

# Radiofrequency Ablation Catheter

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Statement of Confidentiality

The complete senior project report was submitted to the project advisor and sponsor. The results of this project are of a confidential nature and will not be published at this time.

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Medtronic Ablation Frontiers

# Radiofrequency Ablation Catheter

Shaft Design Report

Prepared by: Amand Kasimatis and Ryan Razzari  
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## Abstract

Medtronic Ablation Frontiers develops ablation catheters to treat atrial fibrillation. The design of their catheters is unique in that it employs multiple electrodes to dramatically decrease surgery time and the quality of lesion during the ablation process whereas most competitors' catheters use a single tip electrode.

The current design of Medtronic Ablation Frontier's catheter, TVAC, routes the signal wires, wiring necessary for delivery of energy to the electrodes and measurement of electrode temperature, through the central lumen of the shaft. A competitive company, CathRx based in Australia, produces a similar catheter that incorporates the signal wires in a helical structure within the polymer wall surrounding the central lumen.

The objective of the project is to incorporate the signal wires into the braid structure leaving the central lumen of the TVAC free for other features such as a liquid cooling system. A secondary but crucial objective is the ability to expose the intersection of two wires within the polymer wall for attachment to the electrode and to be able to consistently identify each wire at the proximal end of the shaft for attachment to the connector.

After the consideration of several concepts, a circular design that incorporates two braids, one of signal wires and another of stainless steel support wires, was determined as the most viable design. The signal wire braid consists of eight bifilar wires, but only six of them are functional.

A graphical user interface (GUI) has been developed to track the radial position of the signal wires along the length of the shaft based on the radial starting position of the wire. It is able to take user inputs such as braid density and number of wires so that the interface can be adapted to other products or design changes.

A number of test procedures are already in place by Ablation Frontiers to ensure that the product is fully functional, safe, and meets all design requirements. Some of these tests include buckling, temperature, and fatigue. However, a new procedure to verify the accuracy of the GUI was needed.

Due to time and geometric constraints, certain aspects of the project were reduced to simplify the scope of the project. Both the guide plate and the steering wires have been removed from the design of the required prototype catheters. In addition, the new design complicates the manufacturing process for the T-VAC. The cuts made in the catheter body to access the signal wires are no longer in a linear array. Incorporating the signal wires into the body of the catheter in a braid structure inherently alters the access points for electrode attachment.



## Chapter 1 – Introduction

### Sponsor Background

Medtronic Ablation Frontiers has developed an RF ablation catheter, a surgical tool used to cure atrial fibrillation. Due to the mechanical abilities and level of control in the current model, it is not limited strictly to use in one particular chamber of the heart. The current model is unique in that it uses multiple RF electrodes in comparison to other catheters that only use one. The use of multiple electrodes dramatically decreases the procedure time because clinicians do not have to ablate point to point. The ability to ablate multiple locations at once creates a more consistent lesion compared to a single tip electrode catheter. However the high number of electrodes requires an increased number of wires within the central lumen of the catheter which can be seen in Figure 1.

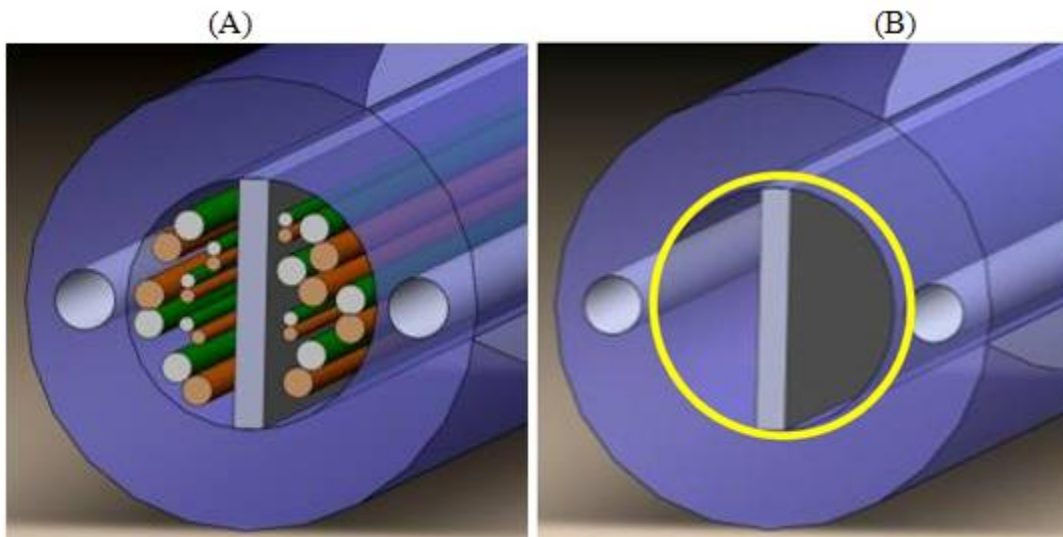


Figure 1:(A) Current Catheter Model. (B) Design will remove the wiring from the center lumen and incorporate them into the braiding.

Diagrams courtesy of Medtronic Project Presentation PowerPoint.

### Scope

The scope of this project is to incorporate the signal wires as the braided structure to free up the center channel of the catheter and to develop a method of tracking the individual wires along the length of the shaft. Medtronic Ablation Frontiers plans to utilize the newly emptied center channel by possibly running a saline solution or liquid nitrogen enclosed in a nitinol tube to cool the electrodes. This will allow for the electrodes to be run at higher powers without excessive temperature for longer periods of time, it can also lead the way to the addition of more electrodes on the catheter shaft.

### Objectives

The focus of this project is to develop an energy delivery structure incorporated into the braid structure of the TVAC shaft. It will be necessary to redesign the braiding structure to achieve the

requirements for the functionality of the catheter and to leave room for the addition of new features for the ablation catheter.

It requires that the materials used must be medical grade and compatible with E-beam radiation sterilization. The catheter shaft must retain the two-directional steering capability and remain the same in diameter and length. There will be signal wires capable of carrying the proper amount of power to perform RF ablation to each electrode. The catheter will be small enough and have a maximum bend radius smaller than the curves of the artery, 20 mm, to move through the cardiovascular system from the entry point to the atriums of the heart. The tip of the shaft will be the steerable section with a full range of motion and it is necessary to be able to transmit a torque to the tip of the shaft to accomplish complete steering capability in all directions. In addition, the tip must be able to buckle under a minimum compressive force to prevent puncturing or damaging the walls of the heart. Upon manufacturing, it must be easy to determine the position of each thermocouple wire on the distal portion of the shaft. The outer surface of the catheter shaft cannot exceed 41° C to prevent thrombus formation within the sheath and must be measured within two degrees to help maintain the temperature. All portions of the shaft must be able to withstand a tensile force greater than the force applied by the pull cables.

The final deliverables for the project are a 3D model in SolidWorks, a listing of the shaft components, and manufacturing of a prototype. Table 1 shows the formal engineering requirements for the project. The diameter of the shaft is listed as high risk since a significantly higher amount of braid strands need to be included outside the center lumen, which may make it difficult to keep the diameter within the required range. Increases in diameter facilitate the use of larger sheaths and are potentially detrimental effects on steering and mobility. The maneuverability of the catheter is also a high risk area because we will need to focus on maintaining the pliable nature while still meeting our requirements for the braid structure.

From the engineering requirements that are listed in Table 1 a Quality Function Deployment (QFD) chart was created for the T-VAC Catheter which can be seen in Appendix A. The QFD is used to identify all customer requirements and engineering specifications. The important features of the QFD are flexibility, ease of use, and short surgery time. The flexibility of the catheter shaft is an integral part of the overall design because the catheter will have to flex and bend as it traverses through vascular vessels. One of the main purposes of this project is to potentially extend the run time of the catheter. The implementation of a cooling system would allow an increase in the electrodes duty cycle and reduce the surgery time.

Spec. #	Parameter Description	Requirement	Tolerance	Risk	Compliance
1	Diameter	7F (0.092")	Max	H	A, S
2	Length	52"	±1.0"	L	S
3	Steerable Length	≈5"	None Specified	L	S, I
4	Steering Directions	2	NA	L	S
5	Tip Deflection	180°	Min	M	A, I
	Bend Radius	10 mm			
6	Maneuverability	9.5F (0.125")	Min	H	A, S, I
7	Wiring	12 Wires	NA	M	S, I
8	Power	45W tip 20W for electrode band	Min	L	A, S
9	Max Shaft Temperature	41°C	Max	M	A, T
10	Tip Buckling	340 gf	Min	M	A, T
11	Shaft Tensile Force	10 lb	Min	L	A, T, S

Table 1. Design Specification with Risk Factors. A=Analysis, T=Testing, I=Inspection, S=Similar to Previous Design

As we developed the QFD chart it became apparent that the tip deflection, consisting of a minimum of 180° range of motion per direction, is a key area of the design of the shaft in that it highly correlates to a large portion of the engineering requirements. The cooling system, wiring, and gage are also important areas that will determine a fair amount of the final design.

Maneuverability is also an item that we discovered will have a major influence in the outcome of the final design. One of the biggest challenges associated with any braid design will be the ability to determine the final position of the thermocouple wires in order to expose them to the corresponding electrode. Incorporating the thermocouple wires into the braid structure causes individual thermocouple wires to change position around the cross section at different lengths along the shaft making it difficult to know which thermocouple wire corresponds to each electrode.

## Chapter 2 – Background

Atrial fibrillation is a disease that affects over 2.2 million people in the United States making it one of the most common diseases in the country. It is characterized by bouts of rapid heart beating where the atria can beat upwards of 250 beats per min. This rapid rate prevents the atria from fully expanding and contracting which does not allow it to pump blood efficiently to the rest of the body. It is caused by errant electrical pathways that disrupt the primary electrical impulses generated by the Atrio-Ventricular Node.

Radio Frequency (RF) ablation is a technique used to correct this defect. When using a radiofrequency ablation catheter, a thin and flexible catheter is inserted through a blood vessel and directed to the heart muscle. Once in position the catheter delivers radiofrequency energy, this energy is used to burn the tissue so that it is no longer able to carry the errant signal. A similar technique uses cryoablation to freeze the tissue to prevent the signal from being conducted along the wrong path instead of burning it.

The success of the procedure is dependent on the continuity of the array of lesions burned onto the tissue. The lesions must be continuous and transmural (spans from inside to outside surface of the muscle tissue) in order to isolate the signal causing the fibrillation. The depth of the lesion is crucial to the subsurface continuity. Multiple variables control the depth of the lesion including burn time and temperature of the electrodes. Temperature is controlled by either regulating the voltage running through the electrodes or using a thermocouple to measure the temperature which is the method Medtronic Ablation Frontiers uses on its current model.

Medtronic Ablation Frontiers produces an advanced radiofrequency ablation catheter which uses 6 electrodes to deliver radiofrequency energy to the target sites in the atria. The current design of this vascular catheter has all of the necessary thermocouple and signal wires for the electrodes running down the center of the catheter shaft, as well as a braided steel structure that helps support and stabilize the catheter shaft. The braided strands are positioned outside of the center channel of the catheter where the thermocouple and signal wires run.

Currently an Australian based company, CathRx, produces an ablation catheter which removes the signal wires from the center lumen. Their design arranges the signal wires in a tight helical pattern around the center lumen leaving it free for additional features. The signal wires are impregnated with a Pebax<sup>®</sup> matrix to form the outer coating of the catheter. CathRx employs a unique manufacturing process in their electrode design. The electrodes have a rough texture as a result of the electroless plating technique used to place the electrodes on the body of the catheter shaft.

Control of the movement of an ablation catheter is crucial because of the severity of the consequences that can arise as a result of a false movement during the procedure. Occurrences of catheter whipping have been found in some models of catheters resulting in puncturing the heart wall or inadvertently ablating the wrong site. Whipping occurs when the tip of the catheter reacts to a torque applied by the operator by spinning rapidly and lashing the wall of the tissue. Whipping is eliminated by removing any eccentricities in the geometry of the shaft and by including a guide plate along the neutral axis of the catheter.

Due to the complexity of the shaft and its many components, analysis requires the use of composite theories. Flexibility and stress requirements are determined through this analysis and allow for the validation of the concept designs. A combination of micromechanics and laminated plate theory are adapted to apply to the tubular shape of the catheter shaft.

There are many intricacies that will have an impact on the future of this project. A fair portion of these intricacies are related to the challenges of making a product that will enter the human body. Products that deal with the human body are subject to higher regulations and standards to make sure that the use of the product will be as safe as possible. Vascular catheters are no exception to these rules and regulations. Depending on where the catheter is to be used different certifications

are needed, i.e. in the European Union the product must receive the CE Mark, and in the United States the product must receive FDA approval. The following are standards that the catheter design must abide by:

- ISO 10555-1: 1995 Sterile, single-use intravascular catheters – Part 1: General requirements
- ISO 10555-2: 1996 Sterile, single-use intravascular catheters – Part 2: Angiographic catheters
- ISO 10993-1: 2003 Biological evaluation of medical devices – Part 1: Evaluation and testing
- ISO 11137-2: 2006 Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose
- ISO 11607-1: 2006 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2: 2006 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing, and assembly processes
- ISO 15223-1; 2007 Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements
- BS EN 552: 1994 Sterilization of medical devices – Validation and routine control of sterilization by irradiation
- BS EN 556: 1995 Sterilization of medical devices – Requirements for terminally sterilized devices to be labeled ‘sterile’
- BS EN 556-1: 2001 Sterilization of medical devices – Requirements for medical devices to be designated ‘Sterile’ – Part 1: Requirements for terminally sterilized medical devices
- BS EN 980: 2008 Symbols for use in the labeling of medical devices
- BS EN 60601-2: 2006 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- BS EN 60601-2-2: 2009 Medical electrical equipment – Part 2-2: Particular requirements for the safety of high frequency surgical equipment
- ASTM F1980-07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM D4169-04a Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM D4332-01: 2006 Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing

## State of the Art

The most difficult requirements to meet for the catheter shaft will be the flexibility and size requirements along with tracking the signal wires through the shaft. The concepts developed are geared toward meeting these requirements first and foremost. The concept designs were inspired by the electrical ribbons found in computers. Variations in the amount wires in each ribbon allows for a variation in the stiffness of the overall structure.

The TVAC catheter shaft is really a composite of two different shafts that meet at a tapered section. The main shaft of the catheter is a 9F (0.118 in) diameter shaft that contains a steel braid for support and stability along with the signal wires for the electrodes at the distal end of the catheter. The other component of the catheter shaft is the distal end of the catheter which drops to 7F (0.09 in) in diameter and contains the six electrodes used for ablation. The electrodes are 9F outer diameter rings of platinum that need to be attached to the outside of the 7F shaft, this means that the distal portion of the catheter must run inside of the electrodes. The inside diameter of the electrodes is 7F which is why the distal shaft drops to that diameter.

