Abstract

KUNIHOLM, JONATHAN FAIRBANK. Automated Knot Tying for Fixation in Minimally Invasive, Robot Assisted Cardiac Surgery (Under the guidance of Dr. Gregory Buckner).

Cardiovascular disease (CVD) is the most significant medical problem facing Americans today. While open-heart surgery is still the predominant treatment, great advancements have been made over the last 20 years in the fields of minimally invasive surgery (MIS) and minimally invasive robotic assisted (MIRA) surgery. MIRA techniques offer patients many benefits over open-heart procedures, but have extended the capabilities of MIS at the cost of increased time spent tying knots with the robot. The additional time spent on bypass limits patient access and is the most significant barrier to the widespread adoption of MIRA techniques.

This research seeks to overcome this barrier by creating a device optimized for MIRA cardiac procedures that automates the repetitive and time-consuming task of knotting suture. If this task can be automated while ensuring the delivery of high-quality knots, great progress can be made in transforming the field. MIRA cardiac procedures can move from novel procedures performed by a select group of surgeons on a limited pool of patients to a viable alternative available to the majority of patients suffering from CVD today. This research presents a design history and proposes a final design for a self-contained device that delivers a pre-tied locking knot for surgical fixation. Experimental results suggest that the device is capable of delivering consistent knots at a time savings of 12 and 26 per cent over knots tied manually for trained and untrained users of a surgical robot, respectively.

Automated Knot Tying for Fixation in Minimally Invasive, Robot Assisted Cardiac Surgery

by

JONATHAN KUNIHOLM

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APPROVED BY:

Dr. Denis R. Cormier
(Advisory Committee Member)

Dr. Larry M. Silverberg
(Advisory Committee Member)

Dr. Gregory D. Buckner
(Chair of Graduate Advisory Committee)

Dedication

To my son Sam and wife Michele, who know that three is the magic number.

Biography

Jonathan Fairbank Kuniholm was born in Durham, North Carolina, in 1971. He attended school in Durham, leaving Jordan High School in 1987 for The North Carolina School of Science of Mathematics, from which he graduated in 1989.

Jonathan attended Dartmouth College, in Hanover, NH, receiving an AB in English in 1993. While at Dartmouth, Jonathan studied abroad in Lyon, France, and interned with the Harvard Institute of International Development in Blantyre, Malawi. After graduating from Dartmouth, he stayed in the Upper Valley, working as a paralegal for a year in White River Junction, VT. In 1994, Jonathan went to Bratislava, Slovakia, to work as an intern for a US Treasury Department Tax Policy Advisor, returning in 1995.

After returning to school to pursue an engineering education, Jonathan joined the US Marine Corps in 1997, serving as a logistics officer with Headquarters Company, Eighth Marines, and First Battalion, Eighth Marines. Jonathan was married to Michele Quinn in 1998. Their son, Sam, was born on the occasion of the planetary alignment in May 2000. Following military service, Jonathan returned to NC State, completing his BS in Mechanical Engineering in 2002, while concurrently pursuing a master's degree in Industrial Design.

Acknowledgements

Thanks to my family, especially my wife Michele and my son Sam, without whose support and encouragement my return to school would not have been either ventured or possible.

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I would like especially to thank Dr. Gil Bolotin for helping to test the devices, and for offering his suggestions for improving the device.

Jesse Crossen and Chuck Messer, both as my classmates in the College of Design, and more recently as participants in this research effort, have provided invaluable assistance and inspiration, and have made valuable contributions to this project.

Finally, thanks to Dr. Gregory Buckner, for inspiring me and his other students, almost ten per cent of the graduate students in the department, to pursue interesting research in mechanical engineering, despite the incentives to do otherwise.

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1. Introduction

Cardiovascular disease (CVD) is the most significant medical problem facing Americans today. CVD afflicts over 60 million people in the U.S. and is the leading cause of death, claiming more lives (2,600 per day) than the next six leading causes combined. Direct and indirect costs resulting from CVD are estimated to be $329.2 billion per year [1]. One of the most common medical procedures associated with CVD is open-heart surgery, a technique used for a variety of procedures including coronary artery bypass grafts (CABGs), heart transplants, valve repairs, and valve replacements. In 1999 there were a total of 753,000 open-heart procedures in the U.S. [1].

1.1 Cardio-thoracic surgery: conventional methods

The first attempts at open-heart surgery date back to World War II, when the invention of an effective cardiopulmonary bypass (CPB) machine made this surgical innovation possible [3]. Conventional cardiac surgery requires splitting and retracting the breastbone with a median sternotomy, as shown in Figure 1. This large incision enables direct visualization of the operative field and manual manipulation of internal organs and instruments. Surgeons use their own hands in a very natural and instinctive manner to sew, cut, and perform various procedures. Typically, the heart is arrested and CPB initiated, providing the motionless environment required for CABGs,

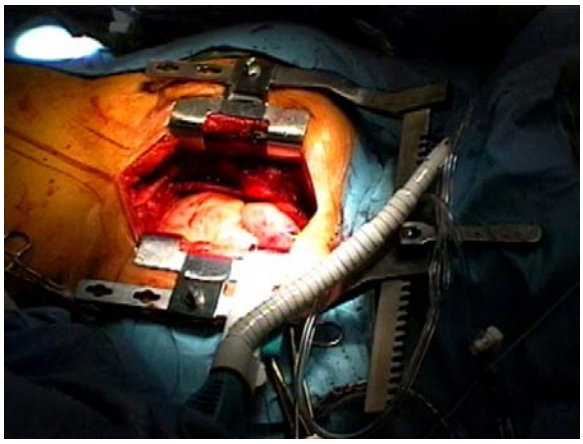

Figure 1. Median sternotomy used in traditional open heart surgery[2].

valve repairs, and valve replacements. Conventional cardiac surgery is now widely used and has proven to be highly effective in the treatment of CVD.

The primary disadvantages of open-heart surgery are significant surgical trauma and long recovery periods. Most problems stem from post-surgical complications and infections, not the procedure itself. The large incisions provide greater opportunities for infection, require longer recovery times for the patient, and are aesthetically displeasing. CPB has been reported to induce several complications, including inflammatory responses, neuro-cognitive dysfunction, temporary reductions in heart muscle contractility, and death in very diseased patients [4, 5]. Another disadvantage of open-heart surgery is the surgeon's decreased dexterity in restricted spaces. Some procedures require precise manipulation of tissue and sutures, and the human hand lacks the required dexterity to effectively manipulate objects at this scale [6, 7].

1.2 Advancements in surgical techniques

Recent advancements in the field have attempted to address the disadvantages of traditional open-heart surgery. The first innovations combined laparoscopic instruments with cardiac surgical techniques. This combination allowed surgeries to be performed through smaller incisions, such as thoracotomies and partial sternotomies (Figure 2). Figure 3 shows a minimally-invasive procedure performed through a mini-thoracotomy. The development of videoscopic instrumentation (endoscopes) provided accurate

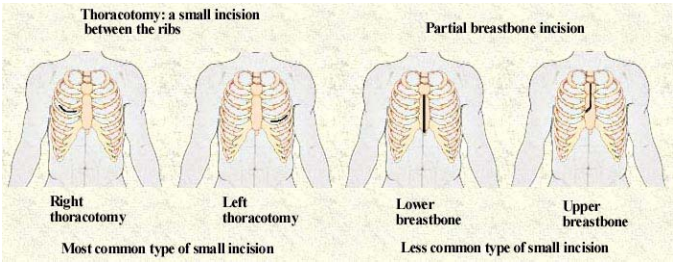

Figure 2. Minimally-invasive cardiac surgery is performed through a variety of small incisions.[8]

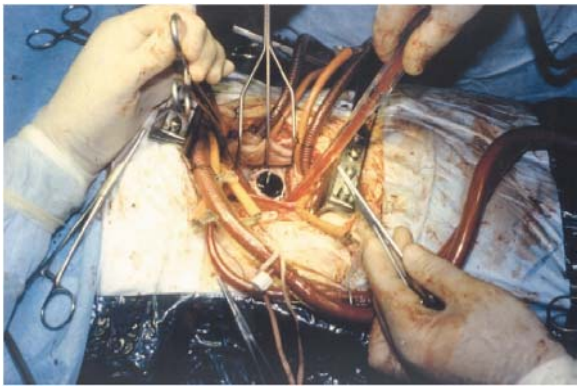

Figure 3. A mini-thoracotomy used for minimally-invasive surgery [10].

visual feedback and served to enhance the surgeon's capabilities [9]. Endoscopic surgery is performed through small ports, enabling long, thin, manually operated instruments to cut, sew, and manipulate tissue (Figure 4).

Endoscopic surgical techniques are collectively described as minimally invasive surgery (MIS). Many patients opt for MIS because of reduced pain, trauma, and recovery times [9, 11-15]. These procedures reduce incidences of infection, provide more aesthetically pleasing results, and result in shorter recovery periods, hospital stays, and out of work periods [15, 16].

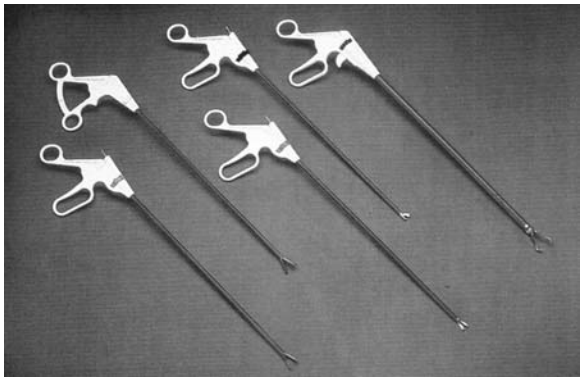

Figure 4. Endoscopic surgical instruments[17].

One primary drawback of MIS involves instrument manipulation. The long instruments amplify tremors and other movements of the surgeon because of the lever/fulcrum effect. This lever/fulcrum effect also results in transposition of motions, where motion in one direction outside the body results in motion in the opposite direction inside the body [6]. Endoscopic techniques require highly experienced surgeons that are capable of using these instruments precisely. Bailey et al. states, "the skills necessary to perform safe laparoscopic or thoracoscopic surgery have not been routinely taught during most surgical training programs" [6]. Another problem with endoscopic surgery involves its limited field of view.

Images from the endoscope are often magnified and displayed on a two-dimensional monitor, resulting in a loss of depth perception. This loss of three-dimensional depth perception "severely hampers the surgeon's ability to dissect tissue and identify important landmarks" [6].

The most recent innovation in cardio-thoracic surgery has been the introduction of tele-operated robots (Figure 5) that allow surgeons to control instruments from remote locations. Minimally invasive, robot-assisted (MIRA) procedures are similar to those of endoscopic surgery, but the instruments are manipulated by a tele-robotic system that is controlled by the surgeon. Two commercial robotic systems, the da Vinci™ system (Intuitive Surgical, Inc., Sunnyvale, CA) and the ZEUS® system (Computer Motion, Inc., Santa Barbara, CA), have been approved for general and cardiac surgical procedures. Both systems consist of two instrument arms and one camera arm that can be introduced through port incisions (5-10 mm), enabling the surgeon to perform closed-chest cardiac procedures. An operator console provides the surgeon with magnified three-dimensional, high-resolution video images of the procedure and allow for very precise instrument control, tremor elimination, and scaled motion. They provide the benefits of endoscopic surgery while giving the surgeons increased dexterity and precision.

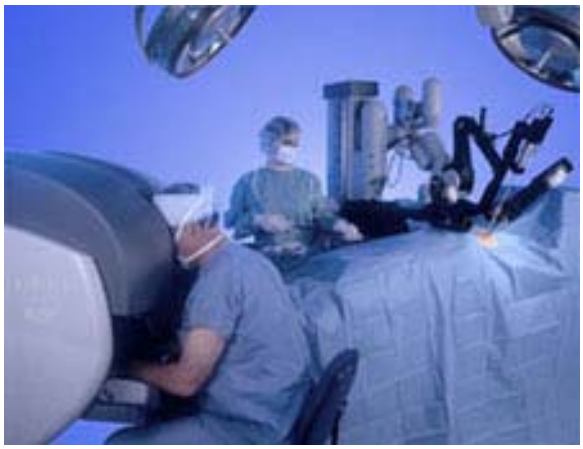

Figure 5. The da Vinci™ surgical robot from Intuitive Surgical [17].

1.3 Drawbacks of MIS techniques

While there are obvious benefits versus traditional open-heart procedures, MIRA cardiac procedures offer no documented patient benefits versus non-robotic MIS techniques in the treatment of CVD. The primary barriers to widespread adoption of MIRA cardiac procedures are associated with increased cardiopulmonary bypass times, increased overall healthcare costs, and increased surgical skill requirements.

Current MIRA technology does not reduce the need for CPB during cardiac procedures. To the contrary, bypass times associated with some MIRA cardiac procedures are actually increased. Based on East Carolinas University's (ECU's) experience in MIRA mitral valve repairs, patient bypass times are increased approximately 60% (1.5 hours using conventional procedures vs. 2.6 hrs with MIRA). CPB has been linked with several adverse patient outcomes, including increased inflammatory responses, neuro-cognitive dysfunction, temporary reductions in heart muscle contractility, and death in very diseased patients [4, 5]. For many MIRA cardiac procedures, the increased time on CPB limits the potential benefits and leads to the exclusion of high-risk patients [16].

Suture management is a primary contributor to increased CPB times in MIRA cardiac procedures. Typical mitral valve (MV) repairs involve 15-20 sutures, each requiring 5-6 knots, causing suturing to consume the majority of operating time [18]. Surgeons are typically very experienced and comfortable tying knots with their hands, but robotic technology adds another level of complexity to this task. Figure 6 is a 10X photo of Intuitive's da Vinci™ robotic manipulators placing a suture during a MV repair procedure. One can easily appreciate the complexity and reduced field of view compared to traditional "open" techniques.

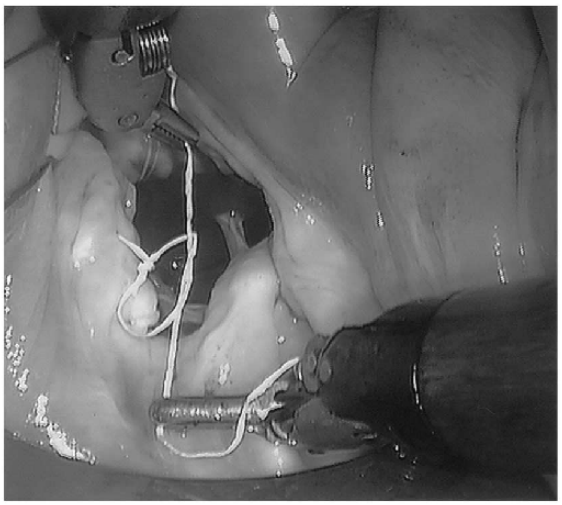

Figure 6. Suturing with the da Vinci™ robotic surgical system [9].

Knot tying with surgical robots, particularly using the smaller 2-0 sutures required for mitral valve prosthesis fixation, takes considerably longer than with laparoscopic instruments. One study involving twenty laparoscopic surgeons compared the time to completion and precision of intracorporeal knot-tying tasks performed with manual and robotically assisted laparoscopic instruments [19]. The results of this study (Table 1) reveal a nearly threefold increase in robotically-assisted suturing times.

Table 1. Time to completion and precision of an intracorporeal knot-tying task performed by 20 surgeons with manual and robotically assisted laparoscopic instruments [19].

Suture	Manual, Mean (CV)	Robotic, Mean (CV)	Difference (Manual – Robotic)	*P*
2-0 silk	154 (42)	456 (37)	–302	<.001
4-0 silk	158 (46)	338 (36)	–180	<.001
6-0 polypropylene	246 (60)	327 (48)	–81	.09
7-0 polypropylene	197 (39)	288 (50)	–91	.07
Overall precision, %	97	98	–1	NA

*Data are presented in seconds unless otherwise noted. See the "Manipulation Tasks" subsection of the "Participants and Methods" section for details of the knot-tying task. CV indicates coefficient of variation (SD as a percentage of the mean); NA, not applicable.

Current MIRA technology requires surgeons to acquire more training and achieve higher levels of surgical skill. Several factors contribute to these increased skill requirements. Reduced incision sizes restrict the surgeon's workspace and limit visibility. With conventional open-heart procedures, the surgeon has a direct view of the operating space. The surgeon must rely on indirect endoscopic imaging, which limits the field of view [6]. Operating within limited space and with limited vision, it is not surprising that surgeons require more time to tie knots in MIRA surgery, despite the assistance of tele-robotic systems.

1.4 Purpose

The purpose of this research is to eliminate obstacles to the widespread adoption of MIRA cardiac surgical procedures by reducing CPB times and required surgical skills. This research focuses on developing technology to facilitate surgical knot tying in MIRA cardiac surgery. The results could have much broader application, including anastomosis (the connection of blood vessels) or any fully endoscopic surgical situation where space and time are at a premium. By making knot tying in MIRA surgery more accessible, surgeons can more quickly become comfortable and proficient in MIRA techniques. By reducing CPB time, more patients will be candidates for MIRA cardiac procedures. Reduced CPB time will also help reduce direct surgical costs and indirect costs associated with post-surgical recovery. An improved method of suture-based fixation for MIRA MV repair will allow surgeons all of the flexibility and precision of current techniques, while requiring less time and training to perform. Such an improvement will allow more patients to benefit more fully from the potential of MIRA cardiac surgery through increased access and reduced cost.

1.5 MIRA Mitral Valve Procedure

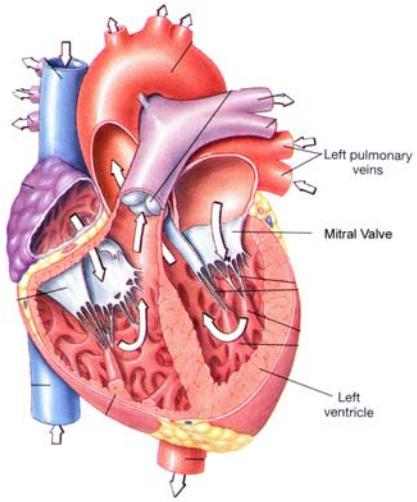

Figure 7. Cutaway view of the heart showing the mitral valve [20].

