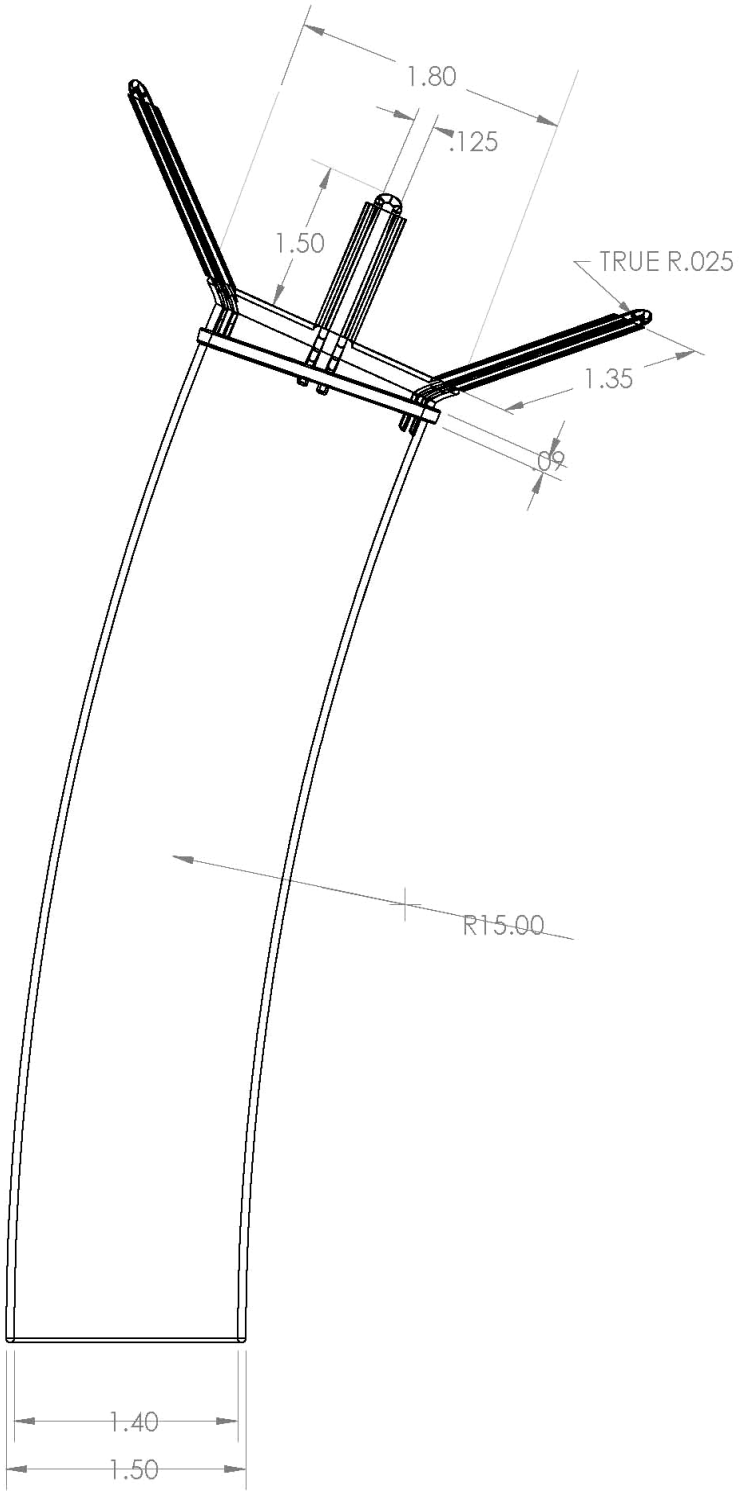

Fig. 16. Pericardial Access and Support System with dimensions.

14. STERILIZATION

Before each use, medical devices should undergo sterilization. The newest medical device sterilization techniques were considered for efficient and inexpensive sterilization of the PASS. The methods researched were first checked for material compatibility with the chosen metals and polymers for the device. Also, since radiation and ethylene oxide sterilization are priced according to such aspects as product density, dose, and turnaround time, these factors were taken into account in the decision-making process.

Although it kills microbial organisms effectively and inexpensively, steam sterilization is not often used for commercial sterilization of medical devices because cycles are run at temperatures of 121°C for 15 minutes or 134°C for 3-4 minutes, which "can melt acrylics and styrene, distort PVC, and corrode some metals" (Rogers, 2006). During research and development, steam sterilization was attempted with a prototype containing hypodermic tubing, and the device shape was altered. Thus, it will not be used for sterilization on the product in the market. Reducing the required temperatures in steam sterilization allows more plastics to undergo the process. However, there are superior sterilization methods available that would be better for the PASS.

Products undergoing EtO sterilization, especially certain plastics, will absorb ethylene oxide (Leventon, 2002). Stainless steel is more resistant to this absorption, but the plastic ring in the PASS would still be a concern with released EtO. The device would need to be aerated to remove harmful residuals prior to use in the procedure, so the post-sterilization efforts would add to overall time and cost. Also, it would be difficult for the EtO gas to reach the Nitinol wires under the plastic securing ring, so the device would possibly require partial disassembly for full sterilization. A more hazardous alternative would be to increase the gas concentration in the sterilization chamber, but this would obvious result in more side effects and EtO residuals (Leventon, 2002).

Electron-beam sterilization sometimes requires dosimeters to confirm that the product received a sufficient dose because the electron beam has issues with reaching all parts of some devices (Leventon, 2002). Since electrons have mass, the penetration distance of the beam may only be half of the distance reached by gamma radiation (Leventon, 2002). The orientation of the device can be changed and run through the sterilization process multiple times. Although e-beam radiation has low penetration and high dosage rates, the shorter exposure time can reduce the breakdown of polymers, such as polypropylene (Sterigenics E-beam, 2009). The shorter penetration distance could become a concern, and the alternative is more sufficient.