The two sections of the catheter are joined by placing the 7F distal shaft inside of the 9F shaft. The joint between the two shafts is reinforced with a sleeve of Pebax<sup>®</sup> during the thermal bonding process. The 7F shaft only exists from the joint to the distal end of the catheter; it is not in the proximal end of the catheter. A plastic lumen runs in the proximal shaft to help keep the interior shape of the catheter, the lumen is the same size and shape as the 7F shaft.

The interior portion of the shaft, both the 9F and 7F, houses the pairs of signal wires for the electrodes. The pairs of signal wires are combined into bifilar wire strands that are 36 gage in diameter. These wire pairs are made up of one copper wire and one constantan wire. Exterior to the plastic lumen but interior to the braid of the 9F shaft runs two pull wires that create the bidirectional steering capabilities of the catheter. When the shaft steps down to the 7F diameter the pull wires are woven into the braiding structure. The proximal ends of the pull wires are anchored at the handle of the catheter on a cam that allows for one pull wire to be put in tension. The distal ends of the pull wires are anchored to an anchoring ring at the very distal tip of the shaft, directly underneath the tip electrode.

In the distal portion of the shaft there is also a guide plate that helps the catheter retain its shape when it is bent by the pull wires. This guide plate also helps to keep the electrodes in plane when the catheter is being dragged during ablation.

The flexibility of the braid will be affected by the Pebax<sup>®</sup> casing that creates the exterior of the shaft. The durometer, a hardness measurement, of the Pebax<sup>®</sup> that is used to create the exterior sheath of the catheter is varied for the different portions of the catheter shaft. The 9F shaft of the catheter uses a Pebax<sup>®</sup> with a high durometer, around 70, to give the shaft more rigidity and strength. The proximal portion of the shaft must remain rigid to allow the catheter to traverse through the veins to the heart. The distal portion of the catheter shaft, the steerable section, uses a lower durometer Pebax<sup>®</sup> to allow for more flexibility since this is the portion of the shaft that needs to be manipulated.

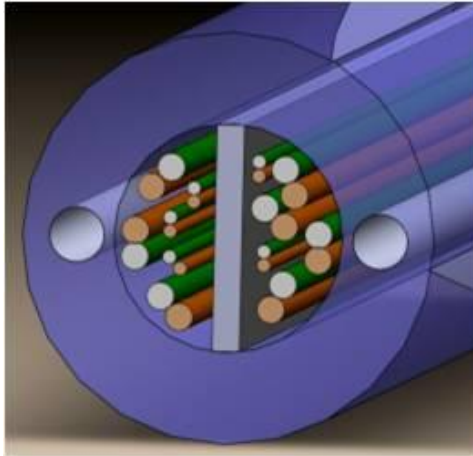


Figure 2. Cross sectional view of current TVAC catheter design used by Medtronic.

## Chapter 3 – Design Development

### Conceptual Designs

The first concept is a circular array of the signal wires. The signal wires will be equally spaced around the circumference of the 7F shaft and run linearly down the length of the shaft. This concept will be used as a baseline for the other concepts. The analysis performed on this concept can be benchmarked to the theoretical results of the other concepts developed down the line. The upside to this linear concept is that the design can be easily manufactured and the signal pairs can be easily picked off. The major downside of this design is that transmitting torque down the shaft will be difficult. This difficulty in the torque transmission will increase the likelihood of whipping. This concept will have issues with support and stability so the durometer of the Pebax<sup>®</sup> may have to be increased to accommodate for this effect. The effective EI, where E is the effective Young's Modulus and I is the moment of inertia, has been found to be approximately 4.36 pound force per square foot. The effective EI is the effective stiffness of the catheter shaft. The effective stiffness has been found using a combination of micromechanics and laminated plate theory. Through buckling analysis using Euler's buckling method it has been found that the critical effective stiffness that our design needs to have to comply with the critical load of 340 grams force is .027 pounds per square foot. The fact that the effective stiffness of this conceptual design is more than 150 times larger than our critical effective stiffness rules this out as a plausible avenue of design.

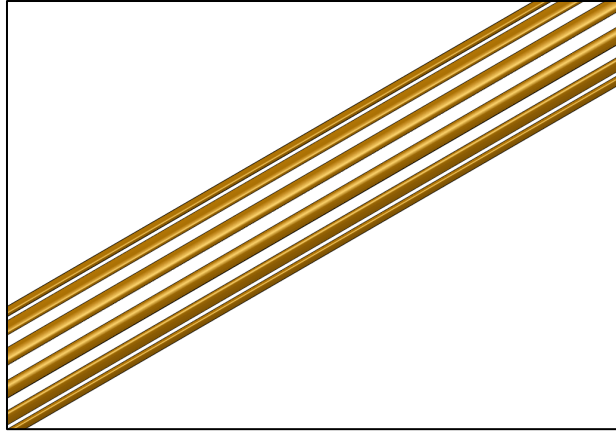


Figure 3. Linear array of 12 signal wires. This concept is to be used as a baseline for comparing other conceptual designs to.

Another concept that has been developed is a braid that consists of the 12 signal wires. This concept is very similar to the concept that is mentioned above only this design will incorporate the braiding whereas the previous was a linear array. This concept will braid the 12 wires together to provide the most structural support for the shaft. One way to overcome these effects will be to alter the durometer of the Pebax<sup>®</sup> to create the optimal conditions. This concept has the potential to be the most difficult to manufacture due to the amount of strands that need to be braided. Tracking the signal wire pairs will be extremely difficult for this design. It is essential to be able to quickly pick out the signal pairs for assembly purposes.

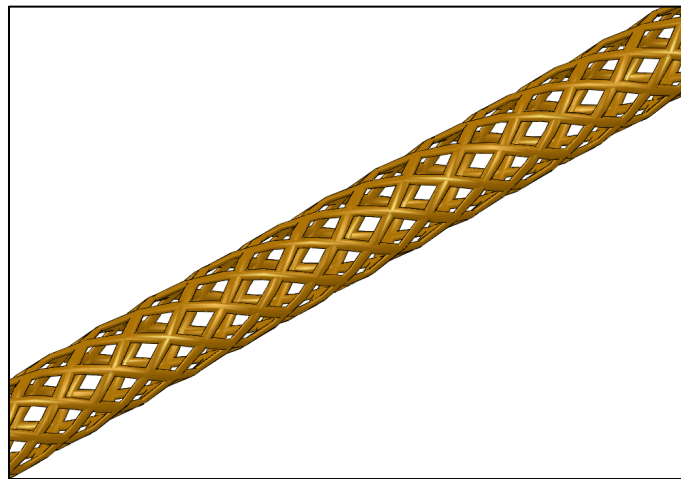


Figure 4. Conceptual design of 12 signal wires braided together. Has potential problems in flexibility and manufactureability.

The third concept is to have six strands consisting of 2 sets of signal wires. The six strands will create larger gaps between each braid strand which will lower the amount of flexibility throughout the shaft. Again the durometer of the Pebax<sup>®</sup> casing can be altered accordingly to get the optimum relationship between strength and flexibility. This concept will increase the ease of picking off signal pairs. The biggest shortcoming of this design is its difficulty in manufacturing. The high amount of strands makes the braid process more difficult than a traditional two or three strand braid configuration.



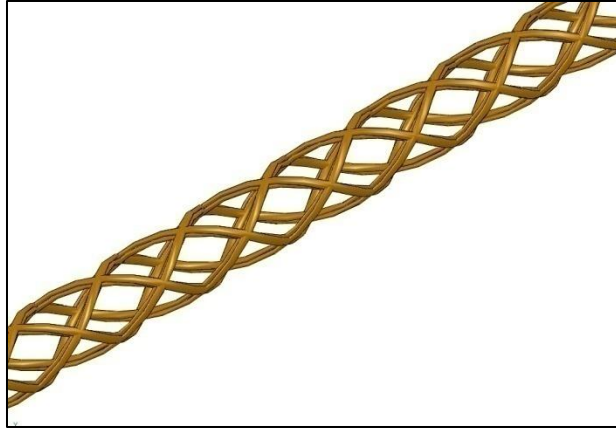


Figure 5. Conceptual design of 6 sets of signal wire pairs formed into braided structure.

The primary design for the catheter shaft has three ribbons consisting of four signal wires. This design is optimal because it allows for the stiffness of the shaft to stay low while maintaining a simple braid manufacturing technique. The braid design contains more spacing between the different arcs of each set of wires which allows for more flexibility. The thickness of the ribbons will help in the structural support of the shaft and will reduce the need to alter the durometer of the Pebax<sup>®</sup>. Altering the durometer of the Pebax<sup>®</sup> is the simplest way to optimize the flexibility and strength of the shaft.

This design also allows for the pull wires to be easily woven into the braid so that they will not pull out or distend the catheter body when force is applied. The torque transmission through this conceptual design will be much easier than through the non-braided concept. The structure of this braid will allow the transmission of the torque to occur close to a 1 to 1 ratio. One difficulty that may arise in any design is keeping track of the specific signal wires to correspond to the individual electrodes; however this design will be easier than the 12 wire braid. The helix angle for this concept can be optimized during our analysis to create the best possible braid structure.

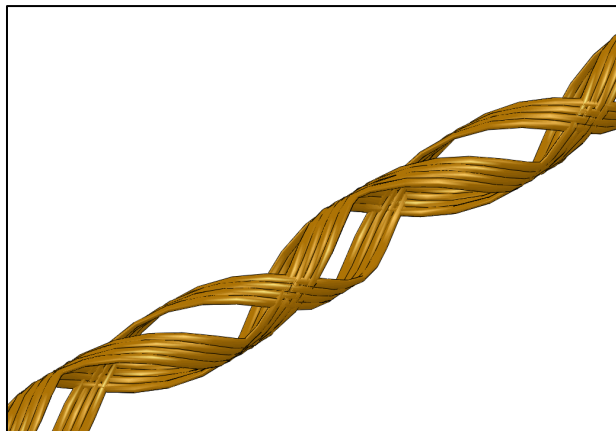


Figure 6. Three strand braid concept. Contains three strands that are made up of ribbons of signal wires. Each ribbon contains 4 sets of signal wires. This design potentially has the best flexibility to strength ratio of the concepts listed.

The last concept is dramatically different from the rest of the concepts. The cross section of the catheter is elliptical and only the signal wires make up the braid. The pull wires are aligned on the minor axis of the ellipse making it easier to deflect in the steering directions

If temperature change to the surface of the catheter is determined as a major issue, this design buries the signal wires, the heat producing elements, deeper in the insulation to minimize the any heat loss to the surroundings.

Accessibility of individual wires is an issue in this design. Aligning the signal wires along the major axis makes it difficult to access the wires close to the center of the shaft. Accessing the individual strands of the signal wires will again provide a challenge in this design since the change position in the cross section along the length of the shaft.

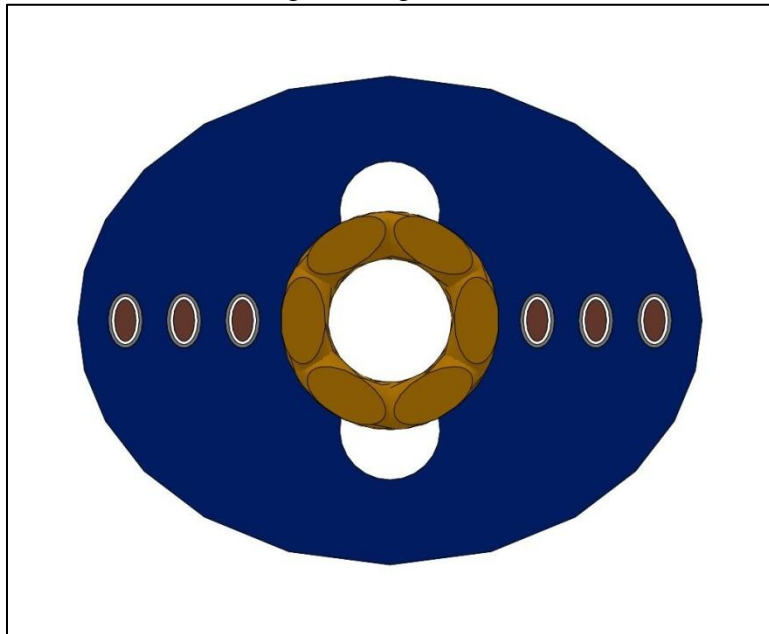


Figure 7 : Elliptical Concept. The signal wires make up the braid structure and the pull wires are aligned along the minor axis of the ellipse.

## Concept Selection

The selection of a concept is based upon the concepts ability to meet the performance requirements set by Medtronic Ablation Frontiers. Composite models were developed in MatLab to analyze the concepts pertaining to their flexibility and ability to transmit torque, as detailed above in the QFD table. The MatLab program was originally developed by Dr. Mello and is has been adapted to the catheter structure. Concepts that meet the minimum requirements in these areas will be considered.

Because a large portion of the assembly of the current TVAC catheter is done manually, ease of assembly has become a major criterion for selecting a concept. After visiting the facility and observing the assembly process in the clean room, judgment of the ease of assembly using the current assembly process and techniques can be made for each concept. Although some process

may need to be changed to accommodate the requirements set for the project, stages of the assembly need to be considered such as accessing the energy wires and determining the location of each wire and either end of the shaft.

## Preliminary Analysis

The only preliminary analysis that was relevant for the concepts is the shaft geometry. Because of the severe size constraints, it is important to make sure that the braid design fits within the required limits. The desired center lumen diameter is 0.05 in and the maximum out diameter is 7F (0.09 in). After determining the minimum circumference that can be made by the braid design based on the size of the 36 gage wire major axis, all concepts fit within the space limitations. Some concepts used more of the allotted space than others, but all of them satisfied the size requirement.

Other forms of analysis are in the process of being developed to further test the validity of the concepts. A MatLab model of the composite structure is being tested which will output the effective modulus of elasticity ( $E_{\text{eff}}$ ), effective flexural modulus ( $G_{\text{eff}}$ ), and effective stiffness ( $EI_{\text{eff}}$ ). Preliminary analysis has also been done on the buckling requirement for this design project using Euler's buckling model. For this analysis the critical load has been given in the form of a design requirement in that the catheter shaft must buckle before reaching 340 grams force. Using this critical load it is possible to calculate a critical stiffness,  $EI_{\text{crit}}$ , of 0.027 pounds per square foot. This means that as long as the effective stiffness calculated by the MatLab program discussed above is equal to or less than  $EI_{\text{crit}}$  then the catheter shaft will buckle in an acceptable manner.