The mitral valve, also called the bicuspid valve, is a two-leafed valve that separates the left atrium from the left ventricle (Figure 7). Oxygenated blood travels from the lungs into the left atrium, is drawn into the left ventricle through the mitral valve, and is pumped from the left ventricle to the rest of the body. Three types of disorders affect the function of the mitral valve: mitral valve stenosis, mitral valve prolapse, and mitral regurgitation.

Mitral valve stenosis is the narrowing of the mitral valve, and is treated medically, or with surgical procedures including balloon valvotomy, mitral commissurotomy, and mitral valve replacement. Mitral valve prolapse (MVP) is an improper closing of the mitral valve, a condition that affects between five to ten per cent of the population. Mild forms of MVP may go unnoticed and need not be treated, or can be treated with medication. More serious prolapse can lead to regurgitation, the leakage of blood from the left ventricle back into the left atrium through the mitral valve [21, 22].

Mitral regurgitation is quantified on a scale from 1+ to 4+ based on the amount of cardiac dye viewed in the left atrium during catheterization. Patients with regurgitation of 3+ or greater (and with associated symptoms) are candidates for surgical treatment of the disease. Surgical treatment of mitral regurgitation includes repair or replacement of the mitral valve.

Whenever possible, surgeons prefer to repair rather than replace the mitral valve, because repaired valves impair function less and last longer than prosthetic valves. Resection or repair of the chordae tendinae may be performed during MV repair, if either leaflet is involved in prolapse. The majority of MV repair surgeries involve, at a minimum, reinforcement of the valve annulus with a polyester annuloplasty ring, shown in Figure 8 [21]. The annuloplasty routinely installed during MV repair resembles an athletic shoelace, which is in fact what the ECU team uses for robotic training.

Figure 8. Annular mitral valve prosthesis.

The annuloplasty requires approximately 12 independently knotted sutures to secure it to the MV perimeter. Each suture is placed through the annuloplasty and valve tissue, and is secured with as many as six overhand knots. The large number of required knots in annuloplasty fixation, coupled with the increased difficulty in tying the knots robotically, cause MIRA MV repair to take longer than MIS approaches [18, 19].

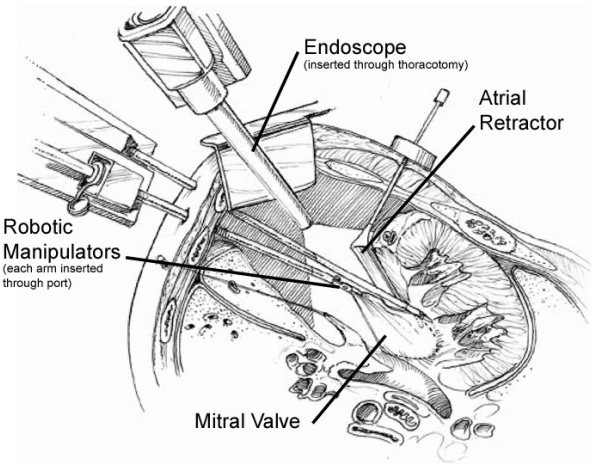

Figure 9. Section view of MIRA MV repair setup showing mini-thoracotomy, robot arm ports, and atrial retractor [23].

The ECU team performs MIRA MV repair using the da Vinci™ robotic surgery system made by Intuitive Surgical, Inc. The surgeons use a mini-thoracotomy to provide initial access to the heart. Through this small incision, the heart is arrested and bypass initiated. The atrium is retracted, and the robotic manipulators are introduced through small ports in the chest wall. The surgeon places an endoscope through the mini-thoracotomy to view the valve and the robot manipulators. A section view of this procedure is shown in Figure 9. Figure 10 reveals the limited endoscopic field of view presented to the surgeon during MIRA MV repair. Note that the poor atrial retraction has also limited access to the annuloplasty being affixed to the valve, which is approximately an inch across. The combined effect of these factors makes knot tying in MIRA MV repair take longer than in traditional MIS.

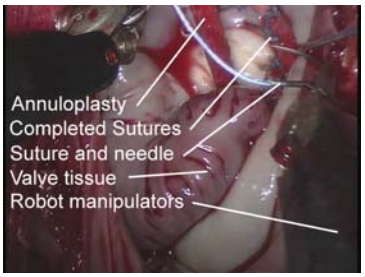

Figure 10. Endoscopic view of MIRA MV repair with less than ideal retraction.

1.6 Fixation in Surgery

1.6.1 Goals and Methods

Figure 11. Six overhand knot throws with extra twist in initial throw.

The goal of surgical fixation is to approximate, or bring together in space, anatomy or prostheses. Since the introduction the suture in the 16th century by Ambroise Paré, the approximation of tissue using needle and thread has been the cornerstone of surgical technique. In the case of MIRA MV repair, as noted above, an annuloplasty ring is fixed to the perimeter of the mitral valve. Once one end of a suture has been passed through tissue during surgery, it must be affixed to the other end to secure the connection and bring the tissue together. This is usually accomplished with a series of overhand knots. The standard surgical knot can consist of as many as six overhand knot throws, representing three complete square knots. A "surgeon's knot" is made by adding an additional twist to the first throw in order to prevent slippage before the second throw is completed [24]. An enlarged example of such a knot is shown in Figure 11.

While sutures have many advantages over other methods of fixation, the time spent tying knots in MIS can pose limitations [19]. Tying knots using endoscopic instruments is a skill possessed by many surgeons, but it is one that takes extensive training to perform efficiently [6]. As indicated by instructions in Figure 12, endoscopic knot tying is not an easy skill to master.

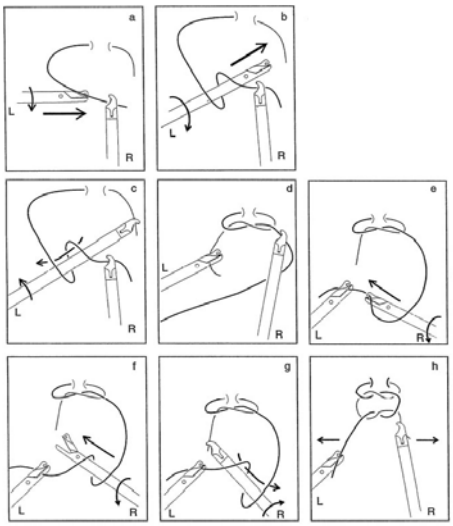

Figure 12. Example of instructions for endoscopic knot tying [25].

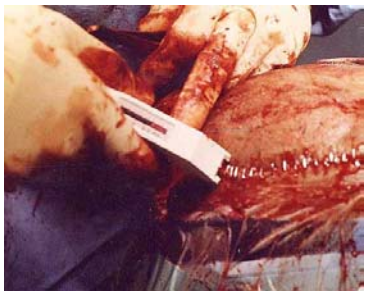

Figure 13. Surgical staples used for wound closure [26].

A variety of suture alternatives have been proposed for use in general surgery, and specifically for valve annuloplasty fixation. Surgical staples (Figure 13) are widely used in wound closure, although not in MV repair. In order to separate the difficulties of tying knots from the advantages of sutures, LSI Solutions® Inc. has developed the Ti-Knot®, a titanium crimp to secure the open ends of a suture (Figure 14). Coalescent® Surgical Inc.'s nitinol U-clips™, shown in Figure 15, have been used for anastomosis and, very recently, for fixation of mitral annuloplasty rings. While these alternative methods have various advantages, they share a common disadvantage in their departure from tradition. Despite any technical advantage, these substitutes face barriers to adoption by surgeons who have spent years mastering sutures.

Figure 14. LSI Solutions Ti-Knot® titanium suture crimp [27].

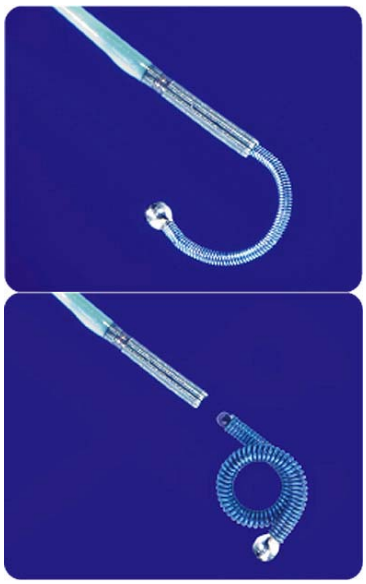

Figure 15. Coalescent® Surgical Inc.'s nitinol U-clips™, before and after deployment [28].

1.6.2 Selection of Fixation Method

This research focused on improving traditional suturing for several reasons. Sutures are ideally suited for MIRA MV repair except for the time required to tie knots. As long as the final product is a knotted suture of quality comparable to those produced by hand, an alternative method of forming knots will face fewer barriers to adoption, both psychological and regulatory, than a completely different method of fixation. The corporate sponsor of this research has a long history with suture products, as do the doctors and hospitals that purchase its products. Cardiovations, Inc. and its clients would be most comfortable finding an improved method of using a product that they know already works. Given the choice of a knotted suture, decisions remain about the type of knot to be used and the method of deployment.

1.7 Types of Knots and Their Surgical Application

1.7.1 Knot Classification and Anatomy

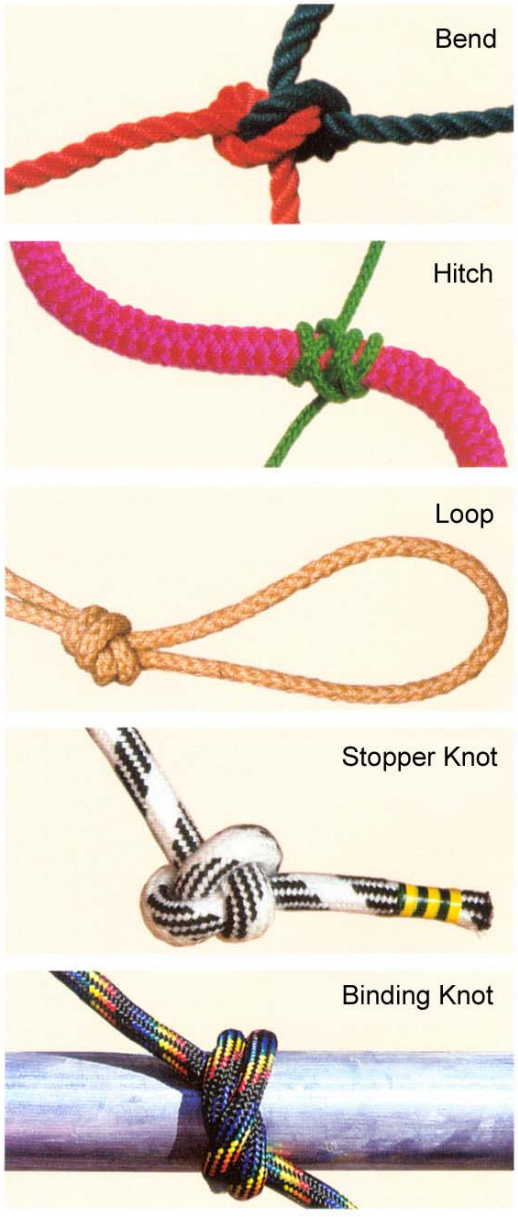

Figure 16. Categories of knots as defined by the type of connection formed between cord ends [29].

Knots can be broadly categorized by the type of connection that they make between cordage. Figure 16 shows some of the categories of knots as defined by these connections. A *bend* joins the ends of two cords; a *hitch* attaches a cord to a fixed object; a *loop* secures the two ends of a continuous line of cord; a *stopper knot* prevents the end of a cord from passing through an orifice; and a *binding knot* secures a cord around a package or the neck of a bag.

Most surgical knots are loops, because they secure the two ends of a length of suture that has been passed through tissue. Loops can be either fixed or sliding, with sliding loops referred to as *nooses*.

Figure 17 illustrates selected knot terminology, as well as a simple overhand noose [29]. The *working end* of a cord is manipulated to tie a knot. The working end is manipulated or *arranged* around the other end of the cord, called the *standing end*. Between the two ends, the standing part remains fixed. A

bend or loop formed in the standing part of the cord is called a *bight*, while a loop formed from passing the working end around or through something is simply called a *loop*. Points at which the cord crosses itself are called *crossing points*.

Knots can also be classified by their holding security, which depends not only on the type of knot, but also on the material used to tie the knot and the quality of the finished knot. Because shear stresses are created at crossing points, knots always reduce the tensile strength of a cord system. Knot strength is characterized by the percentage of holding capacity of the knot and cord system as compared with the tensile strength of the cord alone. This percentage, referred to as *knot efficiency*, varies from around 45 per cent for an overhand knot to around 70 per cent for a clove hitch. Additionally, some knots may slide before they break, which can be tantamount to failure depending on the application [29]. A knot represents a delicate balance between these competing phenomena, as it is the friction created by sharp bends in a cord that prevents the knot from unraveling. Indeed, the very characteristics that help prevent a knot from coming untied may cause it to shear itself.

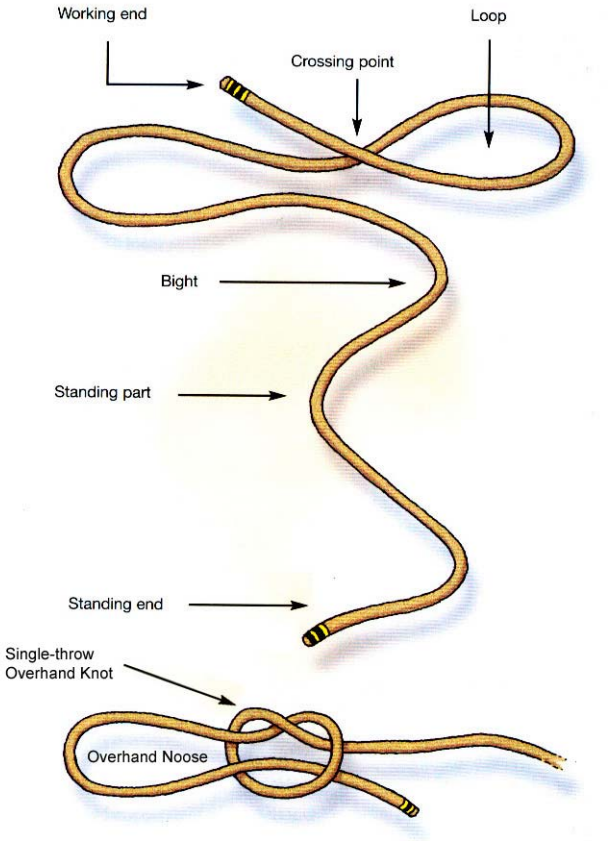

Figure 17. Anatomy of a knot [29].

Knots useful for securing sutures during surgery usually involve different variations on the overhand knot, which is an example of a loop knot. The overhand knot, at 45 per cent efficiency, sacrifices in overall strength what it offers in security. Any proposed alternative to the standard surgical knot must match the standard in terms of security.

1.7.2 Overhand Surgical Knots and Other Locking Knots

A surgical knot is composed of multiple overhand throws, which are the source of the knot's advantages and disadvantages. As depicted in Figure 11, a six throw surgical knot contains at least five bends more than 180 degrees in each strand, and at least six crossing points. The friction created by the sharp bends prevents the surgical knot from loosening. Though the bends make the knot inefficient relative to other knots, the strength of modern suture materials ensures that the tissue being approximated is more likely to fail than either the suture or the knot.

The sharp bends and multiple crossing points that make surgical knots unlikely to unravel also make them difficult to deploy in non-traditional ways. Nooses, which can slide on at least one strand, are well-suited to automatic deployment. A noose can be loosened to the point that the sliding end of the loop is removed from the knot (Figure 18). This end can then be passed around an object and returned to the knot, which can then be tightened around the object.

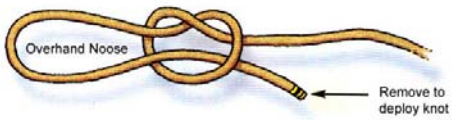

Figure 18. An overhand noose could be prepared for deployment by removing one end of the loop [29].

Each throw of a surgical knot must be completed manually, something surgeons do proficiently with both their hands and instruments. Loosened and separated from its other strand, the surgical knot (like most locking knots) has no loops or windings capable of

Figure 19. Bowline and Double Bowline locking knots.

conveniently receiving the other strand again. Further, locking knots must be "sequenced" by pulling the strands in a particular order to produce the bends that make them so secure. Note the sharp bends in the bowline and double bowline knots shown in Figure 19. While strong, with an efficiency of over 60 per cent[29], it difficult to conceive a method of deployment for these knots any more suitable than that of overhand surgical knots.

Ideally, a device-delivered knot would conform to standard technique, and would only speed up the process. However, most locking knots are difficult to mechanically deploy and often result in "air knots", the failure of a knot to tighten appropriately around the tissue. The knot instead tightens on itself at some distance, leaving slack in the loop. Because locking knots have multiple bends of greater than 180 degrees, pulling on them in loosened form will result in their tightening out of sequence, leaving other parts undesirably loose.

1.7.3 Sliding Knots

In many respects, nooses possess characteristics that make them ideal for surgical procedures. Although nooses are not frequently used in surgery because of their potential to slip, they have a distinct advantage over locking knots in terms of their adjustability and ease of deployment. Because they are often constructed with an end passing through a series of

Figure 20. Sliding knots, from left to right: fisherman's knot, figure eight noose, quadruple overhand noose, and Roeder knot.

turns, nooses are well suited to pre-tying and configurations for rapid deployment. The turns of a noose can be tightened to the desired degree over the sliding end, and the knot slid down to create the desired tension in the loop. While not as secure as locking knots, they may be secure enough to meet the requirements of closure in some surgical situations. A variety of sliding knots are depicted in Figure 20.

Figure 21. Quick Stitch system by Pare Surgical [30].

Studies have examined the relative holding power of various methods of fixation, including sliding knots. Pare Surgical, Inc. presents a study that claims that the sliding Roeder knots (size unspecified, 0-0, 2-0 and 3-0 available) of its Quick Stitch™ system (Figure 21) fail through loosening at 4 – 9 N, while the titanium surgical clips to which they were being compared failed at 0.2 to 1.7 N [31]. This compares unfavorably even to sliding overhand surgical knots ("granny knots"), which in one study exhibit holding power (at 0 days in vivo) of 17 – 23 N for 2-0 and 7 – 11 N for 4-0 suture [32]. Because tissue strength in some applications may prove to be less than even the threshold for sliding knot failure, it may be worth examining the requirements of strength for specific applications. However, the general perception of the overhand surgical knot as the "gold standard" in fixation is not one that will be easily changed, even if sliding knots are shown to be appropriate to fixation tasks.