Gamma irradiation successfully kills microorganisms with deep penetration at low dose rates and little temperature effect (Sterigenics Gamma, 2009). The product will not become radioactive after sterilization, and no residues are created during the process. Radiation sterilization has the potential to change mechanical properties of polymers, such as increasing the cross-linking causing a stiffer material that can be brittle and have a lower strain to failure. In contrast to ethylene oxide sterilization, gamma sterilization can be done on a larger scale, once the device is already packaged and ready for shipment. Gamma penetrates all parts of any design configuration, making it appealing as a sterilization method for the PASS. For all polymers used in medical devices, close attention should be paid to the dose tolerance level to prevent simultaneous reactions of chain scission and cross-linking. Chain scission reduces tensile strength and elongation of the polymer, while cross-linking increases tensile strength and reduces elongation (Sterigenics, 2009). All polymers react differently to radiation sterilization. For example, high molecular weight polymers retain longer molecules and uphold their strength after irradiation, while thin components allow more oxygen into the sterilization process and lead to polymer degradation (Sterigenics, 2009). It is possible to inhibit the effects of this sterilization on the polymer by adding stabilizers, antioxidants and additives. They can absorb the radiation energy to prevent interaction with the polymer, or act as reactants, combining with radiation-generated free radicals in the polymer (Sterigenics, 2009).

Johnson & Johnson developed the Sterrad System, which is a low-temperature hydrogen peroxide gas plasma sterilization, as an alternative to other sterilization methods available. The 75 minute cycle uses hydrogen peroxide vapor and low-temperature gas plasma, leaves no residue, has low humidity, and requires no aeration procedure after sterilization since oxygen and water are the main byproducts (Feldman & Hui, 1997). Liquid peroxide is inserted into the evacuated chamber, and once the peroxide evaporates during the diffusion phase, it fills the chamber and sterilizes the device materials; then, the radio-frequency plasma discharge starts and hydrogen peroxide vapor separates into reactive species, such as free radicals (Feldman & Hui, 1997). However, the reaction does not penetrate as well as gamma irradiation, so it cannot be done after packaging. It will take the vapor longer than the cycle lasts to penetrate long and narrow lumens. This is a problem when considering use for the PASS, because although the device shaft has a diameter that is wide enough for full diffusion, the heat-shrink tubing covering the deployment guide wires would likely make a tunnel too narrow for the vapor to pass through.

After conducting research on the most commonly used methods and the newest developments in sterilization, it was concluded that gamma irradiation will ultimately be used to sterilize the PASS. This method is capable of penetrating all parts of the device shaft and scaffold, and can reach into the small area between the Nitinol guides under the Teflon heat-shrink tubing. Gamma will also leave no residue behind following sterilization, can be executed in large scale after packaging, and will not deteriorate or otherwise damage any of the materials used in manufacturing the product.

15. DESIGN EVALUATION

15.1 Failure Modes and Effects Analysis

A Failure Mode and Effects Analysis (FMEA) is a method for investigation of possible types of failure within a design or process, and the effect of the potential failures on a system. Benchtop studies and efficacy tests are expensive to perform, so a FMEA was completed by listing potential results of device failure and the controls in place to prevent them. Failures can be caused by any errors or defects in the design or process that could affect the user, and thus, their consequences but be analyzed. A FMEA must be performed on the PASS to yield a safe and reliable product, and to ensure that failure modes and their effects have been considered. Reducing the risk of failure will prevent costly mistakes in the system. One FMEA considers the product design and manufacturing as potential causes of failure, while the second enumerates possible failures resulting from the user or user errors.

Each part and its function, as listed in the device Bill of materials, were taken into consideration for FMEA. For success, the device must perform as intended and according to specifications made to meet the user needs. Thus, a potential failure mode was considered from incorrect operation to partial or complete failure of the part. Causes of failure for the PASS include operator error and manufacturing error. Since all designs must have controls in place to prevent these failures, the controls were set and documented as well. The severity of the potential failure was rated on the scale shown in table 12.

Table 12
FMEA Severity Rating

1	Insignificant (undetected by customer)
2	Very Minor
3	Minor (average customer will notice; a few customers annoyed)
4-6	Moderate (reduced performance and convenience)
7-8	High (loss of primary function, dissatisfied customers)
9-10	Hazardous (inoperative product, unsatisfied customers, risk of injury or death)

The likelihood of failure occurrence was rated using the scale in table 13.

Table 13
FMEA Probability of Occurrence

1	No Effect
2-3	Low (relatively few failures)
4-6	Moderate (occasional failures)
7-8	High (repeated failure)
9-10	Very High (likely failure)

The chance for detection prior to device failures was rated using table 14 below.

Table 14
FMEA Probability of Detection

1	Almost Certain
2	High
3	Moderate
4-6	Moderate (customers annoyed)
7-8	Low
9-10	Remote to absolute uncertainty

The Risk Priority Number (RPN) was calculated to help determine the failure modes that required the most immediate action. It was calculated by multiplying the severity rating by the probability of occurrence and the probability of detection. Thus, the failure modes with the highest RPN are given the priority for recommended actions. The actions to reduce the possibility of failure are also included in the FMEA table below. This is the part of the analysis where plans for design improvements or changes in components are documented and acted upon accordingly. The user failure modes and effects analysis in table 15 below presents the capabilities and possible limitations of the surgeon performing the surgery to place the AACSD using the PASS.

Table 15
User FMEA

User	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes of Failure	OCC	Current Controls	DET	RPN	Actions Recommended
Surgeon	Improper placement of suture loops	Poor placement of AACSD; longer deployment time	2	Misalignment	1	User training	1	2	Further efficacy tests for human factors, risk management
	Inability to hold guides together for entry	Possible abrasion; longer deployment time for re-entry	4	Poor grip on device	2	Heat-shrink tubing provides better grip	1	8	Further efficacy tests for human factors , risk management
	Placing device so convex shaft curvature on top	Abrasion; longer healing time; tissue damage	7	Rapid, hazardous entry	1	User training	1	7	Place label on device
	Guide wires dislodge from securing ring	Insufficient pericardial support	9	Excessive force applied	2	User training	1	18	Put adhesive between Nitinol and ring

Table 15 Continued

User	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes of Failure	OCC	Current Controls	DET	RPN	Actions Recommended
Surgeon	Pulling down on securing ring	Inability of ring to hold guides in place; insufficient pericardial support; loose guide wire in pericardial space	9	Excessive force applied	2	User training	1	18	List force limits of device in manual; benchtop testing for device limits
	Scratched shaft surface	Pericardial abrasion or tissue damage at initial incision; corrosion in long-term	4	Poor handling after removal from packaging; stacking instruments and device on prep tray	4	Packaging that prevents scratches while packaged	4	64	Further efficacy tests for human factors, risk management
	Excessive shaft curvature	Abrasion; longer healing time; tissue damage	6	Placing damaged device into body after dropping or bending device	2	Careful handling required	3	36	Further efficacy tests for human factors, risk management