## Chapter 4 - Final Design

The final design is based on the elliptical concept, however the overall shape of the catheter shaft will be circular due to size constraints. After preliminary analysis and sketches were completed it was found that if an elliptical cross section were to be used the minor diameter would be so similar to the major diameter that there would be no significant impact. This discovery led to the implementation of a circular cross section which will allow for more spacing options and larger tolerances/clearances on the placement of wires within the shaft. The tolerances/clearances that are of importance are the distance from the outer wires to the outer wall of the catheter shaft. An eight strand stainless steel braid has been included to provide restitution to the catheter that copper wiring cannot provide on its own. The six signal wires are arranged in the braid pattern around the center lumen, however two more signal wires had to be added due to manufacturing limitations. A Pebax<sup>®</sup> matrix will be placed and impregnated around the braid to provide more structural support and biocompatibility. A diagram of the basic design geometry can be seen in Figure 8 below.

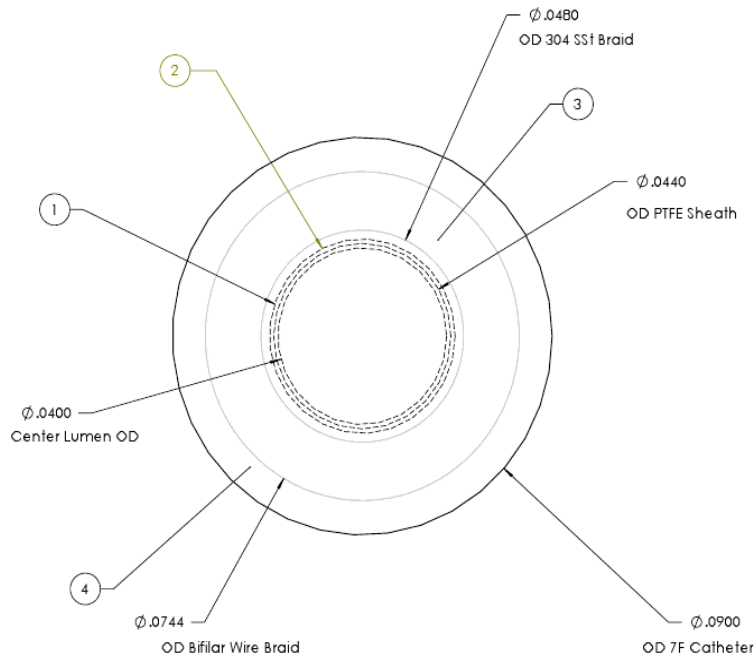


Figure 8: Final design with the inner stainless steel braid surrounded by the signal wire braid. The braids are represented by two layers of concentric helical structures each due to limitations in computing the model

A major objective of the project is to develop a method of tracking the position of the individual signal wires along the length of the shaft. A Graphical User Interface (GUI) has been developed in MatLab which determines the final radial position of the individual strands based on the starting position of the strand and the distance along the shaft the user is interested in. The algorithm for the GUI is based on a helical pattern of the strands that incorporates the variation in diameter during the over-under pattern that occurs in a braid. The GUI was created using a GUI creator in MatLab that will allow for easy implementation of the algorithms that have been created for the other design portions. The ultimate goal of the GUI is to have the user input a desired wire they are wishing to connect an electrode to and the length down the catheter shaft where the electrode needs to be positioned. From this data the GUI determines and presents the end position of the wire strand in question

## Detailed Design

A labeled cross section of the design geometry can be seen in Figure 9. The signal wires are bifilar 36 gage (component specification in Appendix C) consisting of copper and constantan. The signal wires must be large to hold the current that runs through them. The braid has eight strands consisting of the 36 gage signal wires with a density of 30 ppi. The average diameter of the braid is 0.068 in (detailed drawings can be seen in Appendix B). The outer coating of the shaft will be made of Pebax<sup>®</sup> 3533 with a durometer that will be softer than the current TVAC design. The logic behind keeping the durometer of the Pebax<sup>®</sup> is that the majority of the analysis performed for this project is on the braid structure. An assumption has been made that the matrix material will not contribute a large enough amount to affect the effective stiffness of the braid, which analysis listed below has confirmed. Because of limitations in manufacturing, the braids are forced to be stiffer than the original design, so a lower durometer will be needed to keep the

overall stiffness low. The durometer of the 7F section will be less than that of the main body of the shaft (9F) to allow the required amount of tip deflection. The center lumen of the catheter shaft has been downsized from the current TVAC diameter of .05 inches to .04 inches to allow for more internal space for the signal wire braid as well as the signal wires.

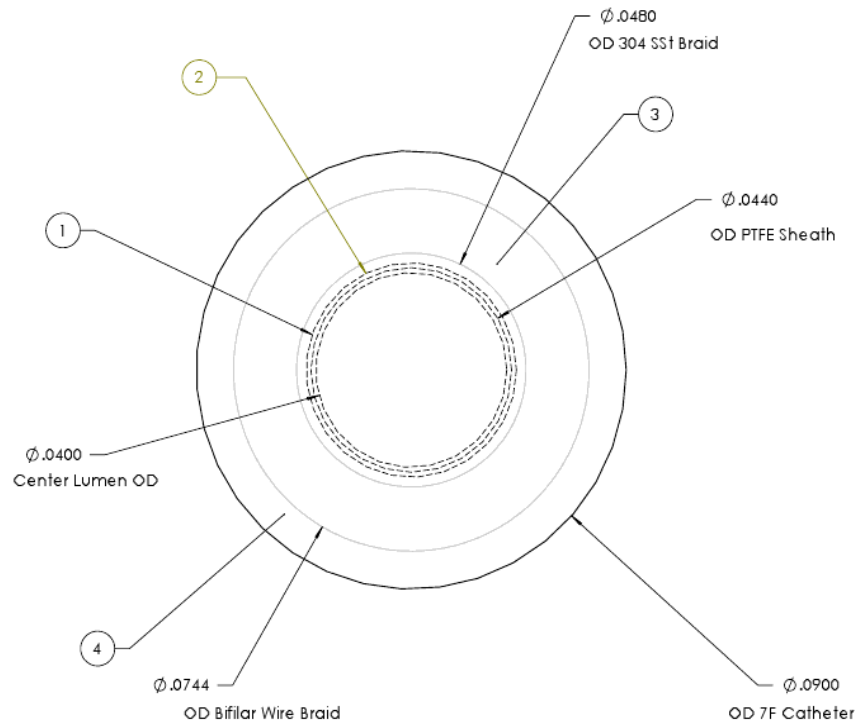


Figure 9: Labeled two braid design. The signal wires are braided around the stainless steel braid. The stainless steel braid provides structural support and spring properties that signal wire braid does not have.

The GUI (Figure 10) will be able to let the user input the starting position and the distance along the shaft toward the distal end where they would like to know the radial position of the wire. Other parameters are the signal wire braid density, number of wires in the braid, catheter outer diameter of the selected distal location, and selected wire that user inputs to fully define the braid. The ability to quickly change the catheter signal braid parameters lets the program determine the location of any braid structure for any catheter where Medtronic Ablation Frontiers chooses to adapt a similar design.

Due to time and geometric constraints, the requirements of the project were reduced. Medtronic Ablation Frontiers has decided to remove the steering wires and guideplate from the prototype catheters that are being produced. The steering wires and guideplate would further complicate the design process than there is time for.

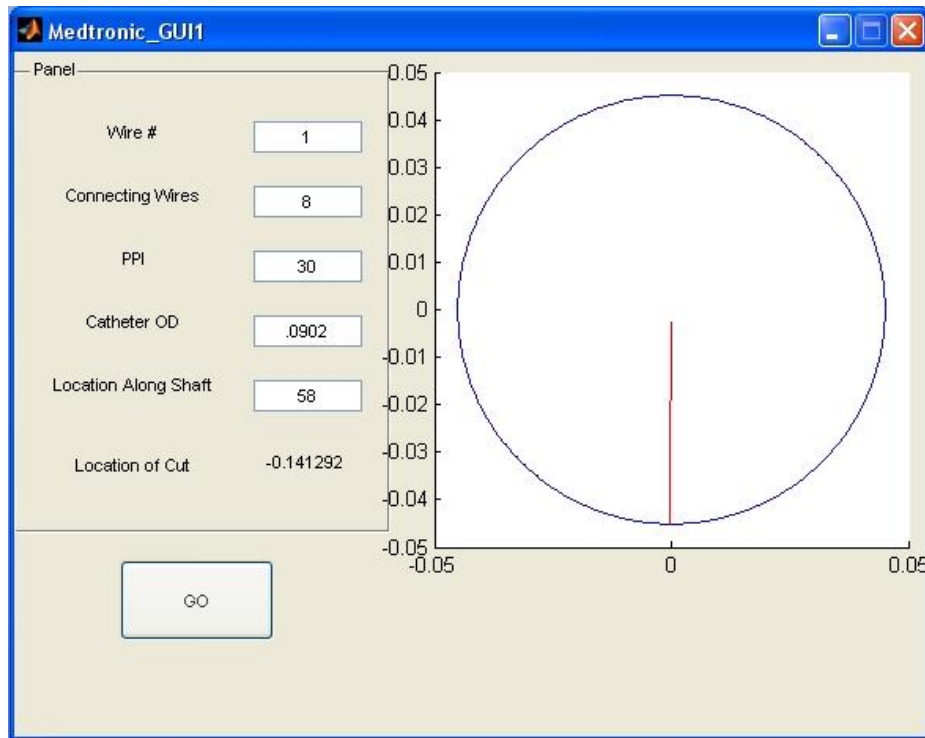


Figure 10: GUI panel. The line between the outer edge of the catheter perimeter and the center represents the position of the desired wire. Location of cut gives the circumferential distance from the top position of the catheter, and a negative number designates a clockwise direction from that position.

## Analysis

The composite and micromechanics analysis used to verify concepts is used to optimize the braid angle and materials. To correctly utilize these forms of analysis the critical data must first be found. One key for micromechanics is what is called the volume fraction. The volume fraction is a ratio of either the fiber material or matrix material to the overall amount of material in the composite structure. In this case the fiber material is the signal and signal wires whereas the matrix material is the Pebax<sup>®</sup> shell.

The calculation for the volume fraction is the cross section area of the material in question, either the fiber or matrix, divided by the entire cross sectional area of the composite structure, in this case a tube. Once the volume fractions have been found the effective Young's modulus,  $E_{eff}$ , can be found. For the design that is being developed the composite structure has been broken into two different subsections or parts. The first part is the helical braid composed of the signal wires, named helical layer, where the second portion is the signal and pull wires, named unilayer.

Once the  $E_{eff}$  of both layers was determined they could then be input into a MatLab program that performs the composite analysis for the structure, based on Laminated Plate Theory. This program outputs the  $E_x$ ,  $G_{12}$ , and  $EI_{eff}$ . The  $EI_{eff}$  is the stiffness of the composite structure and will determine the flexibility and maneuverability of the catheter design. Since many large assumptions had to be made in order to model the catheter design this way the goal is to create a

relative scale between the current TVAC design and the proposed design. The current TVAC design is modeled in the same way as the proposed design with this MatLab program in order to give a baseline  $EI_{eff}$ . This will allow for the logical argument to be made that if the proposed design has a lower stiffness than the current TVAC design then the proposed design will buckle before the critical load of 340 grams force has been reached.

Heat transfer analysis of the catheter is being done to ensure that the surface of the catheter does not exceed 41°C. The Biot Number was calculated (details of the calculation can be seen in Appendix D) to be 0.693 which makes the lumped capacitance assumption invalid. Because lumped capacitance cannot be assumed, an elemental model of the catheter determining the heat distribution across the Pebax<sup>®</sup> coating will need to be developed to verify this specification. Medtronic Ablation Frontiers has a standard test method for gathering empirical data for this specification which involves measuring the shaft temperature during energy delivery. Unfortunately this is as far as we can take the heat transfer analysis due to the fact that it is not plausible to develop a realistic elemental model for the design,

## Safety Considerations

The product specifications set by Medtronic Ablation Frontiers have been developed to either satisfy a performance standard or a safety standard necessary for the use of a vascular catheter.

One important electrical specification for the design is specification 8.3.2 (Appendix C) which states that the catheter must be able to withstand a two kilovolt DC defibrillator pulse and demonstrate no breakdown of insulation and/or loss of functional or safety performance. This specification has only been taken in consideration in material selection in regards to insulation breakdown voltage. It will be important to make sure that the catheter is independently grounded from the patient during a defibrillator pulse to avoid an electrical current surge and heat buildup on the catheter while it is inside heart.

Specification 9.2.5 (Appendix C) is crucial to the safety of the patient as well. It ensures that the catheter will buckle under 340 grams force, the force it would take the catheter to puncture the heart, when gripped two inches from the distal end. Analysis using the composite structure MatLab program (Appendix D) will use the buckling specification as the driving force to determine the braid angle which in turn will determine the braid density.

## Chapter 5 – Design Verification Plan

Ablation Frontiers has a set of tests in place from the previous iteration of the TVAC to test the specifications for the catheter. The most important test will be the verification of the GUI wire tracking program. To test the GUI, a wire and distance down the shaft will be chosen and run through the program with the given prototype dimensions. Using the output from the program the predicted wire will be exposed and a resistance will be measured using a multi-meter. A measured resistance results in a passing test and an infinite resistance results in a failing test.



The buckling requirement will be tested on an Instron machine against a flat plate with a force transducer. The tip of the catheter will be pressed to the plate until it buckles (max compressive force) which is then compared to the 340 grams force specification. An acceptable design will buckle before 340 grams force is reached.

Testing the catheter's ability to withstand a 2 kV defibrillator pulse is crucial for the safety of the product. A standard test for this has been developed and will be completed at an outside testing facility. This test will determine if the catheter insulation breaks down or loses any functionality. The catheter may need to be inserted into a test heart to completely simulate the environment during the surgical procedure.

The rise in surface temperature of the shaft will be tested as well. Medtronic currently tests this specification by submerging the catheter in 37°C and running the catheter for 120 seconds. The surface temperature of the body of the catheter cannot exceed 41°C during the test for an acceptable design.

A steering compliance test will also be performed. The catheter's steering section will be wrapped around a 20 mm test gage to mimic the curvature it might need to take in the human body. No kinking in the steering section can be observed for a passing catheter.

## **Chapter 6 – Project Management Plan**

Due to the limited number of individuals that will be participating in the project, a majority of the tasks that must be completed will be split between the two team members. For example information gathering has been equally divided between both team individuals; this will help to ensure that both will have an equal understanding of the complexities involved with this project. However, a team member will be assigned one of the two major sections of the catheter design to focus on. The two major sections of the project are the steerable length of the shaft and the tracking of the individual braid strands.

This senior project will cover three 10 week quarters, with different milestones due at different points along the way. We plan to use a Gantt chart to help organize tasks and track progress; the initial Gantt chart is attached in Appendix E. The different responsibilities that will be encountered throughout this project will be grouped into corresponding areas and will be assigned to one of the two team members.