1.7.4 Mechanical Knot-Tying

One approach to delivering a standard surgical knot in a manner more efficient than manual tying might be to mechanize the tying process in some way. Sewing machines have performed similarly complicated tasks for over a hundred years, and are capable of both

passing needle and thread through fabric and securely beginning and ending stitching. No similar device has been successfully designed for surgery. A number of devices have attempted to automate the process of passing the needle and suture through tissue, but have ignored the significantly more time-consuming process of securing the suture. Approaches that could warrant further study include the automation of knot-tying tasks as sequences of robotic actions initiated by the surgeon at appropriate points in otherwise tele-controlled procedures, or the design of dedicated instruments more fully integrated into existing robotic platforms. As the da Vinci™ surgical system plans to incorporate a third robotic arm this year, this possibility becomes a more attractive option, as the surgeon would not be required to sacrifice a manipulator in order to have ready access to a tool designed for automated fixation tasks.

Given the complexity of creating multiple-throw surgical knots, as well as the logistics of research involving the companies that manufacture surgical robots, this research was directed at developing platform-independent tools capable of delivering pre-tied knots. Further goals included the optimization of the design for robotic use in MIRA MV repair.

1.8 Suture Assistant™ Duraknot™

Once the decision was made to pursue the development of a deployable knotted suture, the choice of knot became a central design issue. Such a knot should be quickly deployable in pre-tied form, like a sliding knot, but should compare more favorably with the security of traditional surgical knots. The solution was identified in the Suture Assistant™, Figure 22, a laparoscopic fixation device manufactured by Ethicon Endosurgy, a sister company of the sponsor of this research.

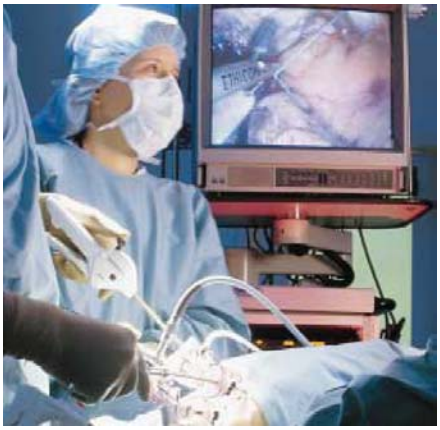

Figure 22. Ethicon Endosurgery, Inc.'s Suture Assistant™ endoscopic suturing device in use [33].

Figure 23. Bowline (left), with Duraknot™ (right).

The Suture Assistant™ is itself a laparoscopic surgical tool, incorporating a needle driver that can be loaded with a cartridge that delivers a single pre-tied knot using lever actions performed by the surgeon. The suture must then be cut, and the device can be reloaded to deliver another knot.

The knot delivered by Suture Assistant™ is the patented Duraknot™, which might in fact be called a triple bowline (Figure 23). The Duraknot™ shares some ideal characteristics with both sliding knots and with other locking knots. Its multiple loops allow its configuration for deployment (Figure 24). The arrows in Figure 24 show the loop before and after invagination of the free end. The cartridge for the Suture Assistant™ uses a tube or mandrel around which the three loops of the Duraknot™ are wound. As configured for deployment,

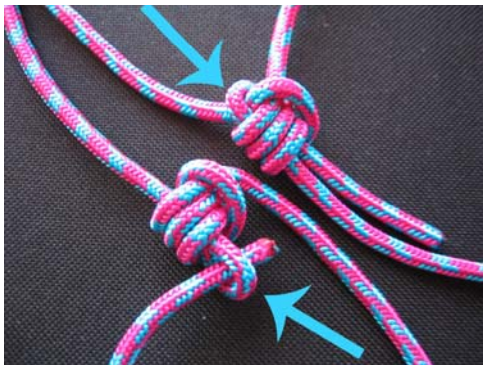

Figure 24. Duraknot™ arranged for deployment (left), and with working end of cord invaginated (right).

the working end is attached to the needle, and the standing end is threaded back through the mandrel. The standing end leads to a loop protruding from the end of the device that invaginates the working end of the suture when the standing end is pulled. The working end and needle are passed through the tissue to be approximated, and then through this loop. The surgeon presses a lever on the handle of the Suture Assistant™ to pull the standing end and loop back through the three encircling turns. The three turns slip off of the mandrel, deploying the knot. The partially dissembled Suture Assistant™ cartridge is shown in Figure 25. The standing end loop leaves the end of the mandrel and leads to the knot, which rests around the mandrel. The working end of the suture leaves the knot, leading to the needle. A schematic from the Suture Assistant™ patent (Figure 26) shows the knot components in relation to the cartridge mandrel.

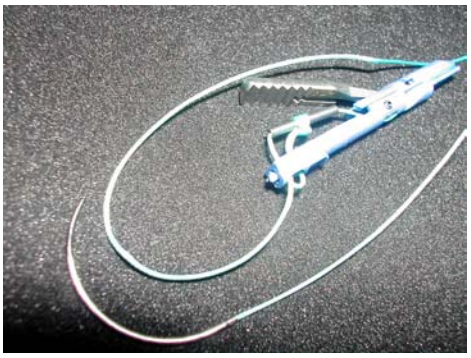

Figure 25. Suture Assistant™ cartridge, partially dissembled to show mandrel and pre-tied Duraknot.

The Suture Assistant™ device, as a laparoscopic hand tool, is not suited to MIRA cardiac surgery. The device is designed exclusively for manual laparoscopic surgery. While a patient side surgeon assists in MIRA cardiac surgery, the intent is to rely as little as possible on this surgeon, in order to proceed toward a totally endoscopic procedure in which the robotic surgeon no longer requires this assistance. As a manual tool, there is no way for the Suture Assistant™ to be used by the robot manipulators.

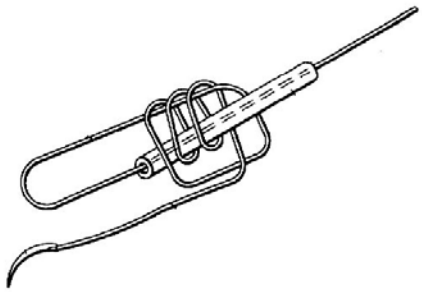

Figure 26. Duraknot™ and mandrel assembly, showing the arrangement knot components before deployment [34].

To enable the MIRA surgeon to more quickly and efficiently tie knots, the research group decided to pursue an alternative method of deploying the Duraknot™. In this way, existing technology could be used as a starting point for developing a device optimized for use by any existing surgical robot with manual manipulators.

2. Project Development

2.1 Organization

The Suture Cartridge development was part of a broader research dedicated to the development of fixation, retraction, and navigation technology to facilitate MIRA cardiac surgery. The project essentially divided fixation and retraction development between two graduate students, and addressed surgical navigation as a secondary collaborative effort. Under the direction of Dr. Gregory Buckner, and working closely with design engineers at CardioVations and heart surgeons at East Carolina University's Brody School of Medicine, weekly teleconferences were scheduled to keep everyone involved in the project and appraised of the progress. More importantly, these weekly teleconferences enabled design input from team members with inparalleled expertise in surgical technology development. Nevertheless, tasks related to the design, prototyping, and testing of the Suture Cartridge remained essentially individual efforts.

While this research effort has been successful, more collaborative R&D efforts related to surgical navigation have suggested a different method for future research efforts, including

future refinements to the Suture Cartridge. In the future, task organization will drive research according to the specific aims of the project. Each multidisciplinary research team, led by a graduate researcher, will assume primary responsibility for one specific aim. Within each team, a single faculty advisor will be responsible for providing guidance to the team and monitoring its progress. Each team will be composed of four to five graduate student researchers, representing all disciplines involved in the project. Each faculty and student researcher will be involved in more than one specific aim team.

With this unique organizational structure, each researcher's responsibilities and contributions will not be limited to a single project. This task organization of teams will encourage cross-pollination among disciplines, encourage creative thinking, and foster innovative solutions to the problems outlined in the specific aims. Student leadership of specific portions of the project will help ensure the success of the project by assigning some responsibility and ownership of a part of the project to a particular graduate leader. Each faculty advisor, while being primarily responsible for coordinating the activities of a specific team, will be available to all teams to offer direction in the advisor's primary area of expertise.

2.2 Design Studio Structure

The entire project will be centered in a design studio environment. This studio will serve as the nerve center of all design and engineering activities, providing an informal environment in which researchers can interact in the development of concepts and prototypes. Weekly meetings will be held in the project studio, focusing each week on a different specific aim and directed by the faculty and graduate researchers leading the team. These weekly meetings will keep all project members informed of team progress, and will initiate brainstorming

sessions involving all of the researchers. The weekly meeting will give all members of the project the opportunity to provide input and learn about the progress on other specific aims.

2.3 Approach

The research methods applied to the development of the Suture Cartridge differ from those of traditional scientific inquiry and more resemble those used in corporate product development. Development progressed through stages of 1) investigation and experience, 2) concept generation, 3) early prototyping, and 4) refinement and redesign through experience in testing. This was not a linear path, but involved constant iteration between steps as investigations refined the development.

First, it was important to clearly define the problem, and the requirements for any effective solution, by identifying the problem and specifying design criteria. The surgical expertise of Dr. Chitwood, Dr. Nifong, and their staff at ECU helped them identify the limitations of current MIRA surgical technology and techniques, and focused efforts on improving and reducing the time spent on fixation. Initial investigation began with the consideration of alternative methods of fixation and an investigation into novel ways to deliver traditional sutures.

The second design phase included conceptualization of potential solutions. This involved collective brainstorming from the diverse perspectives of medicine, mechanical and industrial engineering, and industrial product design. Figure 27 shows a preliminary design concept that suggested the deployment of a pre-tied knot. Design constraints dictated that this cartridge must be compatible with and deployable by existing robotic surgical systems. Graphic methods were used to generate ideas and create fodder for discussion in brainstorming sessions. Through the development of concept sketches such as these, important design issues were quickly conveyed to others.

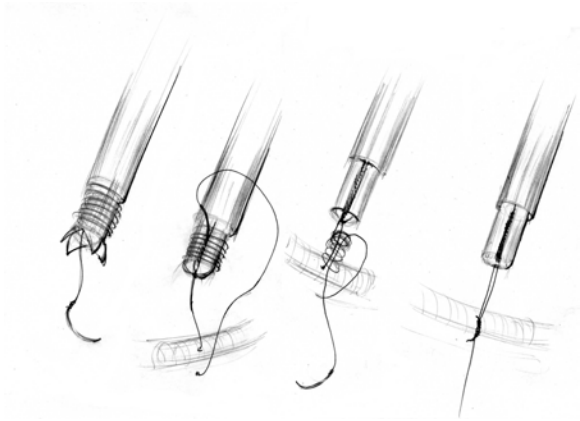

Figure 27. Preliminary design concepts for MIRA fixation cartridge [35].

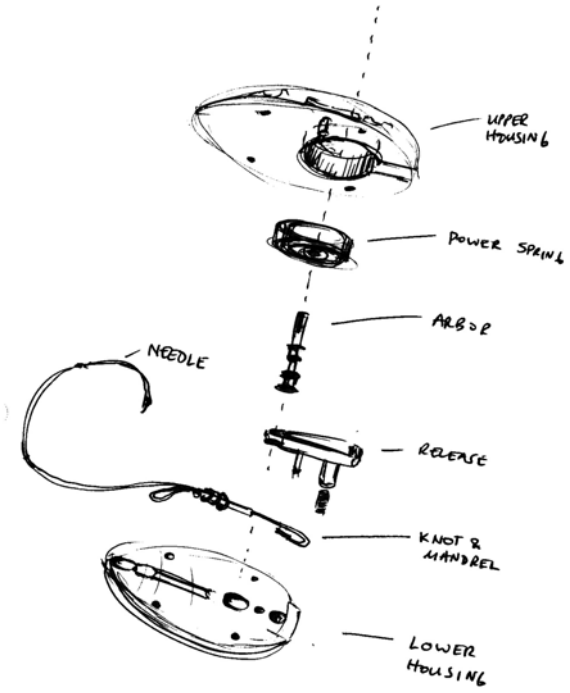

Figure 28. Ideation of Suture Cartridge concept.

Using these sketches as a starting point, refinements or suggestions were made that took advantage of the strengths and probed the weaknesses of the designs. From these initial concepts, and, most importantly from the discussions and the feedback they generated, the ideas were refined. The initial concept generated in Figure 27 led to an initial prototype and then to another concept, shown in Figure 28. Through the

development and refinement of digital renderings, as shown in Figure 28, the features of the proposed design were made clearer.

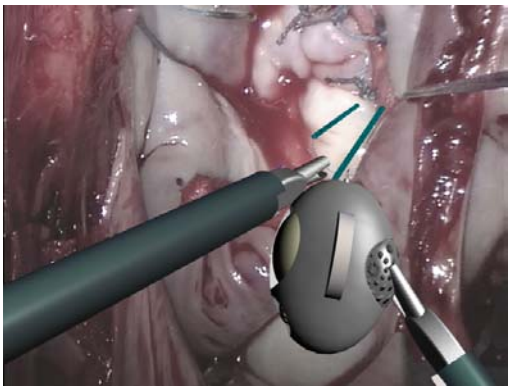

Figure 29. Digital rendering of fixation concept [36].

Once a preliminary concept was identified and refined through early prototyping, the refinement of the design through iterative prototyping began. High-resolution prototypes were created directly from CAD files using rapid prototyping facilities. Rapid prototyping is the generic name for any fabrication technique that produces three-dimensional parts in a layer-wise fashion. Figure 30 shows a computer solid model of a second-generation MIRA fixation cartridge design, and shows the completed prototype, created using stereolithography (SLA) directly from the solid model.

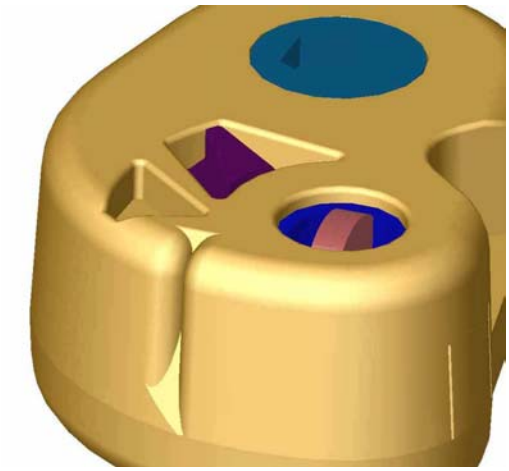

Figure 30. Rendering of fixation device from computer solid model [36].

Through a series of prototypes created using a variety of manufacturing techniques, primarily SLA, iterative design quickly exposed the limitations of different design features and allowed improvements to be rapidly incorporated into successive design iterations. This initial iterative process has led to a design that is capable of delivering pre-tied knots and independently cutting the working and standing ends of the delivered knot, without requiring the intervention of the patient side surgeon or a time-consuming tool change for the robot.

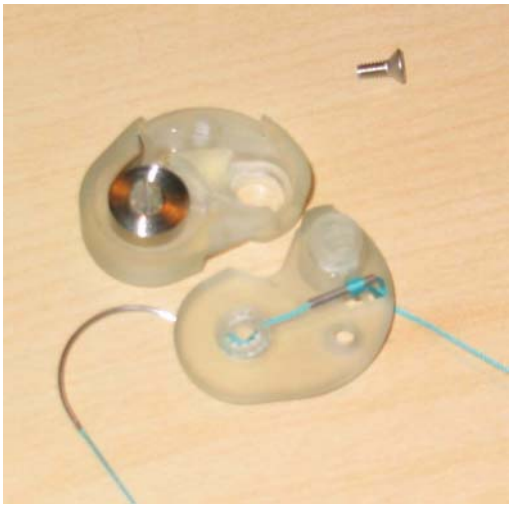

Figure 31. Prototype of the Suture Cartridge created using stereolithography, with components inserted for assembly.

Once a fully iterated prototype is complete at this stage of design, evaluative testing will begin using the robotic surgical platform used to perform MIRA cardiac surgery. Completed prototypes will be evaluated through a progressive series of trials at East Carolina University's surgical robotics lab. Engineers and clinical researchers will first evaluate basic product functionality using ECU's training robot, a fully functional da Vinci system from Intuitive Surgical. Feedback from the surgical staff will be used to refine these prototypes. Advanced prototype testing will be conducted by surgeons using porcine hearts placed inside inanimate cardiothoracic trainers, and will be used to assess the overall effectiveness of a device with respect to its design specifications. Inanimate trainers simulate the constraints that exist when performing robotic cardiac surgery on humans.

Following porcine heart trials, a further iterative process of design refinement and re-evaluation will take place. This will include the correction of any perceived deficiencies and

the incorporation of desired features. Multiple phases of prototype testing will be conducted in the same manner outlined above.

Once prototypes satisfy basic design criteria in the inanimate study environment, acute animal trials will be conducted to test the effectiveness of the design in an actual cardiac procedure. The surgical team at ECU will conduct these acute animal trials, which have Institutional Animal Care and Use Committee (IACUC) approval and are overseen by the Department of Comparative Medicine's three staff veterinarians. In addition, three anesthesia technicians and one cardiopulmonary perfusionist, operating the cardio-pulmonary bypass (CPB) machine, will be involved.

2.4 Requirements

Based on initial investigations into surgical fixation and the deployment of pre-tied knots, several design requirements were chosen. The device would be suture and knot based, and would deliver a pre-tied Duraknot™ using technology developed as part of the Suture Assistant™. The proposed device would be optimized for use by surgical robots, and be as small as possible, supporting the longer-term goal of totally endoscopic MIRA cardiac procedures. Further, the device needed to incorporate suture cutting capabilities to eliminate the need for robot tool changes.