Table 15 Continued

User	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes of Failure	OCC	Current Controls	DET	RPN	Actions Recommended
Surgeon	Kinked guides	Abrasion; longer healing time; tissue damage; insufficient pericardial support	6	Bending Nitinol into plastic deformation; excessive force upon pericardial entry	3	Careful handling required	2	36	List force limits of device in manual; human factors testing
	Device re-use	Contamination	9	Failure to read label; failure to re-sterilize	1	Labeling as single-use device	1	9	Further efficacy tests for human factors, risk management
	Improper deployment	Fail to deploy AACSD	8	Misalignment	4	User training	1	32	Further efficacy tests for human factors, risk management

Human factors issues are addressed through the user FMEA to demonstrate what could fail within the user-device interface. This is the evaluation of the tasks that the surgeon must perform, as discussed in the device life cycle, and how the PASS accommodates to user performance. Most of the potential failure modes relate to handling of the device, user training, and adherence to the instruction manual. For example, the device should be placed with the shaft curving upwards out of the sub-xiphoid incision in ovines, and the guide wires must be held together for entry into the pericardial incision before they are released. If either of these directions is not observed, tissue damage could occur that would result in a longer healing time for the patient, or worse. This is a concern because the patient is already in poor health, so any additional difficulties relating to the surgery could become intolerable. The device should attempt to make the surgery easier and safer, so if these issues arise, the PASS has failed to perform the main function. As long as the PASS is carefully handled after it is removed from packaging so that there are no scratches, kinks, or inappropriate curves in the device, failure can be prevented.

The highest risk priority number is associated with a scratch on the shaft surface. The stainless steel would become very abrasive and cause tissue damage. Further efficacy tests for ergonomics can be performed for this failure mode. If the surgeon uses excessive force with the PASS, the guide wires could become detached from the securing ring or kinked. Both would result in an inoperative product that could lead to injury or death of the patient. However, the problem is easily detected before the accident, and there is a low possibility of occurrence. The device does not require much force to travel to the pericardium, or to be placed into the pericardial space. The ring should certainly not be pulled on, but benchtop studies can be performed to test the limits. The device carries its own potential failure modes, which must also be analyzed for prevention and detection. Table 16 below illustrates the failure modes and effects analysis for the PASS.

Table 16
Device FMEA

Part	Function	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes of Failure	OCC	Current Controls	DET	RPN	Actions Recommended
Shaft Tube	Viewing and deployment tunnel	Metal burr from machining	Burr could pierce the AACSD bladder and CSD would not properly deliver adequate force efficiently to failing heart	9	Manufacturing error in machining	2	Manufacturing should adhere to engineering specifications and smooth all surfaces	4	72	Perform benchtop study to improve deployment; animal efficacy study needed
	Viewing and deployment tunnel	Poor biocompatibility	Contamination of body cavity	9	Inadequate sterilization	1	Biocompatible materials used	3	27	Follow FDA biocompatibility standards
	Viewing and deployment tunnel	Inadequate sterilization	Contamination of body cavity with microbes	9	Inadequate sterilization	1	Gamma radiation of device after packaging	3	27	Radiation dose should be monitored for each device
	Viewing and deployment tunnel	Shaft too curved or too straight	Potential tissue damage	6	Poor manufacturing; failure to follow engineering specifications	2	Shaft radius of curvature was tested during R&D; manufacturing done to engineering specifications	1	12	Further ovine efficacy testing

Table 16 Continued

Part	Function	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes of Failure	OCC	Current Controls	DET	RPN	Actions Recommended
Shaft Tube	Viewing and deployment tunnel	Shaft flare too wide for minimally invasive incision	Potential tissue damage; longer patient healing time	4	Poor manufacturing; failure to follow engineering specifications	1	Shaft diameter reduced as design change; follow engineering specifications to maintain size limits	1	4	Further ovine efficacy testing
	Viewing and deployment tunnel	Sharp corners	Abrasion to cardiac tissue	6	Poor manufacturing	2	Engineering specifications; corners filleted	1	12	Further ovine efficacy testing
Securing Ring	Hold scaffold pieces in place and attach to tube	Slip down tube; detachment	Detachment of support scaffold from PASS, decreasing stabilizing support to pericardium; possible dislodgement of guides into pericardium	8	Improper fastening of ring to device around scaffold ends; improper assembly	2	Tightened to engineering specifications	1	16	Perform bench top study to improve deployment; animal efficacy study needed

Table 16 Continued

Part	Function	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes of Failure	OCC	Current Controls	DET	RPN	Actions Recommended
Securing Ring	Hold scaffold pieces in place and attach to tube	Inability of ring to hold scaffold guides in place; loose fitting	Detachment of support guides into pericardial space	8	Radius of grooves for guides too large; failure of manufacturing to follow engineering specifications	2	Follow engineering specifications	1	16	Perform bench top and efficacy tests
	Hold scaffold pieces in place and attach to tube	Sharp corners	Abrasion to cardiac tissue	6	Poor manufacturing	2	Engineering specifications; corners filleted	1	12	Further ovine efficacy testing
Scaffold guide wires	Open and support pericardium	Kinks in guide wires	Could puncture heart or pericardium	7	Poor manufacturing, damaged in transit	3	Superelasticity Nitinol is very kink-resistant	1	21	Perform bench top study to improve deployment; animal efficacy study needed
	Open and support pericardium	Metal burrs on guides	Puncture tubing sheath, abrasion to heart; pierce AACSD active bladder	9	Poor manufacturing, failure to smooth all surfaces	2	Engineering specifications	4	72	Further ovine efficacy testing

Table 16 Continued

Part	Function	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes of Failure	OCC	Current Controls	DET	RPN	Actions Recommended
Scaffold guide wires	Open and support pericardium	Disengagement of guides from ring during deployment	Dislodge guides into pericardial space; abrasion; tissue damage	8	Poor manufacturing; failure to secure ring around guides	2	Engineering specifications	1	16	Benchtop stress tests
	Open and support pericardium	Entanglement with AACSD Nitinol frame during deployment	Misalignment upon deployment; pierce active bladder of AACSD	8	Poor manufacturing; loose tubing	2	Heat shrink tubing to create solid film between guide wires	3	48	Further ovine efficacy testing
Sutures	Attach AACSD to PASS at scaffold guides	Fatigue	Weakening of suture; break in suture	3	Poor deployment of AACSD at incorrect angle	2	Single-use device so suture strength should be upheld for use	1	6	Perform bench top study to improve deployment; animal efficacy study needed
	Attach AACSD to PASS at scaffold guides	Loosening	Detachment of suture; misalignment upon deployment	3	Overstressed	2	Follow engineering specifications, instructions for use	1	6	Perform bench top study to improve deployment; animal efficacy study needed