The second quarter main deliverable is the Final Design Report due January 21<sup>st</sup> which will be sent to both the project advisor and project sponsor. At this point in the process there will be a design freeze to try to ensure successful completion of the project. On February 4<sup>th</sup> the draft design status report will be completed and a status meeting will be held with Medtronic Ablation Frontiers. In the first weeks of March a prototype and test plan review will be held along with a project update report to Medtronic Ablation Frontiers on March 11<sup>th</sup>.

During the final quarter of this project there are only two main milestones that must be met. Then in the first week of June the senior project design expo will be held with the Final Project



Report due the next day. Although there are only two milestones during this quarter, these have the potential to be the hardest to fulfill.

## Chapter 7 – Manufacturing

Because of the overall size and intricacy of the catheter, it is impossible for the catheter to be produced onsite at Cal Poly. An external manufacturer, previously used by Medtronic Ablation Frontiers, has been contracted to produce the prototypes. The manufacturer is CMD (Catheter & Medical Design) which is located in Roseville Minnesota.

After presenting the proposed design to CMD, some manufacturing limitations became apparent. Preliminary analysis determined that for a six strand signal wire braid, a four strand stainless steel braid was needed. Braid machines that CMD has are limited to eight or sixteen carrier. Because of the braid machine limitations, the design had to use an eight strand bifilar signal wire braid and an eight strand stainless steel braid. To compensate for the dummy wires that needed to be included, the braid diameters were reduced to be adjacent to the center lumen with no separating Pebax<sup>®</sup>. Due to time limitations and the additional complexity it would add to the design the steering wires were decided to be omitted from the prototype design by Medtronic Ablation Frontiers.

Due to the relatively large size of the signal wire, CMD could not braid the wires at the designated braid density of 60 ppi. The braid density had to be reduced to 30 ppi. After investigating the effect of the change in braid density on the stiffness of the shaft, it was determined that the change would have an insignificant effect to the stiffness.

The initial catheter design only had the signal wires braided through the steering section (7F section) to minimize the amount of wire used to produce the catheter and to reduce any error propagation arising from any inaccuracies in the tracking program. CMD recommended braiding the entire length of the catheter for ease of manufacturing. CMD also could not guarantee that the signal wires would lay straight along the rest of the length of the shaft, which would produce inaccuracies in the wire tracking program.

Once a final design was agreed upon, a purchase order (Appendix C) for a lot of 25 prototypes was put in motion through Medtronic Ablation Frontiers. Two variations in the design were ordered; one variation has a center lumen diameter of 0.04 inches and the other has a center lumen diameter of 0.05 inches. The prototypes are shipped to Medtronic Ablation Frontiers with no handle or electrodes attached.

## Chapter 8 – Testing

The most critical test performed was the test for the accuracy of the GUI wire tracker. Seven different catheters were tested with different distances and wires on each catheter. Six catheters with a 0.04 inch diameter center lumen were tested and time only permitted for one catheter with a 0.05 inch diameter center lumen to be tested. A resistance was measured for each test performed, resulting in a passing test for each catheter. Table 2 shows a summary of the results

for both the GUI test and the steering compliance test. The resistance of the 0.05 in diameter center lumen catheter was larger than the resistances from the other catheters, due to the larger amount of wire needed to travel around the larger center lumen.

Table 2: Summary of GUI and steering compliance test. All tested catheters passed both tests.

Catheter Number	Center Lumen Size [in]	Linear Distance [in]	Wire Number	Resistance [ $\Omega$ ]	Steering Compliance	Run
1	0.04	58.6875	1	48.5	Yes	1
1	0.04	58.6875	2	61.5	Yes	2
2	0.04	60.5	1	52.2	Yes	3
3	0.04	61.0625	1	34	Yes	4
4	0.04	58.9375	1	32	Yes	5
5	0.04	57.3125	1	79.2	Yes	6
6	0.04	59	2	63	Yes	7
7	0.05	58.6875	1	97	Yes	8

Each of these catheters was tested for steering compliance as well. All catheters were observed to wrap around the test gage without kinking. Figure 11 shows a passing catheter around the test gage.

In order to perform the buckling, defibrillator, and surface temperature test, a fully built and functional catheter must be available. Because the process for connecting an electrode to the bifilar wires is unknown, these tests were not performed.



Figure 11: Catheter during steering compliance test. There are no sections of the catheter that have kinks as a result of wrapping around the test gage.

One area of concern for the ease of manufacturing is that the cuts made in the catheter body to access the signal wires are no longer along the top of the catheter. On the current T-VAC catheter the cuts to access the wires are made in an orderly fashion along the top of the catheter due to all of the wires being in roughly the same location in the center lumen. The prototype catheters that were tested have the signal wires in a helical braid through the body of the catheter and therefore the wires are not guaranteed to be on the top of the catheter at the point of interest. If a specific wire and distal location down the shaft are defined, there is the possibility that the wire will be located in another plane on the surface of the catheter.

## Chapter 9 – Conclusions and Recommendations

The wire tracking GUI accurately predicted the location of the signal wires on the distal end of the catheter during testing. The success of the GUI shows that it is possible to incorporate the signal wires in a braid outside of the center lumen and find the proper signal wire when attaching electrodes. The process to locate and expose the proper signal is time consuming, and the process can be improved.

The wire tracking GUI assumes that the topmost wire is braided in a counterclockwise direction and identifying this wire as counterclockwise is crucial to using the GUI. It was difficult to initially identify the direction in which the wires were braided on the proximal end of the catheter. To avoid errors in the identification of the topmost wire, it is advantageous for the manufacturer to provide a marker on each catheter that would identify a counterclockwise signal wire for the technicians.

The mechanical functionality of the catheter was not fully tested, but all tested catheters passed the steering compliance test. This suggests that the tested catheter's steering sections are flexible enough to navigate the path through the human body to ablate the targeted site in the heart. The remaining tests still need to be completed, in order to carry out the remaining tests fully functioning catheters need to be assembled. The remaining structural, electrical, and thermal tests were not initially done because the process and materials required to electrically connect the electrodes to the signal wires are still unknown. The signal wires cannot be pulled out and soldered to the electrode like the current T-VAC because of the helical braid pattern they are in.

A process similar to the process CathRx uses could be adopted for this design. CathRx laser cuts a precision hole to expose the desired wire and injects conductive silver epoxy in the hole to establish the connection between the signal wire and the electrode. This process is applicable for the designed catheter and can be adopted with relative ease. Further development needs to be done on this topic due to the wide range of potential solutions involved.

Consistency in manufacturing can potentially develop into a complication in the accuracy of the GUI. During testing, it was observed that the braid density of the signal wire changed for a brief length at the proximal end of the catheter (Figure 12). The algorithm used to predict the location of the signal wires depends on a constant braid density and inconsistencies will cause the GUI to output the wrong radial cut location. Though the change in braid density can raise a serious

issue, it was observed that only a minimal amount of prototype catheters exhibited this behavior. Unfortunately the technicians cannot adjust the catheters that display this behavior on site, the catheters have a tail of extruded wires that connect in the handle of the device. The technicians cannot simply trim off the affected portion of the catheter and continue through the manufacturing process, the affected catheters must be discarded.



Figure 12: Change in braid density at proximal end of catheter. The variation in the braid density will affect the accuracy of the wire tracking GUI.

Because the location of the signal wire access point is no longer coplanar for all electrodes, a different braid density might be advantageous to use. A different braid density where signal wire crossings occur on a multiple 3.5 mm, the distance between electrodes, might allow for the access points to the signal wire to be on the same plane. Forcing the access points to the signal wire to occur on the least amount of planes possible can be better controlled if the distance between electrodes can be altered as well. This will require further research on both fronts to ensure that the ablation lesion remains consistent. The consistency of the lesion is crucial to maintaining the quality of care that the patient receives from this medical device. The ease of access to the signal wires in a coplanar fashion is ideal, however with the electrode attachment process still being unknown there is a large area for adaption to optimize this area of the design.

The final design of the catheter uses an eight strand signal wire braid to supply power to six electrodes. The two extra wires are nonfunctioning and could be used to add more electrodes to the array. This would allow the catheter to ablate a larger area during surgery and potentially reduce surgery time. Surgery time can be reduced by incorporating a cooling system in the newly vacated center lumen. Two possible cooling systems that could be incorporated into the catheter are a saline solution run by capillary action through the center lumen or a liquid nitrogen system run through a nitinol tube in the vacated center lumen. Incorporating a cooling system not only allows for the surgery time to be reduced, but the catheter would also be able to be used in the low flow areas of the heart. The blood in the low flow areas of the heart is more stagnant and thus is more susceptible to higher temperatures. Since the blood is more stagnant it is exposed to the heat from the electrodes for a longer period of time, an internal cooling system could negate these effects. The ability to vacate the center lumen for additional features like a cooling system or additional electrodes was the driving force for the proposal of this project.

Having accomplished this task opens up many more avenues for further research as well as development.

## References

1. Agarwal, Bhagwan D. *Analysis and performance of fiber composites*. New York: Wiley, 1980. Print.
2. "Atrial Fibrillation." *American Heart Association*. Web. 10 Oct. 2009. <<http://www.americanheart.org/presenter.jhtml?identifier=4451>>.
3. "Cardiac Ablation." *Patient and Public Information Center : Heart Rhythm Society*. Web. 11 Oct. 2009. <[http://www.hrspatients.org/patients/treatments/cardiac\\_ablation.asp](http://www.hrspatients.org/patients/treatments/cardiac_ablation.asp)>.
4. "CathRx - Cardiac Catheters - Manufacturing Platform." *CathRx - Cardiac Catheters*. Web. 22 Nov. 2009. <<http://www.cathrx.com/home.asp?pageid=2057C20DB2B6A5F7>>.
5. Chao, Ting-Hsing, Lian-Miin Tsai, Wei-Chuan Tsai, Yi-Heng Li, Li-Jen Lin, and Jyh-Hong Chen. "Effect of Atrial Fibrillation on Pulmonary Venous Flow Patterns Assessed by Doppler Transesophageal Echocardiography." *CHEST* 1546th ser. 117.6 (2000): 1546-550. *Chestjournal.chestpubs.org*. American College of Chest Physicians. Web. 1 Dec. 2009.
6. De Marchi, S. F., M. Bodenmuller, D. L. Lai, and C. Seiler. "Pulmonary venous flow velocity patterns in 404 individuals without cardiovascular disease." *Heart* (2001): 23-29. *Heart.bmj.com*. Swiss Cardiovascular Centre Bern, 12 Sept. 2000. Web. 1 Dec. 2009.
7. "Frequently Asked Questions \* Medtronic Ablation Frontiers, LLC. \* Ablation Therapy \* Atrial Fibrillation \* United States." *Medtronic Ablation Frontiers, LLC. \* Atrial Fibrillation \* Ablation Therapy \* United States & International*. Web. 10 Oct. 2009. <<http://www.ablationfrontiers.com/us/faq.html>>.
8. *Online Materials Information Resource - MatWeb*. Web. 12 Nov. 2009. <<http://www.matweb.com>>.

# Appendix A - QFD

## Engineering Requirements

Benchmarks

Medtronic Ablation  
Frontiers  
Customers: Medtronic,  
Manufacturing

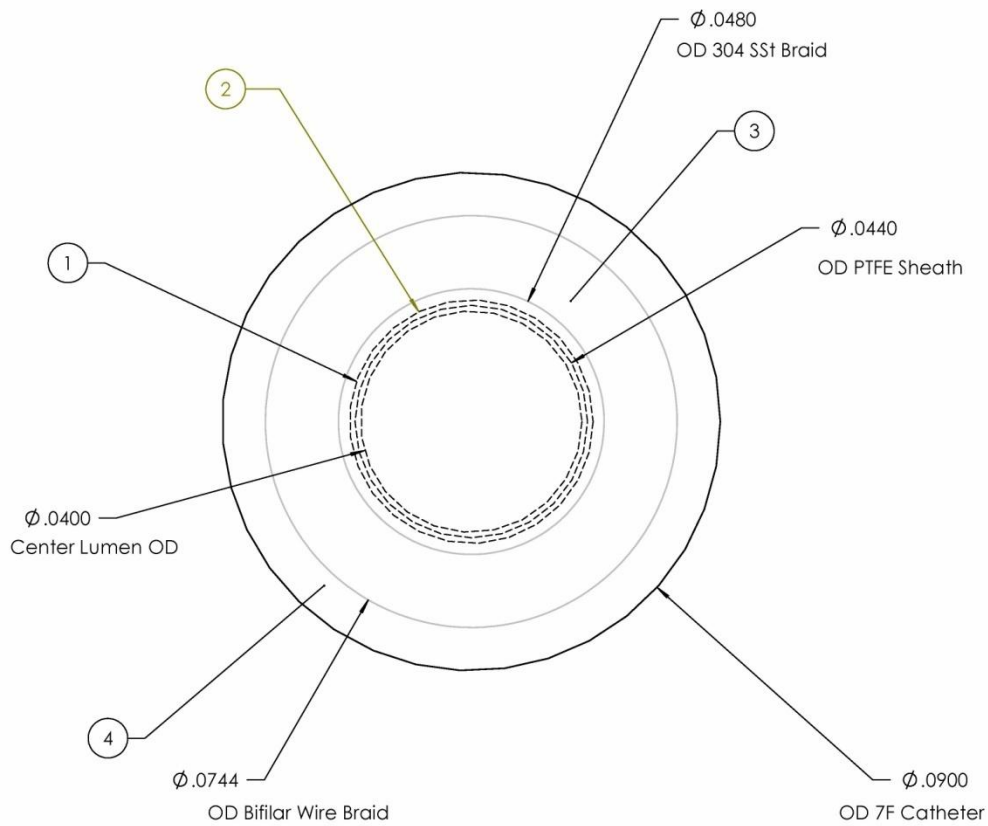
Customer Requirements	Weighting (Total 100)	Diameter	Overall Length	Steerable Length	Steering Directions	Tip Deflection	Maneuverability	Wiring	Gage	Medical Grade Materials	Cooling System	Current Design
	Functional Performance											
	Flexibility		7	5	6		9	9	7	7	9	5
	Long Run time										9	2
	Easy to Use				8	5	8	9	5	5	9	4
	Human Factor											
	Biocompatibility									9		5
	Short Surgery Time				4	5	5	6	4	5	9	3
Units		in	in	in	#	deg	-	#	AWG	-	-	
Targets		0.090	45	3	2	180	-	12	36	-	Yes	
Benchmark #1		0.090	45		2		-			-	No	
Benchmark #2												


- 9 Strong Correlation
- 4 Medium Correlation
- 1 Small Correlation
- Blank No Correlation



## Appendix B – Technical Drawings

ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	1	PTFE Sheath	1
2	2	8 strand 304 SS Braid	1
3	3	8 strand 36 AWG Bifilar Wire Braid	1
4	4	Outer Pebax	1