2.5 Prototype History

Initial concepts for the device were developed by duplicating the effects of the mechanism used in the Suture Assistant™ device, while packaging the device in a compact, self-contained form. The device needed to pull the standing end of the suture (the end threaded through the cartridge mandrel), causing the loop to invaginate the needle end of the suture

and deploying the knot. Experiments were conducted to determine the force required to ensure repeatable knot deployment. Cartridges from the Suture Assistant™ were secured to a lab table and the standing end of the knot was pulled with a wire crimped to a scale. The required deployment force was determined to be 6.75 N. Concurrently, work began to develop a first-generation prototype to demonstrate automated deployment of the knot.

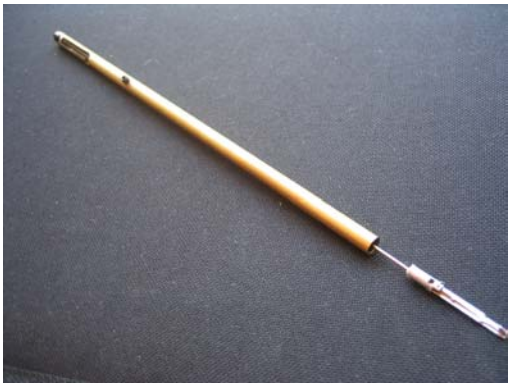

Figure 32. The initial prototype.

2.5.1 Suture Cartridge I

The initial prototype represented an effort to quickly reproduce, in a small package, the actions that the Suture Assistant™ uses to deploy the Duraknot™. This prototyping effort led to a deeper understanding and appreciation of the Suture Assistant™ design. Suture Cartridge I, shown in Figure 32, was conceived with two actions to deploy the knot: 1) pulling on standing end of the knot using the hooked portion of the Suture Assistant™ interior assembly and 2) pulling the entire cartridge assembly away from the tissue, much as a surgeon might do manually. These actions were accomplished with a linear spring and a simple catch using a setscrew. The resulting prototype was much too long to be appropriate for robot use. The two-stage action was determined to be unnecessary, and there was no provision for cutting the ends of the suture either internally or externally. In order to reduce the length, a torsional spring was proposed to deploy the knot.

2.5.2 Suture Cartridge II

Suture Cartridge II was designed using Pro/Engineer™ CAD software (Figure 33), with stereolithography (SLA) as the intended fabrication material. Eliminating parts of the Suture Assistant™ device related to the needle grabber mechanism, Suture Cartridge II incorporated only the mandrel and pre-tied Duraknot™. The mandrel groove and other design features of the Suture Assistant™ cartridge from which the knot and standing end loop protrude were duplicated for the second Suture Cartridge prototype.

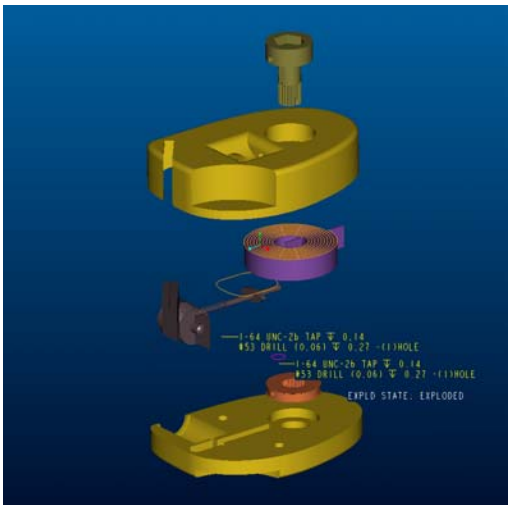

Figure 33. Suture Cartridge II.

The needle and working end of the suture protruded from the bottom of the case. In a manner identical to the Suture Assistant™, the surgeon would pass the needle and suture through the tissue to be approximated, and then through the protruding loop. To maintain tension on the free end of the suture, the surgeon would secure the free into a rubber cleat insert (only the diagonal hole for the insert is shown in Figure 33). The standing end of the suture (threaded through the mandrel) was taken up by a spool (rendered in orange in Figure 33) using energy stored in the torsional spring (shown in purple). The spring-loaded arbor was secured using a release pin, which, when actuated by the surgeon, allowed the spring, arbor, and spool to spin freely, pulling the standing end of the suture. The working end of the suture required manual cutting, but the internal end was cut by a spring-loaded blade.

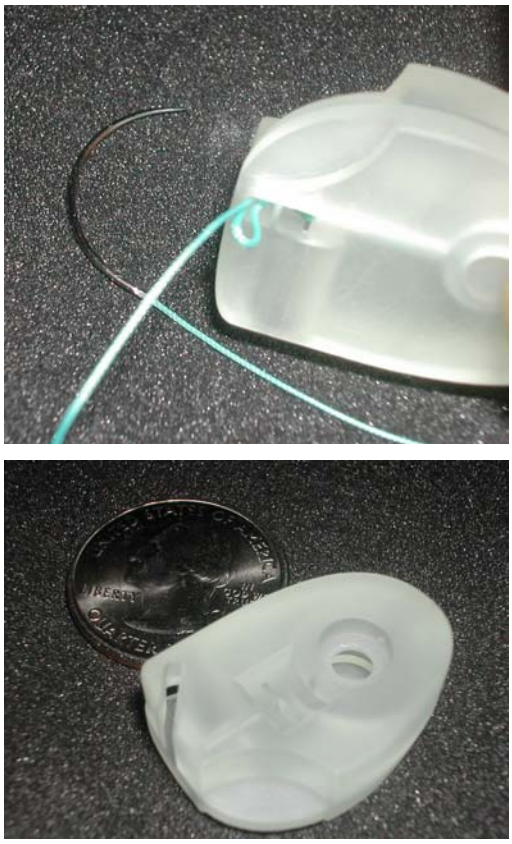

Figure 34. Suture Cartridge II prototype case, shown with loop and free end of suture protruding, and with coin for scale.

Suture Cartridge II successfully produced a knot, but revealed several targets for improvement. Neither the internal cutter parts nor the arbor release mechanism were fully realized in this model. The prototype was actuated by pulling a stop pin in the end of the device. The cleat was angled inappropriately, requiring an awkward repositioning using the robotic manipulator to secure the suture. The smooth finish on the device did not provide a secure gripping surface for the manipulator.

2.5.3 Suture Cartridge III

Capitalizing on the successes of SLA prototype fabrication, Suture Cartridge III featured several internal components made of the same SLA material. The bottom of the case retained the same mandrel groove and opening from which the standing end loop and working end protrude.

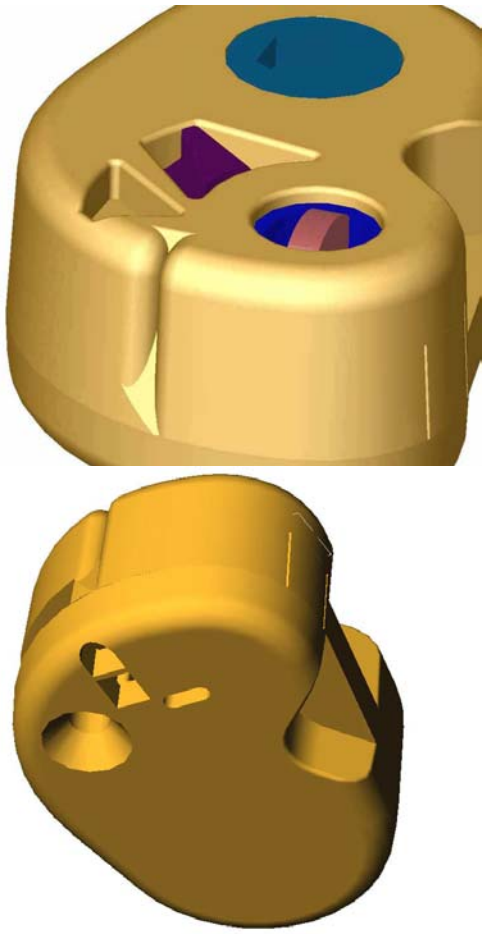

Figure 35. Suture Cartridge III solid model, including cutter release in pink, arbor in blue, and pawl/arbor release in purple.

The device contained a redesigned arbor release mechanism, consisting of a ratcheted arbor and a spring-loaded pawl for simplified pre-tensioning. The cleat was integrated into the SLA case. Suture Cartridge III was actuated using a robotic manipulator by pressing the purple switch shown in Figure 35, freeing the spring-loaded pawl and allowing the arbor and take up spool to turn. The surgeon would then turn the pink cutter release, allowing the spring-loaded cutter to sever the standing end of the suture internally. Suture Cartridge III was produced in SolidWorks™, rather than Pro/Engineer™, to address previous difficulties with the execution of top-down assemblies.

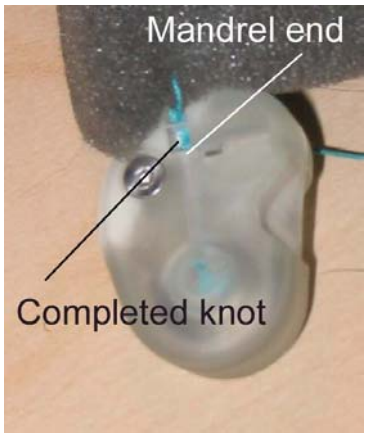

Figure 36. Suture Cartridge III prototype, following delivery of knot. Cutting the knot at the front of the mandrel destroyed it.

Like previous prototypes, Suture Cartridge III produced viable knots, and the arbor and pawl/arbor release mechanisms worked well. Figure 36 shows a knot produced by the device. The knot is uncut and remains in the case.

While the internal cutter parts of the device moved properly, the spring used was not strong enough to cut the suture (nor was a stronger one available that would fit inside the housing). This design flaw went unnoticed until experimental testing revealed it. Suture Cartridge III, like version II, had problems with the SLA cleat integrated into the case. which failed to secure the free end of the suture.

2.5.4 Suture Cartridge IV

Suture Cartridge IV retained the same basic shape of version III, but eliminated the internal cutter assembly to focus exclusively on knot-tying refinements. A second cap screw replaced the cutting mechanism to improve housing closure. A cutting slot at the end of the mandrel groove allowed scalpel cutting of the standing end of the suture. Textural grooves on the grip gave the robot manipulator purchase when grasping the device. The SLA cleat was replaced with a polyurethane rubber cleat insert, molded from a positive created in SLA, in a mold

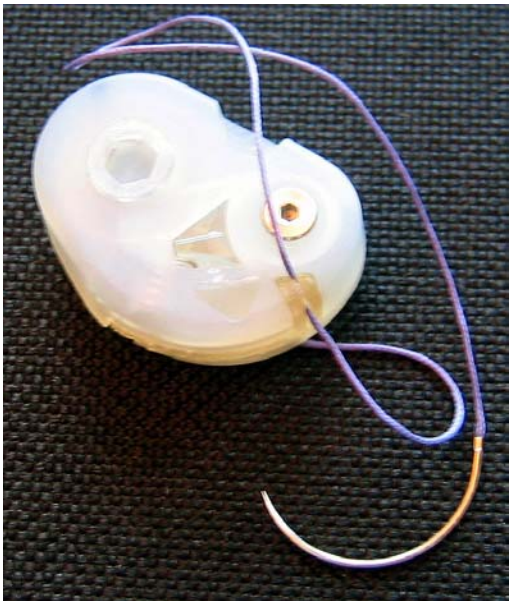

Figure 37. Suture Cartridge IV prototype.

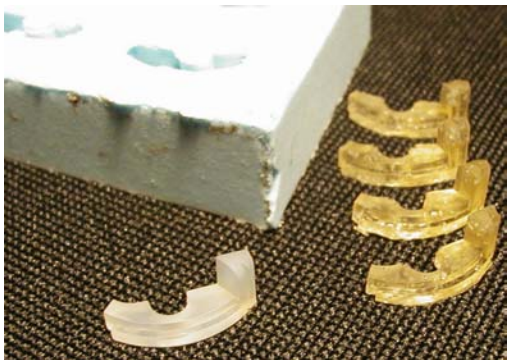

Figure 38. Manufacture of elastomer cleat insert for Suture Cartridge IIa, showing SLA positive, RTV silicone mold, and cast polyurethane rubber parts.

poured using room temperature vulcanizing silicone. The SLA positives, the silicone mold, and cast polyurethane parts are shown in Figure 38. This refined cleat proved to successfully secure the suture (Figure 37), although the force required to secure the suture was large enough to potentially damage tissue.

Version IV was the first prototype to successfully deploy multiple knots in silicone test tissue. Each of the "successful knots" shown in Figure 39 (4 out of 5 attempts) were tight and showed no air gaps (none were "air knots"). Note that one of these knots pulled through the silicone due to the force of deployment. This failure could have resulted from excessive cleat pre-tensioning, and will be examined closely in future versions.

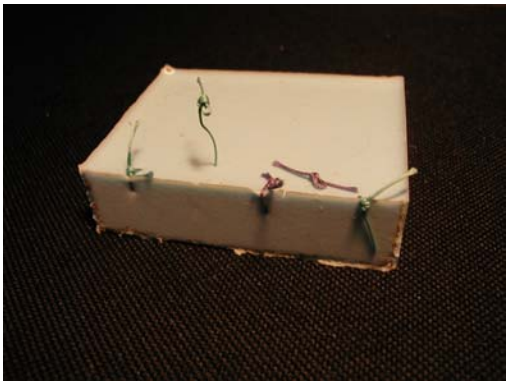

Figure 39. Knots tied with Suture Cartridge IV. Knot second from the right is complete, but pulled through the silicone upon deployment.

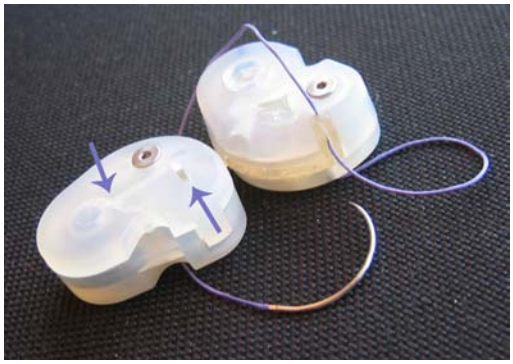

Figure 40. Suture Cartridge IV prototype. Note the intended access slot for cutting the interior end of the suture (right arrow) and the modified access slot (left arrow).

Testing revealed that the only appropriate points for internal suture cutting were near the spool or the back end of the mandrel (see left arrow in Figure 40). When the Duraknot™ is deployed, its three turns are forced off of the mandrel as the standing end loop is invaginated, and then back against the mandrel's end as the knot tightens. If

the standing end is cut at this point (right hand arrow in Figure 40) the encircling turns will invariably be cut. For this reason, a second access slit was made at the spool end of the mandrel, allowing several successful knots to be deployed.

Suture Cartridge IV successfully demonstrated that the Duraknot™ could be automatically deployed. The internal cutter location was solidified with experimentation using cutter access slits in this prototype. Testing at this phase also suggested the need for an external cutter, for severing the working end of the suture and for trimming the end left by the internal cutter.

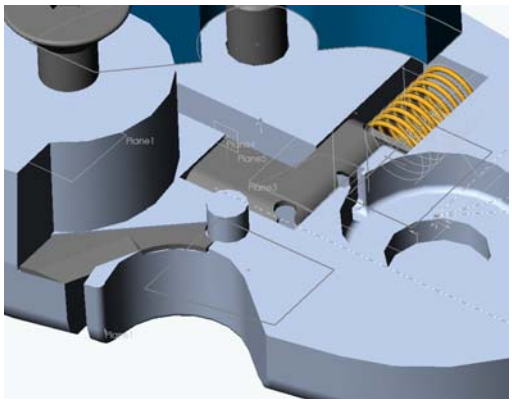

Figure 41. Internal cutaway view of Suture Cartridge III solid model, showing the external cutter (left) and the internal cutter parts (right) constructed of sharpened 0.010" sheet metal stock. The internal cutter uses a spring identical to the pawl return.

2.5.5 Suture Cartridge V

Version V of the Suture Cartridge incorporated all of the design changes required for a viable proof of principle prototype, meeting all of the initially prescribed design criteria. These included: the delivery of a Duraknot™ using unassisted robotic manipulators, and the ability to cut the standing and working ends of the suture from the knot without additional tools or assistance from the patient side surgeon. Version V also possesses a grip for the right hand manipulator, visible in Figure 42, to aid in delivery and repositioning.

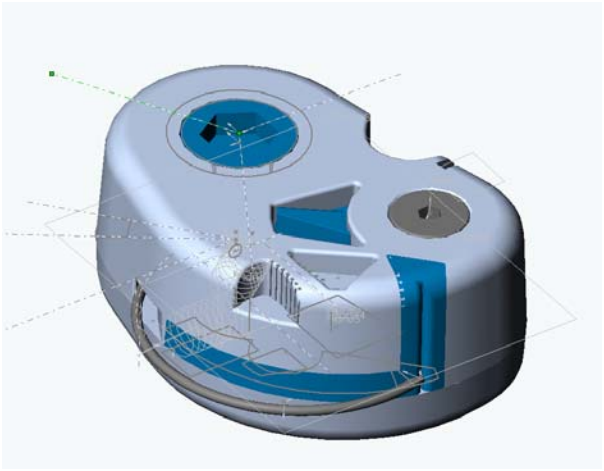

Figure 42. External perspective view of Suture Cartridge III solid model, showing the right hand manipulator grip

The development of internal cutting blades was particularly challenging. These blades were fabricated directly from CAD files through a process called photo etching or chemical milling, outlined in Figure 43-Figure 47. This method was selected due to the small part sizes and because of their highly irregular contours.

A two-dimensional CAD file was used to create a photo die with a negative of the part to be produced. The thin sheet stock selected for the parts, 0.009 inch 304 stainless steel, was coated with a photo resistive laminate. The stock was exposed to light though the photo negative, developing the photo resist only in the areas of metal that would remain in the finished part. The undeveloped photo resist was removed from the stock, leaving an acid resistant mask on the stock in the desired part pattern. The stock was exposed to acid, removing the stock material in all of the places not protected by the photo resist mask. The photo resist was then removed, leaving complete parts. One of the parts required further bending with a stamping die to create bend tabs in the photo etched blank.

The completed parts, shown in Figure 48, were then sharpened, first by hand, and then using a custom-

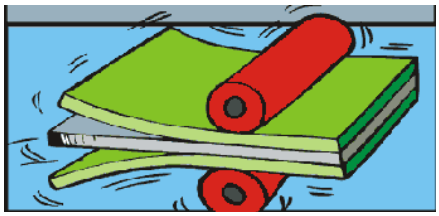

Figure 43. A photo resistive laminate is applied to the thin sheet metal material to be etched [37].