Table 16 Continued

Part	Function	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes of Failure	OCC	Current Controls	DET	RPN	Actions Recommended
Heat-shrink tubing	Create solid film between guide wires	Loose tubing	Detachment of tubing; entanglement of AACSD framework and guides; potentially pierce AACSD active bladder; poor deployment	8	Tubing not heated to optimal temperature to secure to guides	2	Follow engineering specifications	3	48	Further bench top studies, efficacy tests
	Create solid film between guide wires	Hole in tubing	Hole in cover over guide wires; potential entanglement with AACSD frame; potential piercing of AACSD active bladder	8	Damage during manufacturing	2	All devices should be checked to ensure engineering done to specifications	2	32	Further bench top studies, efficacy tests

The sterilization and biocompatibility of the device carries little concern because they are easy to control. Also, most of the potential failure modes for the device relate to manufacturing the product to specifications. Thus, provided the manufacturer follows specifications for shaft size, degree of flare, length and curvature of the device, it should properly adapt to the ovine anatomy. To ensure the safety of the PASS, all edges are filleted on the model, which should be followed by manufacturing. Also, the inner and outer shaft surfaces must be smooth to prevent abrasion, tissue damage, or puncturing of the active bladder of the AACSD. Damage to the AACSD carries a high risk priority number because it would lead to loss of the primary function of the device, which is to restore motion in the heart. The device would be unable to apply as much pressure as is needed to heal a patient with congestive heart failure. Simple quality control measures would prevent this failure mode. Detachment of the scaffold guide wires would be very hazardous, because the part could become loose in the pericardial space. The surgeon would have to search for the piece and remove it with other surgical instruments that could potentially damage the heart or pericardial tissue. Also, since the PASS is intended to reduce deployment time for the PASS and make it easier for the surgeon, the device would not meet user needs under these conditions. However, there is little chance for occurrence of this failure mode, and detection of the detached part is almost certain.

Another potential event is the entanglement of the AACSD Nitinol framework with the PASS Nitinol guides. The guides would delay delivery of the AACSD and the surgeon would have to manually untangle the wires and attempt to deploy the cardiac support device again. There is a possibility of the guides piercing the active bladder of the AACSD, making it inoperative. This problem is currently managed by the heat-shrink tubing creating a solid film between the guides where the AACSD cannot pass through. If the shaft becomes bent or the guide wires kink prior to use, the device should not be used because the geometry would become a concern. It is almost certain that the majority of the potential failures would be detected, and the risks can be prevented or reduced prior to entry of the PASS into the pericardial space. For example, if the suture loops that slide

over the guide wires become detached or loose, or there was a hole in the tubing, the surgeon would see the problem before placement.

The nature of medical device instruments is low risk, because they should be aiding in ease and safety of the operation, not adding to the possible hazards. Controls in place to detect potential failures, and steps taken to prevent these failures prove the safety of the device, which is of utmost importance in the design of any medical device. The recommended action for the failure modes with high risk priority numbers will be followed to improve the quality of the design. For most of the potential failure modes, this includes benchtop testing and further efficacy studies. After the actions are executed, the severity, occurrence and detection levels within the FMEA will be reassessed.

Problems may still arise late in the design process during production due to the differences seen between a laboratory-built prototype and a manufactured product made on an assembly, for example. For this reason, the design and production teams will maintain open and consistent communication when the PASS first reaches production.

16. AIM II FUTURE CONSIDERATIONS

The device can be advanced further by including a component to aid in the initial grasping of the pericardium for entry of the stabilization mechanism. The surgery requires the surgeon to make the incision into the pericardium at the apex and thread sutures, equally-spaced around the incision to seize the pericardium and gain control of the flaccid tissue. This means that to put the PASS into the incision at this point, the user must use one hand to hold the sutures coming out of the pericardium taut, and the other to hold the scaffold deployment wires. Research and design demonstrated that an increased surface area of the PASS guides contacting the inside of the pericardium leads to better pericardial support. A future design improvement would be to extend the idea of the heat-shrink tubing creating the film across the guides by creating thin plastic film sections between each of the six guides connecting it to the next. This could prove to stabilize the pericardium better than the current design method, achieving this end similar to a kite collecting air in the taut sections. Nylon, a polyamide, would be a good material choice for these pieces because it would create smooth, thin sheets to contact the pericardium that are relatively resistant to abrasion by the Nylon and Nitinol framework of the AACSD.

The more minimally invasive the surgery, the better the likely outcome and recovery time for the patient. Thus, if the access device can be reduced further in size, along with the AACSD, a smaller incision can be made. Of course, the surgeon would still need enough room to work inside of the pericardial space to place the AACSD and maneuver the PASS, and compatibility with the cardiac support device must be maintained.

Validation, in section 820.30(g), is the “confirmation by objective evidence that the particular requirements for a specific intended use can be consistently fulfilled” (U.S. FDA, 2009). The validation proves that the device is reproducible in technical performance and meeting user needs. The methods defined for validation should mimic how the produced device will be used in practice in order to determine that the device is

ready for market. As with verification, all methods, and other documentation should go into the design history file. Before the device can be used in a practical setting on humans, it must go through rigorous animal testing, and the results must be analyzed for safety and efficacy. Results of the testing and FMEA are compared with the design specifications for quality assurance purposes.

After the final design output is made, the design will be transferred to the production specifications as per section 820.30(h) of the QSR, which will reflect any necessary design changes made throughout the process after the efficacy studies and clinical trials are completed (U.S. FDA, 2009). All design changes made throughout the design process, particularly after aspects of the design have been verified and accepted, will be documented and will reflect section 820.30(i) of the QSR. The design history file is a collection of records that depicts the entire history of the device throughout the design and development process, which should follow the approved design plan, as per QSR section 830.40(j) (U.S. FDA, 2009). It will consist of the R&D summary, design and development plan, design review meeting agendas and action items, all sketches and computer-aided design drawings, specifications, and verification and validation plans and results. The file exists to prove that a design plan that follows the QSR was created and followed. The design history file was produced, but will be continuously updated as the design progresses to market.