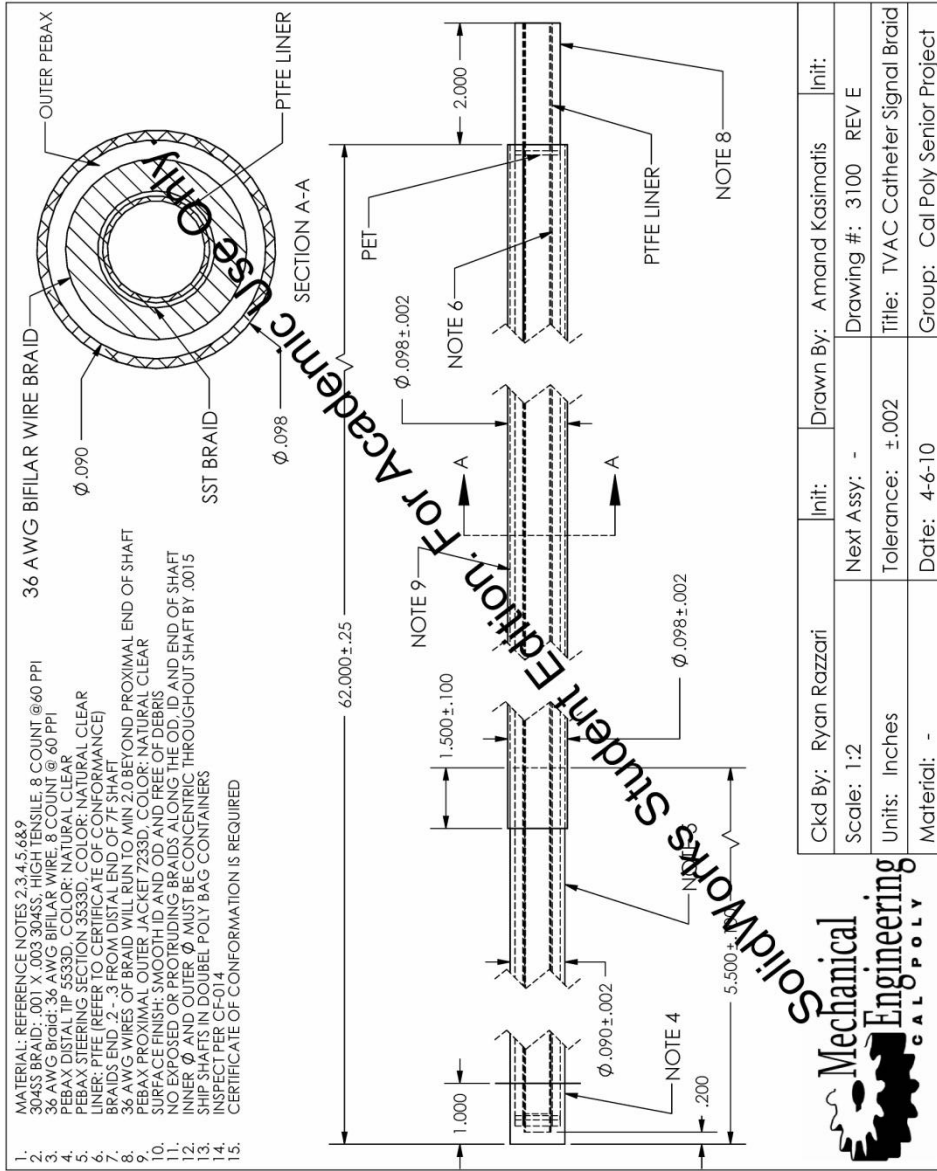
	REV: E	NEXT ASSY: -	CHKD BY: Ryan Razzari
		DRAWING #: 3100	MATERIAL:
	TOL: $\pm .002$	UNITS: Inches	TITLE: 7F Catheter Cross Section 50 Thou
	SCALE: 40:1	DATE: 3/12/10	NAME: Amand Kasimatis



ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	1	PTFE Sheath	1
2	2	8 strand 304 SS Braid	1
3	3	8 strand 36 AWG Bifilar Wire Braid	1
4	4	Outer Pebax	1

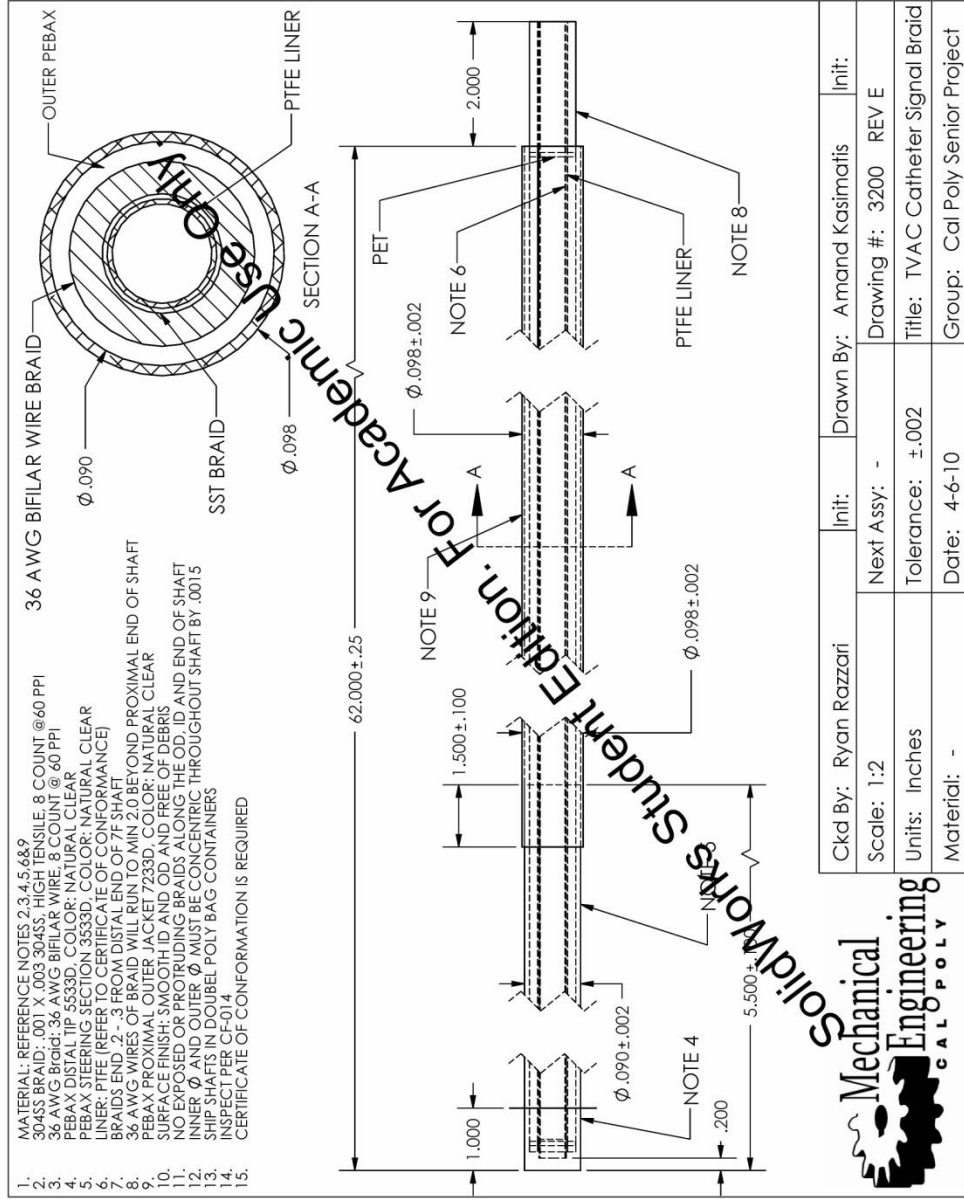
	REV: E	NEXT ASSY: -	CHKD BY: Ryan Razzari
		DRAWING #: 3200	MATERIAL:
	TOL: ±.002	UNITS: Inches	TITLE: 7F Catheter Cross Section 50 Thou
	SCALE: 40:1	DATE: 3/12/10	NAME: Amand Kasimatis




1. MATERIAL: REFERENCE NOTES 2,3,4,5,6&9
2. 304SS BRAID: .001 X .003 304SS, HIGH TENSILE, 8 COUNT @ 60 PPI
3. 36 AWG Braid: 36 AWG BIFILAR WIRE, 8 COUNT @ 60 PPI
4. PEBAx DISTAL TIP 55333D, COLOR: NATURAL CLEAR
5. PEBAx STEERING SECTION 35333D, COLOR: NATURAL CLEAR
6. LINER: PTFE (REFER TO CERTIFICATE OF CONFORMANCE)
7. BRAIDS END: 2: .3 FROM DISTAL END OF SHAFT
8. 36 AWG WIRES OF BRAID WILL RUN TO MIN 2.0 BEYOND PROXIMAL END OF SHAFT
9. PEBAx PROXIMAL OUTER JACKET 7233D, COLOR: NATURAL CLEAR
10. SURFACE FINISH: 320 AND 400 GRIT AND BEVEL EDGES
11. EXPOSED PROXIMAL Braid AND SST Braid
12. INNER Ø AND OUTER Ø MUST BE CONCENTRIC THROUGHOUT SHAFT BY .0015
13. SHIP SHAFTS IN DOUBEL POLY BAG CONTAINERS
14. INSPECT PER CF-014
15. CERTIFICATE OF CONFORMANCE IS REQUIRED

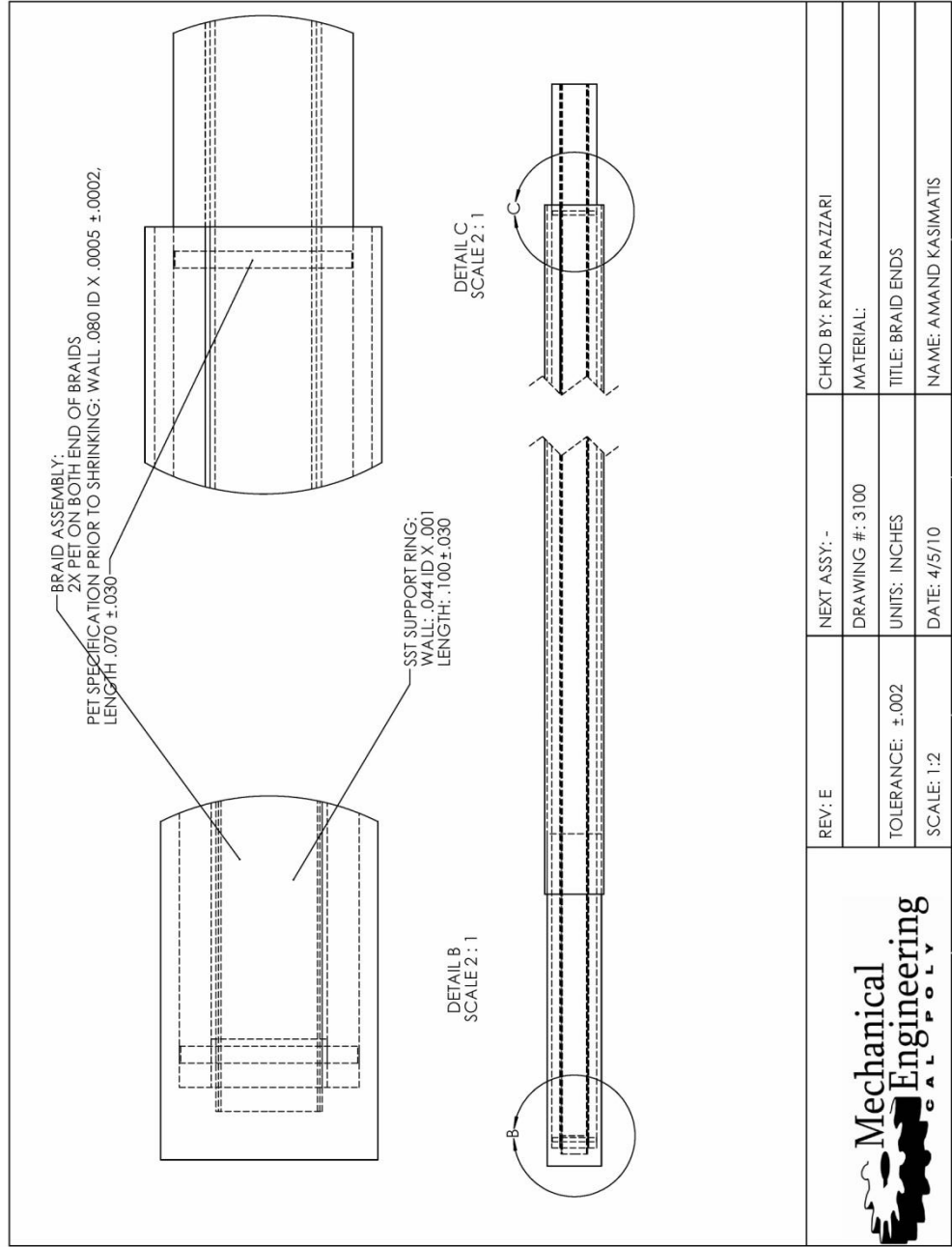
Ckd By: Ryan Razzari	Init:	Drawn By: Amand Kasimatis	Init:
Scale: 1:2	Next Assy: -	Drawing #: 3100	REV E
Units: Inches	Tolerance: ±.002	Title: TVAC Catheter Signal Braid	
Material: -	Date: 4-6-10	Group: Cal Poly Senior Project	