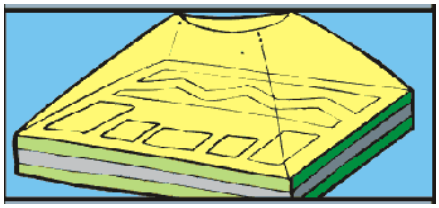

Figure 44. The photo die is used to expose the photo resist laminated on the material, fixing the photo resist in the form of the part positive [37].

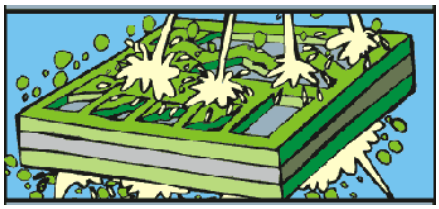

Figure 45. The photo resist is developed, leaving the coating only in the areas exposed to light through the photo die [37].

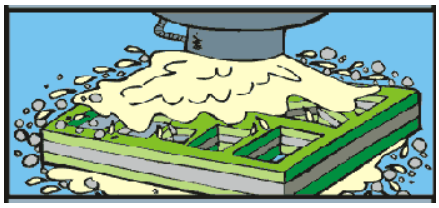

Figure 46. Acid is used to etch away all of the material unprotected by the photo resistive laminate, creating the parts [37].

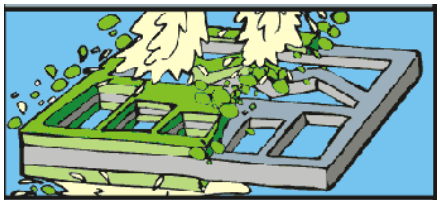

Figure 47. A stripper is applied to remove the photo resistive laminate, leaving the fully formed parts [37].

Figure 48. Internal and external cutter parts in 304 stainless steel.

designed sharpening jig, shown in Figure 49. The 304 stainless steel used in the first generation of cutter prototypes proved to be inadequate for this application. The sharpened blade surfaces in this material bent easily under pressure against the strong suture material, easily rolling over and dulling without cutting the suture.

A second generation of cutter prototypes was created using harder 410 stainless steel, a material frequently used in knife and cutter parts that is heat-treatable after forming and grinding, yielding a much stronger cutting edge. The parts were photo etched, bent and sharpened in their annealed form, and then tempered and stress relieved.

Following the fabrication of cutter parts using 410 stainless steel, the external cutter was operational. The internal cutter, however, had persistent complications. While hardness was greatly improved in this second generation, internal cutting performance was unchanged. A redesign of the bottom half of the device attempted to solve problems associated with holding the suture in place against the cutting edge. However, these problems remained and the team abandoned

Figure 49. Jig for sharpening internal and external cutter parts.

internal cutting of the suture material for final testing of the device.

3. Final Testing

Suture Cartridge V was tested in timed knot tying trials using the da Vinci™ surgical robot training system at ECU. Manual knot tying (with robotic manipulators) was compared to Suture Cartridge-assisted knot tying using a silicone heart model. Experienced and inexperienced operators of the surgical robot used standard 2-0 Ethibond™ sutures and pre-tied knots loaded in Suture Cartridge devices to affix an annuloplasty to the perimeter of the mitral valve.

The manual and device-assisted fixation tasks were divided into three sections. After a Suture Cartridge or standard suture was delivered to the robot, the operator was timed in the task of passing the needle and suture through the annuloplasty and silicone valve tissue. Once the suture was placed, the operator was timed in the placement of six alternating overhand surgical knots (manual fixation), or in the tasks required to deliver the Duraknot™ using the Suture Cartridge V device (device-assisted fixation). Suture cutting tasks were timed as well. Data for knot tying and deployment tasks is presented in Table 2. Cutting tasks were segregated from suture placement and knot tying tasks because the internal cutting tools of the Suture Cartridge were not functional at the time of testing.

Table 2. Time to complete knotting tasks with surgical robot manually and assisted by Suture Cartridge automatic knot tying device.

Subject	Robotic Surgical Experience	Method	Time to complete knot (seconds)	Mean for group	Median for group	
1	No	Manual	269			
1	No	Manual	132			
1	No	Manual	121	174	132	
1	No	Suture Cartridge	86			
1	No	Suture Cartridge*	87			
1	No	Suture Cartridge†	216			
1	No	Suture Cartridge	45			
1	No	Suture Cartridge	151			
1	No	Suture Cartridge	143			
1	No	Suture Cartridge	88			
1	No	Suture Cartridge	209	128	116	-26%
2	Yes	Manual	119			
2	Yes	Manual	88	104	104	-12%
2	Yes	Suture Cartridge	94			
2	Yes	Suture Cartridge*	92			
2	Yes	Suture Cartridge	86	91	92	
All	-	Manual	-	146	121	
All	-	Suture Cartridge	-	118	92	-19%

*Difficuly in disengaging pawl
† Difficulty in passing needle through loop

For knot tying tasks alone, the Suture Cartridge device resulted in time reductions for experienced and inexperienced users alike. Overall, the mean time to produce a knot was 146 seconds manually, and 118 seconds with device assistance. The surgeon experienced with the use of the robot performed both manual and device-assisted tasks more quickly, with mean times of 104 and 91 seconds for unassisted and assisted knot tying tasks, respectively. The untrained user (untrained in both surgery and surgical robotics) performed manual and device-assisted tasks in 174 and 128 seconds, respectively. The Suture Cartridge resulted in a 12% reduction in the time required for a knotting task as performed by an experienced surgeon trained in the use of the surgical robot, and a 26% reduction for an untrained user. This data suggests that a device for facilitating knot tying could help make surgical robotics more accessible to surgeons new to the platform, and could simultaneously reduce CPB time by reducing the time spent tying knots.

Two of the device-assisted knotting cases (noted in Table 2) encountered difficulties in disengaging the pawl from the arbor (once for each subject). In each of these cases, attempts to actuate the device using the robotic manipulators failed. An assistant actuated the device manually in each of these cases. In order to accurately reflect the time taken for the task up to the point of that difficulty, the time for knotting tasks for these two knots was stopped at the first attempt to disengage the pawl.

4. Future Development and Improvement

While the Suture Cartridge at this stage of development is a successful proof-of-principle prototype, testing and evaluation have helped identify several areas of improvement that could lead to the development of a commercially viable product.

As discussed previously, the automatic cutting features of the device are not fully realized. While manual cutting is a step in the completion of a manual suture, automatic cutting will save more time and simplify the procedure. It is worth noting that once internal cutting tasks are fully integrated into the device, they should further reduce the time required and eliminate another area of reliance on the patient side surgeon.

The footprint of the device, while small, is still too large for viable use in MIRA MV repair. Several constraining factors could be addressed in order to further reduce the device footprint: 1.) The spool of the device was arbitrarily sized, and the torsional spring was selected to achieve the torque necessary to deliver the knot. The spool and spring diameters could be reduced and matched by adjusting the spring width to achieve the smallest overall footprint while maintaining the required actuation torque. 2.) The mandrel is longer than required. The mandrel represents a significant portion of the overall length of the device, and could be cut at least in half in future versions, along with the corresponding length of the top and bottom case halves. 3.) The pawl could be reduced in length and width at the point around which it pivots. 4.) The use of a linear spring could be reexamined. If the spring and moving parts were nested, such a design could provide a narrower profile more suitable to the limited operating field.

To remove another step in the operation of the device, the cleat could be reoriented. If the working end of the suture were routed through the area cleaved by the internal cutter, the suture could be cut in a single step. Trimming would minimize the size of suture tags remaining on the knot.

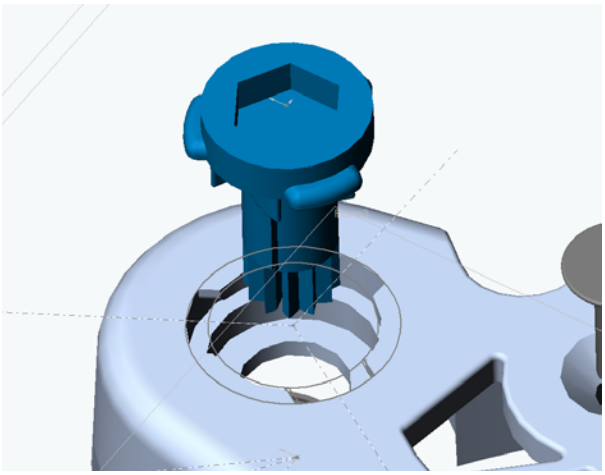

Figure 50. Possible redesign of arbor and top of case to prevent arbor from exiting or moving axially during operation.

The arbor in the current design is sometimes partially ejected from the case during use, because it is unconstrained vertically. If the spring were inserted into the arbor instead of being inserted the length of the shaft, the spring could constrain the arbor and prevent it from being pushed up by the pawl teeth. Alternatives include a redesign of the case halves to create a third intermediate piece sandwiched in between, allowing the arbor to be inserted into and retained by the top half. Another possibility, shown in Figure 50, is the keying of the arbor to allow it to enter and exit the top half of the case in only three orientations.

The SLA material used in the fabrication of prototypes tended to be fragile in early testing of the device. Fabrication of arbor and pawl parts out of polycarbonate or another stronger plastic would make the prototypes more robust. Short-run rapid tooling could be constructed to allow injection molding of the parts.

Dr. Gil Bolotin of ECU pointed out that while visibility of the tissue and annuloplasty was sufficient in placing and tightening the suture, the enclosure of the knot within the device

deprived the surgeon of visual confirmation that the knot was complete. This is particularly important given the lack of any tactile feedback to the operator. In the initial design, the configuration of the Suture Assistant™ cartridge was duplicated in the bottom half of the case, to include the twin holes and groove to receive the mandrel. The device could provide improved visual feedback by incorporating one of the alternative delivery mechanisms proposed in the paten of the Duraknot, as shown in Figure 51. If a tapered mandrel were incorporated into the front of the case, the separate metal mandrel could be eliminated entirely.

The use of a torsional spring and spool was inspired by the lack of space for linear actuation based on the inclusion of many of the features of the laparoscopic Suture Assistant™ device that are not required for delivering the knot in a self-contained device. If a tapered mandrel as shown in Figure 51 were used in conjunction with a linear spring as part of a nested concentric construction, limitations due to the length of such a design could be overcome. It is certainly true that a device with a front end such as that of Figure 51 would appear much more precise and would block the surgeon's view of the tissue being approximated much less than the current design.

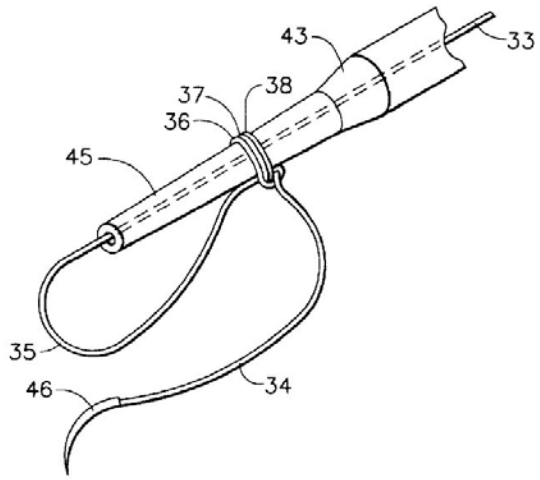

Figure 51. Alternative deployment method for Duraknot™ from patent. [34]

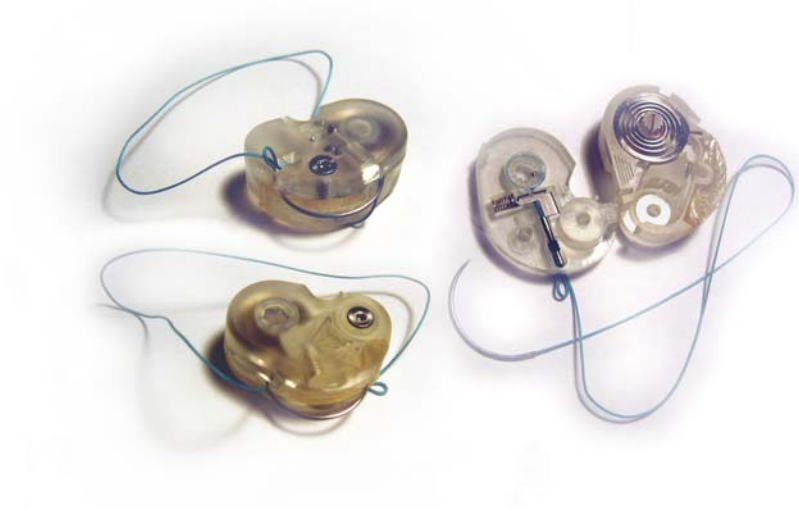

Figure 52. Views of the completed prototype.

Several important points for redesign were noted only on working with the device using the robotic manipulators. As noted in Table 2, two of the device-assisted knots required external assistance to actuate the release of the pawl. This was because of the combined effects of the manipulator grip slipping on the SLA material and the geometry of the manipulators and the grip on the pawl release. The release could be angled to better accommodate the manipulators and increase the contact area, as well as relocated to increase the lever arm on which the manipulators are pulling. Another possible improvement might be allowing access to the lever from the side rather than the top of the device. This would also be more natural from an ergonomic standpoint.

Because the pre-tied knots used in the Suture Assistant™ were used in the Suture Cartridge, the length of suture between knot and needle was dictated by the Suture Assistant™. This device was designed for a particular type of abdominal surgery, and the length was significantly greater than required for annuloplasty fixation. Reducing the length of suture between knot and needle could make the Suture Cartridge easier to use and reduce the time required to produce knots by reducing the number of times that the surgeon has to release and pull on the suture to thread it through the loop of the pre-tied knot.

The cleat functioned much as expected, but several improvements could be made. Time could be saved in introducing the working end of the suture into the cleat if the cleat rested in a depression in the device rather than a protrusion. In this way the suture could be directed towards the cleat by a feature on the device, requiring less precision from the operator.

In assembling and preparing the prototypes for testing, some difficulties were encountered that could be addressed in redesign. The number of parts could be reduced and assembly made easier if the mandrel were integrated into the case, as previously discussed. If the mandrel were integral to the device and the knot tied externally, assembly would be considerably easier. Assembly of the device also relied on cutting off a portion of the crimp placed on the standing end of the suture in Suture Assistant™ cartridges. An alternative method of securing the standing end of the suture to the spool could further simplify assembly. If this method of attachment were adjustable, it would allow the adjustment of loop size after assembly, improving the consistency of loop size.

5. Conclusion

While much research and development remains before the Suture Cartridge can be considered a surgically viable product, the latest version is a successful proof of principle prototype. This research has demonstrated that it is possible to automate the single most time-consuming repetitive task involved in MIRA MV repair without any redesign of the robot itself. Through this automation, the potential exists to reduce the time in surgery spent tying knots by 12 to 26 per cent, potentially making the procedure accessible to more patients. By simultaneously reducing the surgical skill requirements, this device, if fully

developed, could make MIRA procedures accessible to more surgeons and correspondingly to more patients.

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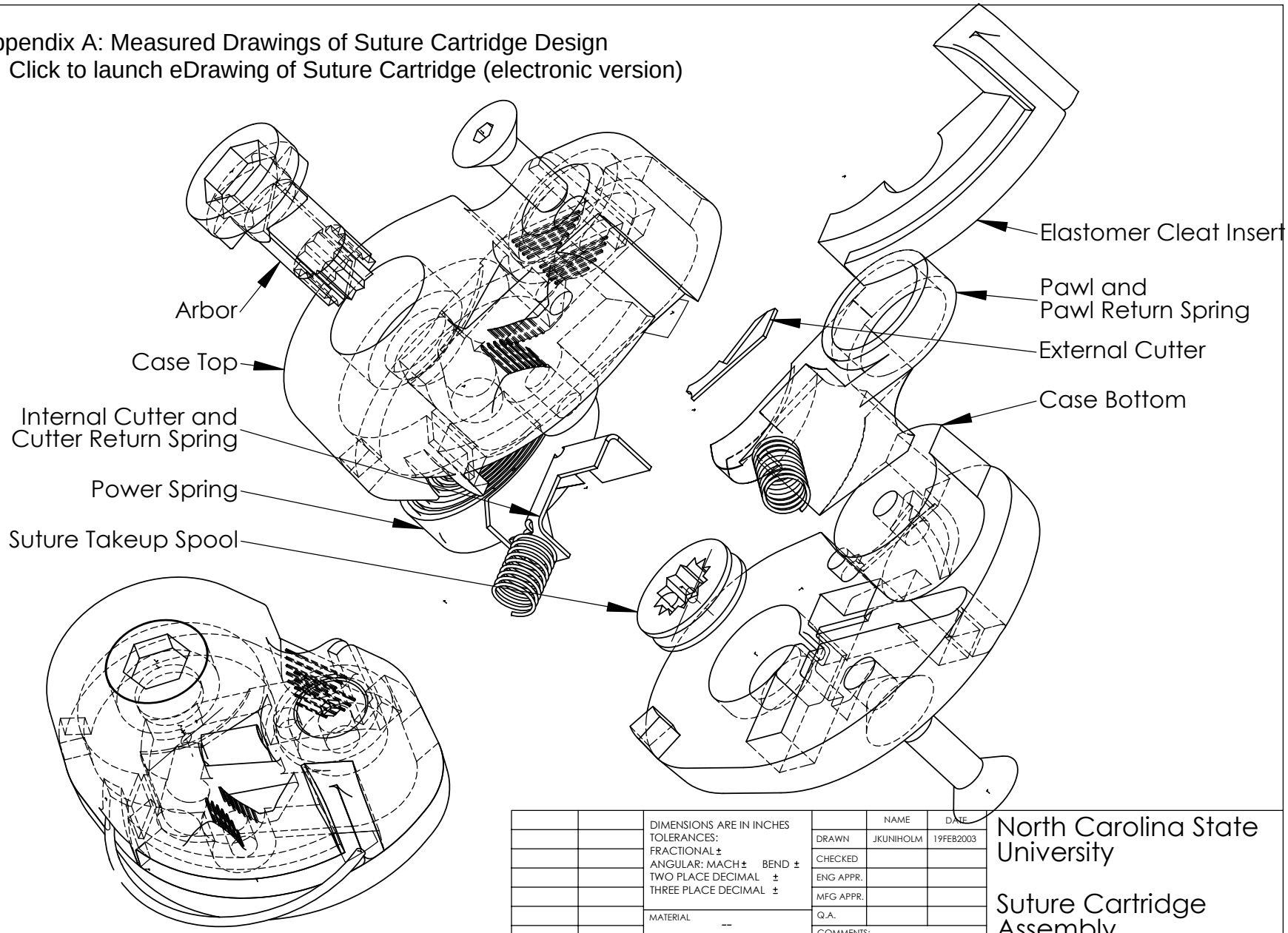
Appendix A: Measured Drawings of Suture Cartridge Design