The PASS will be labeled as a single-use device. Also, the packaging will contain a brief description of the intended use of the product in conjunction with the AACSD to deter off-label use. Discussion of device installation will be found in the AACSD instruction manual under delivery and deployment.

The PASS was motivated by a human need for the device in patients experiencing congestive heart failure. The final step in making the PASS available for use to move from sheep studies to human trials once the human design is finalized. This includes altering the depth and orientation of the device for a human heart and mini-thoracotomy point of entry, as well as the size and geometry. The cross-section of the PASS shaft will assume more of an ellipse for entry into the human anatomy. Thus, once

the device has been validated and production specifications are made for ovine models, the design will move to clinical trials, which will test the safety and efficacy of use in humans.

17. SUMMARY

The incidence of congestive heart failure cases is increasing, as are the costs related to treatment of the disease. As the population grows, and the lack of donor hearts available remains a problem, cardiac assist devices and devices that remodel the heart back to normal function are proving useful. The need for the pericardial access and support system (PASS) surfaced after ovine model studies with the Active and Adjustable Cardiac Support Device (AACSD). The cardiac support device proved difficult to insert into a small incision for the surgeon without a device to aid in delivery. The PASS deploys the AACSD into the pericardial space surrounding an infarcted heart. The instrument allows unobstructed access for the AACSD, without altering its performance. Previous methods of restoring motion in the myocytes do not use a stabilizing device to shorten recovery time, but this innovative apparatus allows a minimally invasive surgery, which will reduce recovery time and medical costs.

The design process for the device followed the design controls in the quality system regulations laid out by the FDA. A design and development plan was created to list the tasks necessary to design the device. The first design inputs included reviewing the device life cycle, user needs, and the research and development prototypes to determine what the device would need to accomplish and how it would be implemented. The design focused on technical performance, patient safety, ease of use, and quality assurance. Once the design requirements were itemized, the more detailed and comprehensive design specifications became the first design output.

Three design concepts were developed and sketched for consideration. The designer chose design criteria as a basis for the design decision, and used a Pugh chart for selection. The criteria included ease of entry and deployment of the AACSD, view for the surgeon, support of the pericardium, manufacturability, and compatibility with the cardiac support device. Once a single design concept was favored, the concept was checked against the design specifications to ensure that the device structure fulfilled all

of the functional requirements before the product began its iterative progression to concrete form.

Design embodiment continued with the selection of biocompatible materials. Mechanical properties of the materials were researched to determine which materials would perform best in vivo for the particular application. It was decided that the shaft of 1.5” outer diameter would be stainless steel, with a flared end to aid in pericardial stabilization, and a 15” radius of curvature to better accommodate the surgeon and the body. Six super-elastic Nitinol guide wires extend 1.5” up from the shaft flare, and open once they have entered the pericardial space to support the pericardium. Teflon heat-shrink tubing will cover the guide wires to prevent tissue abrasion and entanglement of the PASS with the AACSD Nitinol frame. Finally, gamma radiation-resistant polycarbonate will form a ring over the Nitinol guides to hold them in place, and prevent any parts from lodging into the pericardial space.

The device is intended for single-use, but will be sterilized using gamma irradiation after packaging. Risk assessment was completed by performing failure modes and effects analyses for the device and the user. It was concluded that the failure modes with high risk priority numbers were unlikely of occurring and could be easily detected, but further efficacy studies and benchtop testing will take place for quality control purposes. Verification and validation of the device must be performed to ensure that specifications, user needs, and functional performance standards were met before the PASS advances to production. The PASS will eventually undergo clinical trials to bridge the gap between ovine studies and human use.

REFERENCES

Acorn Cardiovascular, 2005. About the CorCap™ Cardiac Support Device. Acorn Cardiovascular, St. Paul, MN. 20 October 2008 <http://www.acorncv.com/ patients_families/ corcap.cfm>.

American Heart Association (AHA), 2009. Heart Disease and Stroke Statistics-2009 Update. American Heart Association, Dallas, TX. 2 June 2009 <http://www.americanheart.org/downloadable/heart/1240250946756LS-1982%20Heart%20and%20Stroke%20Update.042009.pdf>.

ASTM F 138, 2008. Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673). ASTM Standards. Vol. 13.01. 2008. ASTM International, West Conshohocken, PA.

ASTM F 2063, 2008. Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants. Standards. Vol. 13.01. 2008. ASTM International, West Conshohocken, PA.

Biophan Technologies, Inc., 2009. MyoTech Circulatory Support System. Biophan Technologies, Inc., Pittsford, NY. 03 April 2009 <http://www.biophan.com/ index.php?option=com_content&task=view&id=18&Itemid=40>.

Blom A.S., Pilla J.J., Gorman R.C., Gorman J.H., Mukherjee, R., Spinale, F.G., 2005. Infarct Size Reduction and Attenuation of Global Left Ventricular Remodeling with the CorCap™ Cardiac Support Device Following Acute Myocardial Infarction in Sheep. Heart Failure Reviews; 10:125-139.

Bryg, R.J., 2009. Heart Disease and the Left Ventricular Assist Device. March 2009. WebMD: Heart Disease Health Center. 18 October 2008 <http://www.webmd.com/heart-disease/treating-left-ventricular-device>.

CorInnova, 2007. Cardiac Rekinesis Therapy. CorInnova, College Station, TX. 5 January 2008. <http://www.corinnova.com/ CorInnova%20Blue%20-%20Home.htm>.

Duerig, T.W., Pelton, A.R., Stockel, D., 1997. Superelastic Nitinol for Medical Devices. March 1997. Medical Plastics and Biomaterials Magazine. 21 May 2009 <http://www.devicelink.com/mpb/archive/97/03/003.html>.

Feldman, L.A., Hui, H.K., 1997. Compatibility of Medical Devices and Materials with Low-Temperature Hydrogen Peroxide Gas Plasma. Medical Device & Diagnostic Industry. 22 May 2009. <http://www.devicelink.com/mddi/archive/97/12/011.html>.

Fossum, T.W., 2006. Proactive Modulation of Strain for Ventricular Recovery. Progress Report Summary for CorInnova, Inc. 5-14.