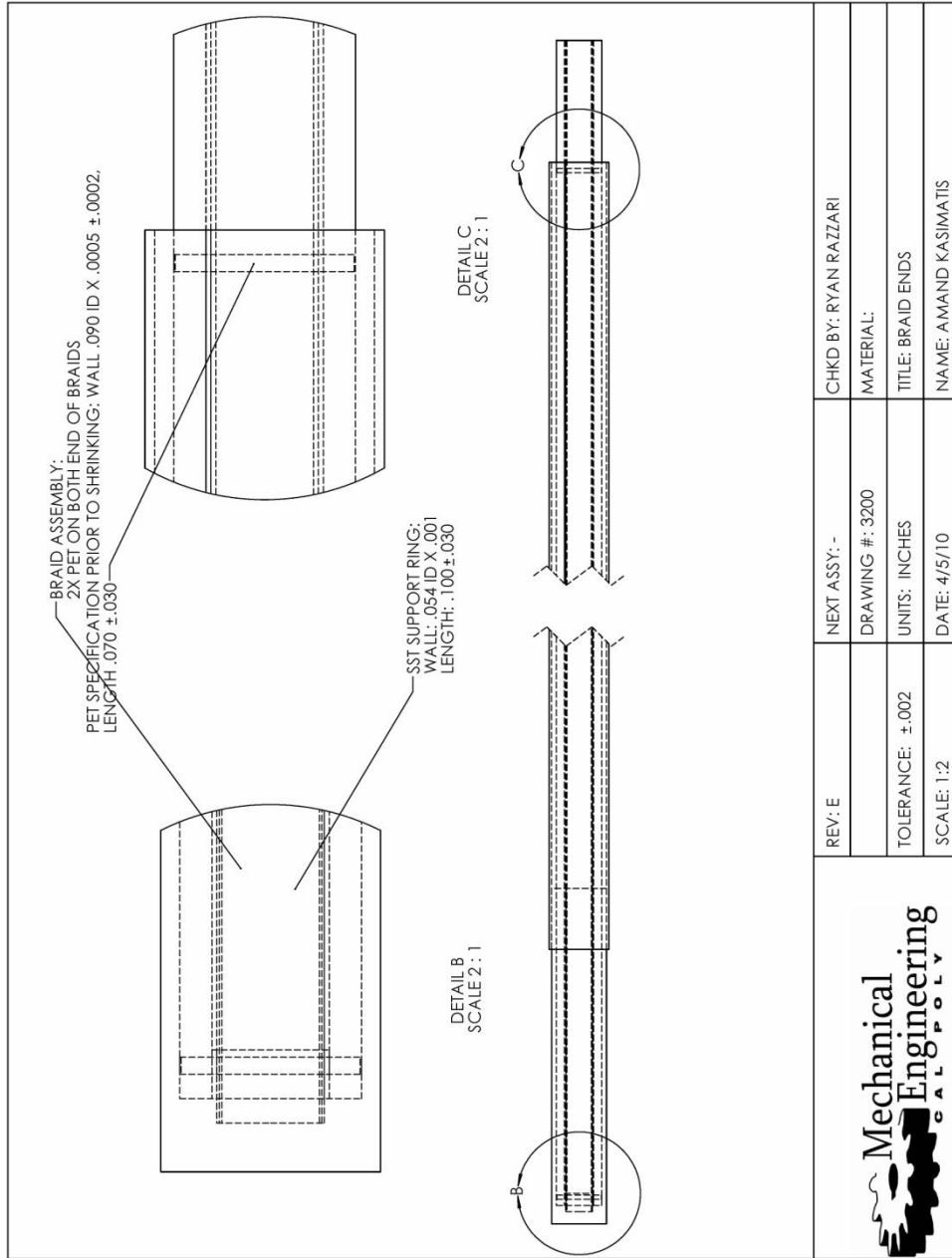


1. MATERIAL: REFERENCE NOTES 2, 3, 4, 5, 6 & 9
2. 304SS BRAID: .001 X .003 304SS, HIGH TENSILE, 8 COUNT @ 60 PPI
3. 36 AWG Braid: 36 AWG BIFILAR WIRE, 8 COUNT @ 60 PPI
4. PEBAX DISTAL TIP: 5533D, COLOR: NATURAL CLEAR
5. PEBAX STEERING SECTION: 3533D, COLOR: NATURAL CLEAR
6. LINER: PTFE (REFER TO CERTIFICATE OF CONFORMANCE)
7. BRAIDS END: .2 - .3 FROM DISTAL END OF 7F SHAFT
8. 36 AWG WIRES OF BRAID WILL RUN TO MIN 2.0 BEYOND PROXIMAL END OF SHAFT
9. PEBAX PROXIMAL OUTER JACKET 7233D, COLOR: NATURAL CLEAR
10. SURFACE FINISH: SMOOTH ID AND OD AND FREE OF DEBRIS
11. NO EXPOSED OR PROTRUDING BRAIDS ALONG THE OD, ID AND END OF SHAFT
12. INNER Ø AND OUTER Ø MUST BE CONCENTRIC THROUGHOUT SHAFT BY .0015
13. SHIP SHAFTS IN DOUBEL POLY BAG CONTAINERS
14. INSPECT PER CF-014
15. CERTIFICATE OF CONFORMANCE IS REQUIRED

	Ckd By: Ryan Razzari	Init:	Drawn By: Amand Kasimatis	Init:
	Scale: 1:2	Next Assy: -	Drawing #: 3200	REV E
	Units: Inches	Tolerance: ±.002	Title: TVAC Catheter Signal Braid	
	Material: -	Date: 4-6-10	Group: Cal Poly Senior Project	



	REV: E	NEXT ASSY: -	CHKD BY: RYAN RAZZARI
	TOLERANCE: ±.002	DRAWING #: 3100	MATERIAL:
	SCALE: 1:2	UNITS: INCHES	TITLE: BRAID ENDS
		DATE: 4/5/10	NAME: AMAND KASIMATIS



	REV: E	NEXT ASSY: -	CHKD BY: RYAN RAZZARI
	TOLERANCE: ± .002	DRAWING #: 3200	MATERIAL:
	SCALE: 1:2	UNITS: INCHES	TITLE: BRAID ENDS
		DATE: 4/5/10	NAME: AMAND KASIMATIS

# Appendix C- Prototype Purchase Order



Phone: (651) 636-6505  
Fax: (651) 636-4369  
E-mail: [cmd@cmd-inc.biz](mailto:cmd@cmd-inc.biz)

1758 Terrace Dr., Roseville, MN 55113-1315, USA

Quotation Number: QN101839

To: Amand Kasimatis  
Name of the customer: Amand Kasimatis  
Address: N/A

Tel: 619-322-6032  
Fax:

Description of Quotation: .040" ID x .090" distal and .098" proximal OD & .050" ID x .090" distal and .098" proximal OD

PN: 3100 & 3200  
Rev: E  
Ver:

**Materials use/Specification:**

**Inner layer:** .002 wall thickness, ptf etched OD, @ .2" from distal to end of shaft

**First Wire Layer:** .001x.003 flat wires, 304V SS, 8 wires, HT, 60PPI @ .2" from distal to proximal end of .98OD

**Second Wire Layer:** 36AWG Bifilar polyimide coated wires, 8 wires, HT, 60PPI, @ .2" from distal to end of shaft, provided by customer

**Outer Layer:** Pebax 5533, 20%BaSO4, Natural Clear, 1.00 +/- .1"  
Pebax 3533, 20%BaSO4, Natural Clear, 3.00 +/- .1"  
Pebax 7233, 20%BaSO4, Natural Clear, 58.0 +/- .1"

Overall Length: 62.00 +/- .25

ID: .050 +/- .002" AND .040 +/- .002"

OD: .090 +/- .002 distal and .098 +/- .002 proximal

Lead Time: 4-5 weeks

Qty: 25pcs Any combination of .050ID and .040ID Shaft.

Price: \$5200

Quote Valid: 90 Days

Ship Via: Fob/CMD. Customer to responsible for all taxes and duty fees.

Terms: Net 30. CMD reserves the right to ship +/-10% of the quantity ordered. If for any reasons Amand decides to cancel the order, Amand will be responsible for all materials and will purchase at cost plus an agreed upon percentage mark up to be determined.

**We are ISO 13485 Certified**

CMD Inc. would like to thank you for the opportunity to quote you the above information. This quotation is the property of CMD Inc. and it reserves the right to serve the above names or persons as descript only, any other uses of this quotation is prohibited. Please feel free to contact CMD personnel for any question regarding to this quotation.

\* Thank you for this opportunity to quote. \*

Quoted by: Kong Vang

Date: 4/8/10

◆ CMD Inc. is the solution for your medical application needs ◆

Please visit us at [www.cmd-inc.biz](http://www.cmd-inc.biz)

Form 72-01-01 Rev A  
Quotation Form

## Terms & Conditions

1. **ACCEPTANCE:** This order is for the purchase and sale of the goods and/or services (herein referred to as "Goods" or "Services" described on the front hereof and is Buyer's offer to Seller. Acknowledgment hereof by Seller to Buyer shall constitute Seller's acceptance of such order, including all of the terms and conditions herein. In the absence of such acknowledgment, commencement of delivery of the Goods or Services and acceptance by Buyer constitute a firm contract on the terms and conditions hereof. Any acceptance of this purchase order is limited to acceptance of the express terms contained on the face and back thereof. Any proposal for additional or different terms or any attempt by Seller to vary in any degree any of the terms of this offer in Seller's acceptance is hereby objected to and rejected, but such proposals shall not operate as a rejection of this offer unless such variances are in the terms of the description, quantity, price or delivery schedule of the Goods or Services, but shall be deemed a material alteration thereof, and this offer shall be deemed accepted by Seller without said additional or different terms.

2. **PRICES:** Buyer shall not be billed at prices higher than those stated on the front of this order. Unless otherwise specified, the price stated includes all charges for packing, hauling, storage and transportation. Seller will pay all delivery charges in excess of any delivery charge Buyer has agreed to pay. The price stated includes all taxes except state or local sales or use taxes or similar taxes, which Seller is required by law to collect from Buyer, including Value Added Taxes, where applicable. Such taxes, if any, shall be separately stated in Seller's invoice and paid by Buyer unless an exemption is available. Seller agrees that any price reduction made with respect to the items covered by this order subsequent to its placement but prior to payment will be applicable to this order.

3. **INVOICES:** Invoices shall contain purchase order number, item number, description of terms, sizes, quantities, unit prices and extended totals in addition to any other information specified elsewhere herein. A bill of lading or express receipt shall accompany each invoice and shall, if applicable, state the release price. Payment of invoice shall not constitute acceptance and shall be subject to adjustment of errors, shortages, defects in the articles or services or other failure of Seller to meet the requirements of this purchase order.

4. **CERTIFICATION:** In the event the Goods are chemicals, the parties agree that as a condition precedent to Buyer's obligations under this purchase order, Seller shall furnish Buyer with a certificate of origin of the Goods which shall provide sufficient information to completely trace the title and possession of the Goods from their manufacture to their delivery to Buyer, and Seller shall furnish to Buyer with a certificate of analysis which shall indicate the complete chemical composition of the Goods. Failure of Seller to furnish any of above at the time of delivery of the Goods to Buyer shall totally relieve Buyer of all obligations under this purchase order but shall have no effect on Buyer's right to resort to remedies against Seller as provided in this purchase order, as prescribed by law.

5. **CASH DOCUMENTS:** Time in connection with any discount offered will be computed from (i) the date of actual delivery at Buyer's plant, or (ii) the date and invoice conforming to Paragraph 3 is received, whichever is later. Payment is deemed to be made for the purpose of earning the discount on the date Buyer's check is deposited postage paid in the mail.

### 6. **WARRANTIES:**

(a) Seller warrants that all Goods delivered hereunder shall be free from defects in workmanship, material, manufacture and design and shall comply fully with the requirements of this purchase order. Seller further warrants that all material purchased hereunder shall be of merchantable quality, new and unused (unless otherwise specified in this purchase order), and shall be fit and suitable for the purposes intended by Buyer. The foregoing warranties shall constitute conditions and are in addition to all other warranties, whether expressed or implied, and shall survive delivery, inspection, acceptance or payment by Buyer. Buyer's approval of Seller's material or design shall not relieve Seller of the warranties set forth in this clause. All warranties shall run to Buyer and to Buyer's customers. Approval of Seller's material or design by Buyer shall not relieve Seller of the warranties set forth in this clause.

(b) Seller agrees to indemnify, defend, and hold Buyer harmless and Buyer's directors, officers, employees, distributors, agents, dealers, representatives, customers and users of the Goods or Services from and against all damages occasioned by or arising as a consequence of any breach of the warranties set forth herein, including the cost of replacing or recalling Buyer's material which may be damaged or rendered defective by Goods or Services furnished or work done in breach of such warranties.

(c) Seller warrants that the prices charged Buyer, as indicated on the front side hereof, are no higher than prices charged on orders placed by others for similar quantities or similar conditions subsequent to the last general announced price change. In the event Seller breaches this warranty, the prices of the Goods or Services shall be reduced accordingly retroactively to the date of such breach.

### 7. **INSPECTION:**

(a) All material purchased hereunder shall be subject to inspection and tested by Buyer to the extent practicable at all times and places, including during the period of manufacture and in any event prior to final acceptance. If Buyer makes inspection or test on Seller's premises, Seller, without additional charge shall provide all reasonable facilities and assistance for the safety and convenience of Buyer's inspectors. Buyer's inspectors shall be allowed to inspect Seller's facilities at anytime during business hours either announced or unannounced. No inspection or test made prior to final inspection and acceptance shall relieve Seller from responsibility for defects or to other failure to meet the requirements of this purchase order. Notwithstanding any prior inspections or payments made hereunder by Buyer, all material shall be subject to final inspection and acceptance at Buyer's plant within a reasonable time after delivery.

(b) In the event any Goods are found defective or not in conformity with Buyer's specifications or the requirements of this purchase order prior to final inspection, Buyer shall have the right either to reject the Goods and require Seller to replace it within the delivery schedule, or to require Seller to correct it within the delivery schedule or to accept it with an adjustment in price, all at the expense of the Seller, including any transportation and handling cost. If Seller fails to replace or correct any Goods which have been rejected or required to be corrected within the delivery schedule, or if Buyer rejects any Goods prior to final inspection as not conforming to this purchase order, Buyer may (i) replace or correct such material and charge Seller with the expense incurred thereby, or (ii) cancel this purchase order and cancel any outstanding deliveries

hereunder, without prejudice to Buyer's right to claim damages or to enforce any other remedy provided by law. Non-conforming material may be returned at Seller's expense, including any transportation and handling costs.

These remedies are in addition to all other remedies at law or in equity or under this purchase order and shall not be deemed to be exclusive.

8. **DELIVERY:** Time is of the essence in this purchase order. If any shipment or delivery is made which is not in all respects in accord with the provisions of this order (including time of shipment or delivery), Buyer reserves the right without liability to reject such delivery and, if Buyer so elects, Buyer may treat this order as repudiated by Seller and cancel any outstanding deliveries hereunder, without prejudice to Buyer's rights to claim damages or to enforce any other remedy provided by law. All expenses of transportation and storage, if any, resulting therefrom shall be for Seller's account. Buyer may reuse any delivery if prevented by strikes, casualties or other causes beyond its control from receiving or using it.

9. **TITLE:** The property in or title to, and the risk of loss of Goods purchased under this purchase order shall remain in Seller and not transfer to Buyer until such Goods are delivered and unloaded at the F.O.B point specified in the purchase order. Further, Seller shall indemnify, defend, and hold Buyer harmless from and against any damages caused or engendered by, or traceable to, Goods purchased hereunder (whether or not hazardous), or the transportation or handling thereof, prior to the completion of unloading at Buyer's plant or warehouse.

10. **OVERSHIPMENTS:** Buyer shall pay only for maximum quantities ordered. Seller shall pay return shipping charges for excess quantities delivered to Buyer.