Click to launch eDrawing of Suture Cartridge (electronic version)



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North Carolina State University

Suture Cartridge Assembly

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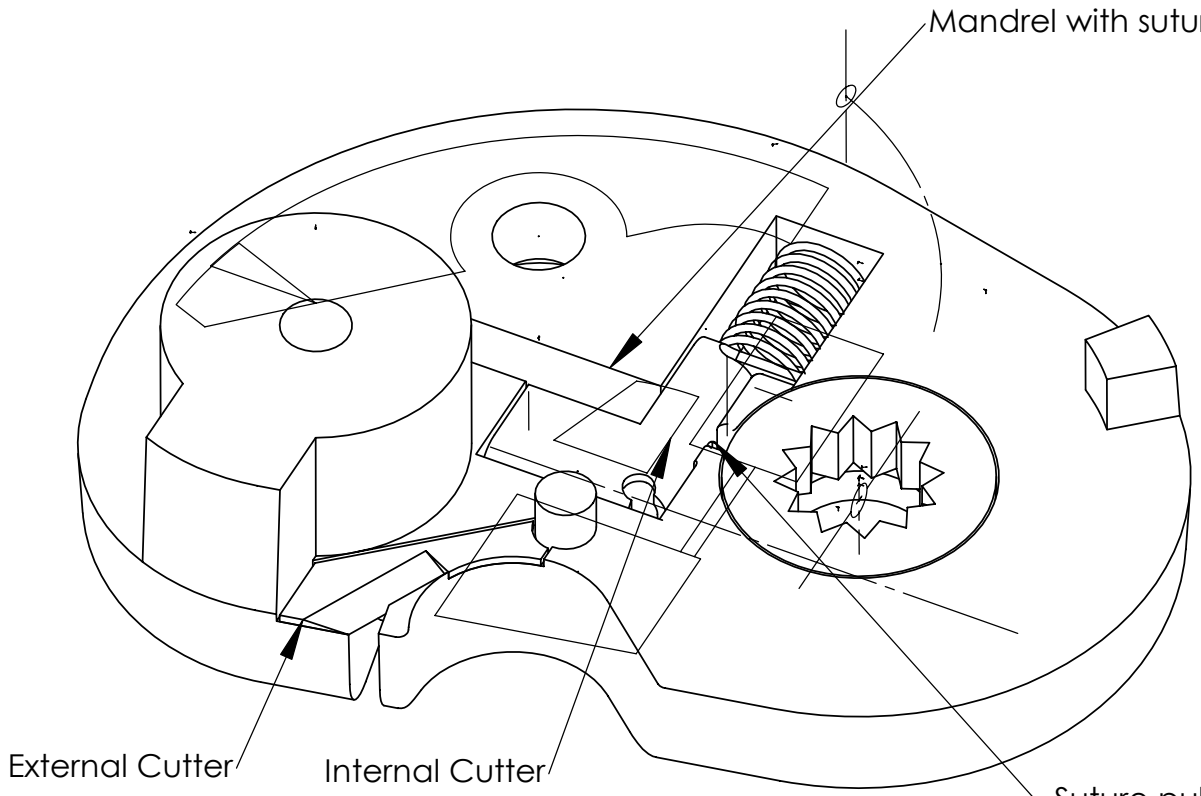

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North Carolina State University

Suture Cartridge Assembly Cutaway

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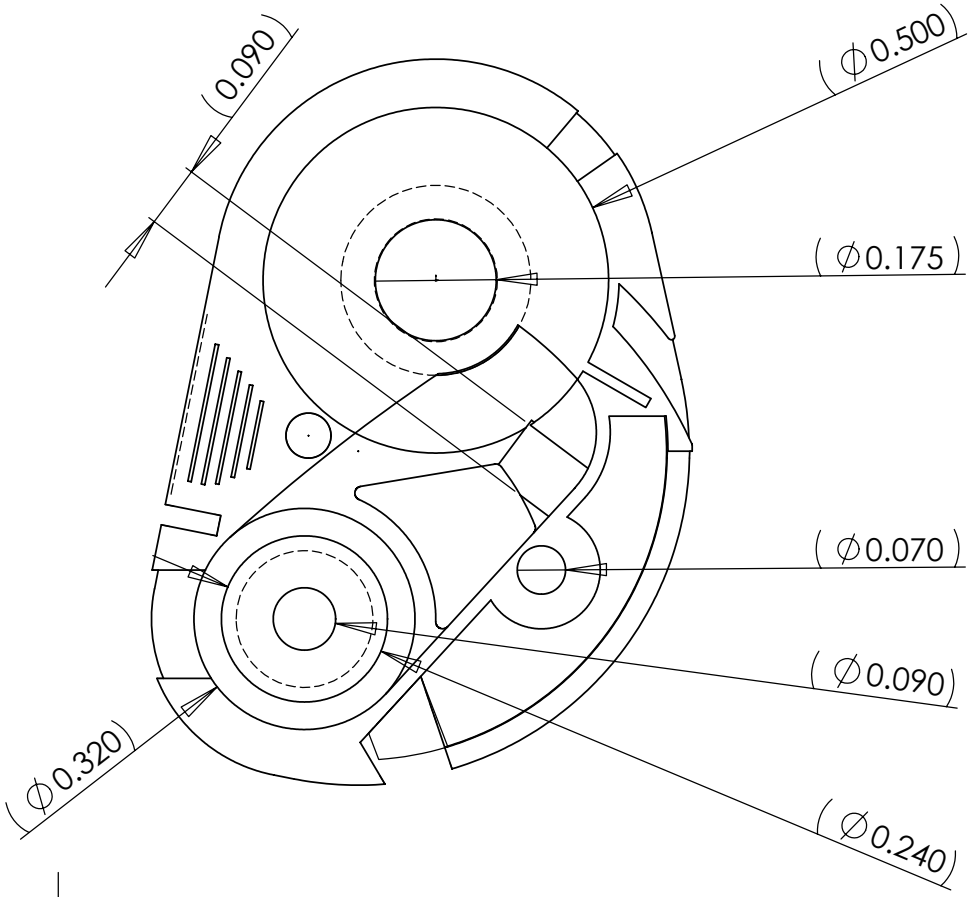

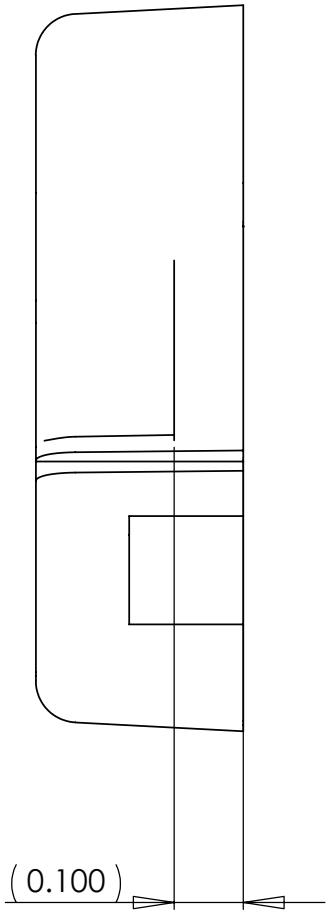

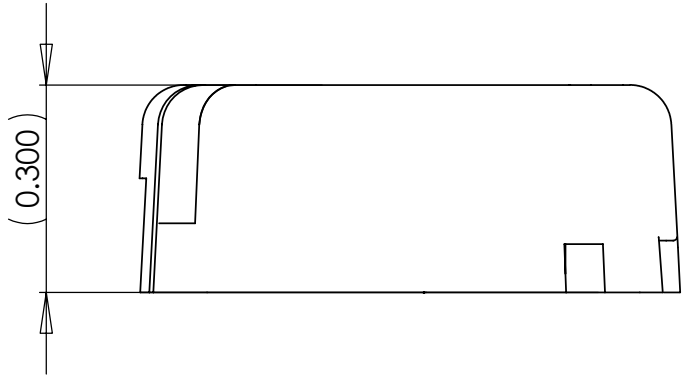

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North Carolina State University

Suture Cartridge Case Top

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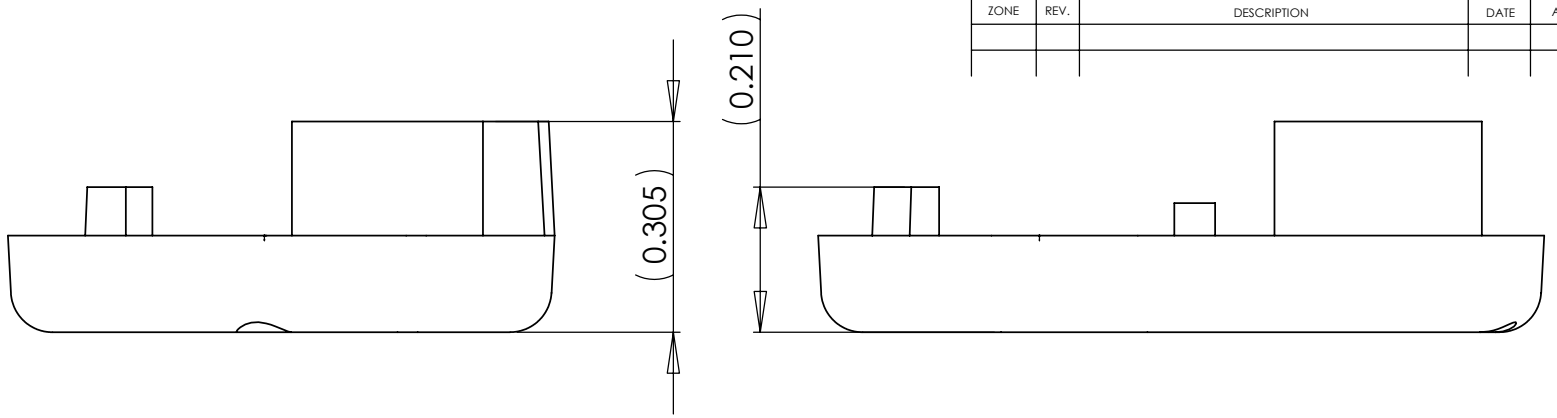

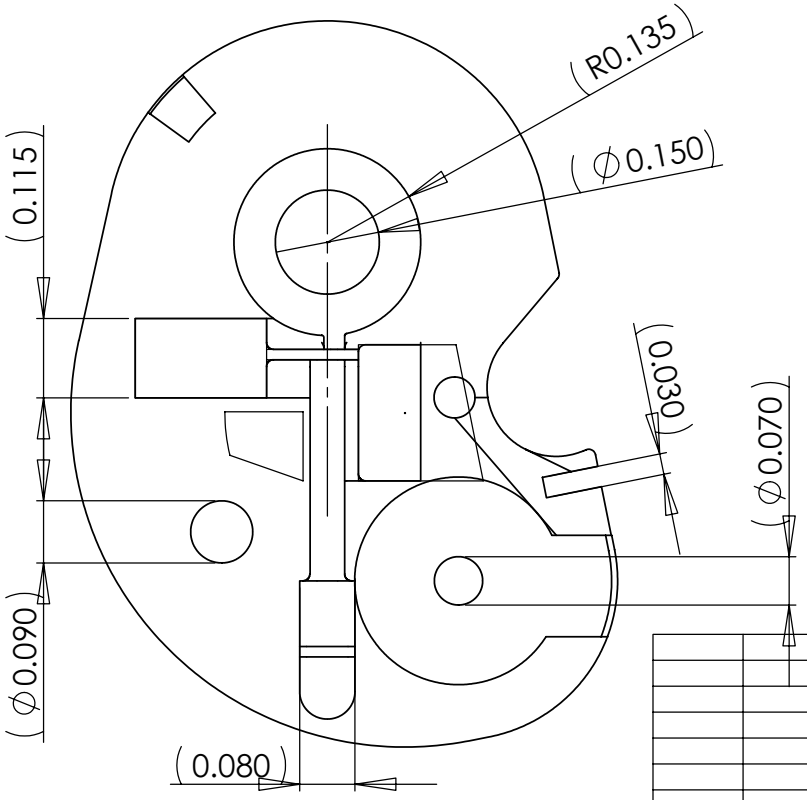

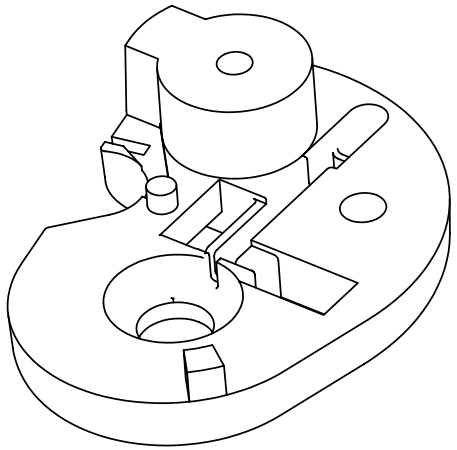

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North Carolina State University

Suture Cartridge Case Bottom

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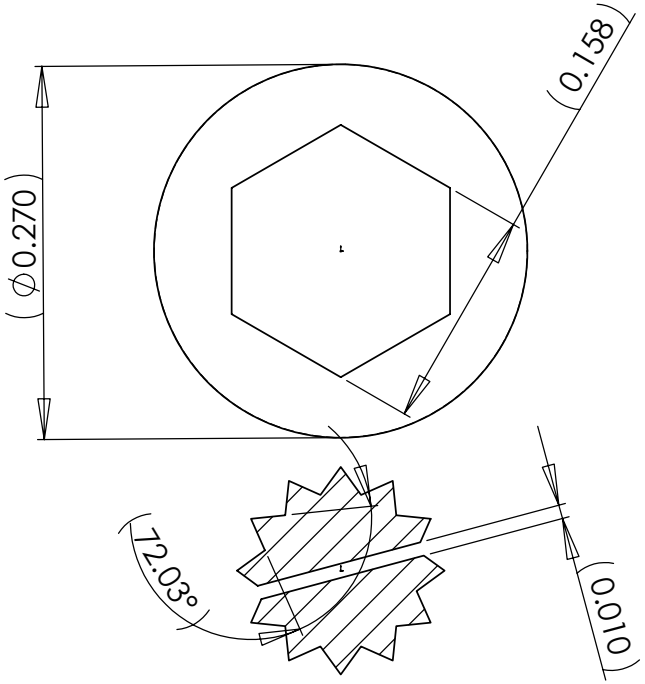
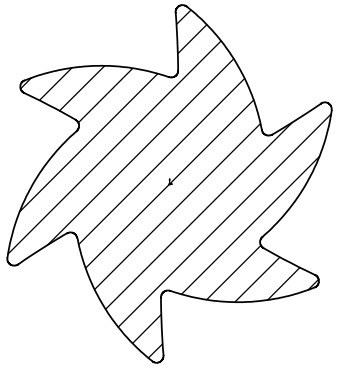
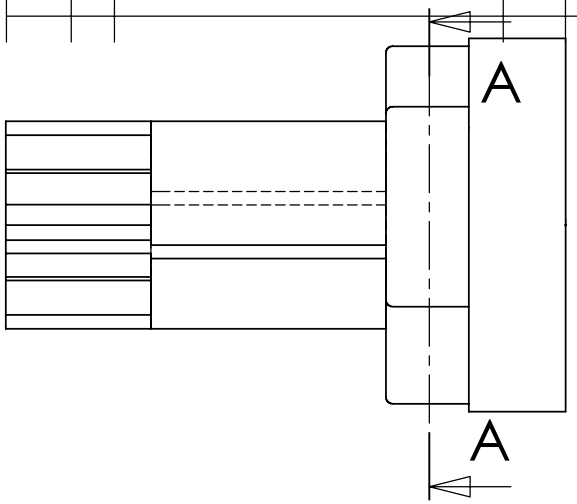
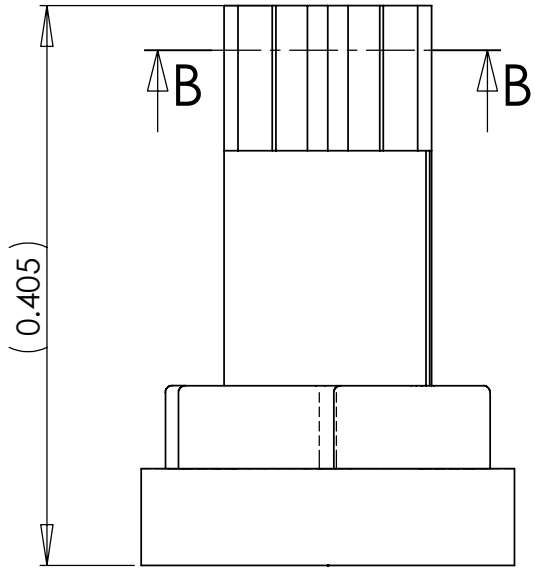


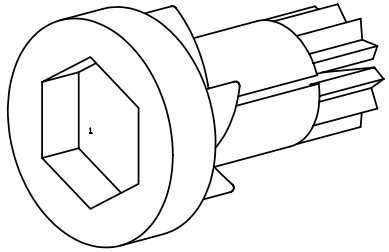


A-A



B-B





REVISIONS				
ZONE	REV.	DESCRIPTION	DATE	APPROVED

NEXT ASSY	USED ON
APPLICATION	

DIMENSIONS ARE IN INCHES
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±

MATERIAL --

FINISH --

DO NOT SCALE DRAWING

	NAME	DATE
DRAWN	JKUNIHOLM	19FEB2003
CHECKED		
ENG APPR.		
MFG APPR.		
Q.A.		