Hou, D., March, K., 2003. A Novel Percutaneous Technique for Accessing the Normal Pericardium: A Single-Center Successful Experience of 53 Porcine Procedures. Invasive Cardiology 15 (1). <http://www.invasivecardiology.com/article/1228>.

Lenntech, 2008. Teflon, Mechanical Properties. Lenntech, Delft, The Netherlands. 26 May 2009. <http://www.lenntech.com/teflon.htm>.

Leventon, W., 2002. Medical Device Sterilization: What Manufacturers Need to Know. Medical Device & Diagnostic Industry. 21 May 2009. <http://www.devicelink.com/mddi/archive/02/09/003.html>.

Mann, D.L., 2005. Cardiac Remodeling as Therapeutic Target: Treating Heart Failure with Cardiac Support Devices. Heart Failure Reviews 10 (2), 93-94.

Matweb, Material Property Data: ASTM F 2063. Special Metals: Nitinol Superelastic Ni-Ti Alloy. MatWeb, Material Property Data. 26 May 2009. <http://www.matweb.com/search/DataSheet.aspx?MatGUID=1e9687d919244e51a7d0a7fc0459b356&ckck=1>.

MatWeb, Material Property Data: Polypropylene. Overview of Materials for Polypropylene, Molded. MatWeb, Material Property Data. 26 May 2009. <http://www.matweb.com/search/DataSheet.aspx?MatGUID=08fb0f47ef7e454fbf7092517b2264b2>.

MatWeb, Material Property Data: ASTM F 997-98a. Overview of Materials for Polycarbonate, Gamma Radiation Resistant. MatWeb, Material Property Data. 26 May 2009. <http://www.matweb.com/search/DataSheet.aspx?MatGUID=724f2b8fb5964bfda08b33277d87ca9e>.

Medtronic, 2008. The Medtronic Octopus® System: The Starfish™ Heart Positioner and the Octopus® 3 Tissue Stabilizer**.** Medtronic, Minneapolis, MN. 20 October 2008 <http://wwwp.medtronic.com/Newsroom/LinkedItemDetails.do?itemId=1101864398829&itemType=backgrounder&lang=en_US>.

Otto, K., Wood, K., 2000. Product Design: Techniques in Reverse Engineering and New Product Development. Prentice-Hall, Englewood Cliffs, NJ.

Paracor Medical, Inc. HeartNet™ Procedure. Paracor Medical, Inc., Sunnyvale, CA. 20 October 2008 <http://www.paracormedical.com/ourTechnology02.asp>.

Rogers, W., 2006. Steam: Uses and Challenges for Device Sterilization. Medical Device & Diagnostic Industry. 21 May 2009. <http://www.devicelink.com/mddi/archive/06/03/003.html>.

Small Parts, 2008. Nitinol wire-0.025 OD SuperElastic Nitinol. Small Parts, Miramar, FL. 26 May 2009.<http://www.smallparts.com/Nitinol-Wire-SuperElastic-Nickel-Titanium/dp/B001DELQ3C?ie=UTF8&qid=1244664554&pf_rd_r=0N5XPGY126W9HE9ZM2P6&pf_rd_p=467590031&pf_rd_i=0&sr=1-22&pf_rd_s=center-3&pf_rd_m=AIUBT5HP6PMAF&pf_rd_t=301 >.

Sterigenics, 2009. Material Considerations, Irradiation Processing. Sterigenics International, Inc., Oak Brook, IL. 21 May 2009. <http://www.sterigenics.com/services/medical_sterilization/contract_sterilization/material_consideration__irradiation_processing.pdf>.

Sterigenics E-beam, 2009. Electron Beam Radiation. Sterigenics International, Inc., Oak Brook, IL. 21 May 2009. <http://www.sterigenics.com/ebeam.htm>.

Sterigenics Gamma, 2009. Gamma Irradiation. Sterigenics International, Inc., Oak Brook, IL. 21 May 2009. <http://www.sterigenics.com/gamma.htm>.

U.S. Food and Drug Administration (FDA), 1997. Design Control Guidance for Medical Device Manufacturers. FDA Center for Devices and Radiological Health. March 11, 1997. U.S. Food and Drug Administration, Silver Spring, MD. 3 June 2009 <http://www.fda.gov/ downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070642.pdf>.

U.S. Food and Drug Administration (FDA), 2009. Design Controls. U.S. Food and Drug Administration. May 1, 2009. Department of Health and Human Services, FDA, Silver Spring, MD. 3 June 2009 <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystems Regulations/MedicalDeviceQualitySystemsManual/ucm122416.htm>.

APPENDIX A

Rough sketches were made of several concepts before they were eventually narrowed down to the three alternatives used in the Pugh chart for concept selection. The concepts were discussed with Dr. Criscione to find the most beneficial features, and those that could be left on the drawing table before moving onto the next round of decision-making. The shaft outer diameter on all concepts is 1.5 inches. Figure 17 depicts one of the original concepts following research and development.

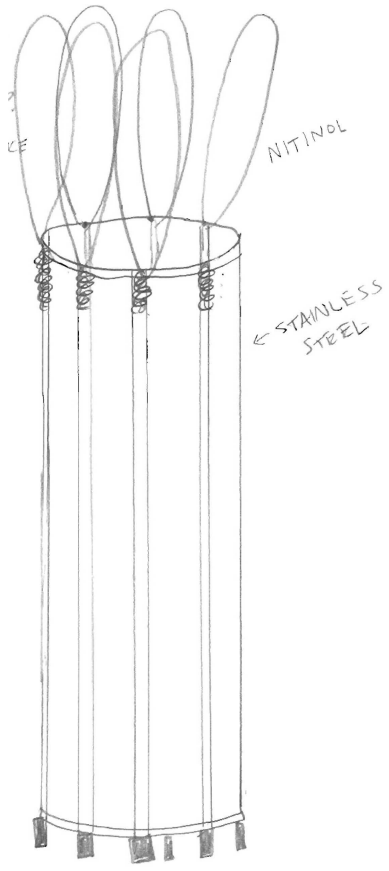

Fig. 17: Sketch of original design concept 1.