11. **PACKING AND SHIPMENT:** Unless otherwise specified, the price includes the costs of boxing, crating, handling, damage claims, drayage, storage or other packing requirements. Unless otherwise specified, all material shall be packed, packaged, marked and otherwise prepared for shipment in a manner which is (i) in accordance with good commercial practice, (ii) acceptable to common carriers for shipment at the lowest rate for the particular material and in accordance with I.C.C. regulations and (iii) adequate to ensure safe arrival of the material at the named destination. Seller shall mark all containers with necessary filling, handling and shipping information and also purchase order number, date of shipment and the names of the consignee and consignor. An itemized packaging sheet must accompany each shipment unless otherwise specified. Not partial or complete delivery shall be made hereunder prior to the date or dates shown without prior written consent of Buyer.

### 12. **MSDS'S:**

(a) An appropriate Material Safety Data Sheet (MSDS) and labeling, as and if required by law will precede or accompany each shipment. Further, Seller shall send to Buyer updated MSDS's and labeling as required by law.

(b) Any Seller subcontractors doing work on Buyer's property shall provide MSDS's for Goods used by the contractor. These MSDS's shall be supplied to Buyer's Department of quality of compliance in advance of the performances of services. Buyer and the Seller shall mutually share all necessary health and safety information. All hazardous waste created by Seller's work shall be disposed of at a Buyer-approved disposal facility.

13. **BUYER-FURNISHED PROPERTY:** Seller shall not use, reproduce, or appropriate for, or disclose to anyone other than Buyer, any material, tooling, dies, drawings, designs or other property or data furnished by Buyer, nor shall Seller use the same to produce or manufacture more Goods than are required hereunder. Seller shall bear the risk of loss or damage to such property furnished by Buyer unless such loss or damage is solely, directly and approximately caused by Buyer's negligence. All such Buyer-furnished property, together with spoiled and surplus Goods, shall be returned to Buyer at termination or completion of this order unless Buyer shall otherwise direct.

14. **SETOFF:** Buyer may set off any amount due from Seller to Buyer or any division subsidiary of Buyer, whether or not under this order, against any amount due Seller hereunder.

15. **CHANGES:** Buyer shall have the right to make, from time to time, without notice to any sureties or assignees, changes to packing, testing, destinations, specifications, designs, and delivery schedules, but no additional changes shall be allowed unless authorized in writing by Buyer. If changes affect the amount to be paid by Buyer, Seller shall notify Buyer within fifteen (15) days from date of receipt by Seller of notice of change. Substitutions or changes in materials, quantities, or specifications by Seller shall not be made without Buyer's prior written approval.

### 16. **TERMINATION:**

(a) Buyer may cancel this order, in whole or in part, without liability to Buyer, if deliveries are not made at the time and in the quantities specified or in the event of a breach or failure of any of the other terms or conditions hereof.

(b) Buyer may terminate this order in whole or in part, at any time for its convenience, by notice to Seller in writing. On receipt by Seller of such notice, Seller shall, and to the extent specified therein, stop work hereunder and the placement of subcontracts, terminate work under subcontracts outstanding hereunder and take any necessary action to protect property in Seller's possession in which Buyer has or may acquire an interest. Seller shall deliver such property promptly upon Buyer's request to Buyer or Buyer's designee. Any termination claim must be submitted to Buyer within sixty (60) days after the effective date of the termination.

(c) In no event and under no circumstances shall Seller have any rights to claim from Buyer special, consequential or indirect damages (including lost profits) hereunder or otherwise.

(d) Buyer shall have the right to audit all elements of any termination claim and Seller shall make available to Buyer on request all books, records and papers relating thereto.

17. **PATENT INFRINGEMENT:** Seller shall, at its own expense, indemnify, defend and hold Buyer harmless and Buyer's directors, officers, employees, distributors, agents, dealers, customers and users from and against any and all claims that the Goods furnished by Seller under this purchase order infringes any patent, or any other proprietary rights and with respect to any and all suits, controversies, demands and

## Terms & Conditions

liabilities arising out of any such claims, provided that the foregoing shall not apply to any infringement claim necessarily resulting from Seller's adherence to written specifications or drawings submitted by Buyer.

### 18. INDEMNIFY AND INSURANCE:

(a) Seller shall defend, indemnify and hold Buyer harmless and Buyer's directors, officers, employees, distributors, agents, dealers, representatives, its employees, customers and users of the Goods or Services, from and against any claim, loss, recall or costs of recall, damage or expense arising out of the purchase and/or use of the Goods or Services purchased hereunder or of Seller's (or its subcontractor's) work or performance hereunder, or the assessment by any third party of any liquidated damages or proven actual damages arising out of the failure of Seller to timely deliver the Goods or Services purchased hereunder, and from and against any claim or loss, including the cost of any Goods lost by condemnation or voluntary recall damage or expense arising out of any claim or finding by government or any governmental agency or instrumentality thereof that the Goods are not as herein guaranteed and warranted.

(b) Seller shall maintain adequate insurance coverage, including, at a minimum, Workers' Compensation and Employers' Liability in statutory compliance with the Compensation Law of the state; General & Products Liability Insurance, indicating on the Certificate of Insurance the following coverages: Premises - Operations, Products & completed Operations, Broad Form Contractual Liability and Independent Contractor & Sub-Contractors, and Automobile Liability Insurance. Seller shall on or before delivery of the Goods or Services purchased hereunder, on Buyer's request, furnish to Buyer a Certificate of Insurance evidencing the foregoing coverages and limits. Additional Insurances may be required in the event of Services being performed on Buyer's property, or where otherwise deemed by Buyer to be warranted.

19. **ASSIGNMENT:** Seller shall not assign this order or any interest herein, or subcontract or delegate any performance or any amount which may become due hereunder, without Buyer's prior written consent. Buyer may freely assign this order.

20. **ADVERTISING:** Seller shall not advertise, publish, or otherwise disclose the fact that Buyer has placed this order without Buyer's prior written consent except as may be necessary to comply with a proper request for information from an authorized representative of any government unit or agency.

21. **TRADEMARKS:** If requested by Buyer, Seller shall affix Buyer's trademarks to the Goods purchased hereunder. Seller shall not acquire or claim any rights, title or interest therein, or use any of such trademarks on any Goods produced for itself or anyone other than Buyer.

22. **EXCUSABLE DELAYS:** Neither party shall be liable for any delay or failure of performance due solely to strikes, fires or other causes beyond its control and without its fault or negligence, provided that Seller shall give notice in writing to Buyer of any such cause for delay or anticipated delay promptly after first obtaining notice thereof, and shall have used its best efforts to make deliveries as expeditiously as possible taking such cause for delay into account. If Seller should be unable, due to such a cause, to meet all of its delivery commitments for the Goods or Services ordered herein as it becomes due, Seller shall not discriminate against Buyer or in favor of any other customer in making deliveries of such material. If Buyer believes that the delay or anticipated delay in Seller's deliveries may impair its ability to meet its production schedules or may otherwise interfere with its operations, Buyer may at its option and without liability to Seller, cancel outstanding deliveries hereunder wholly or in part.

23. **NOTICE OF LABOR DISPUTES:** Whenever an actual or potential labor dispute delays or threatens to delay the timely performance of this order, Seller shall immediately give notice thereof, including all relevant information with respect thereto, to Buyer. Seller shall insert the substance of this paragraph in any subcontract hereunder so that each such subcontract shall provide that in the event its timely performance is delayed or threatened by delay by any actual or potential labor dispute, the subcontractor shall immediately notify Seller of all relevant information with respect to such dispute.

24. **COMPLIANCE WITH LAWS:** In filling this order, Seller shall comply with all applicable laws and government regulations and orders. For orders within the United States of America, Seller specifically warrants and guarantees to Buyer:

(a) that the goods are in compliance with Sections 5 and 12 of the Federal Trade Commission Act and are properly labeled as to content as required by applicable Federal Trade Commission Trade Practice Rules;

(b) that the Goods are in compliance with the provisions of the Fair Packaging and Labeling Act and meet all U.S. Department of Transportation shipping requirements for packaging and labeling;

(c) that the Goods are not adulterated or misbranded within the Federal Food, Drug, and Cosmetic Act, as amended, or within the meaning of any applicable state or municipal law in which the definition of adulteration and misbranding are substantially identical with those contained in the Federal Food, Drug and Cosmetic Act, or are not Goods which may not under the provisions of Sections 404 and 505 of said Act be introduced into interstate commerce or which may not under substantially similar provisions of any state or municipal law be introduced into commerce;

(d) that the Goods are in compliance with the Consumer Product Safety Act of 1972, are not hazardous substances or, if they are hazardous substances, are not misbranded hazardous substances or banned hazardous substances within the meaning of the Federal Hazardous Substances Act (including the former Federal Causic Poison Act); and that the Goods have been manufactured, processed or imported in compliance with all requirements of the Toxic Substances Control Act of 1976;

(e) that the Goods are not manufactured or sold in violation of the Occupational Safety and Health Act of 1970, and

(f) that it will comply with all applicable Equal Employment Opportunity requirements including those set forth in Section 202 of executive Order 11246, as amended, which requirements are incorporated herein by reference.

Seller agrees to indemnify, defend and hold Buyer harmless from and against all damages occasioned by or arising as a consequence of the violation of said laws, regulations, and governmental orders.

25. **CONTROLLING LAW:** This order and the performance of the parties hereunder shall be controlled and governed by the laws of the State of California.

26. **WAIVER:** The failure of Buyer to enforce at any time any of the provisions of this purchase

order, or to exercise any election or option provided herein, or to require at any time performance by Seller of any of the provisions hereof, shall in no way be a waiver of such provisions and shall not affect the right of Buyer thereafter to enforce each and every provision.

27. **ENTIRE AGREEMENT:** This purchase order represents the entire understanding as of the effective date hereof between the parties with respect to the subject matter hereof, and supersedes all prior agreements, negotiations, understandings, representations, statements and writings between the parties relating thereto. No modification, alteration, waiver or change in any of the terms of the purchase order shall be valid or binding upon the parties hereof unless made in writing and duly executed by each of the parties hereto.

28. **ATTORNEY'S FEES:** In the event it shall become necessary for either party to retain an attorney to enforce any provisions in the purchase order, the prevailing party shall have its attorney's fees and other related costs paid by the other party.





**PURCHASE REQUEST**

PROJECT NAME: General R4D  
 INITIATION DATE: 4/9/10 Quote No: QN101839  
 Delivery Options: GROUND  3-DAY  2-DAY  NEXT DAY  Expected Delivery Date:

SUPPLIER: CMD  
 TYPE: INVENTORY  NON-INVENTORY

AFIP/N or MFG P/N	Rev	Item Description	Qty	UOM	Unit Price	Extended
3100 4 3200	E	Prototype	25	EA	\$208	\$5,200
		*040" ID x .090" distal & .058" prox 2.0				
		*040" ID x .090" distal & .058" prox 2.0				
		*040" ID x .090" distal & .058" prox 2.0				
		.050"				

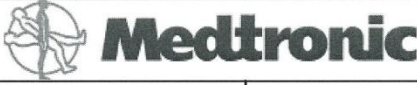


Please attach quotes, drawings, specifications, emails.  
 Comments:  Total:

MATERIALS CERTS REQUIRED:  Yes / No  
 INSPECTION REQUIRED: Yes / No  
 PROTOTYPE: Yes / No  
 \*\* If shipping address is different, please indicate shipping address.

BILL TO/ SHIP TO ADDRESS: **Medtronic Ablation Frontiers LLC.  
 2210 Faraday Ave. STE 100  
 Carlsbad, CA 92008**

ATTN: Ricky

	DATE	DEPT
REQUESTED BY PRINT NAME: <u>RRoman</u>	<u>4/9/10</u>	<u>R&amp;D</u>
REQUESTED BY SIGNATURE: <u>[Signature]</u>		
APPROVED BY PRINT NAME: <u>Tim Cary</u>		
APPROVED BY SIGNATURE: <u>[Signature]</u>	<u>9-Apr-2010</u>	<u>R&amp;D</u>

PURCHASE ORDER REQUEST							Taxable	X	PO Number
							Resale		10-561
Vendor Name		Material Certs Required		Yes				Date PO Placed	
CMD, Inc.		Inspection Required		Yes				04/09/2010	
Address		Requestor:				Ship Via:		Payment Terms	
1758 Terrace Drive		Tim Corvi / Cal Poly				UPS Next Day Air		Net 30	
City, State, Zip		Ship To:					FOB Point		
Roseville, Minnesota, 55113		Medtronic Ablation Frontiers LLC 2210 Faraday Avenue, Suite 100 Carlsbad, California 92008					Origin		
Contact				Buyer:				Delivery Date	
Marcus Yang				Chris Mikoczi				05/14/2010	
Phone: 651-636-6505		Phone: 760-827-0001							
Fax: 651-636-4369		Fax: 760-827-0015							
Item	Part Number	Rev.	Description	Qty	UOM	Account	Dept	Unit Price	Extended Price
1	Non-Inventory - Prototype Parts	E	6400 - Prototype Parts (.040" ID x .090" distal and .098"proximal OD)	13	ea	6400	R&D	\$ 208.0000	\$ 2,704.00
2	Non-Inventory - Prototype Parts	E	6400 - Prototype Parts (.050" ID x .090" distal and .098"proximal OD)	12	ea	6400	R&D	\$ 208.0000	\$ 2,496.00
Notes:								<b>Total</b>	\$ 5,200.00
Estimated Sales Tax : 8.75% = \$455.00 Quote #: QN101839 UPS Account #: 04X- Y35  *Cal Poly Senior Project*								Initiator's Signature  04.09.10	
								Approver's Signature  12 APRIL 2010	

# Appendix D – Supplied Component Specification and Data Sheets

## Project Specifications



PS06-001 REV AF

TITLE: **Product Specification, Tip-Versatile Ablation Catheter (T-VAC), (Model 990022)**

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**1. Purpose**

1.1 The purpose of this document is to describe the product specifications for the Ablation Frontiers™ Tip-Versatile Ablation Catheter (T-VAC) (Model 990022).

**2. Scope**

2.1 This document applies to the T-VAC only which is one component of the Ablation Frontiers™ Cardiac Ablation System.

**3. General Description**

3.1 The Ablation Frontiers™ Tip-Versatile Ablation Catheter is designed to ablate cardiac tissue in the atrium for the treatment of supraventricular arrhythmias and atrioventricular node ablation.



**Figure 1: T-VAC Distal Segment**

**4. Intended Use**

4.1 The device is intended to be used in conjunction with the Ablation Frontiers™ GENius™ Multi-Channel RF Ablation Generator and its components to deliver precise, temperature controlled radio frequency (RF) ablation therapy within the atrium of the heart.

4.2 In addition, the device works as a pass through for the assessment of cardiac electrophysiological mapping and delivery of diagnostic pacing stimuli.