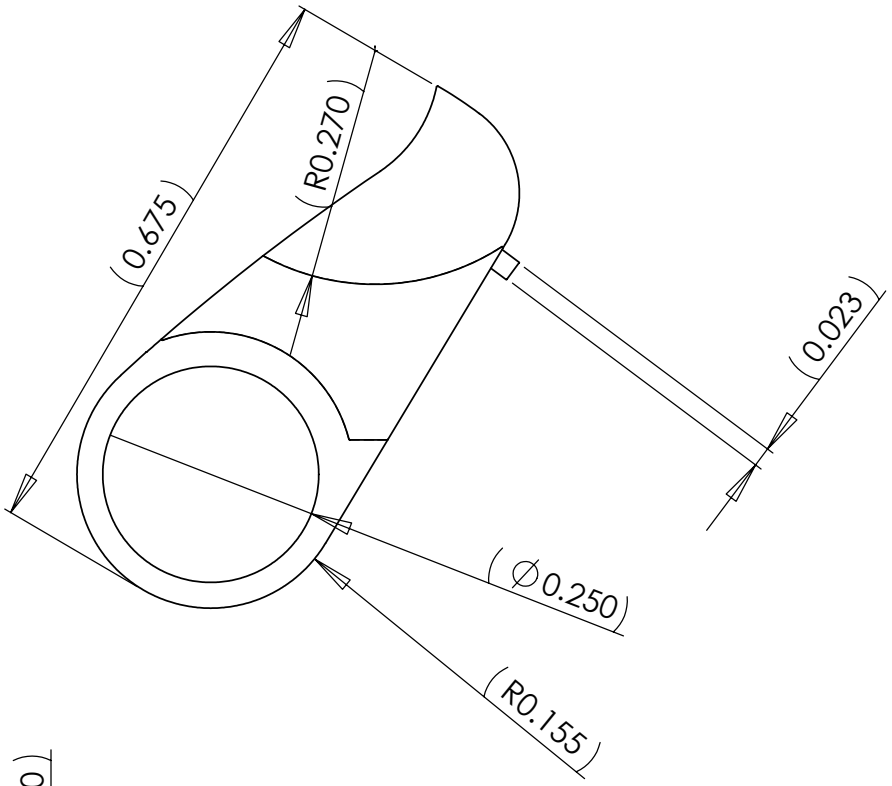
COMMENTS:

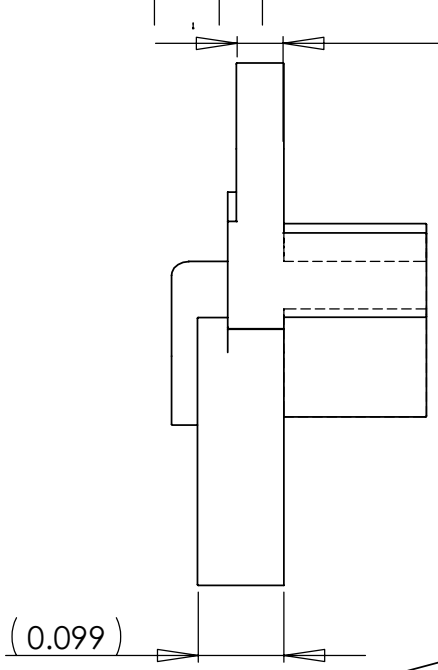
North Carolina State University

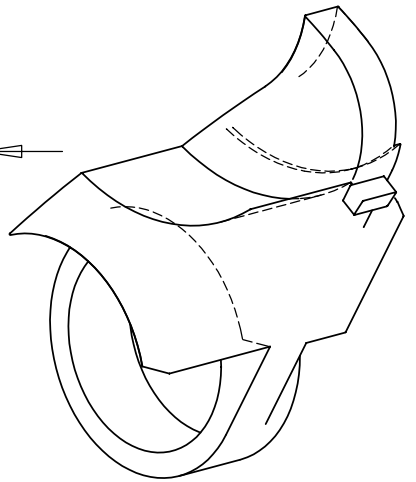
Suture Cartridge Spring Arbor

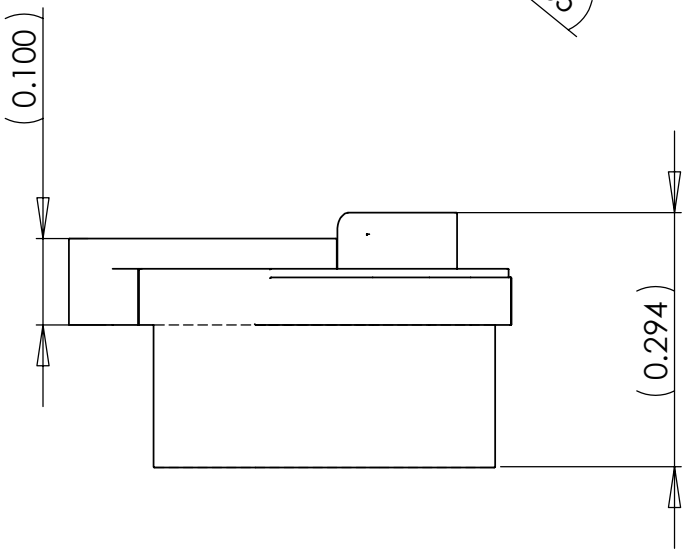
SIZE	DWG. NO.	REV.
A		
SCALE:8:1	WEIGHT:	SHEET 5 OF 12

REVISIONS				
ZONE	REV.	DESCRIPTION	DATE	APPROVED









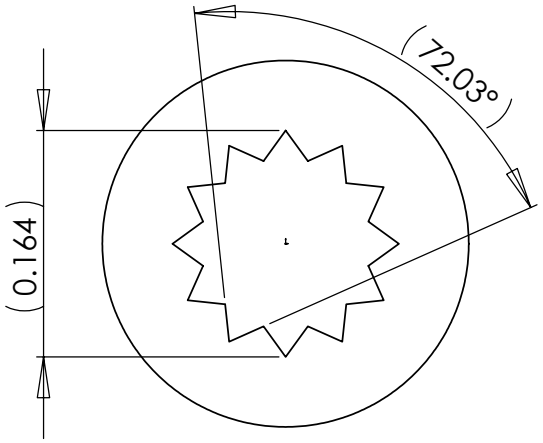
		DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± THREE PLACE DECIMAL ±		NAME	DATE
			DRAWN	JKUNIHOLM	19FEB2003
			CHECKED		
			ENG APPR.		
			MFG APPR.		
			Q.A.		
		MATERIAL --	COMMENTS:		
NEXT ASSY	USED ON	FINISH --			
APPLICATION		DO NOT SCALE DRAWING			

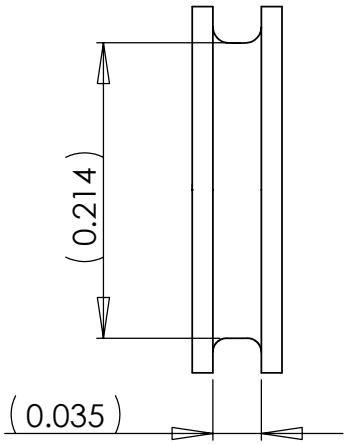
North Carolina State University

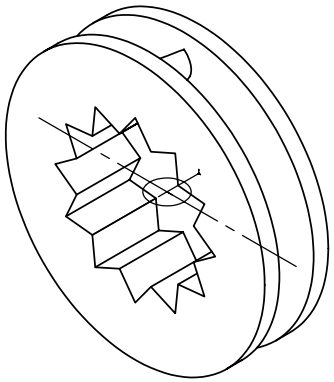
Suture Cartridge Pawl

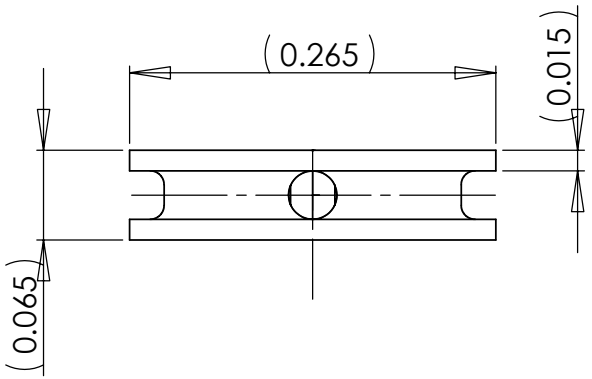
SIZE	DWG. NO.	REV.
A		
SCALE:5:1	WEIGHT:	SHEET 6 OF 12

ZONE	REV.	REVISIONS DESCRIPTION	DATE	APPROVED









		DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± THREE PLACE DECIMAL ±
		MATERIAL --
NEXT ASSY	USED ON	FINISH --
APPLICATION		DO NOT SCALE DRAWING

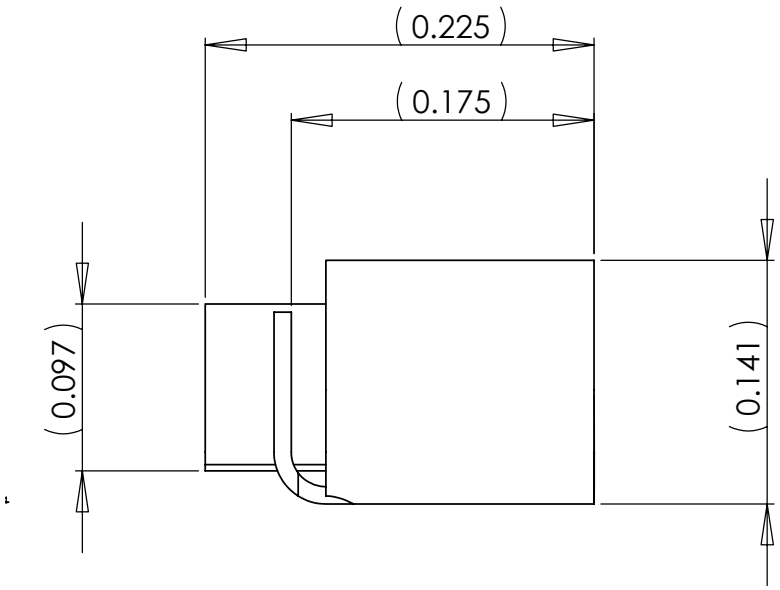
	NAME	DATE
DRAWN	JKUNIHOLM	19FEB2003
CHECKED		
ENG APPR.		
MFG APPR.		
Q.A.		
COMMENTS:		

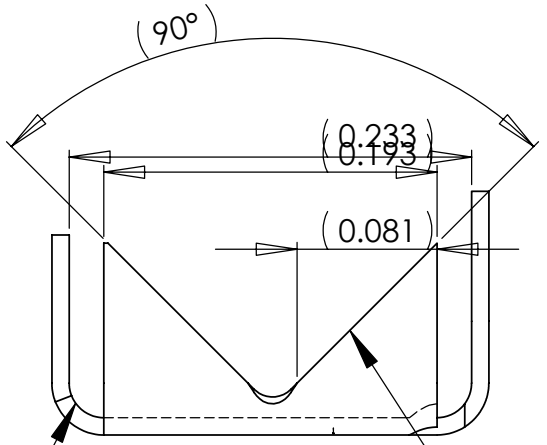
North Carolina State University

Suture Cartridge
Suture Takeup Spool

SIZE	DWG. NO.	REV.
A		
SCALE:8:1	WEIGHT:	SHEET 7 OF 12

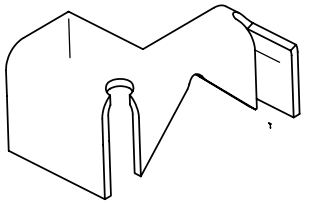
REVISIONS				
ZONE	REV.	DESCRIPTION	DATE	APPROVED

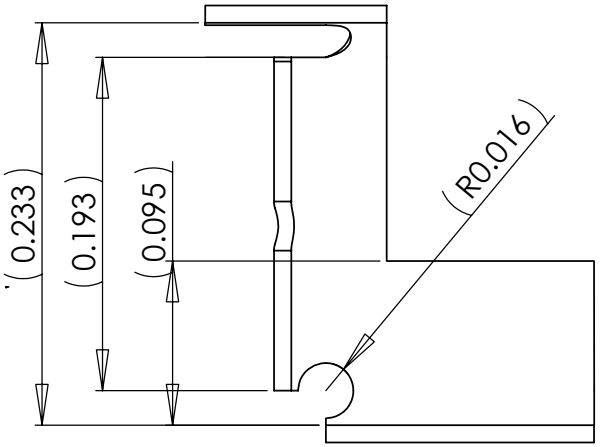




Razor Edge

All bends radius 0.020"





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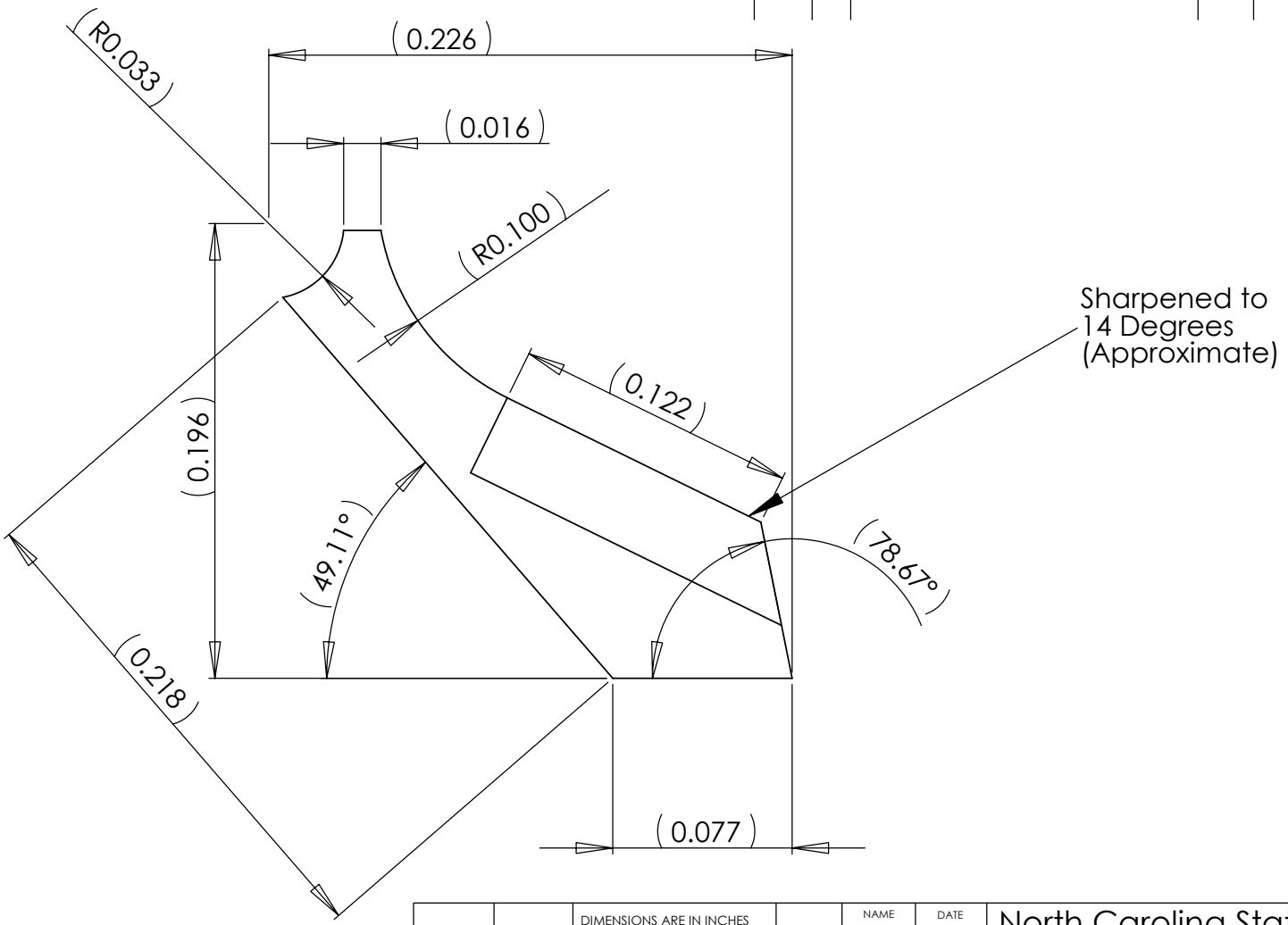
			DRAWN	JKUNIHOLM	19FEB2003
			CHECKED		
			ENG APPR.		
			MFG APPR.		
		MATERIAL --	Q.A.		
NEXT ASSY	USED ON	FINISH --	COMMENTS: ALL MATERIAL 0.009" STAINLESS ALL BENDS 0.020" RADIUS		
APPLICATION		DO NOT SCALE DRAWING			