There are springs to connect the top ring and the guides for flexibility. However, this addition could make entry into the pericardium messier, because there are more components that could potentially grab the pericardium. The guides in this concept should allow less interference with the pericardium because they are less flared than previous ideas. Instead of one guide entering and exiting different struts as in some of the research and development prototypes, each guide enters where it exits for this alternative. The scaffold guides are controlled by thin wires connecting to larger control arms at the bottom of the device. The smaller wires will slide through the struts down the length of the shaft, and open into the guide wires at the top of the PASS. This is what allows the scaffold to be retractable and allows more control for the surgeon overall. Nitinol and stainless steel were suggested for the materials at this point. Concept 2 maintains the same retractable scaffold as concept 1, but the shape of the guide wires is much different. The wires will follow the end of the shaft curvature to curve into the pericardial space, but they are now single wires capped with small spheres to prevent abrasion. The concept is shown below in figure 18.

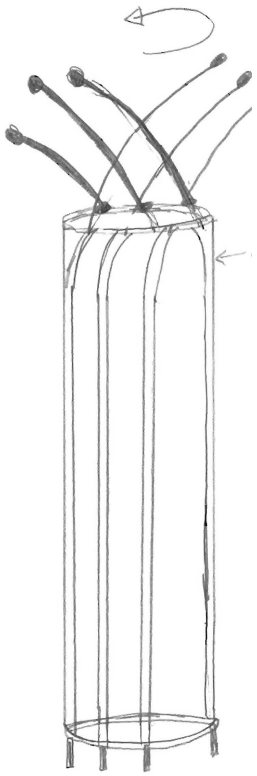

Fig. 18. Sketch of original design concept 2.

Both beads or various polymers were discussed for the tips with this design. Original design concept 3 features a curved shaft that will use the same radius of curvature of 15 inches as the research and development prototypes. The scaffold will be held together for entry into the pericardial space as in prototype 7. There is a solid, hollow shaft, which will hold the AACSD at the top on the guide wires for the surgeon to place the device. There are also deep grooves on the bottom of the shaft for the surgeon to put the sutures sewn through the pericardium. These will give the surgeon a free hand without the need of more instruments once the pericardium is pulled away from the heart. Figure 19 depicts the described device below.

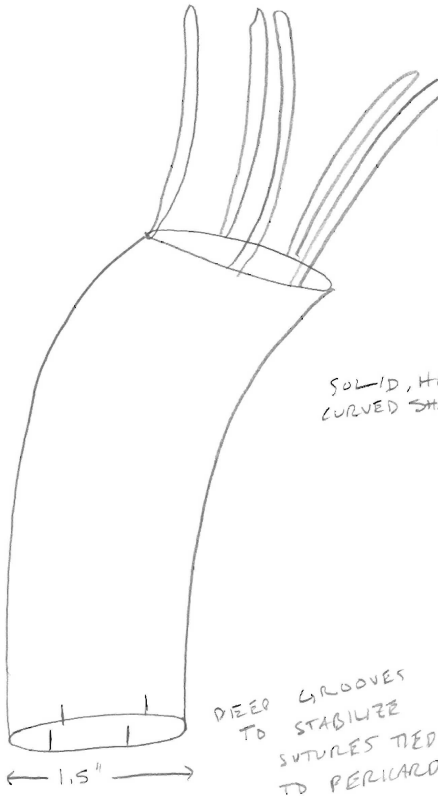

Fig. 19. Sketch of original design concept 3.

The idea for the ring to secure the guide wires was first introduced with original design concept 4, which is shown in figure 20 below.

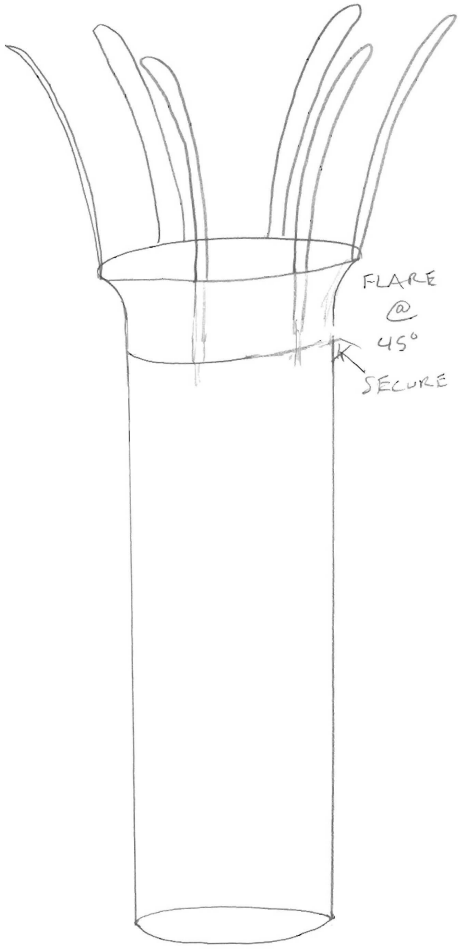

Fig. 20. Sketch of original design concept 4.

The scaffold guides will be held by the surgeon before they pass into the pericardium, and released once they have entered the pericardial space to stabilize the tissue. Thus, the scaffold is not retractable, but simply rests on the straight, hollow shaft. It was also proposed with this idea that a slightly larger solid tube could go over the shaft and guide wires to hold them together for the surgeon, but the diameter of the shaft would need to be reduced to allow more components to enter the limited space. The shaft includes a flared end to increase the level of support for the pericardium. It is proposed that the flare reach an angle of 45 degrees in relation to the rest of the shaft.

Variations of this design can be made by changing the angle of flare or using a flared shaft.

Original concept 5 is similar in simplicity to the previous concept, but the shaft does not flare at the tip. The scaffold guides will be held by the surgeon for deployment, once again. This method allows the AACSD to be placed on the heart apex end of the PASS via sutures, instead of traveling through a system with a retractable scaffold. The AACSD collapses inside of the device scaffold. The cardiac support device will take on the shape of the shaft that it is placed in, so a flared end may be better than this idea because it encourages and accommodates for the device to flare around the heart. Figure 21 shows design concept 5 before concept selection alternatives were made.

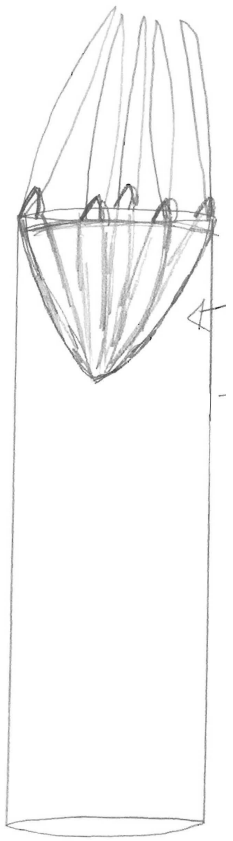

Fig. 21. Sketch of original design concept 5.

Aside from less interference with the pericardium and the AACSD, another benefit of the non-retractable guide is manufacturability.

APPENDIX B

The perimeter of the cone after removing a 90° sector was set equal to the perimeter of a new circle as follows:

$1.5*pi*r_1 = 2*pi*r_2$

$r_2 = 0.75* r_1$

Angle of flare = Arcsin(3/4) = 0.848062 radians

Degree in radians = 0.848062 * (180°/π) = 48.59°

Tan(0.848062) = 1.133893 = (0.15in./perpendicular height)

Perpendicular height of cone = (0.15/1.133893) = 0.132288in.

APPENDIX C

The design concept selected was drafted in SolidWorks, as shown below in figure 22.

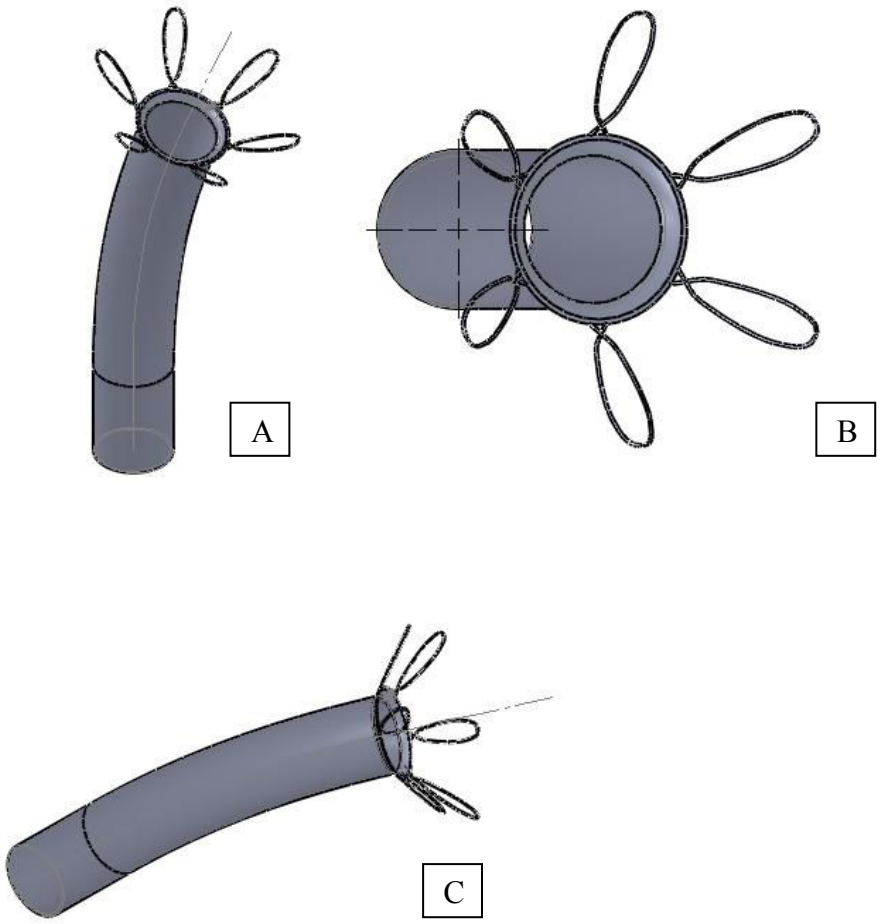

Fig. 22. PASS selected in SolidWorks. (A) Isometric view; (B) top view;(C) side view.

Design changes were made because although the calculated flare angle was correct, the height of the cone used to create the flare was extended too high. This made

the diameter of the PASS shaft that first entered the pericardial space too large. The top of the flare diameter was 1.90 inches and needed to be reduced to 1.80 inches to meet the requirements of the device more soundly. The material thickness of 0.05 inches made the inner diameter 1.7 inches for the new design. Also, the deployment guide wires were to be made by two wires extending straight out from the outer flare surface, with an arc for the rounded tip to prevent abrasion. Additionally, a securing ring was placed around the base of the scaffold guides to secure them to the shaft as a control for one of the most severe potential failure modes. Heat-shrink tubing was also added as a design change to prevent entanglement of the AACSD frame in the guides. The changed design concept is shown below in figure 23.

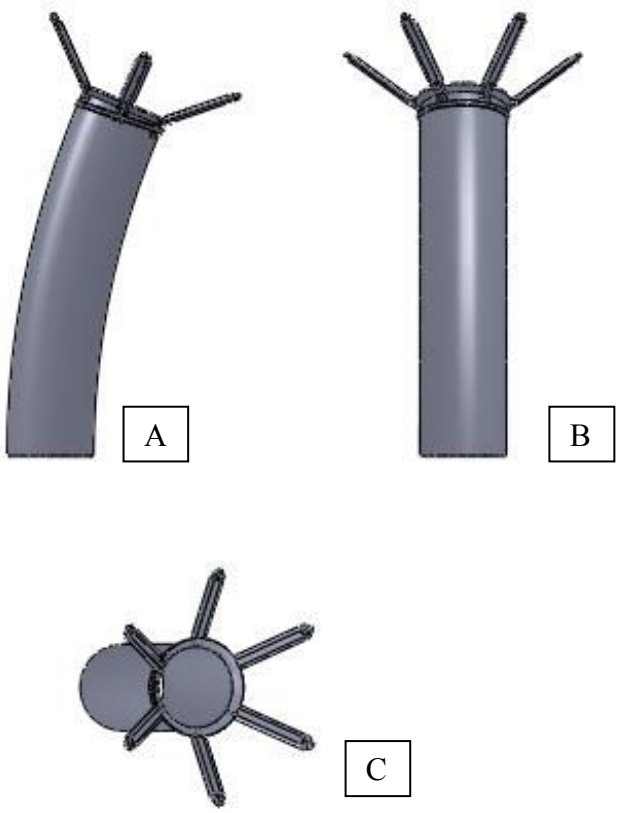

Fig. 23. PASS after design changes. (A) Isometric view; (B) front view; (C) top view.

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