North Carolina State University

Suture Cartridge Interior Cutter

SIZE	DWG. NO.	REV.
A		
SCALE:10:1	WEIGHT:	SHEET 8 OF 12

		REVISIONS		
ZONE	REV.	DESCRIPTION	DATE	APPROVED



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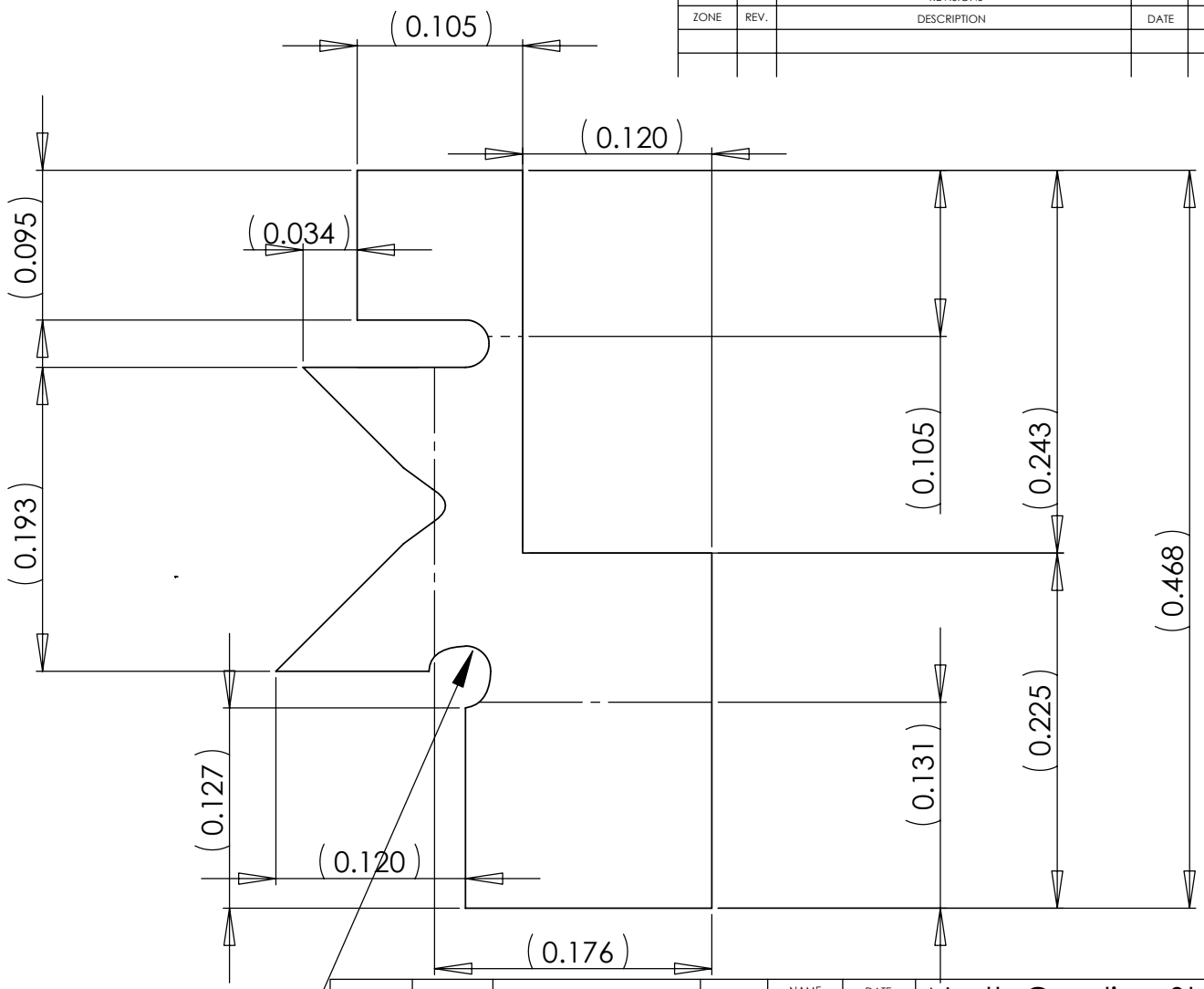
			DRAWN	JKUNIHOLM	19FEB2003
			CHECKED		
			ENG APPR.		
			MFG APPR.		
			Q.A.		
		MATERIAL --	COMMENTS: MATERIAL 0.009" STAINLESS		
NEXT ASSY	USED ON	FINISH --			
APPLICATION		DO NOT SCALE DRAWING			

North Carolina State University

Suture Cartridge Interior Cutter

SIZE	DWG. NO.	REV.
A		
SCALE:15:1	WEIGHT:	SHEET 9 OF 12



REVISIONS				
ZONE	REV.	DESCRIPTION	DATE	APPROVED

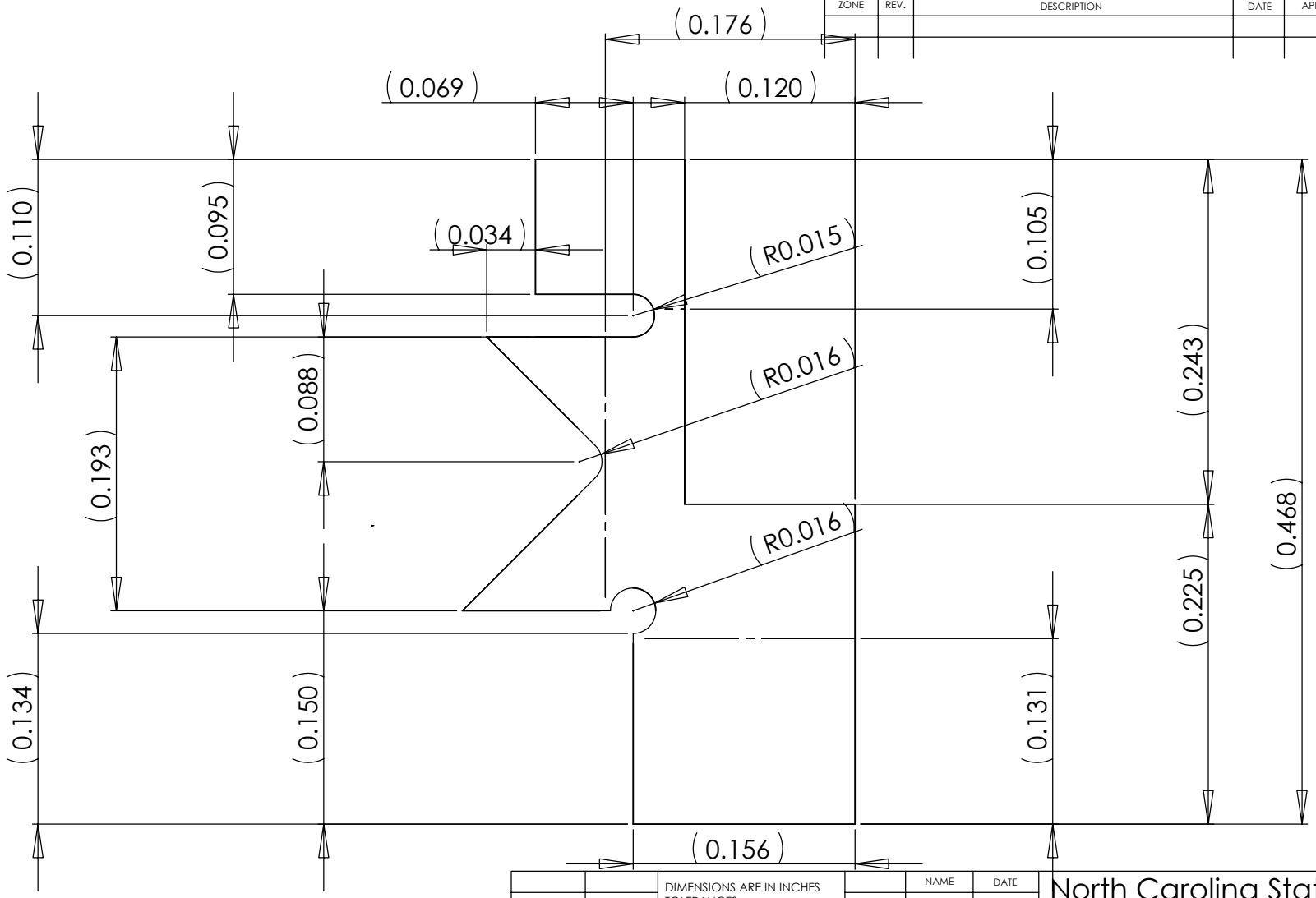
Deformity from SolidWorks Sheet
Metal Unfolding--See Interior Cutter Blank
Drawing for Fabrication Dimensions

			NAME	DATE
DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± THREE PLACE DECIMAL ±		DRAWN	JKUNIHOLM	19FEB2003
		CHECKED		
		ENG APPR.		
		MFG APPR.		
		Q.A.		
MATERIAL --		COMMENTS:		
NEXT ASSY	USED ON	FINISH --	ALL MATERIAL 0.009" STAINLESS ALL BENDS 0.020" RADIUS	
APPLICATION		DO NOT SCALE DRAWING		

North Carolina State University

Suture Cartridge
Interior Cutter (Unfolded)

SIZE	DWG. NO.	REV.
A		
SCALE:10:1	WEIGHT:	SHEET 10 OF 12



REVISIONS				
ZONE	REV.	DESCRIPTION	DATE	APPROVED

	NAME	DATE
DRAWN	JKUNIHOLM	19FEB2003
CHECKED		
ENG APPR.		
MFG APPR.		
Q.A.		

DIMENSIONS ARE IN INCHES
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ± BEND ±
TWO PLACE DECIMAL ±
THREE PLACE DECIMAL ±

MATERIAL --

FINISH --

NEXT ASSY | USED ON

APPLICATION

DO NOT SCALE DRAWING

COMMENTS:

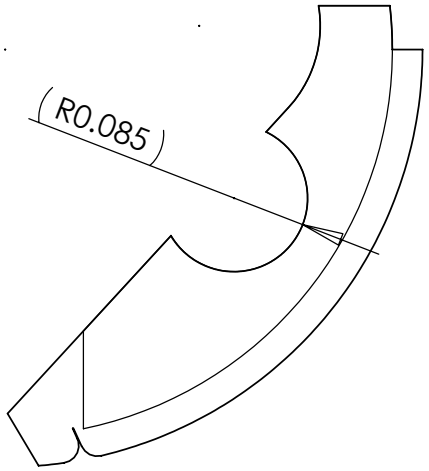
North Carolina State University

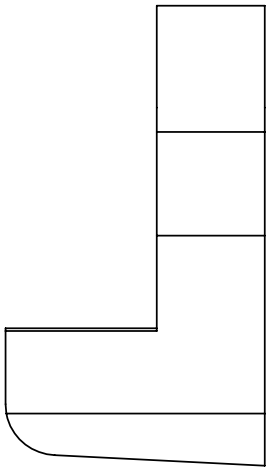
Suture Cartridge Interior Cutter Blank

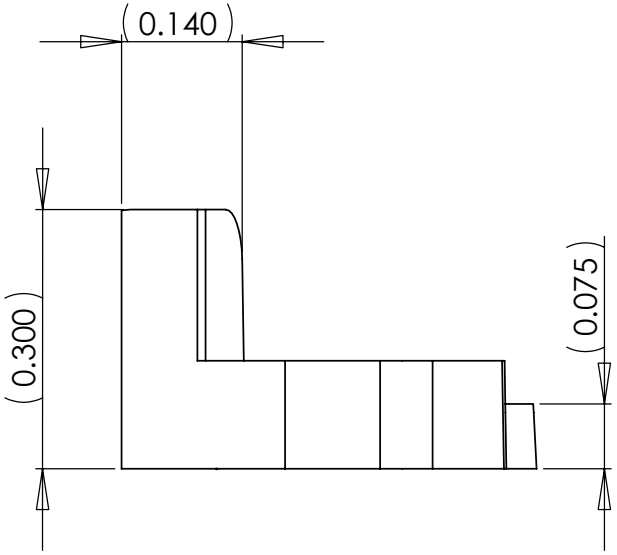
SIZE	DWG. NO.	REV.
A		

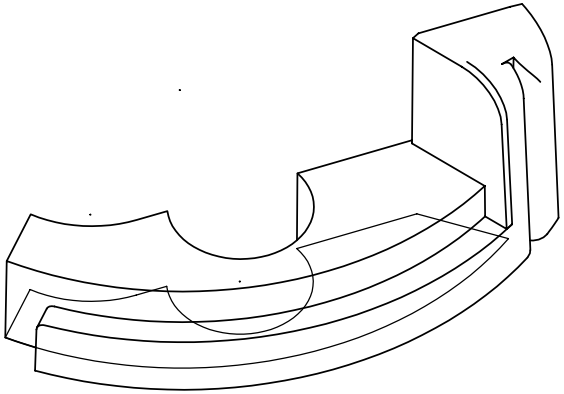
SCALE:10:1 | WEIGHT: | SHEET 11 OF 12

REVISIONS				
ZONE	REV.	DESCRIPTION	DATE	APPROVED







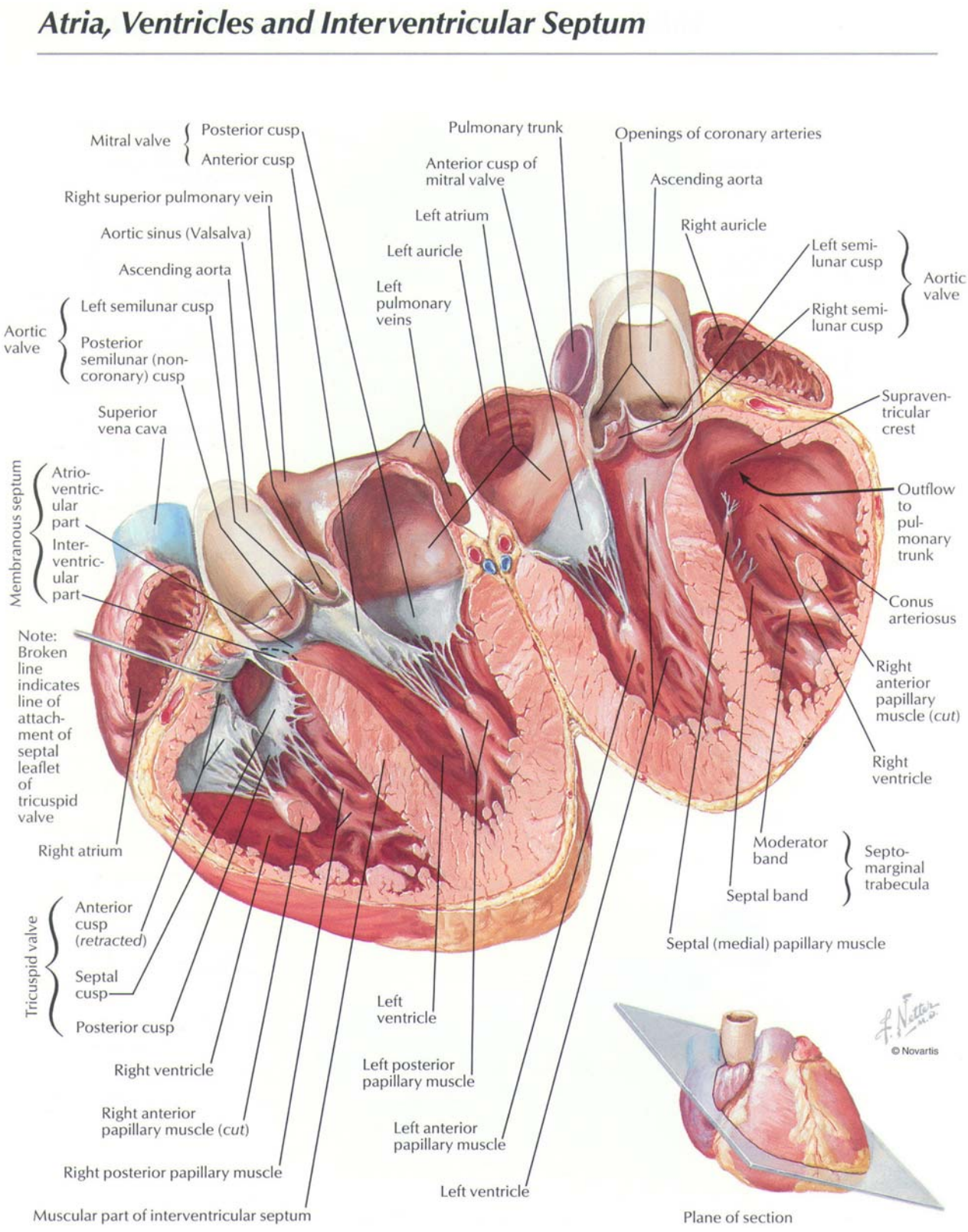


		DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ± BEND ± TWO PLACE DECIMAL ± THREE PLACE DECIMAL ±		NAME	DATE
			DRAWN	JKUNIHOLM	19FEB2003
			CHECKED		
			ENG APPR.		
			MFG APPR.		
		MATERIAL --	Q.A.		
NEXT ASSY	USED ON	FINISH --	COMMENTS:		
APPLICATION		DO NOT SCALE DRAWING			

North Carolina State University
Suture Cartridge Elastomer Cleat Insert

SIZE	DWG. NO.	REV.
A		
SCALE:5:1	WEIGHT:	SHEET 12 OF 12

Appendix B: Heart Anatomy[38]



Appendix C: Videos of Manual and Device Knotting

Click on the images below to launch short videos of manual knot tying and device knot deployment using the da Vinci robotic surgical system (electronic version).

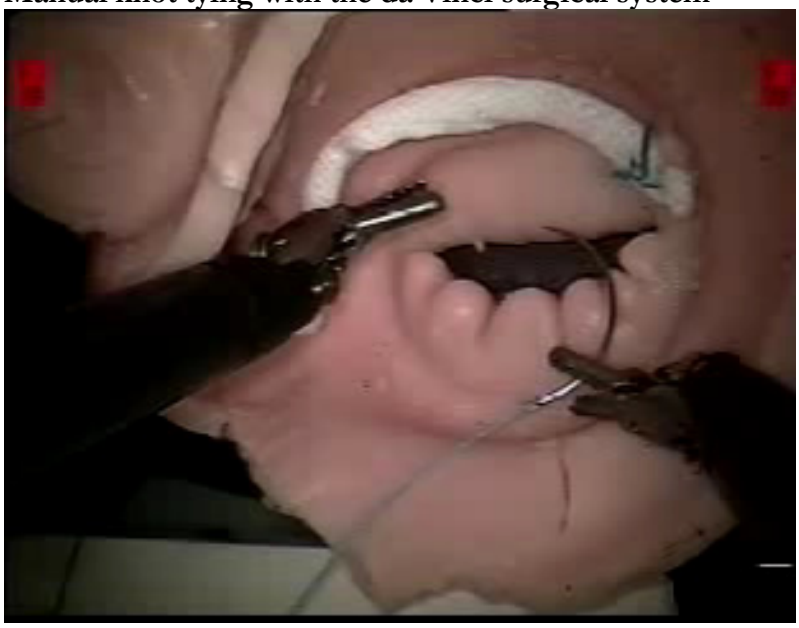
Manual knot tying with the da Vinci surgical system

Knot deployment with the Suture Cartridge

Appendix C: Videos of Manual and Device Knotting

Click on the images below to launch short videos of manual knot tying and device knot deployment using the da Vinci robotic surgical system (electronic version).

Manual knot tying with the da Vinci surgical system



Knot deployment with the Suture Cartridge