**5. Reference Documents**

5.1 Council Directive 93/42/EEC

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- 5.2 ISO 10555-1: 1995 Sterile, single-use intravascular catheters -- Part 1: General requirements
- 5.3 ISO 10555-2: 1996 Sterile, single-use intravascular catheters -- Part 2: Angiographic catheters
- 5.4 ISO 10993-1: 2003 Biological evaluation of medical devices -- Part 1: Evaluation and testing
- 5.5 ISO 11137-2: 2006 Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose
- 5.6 ISO 11607-1: 2006 Packaging for terminally sterilized medical devices -- Part 1: Requirements for materials, sterile barrier systems and packaging systems
- 5.7 ISO 11607-2: 2006 Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes
- 5.8 ISO 15223-1: 2007 Medical devices -- Symbols to be used with medical device labels, labeling and information to be supplied -- Part 1: General requirements
- 5.9 BS EN 552: 1994 Sterilization of medical devices -- Validation and routine control of sterilization by irradiation
- 5.10 BS EN 556: 1995 Sterilization of medical devices -- Requirements for Terminally-Sterilized Devices to be Labeled 'Sterile'
- 5.11 BS EN 556-1: 2001 Sterilization of medical devices -- Requirements for medical devices to be designated "STERILE" -- Part 1: Requirements for terminally sterilized medical devices
- 5.12 BS EN 980: 2008 Symbols for use in the labeling of medical devices
- 5.13 BS EN 60601-1: 2006 Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
- 5.14 BS EN 60601-2-2: 2009 Medical electrical equipment -- Part 2-2: Particular requirements for the safety of high frequency surgical equipment
- 5.15 ASTM F1980-07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- 5.16 ASTM D4169-04a Standard Practice for Performance Testing of Shipping Containers and Systems
- 5.17 ASTM D4332-01: 2006 Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing

## 6. Interface Requirements

- 6.1 GENius Multi-Channel RF Ablation Generator ('Generator')
  - 6.1.1 The catheter shall include a twenty-six (26) pin receptacle to provide an electrical connection to the generator via the Catheter Interface Cable and ECG Interface Box.
  - 6.1.2 The measured temperature of the catheter should be within  $\pm 2^{\circ}\text{C}$  of actual temperature.

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- 6.1.3 The electrical design of the catheter shall allow for the temperature acquisition circuitry of the Ablation System to respond in one (1) second after twenty-five (25) applications of RF energy.
- 6.1.4 The catheter shall contain circuitry that allows the RF ablation generator to assess "single use."
- 6.1.5 The signal wire size must support the RF Ablation Generator's requirements for voltage and power.
- 6.2 Sheath and Hemostasis Valve
  - 6.2.1 The T-VAC shall have a maximum OD and electrode array that allows for insertion and withdrawal through a 9.5F sheath (minimum).

## 7. Physical Requirements

- 7.1 Length
  - 7.1.1 Overall length must be 135±5cm.
  - 7.1.2 Working length must be 105±5cm.
- 7.2 Materials
  - 7.2.1 All materials in contact with blood or tissue shall be non-thrombogenic, nontoxic and biocompatible as defined by ISO 10555-1 § 4.2 and ISO 10993-1.
  - 7.2.2 The system will pass the tests for externally communicating device as outlined in ISO 10993-1.
  - 7.2.3 The system will pass the tests for contact in circulating blood for ≤ 24 hours as outlined in ISO 10993-1.
  - 7.2.4 The device shall be able to remain indwelling for up to four (4) hours without thrombo-embolic complications.
  - 7.2.5 The catheter design shall utilize materials that minimize surface roughness to avoid excessive trauma to anatomical structures that may come in contact with the catheter (as prescribed in Council Directive 93/42/EEC Annex 1 § 12.7.1, ISO 10555-1 §4.3 and ISO 10555-2 §4.4.1).

## 8. Environmental Requirements

- 8.1 Operating Environment
  - 8.1.1 The device shall not exhibit visual evidence of corrosion after being subjected to the test conditions prescribed in ISO 10555-1 §4.4.
- 8.2 Shipping/Storage
  - 8.2.1 Packaging containers shall be designed to protect and maintain product functional performance after being exposed to (-)20°C to 50°C) in accordance with ASTM D4332-01 and ASTM F1980-07.
  - 8.2.2 The packaging shall protect and maintain product functional requirements per the requirements of ASTM D4169-04a.
- 8.3 Electrical Safety Requirements

- 8.3.1 Dielectric breakdown should be 500 V AC minimum for a period of two (2) seconds with a runaway current of two (2) mA per BS EN 60601-1.
- 8.3.2 The catheter shall withstand a two (2) KV DC defibrillator pulse and demonstrate no breakdown of insulation and/or loss of functional or safety performance per BS EN 60601-2-2.

## 9. Performance Requirements

- 9.1 Device Delivery
  - 9.1.1 Visibility of the catheter shall be sufficient to identify position of the array arm under fluoroscopy in manner consistent with ISO 10555-2 §4.2.
  - 9.1.2 All surfaces of the catheter must be smooth and clean, free of detachable particles, and coloration must appear uniform when inspected under 20/20 corrected vision at eighteen (18) inches using normal lighting conditions as per ISO 10555-1 §4.3.
- 9.2 Device Manipulation
  - 9.2.1 Tip Deflection
    - 9.2.1.1 Asymmetrical: the tip deflection must be a minimum of 120° for F-curve and 180° for D-curve.
    - 9.2.1.2 Symmetrical: the tip deflection must be a minimum of 180°.
  - 9.2.2 Catheter Shaft Flexibility - Bend Radius must be less than or equal to 20mm diameter without exhibiting visual evidence of kinking or bond separation.
  - 9.2.3 Device will transfer torque from the proximal end to the distal end.
  - 9.2.4 Torsional Rigidity - The catheter shaft shall withstand two rotations (720°) while the tip is held-constant without causing any mechanical failures.
  - 9.2.5 Buckle Force - The average force required to buckle the distal section shall not exceed 340 gf when gripped 2.0 inches from the distal end.
  - 9.2.6 Steering (cycle test) - The steering mechanism shall withstand a minimum of fifty (50) steering cycles per steering wire through the entire range of motion without compromising physical or electrical integrity.
- 9.3 Bond strengths at locations where adhesives or other junction bonding methods are used for bonding between parts of the catheter shall be in accordance with ISO 10555-1 unless otherwise stated.
  - 9.3.1 Signal wire to Electrode – (0.5 lbf). This is a location weld only, with no specification limit. The 0.5 lbf is for reference only, to allow the wire to remain intact to the electrode during manufacturing assembly and handling.
  - 9.3.2 Tip Electrode to Distal shaft bond  $\geq 5.0$  lbf
  - 9.3.3 Band Electrode to Distal shaft bond  $\geq 1.0$  lbf
  - 9.3.4 Distal to Proximal shaft  $\geq 10.0$  lbf
  - 9.3.5 Proximal shaft to outer shaft support  $\geq 5.0$  lbf

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- 9.3.6 Catheter shaft tensile strength  $\geq 10.0$  lbf
- 9.3.7 Steering wire termination Bond  $\geq 10.0$  lbf
- 9.3.8 7F Shaft 35D/72D Durometer Transition tensile strength  $\geq 10.0$  lbf
- 9.3.9 7F Shaft 35D/40D Durometer Transition tensile strength  $\geq 10.0$  lbf
- 9.4 Mapping, Pacing, and Ablating
  - 9.4.1 One (1) linear array that is able to accommodate mapping/ablation electrodes of which the distal tip electrode is four (4) mm in length, and the more proximal band electrodes are two (2) mm in length with a 2.5mm to 3.5 mm spacing in between adjacent electrodes.
  - 9.4.2 The array must be designed in a manner that facilitates tissue contact for purposes of mapping and ablating.
  - 9.4.3 The outer surface of the catheter body shall not exceed  $41^{\circ}\text{C}$  after ablating for 120 seconds at the maximum power setting when located in a  $37^{\circ}\text{C}$  saline solution bath (based on Council Directive 93/42/EEC Annex 1 §12.7.5).

## 10. Packaging Requirements

- 10.1 The catheter will be packaged in a tray within a Tyvek/Mylar pouch, with the pouches packed in carton boxes for shipping and storage as per Council Directive 93/42/EEC Annex 1 §8.3, ISO 11137-2 §5.1.1, ISO 11607-1, and ISO 11607-2.
- 10.2 Packaging materials shall withstand E-Beam sterilization and maintain the sterile integrity barrier as per, BS EN 552, BS EN 556, BS EN 556-1, ISO 11137-2 §5.1.1, ISO 11607-1 and ISO 11607-2.

## 11. Labeling Requirements

- 11.1 The catheter shall meet all labeling requirements set forth by the applicable standard(s), Council Directive 93/42/EEC Annex 1 §13, BS EN 980, ISO 10555-1 §6 and ISO 15223-1.
- 11.2 Where appropriate, symbols/ icons will be used in labeling. At a minimum, the labeling shall include, Model Name and Number (Type), Manufacturer address (and origin if different than mfr), Date of Manufacture and Sterility Expiration Date.
- 11.3 Defibrillator proof CF symbol, Warning symbol, any labeling requirement by governing agencies and Clinical trial, device exemption or not for human use labeling as required for non-commercialized product.
- 11.4 The catheter shall be labeled for sterile, single use only.

## 12. Sterility Requirements

- 12.1 Per ISO 11137-2, Sterility Requirement, shall be E-Beam Sterilized and meet SAL  $10^{-6}$ .
- 12.2 Product shall be compatible with single-dose twenty-five (25) to fifty-five (55) kGy E-Beam radiation sterilization methods.

**13. Manufacturing Requirements**

- 13.1 Product shall be manufactured in accordance with Good Manufacturing Practices (GMP), with manufacturing processes that are validated, and quality assurance document controlled revisions of changes.

**14. Product Life**

- 14.1 Catheter shall have an eighteen (18) month shelf life from the date of sterilization as per Council Directive 93/42/EEC Annex 1 §13.3(e) and ASTM F1980-07.

PRODUCTION RELEASED -- PS06-001: AF -- Print Time: 11/6/2009 09:05:51



## Energy Delivery Wire Specification

COMPONENT SPECIFICATION			
Part No.:	 <b>AblationFrontiers</b> EXPANDING YOUR POSSIBILITIES	Title: Signal wire, 36ga, Bi-filer, copper/ constantan	
Rev			Page 42 of 82

**Description:** Signal wire, 36ga, Bi-filar, Copper Alloy / Constantan, Double Pass Heavy Polyimide Coating. Colored: Constantan: Green. Alloy11: Red.

**Specifications:** CONST. TC T SPEC, Copper Alloy, Size:.005 H-ML, BIFILAR, DOUBLE PASS COATING (Material: Pyre-ML RC5019, ML-101) Colored: Constantan: Green. Alloy11: Red.

**Construction:** The bifilar signal wire shall be constructed of one insulated conductor of Copper Alloy and one insulated conductor of Constantan, bonded together by a single bonding coat. The conductor pair shall be parallel to each other with no twist greater than one (1) full twist per linear foot.

**Dimensional:** The individual conductors shall be 36 AWG, 0.0049/0.0051" diameter. The final maximum dimension of the minor axis shall be 0.0066" after application of the insulation. The final maximum dimension of the major axis shall be 0.0128" after application of the insulation.

**Electrical:** The resistance of the conductors shall be:

Copper Alloy: 1.18 ohms/foot  $\pm$  15%  
 Constantan: 12.59 ohms/foot  $\pm$  15%

**Insulation:** The insulator of the bifilar pair shall provide a minimum insulation voltage breakdown of 900 VDC.

**Voids:** The insulation shall contain no voids that cause the insulation protection to fall below the minimum voltage insulation limit of 900 VDC.

**Holes:** The insulation shall contain no holes. A hole shall be defined as a breach of the insulation layer that exposes any conductor.

**Material** Conductor, Copper Alloy consisting of 1.0 $\pm$ 0.1% Nickel, 0.5% maximum Manganese, Balance Copper (Alloy 11). Presence of other trace elements shall not exceed 0.1% per element, 0.5% collectively.  
 Conductor, Constantan TC Type T (Reference only: 45% Nickel, 55% Copper)  
 Insulation, Polyimide rated at 240 C as per NEMA MW-1000, MW-16C

## Matrix Material Data Sheet

### Arkema Group Pebax® 3533 Polyether Block Amide (PEBA)

**Categories:** [Polymer](#); [Thermoplastic](#); [Elastomer, TPE](#); [Polyether Block Amide \(PEBA\)](#)

**Material**

**Notes:** Information provided by Arkema Group

**Vendors:** No vendors are listed for this material. Please [click here](#) if you are a supplier and would like information on how to add your listing to this material.

Physical Properties	Metric	English	Comments
Density	1.01 g/cc	0.0365 lb/in <sup>3</sup>	ASTM D792
Water Absorption	1.20 %	1.20 %	24 hr in water at 20°C; ASTM D570
Water Absorption at Saturation	0.500 %	0.500 %	20°C and 65% RH; ASTM D570
Melt Flow	8.00 g/10 min	8.00 g/10 min	ASTM D1238
Mechanical Properties	Metric	English	Comments
Hardness, Shore A	83	83	ASTM D2240
Hardness, Shore D	33	33	ASTM D2240
Tensile Strength at Break	30.0 MPa	4350 psi	ASTM D638
Elongation at Break	670 %	670 %	ASTM D638
Modulus of Elasticity	0.0146 GPa	2.12 ksi	ASTM D638
Flexural Modulus	0.0250 GPa	3.63 ksi	ASTM D790
Resilience	0.700	0.700	BS 903 par: A 8
Flex Crack Resistance	2.00	2.00	[mm] 20°C / 100000 flexures; ASTM D813
	2.50	2.50	[mm] -20°C / 50000 flexures; ASTM D813
Izod Impact, Unnotched	NB	NB	ASTM D256-A

Tear Strength	45.0 kN/m	257 pli	notched; ASTM D624 (C)
	71.0 kN/m	405 pli	unnotched; ASTM D624 (C)
Taber Abrasion, mg/1000 Cycles	81.0	81.0	ASTM D1242
Abrasion	96.0	96.0	mm <sup>3</sup> ; DIN 53516
Compression Set	54.0 %	54.0 %	Load = 9.3 MPa (22 hr / 70°C); ASTM D395 Method A
Izod Impact, Notched @ - 40°C	NB	NB	ASTM D256-A
Izod Impact, Unnotched @ - 40°C	NB	NB	ASTM D256-A
Izod Impact, Notched	NB	NB	ASTM D256-A

Electrical Properties	Metric	English	Comments
Surface Resistance	2.00e+12 ohm @Temperature 20.0 °C	2.00e+12 ohm @Temperature 68.0 °F	65% RH; ASTM D257

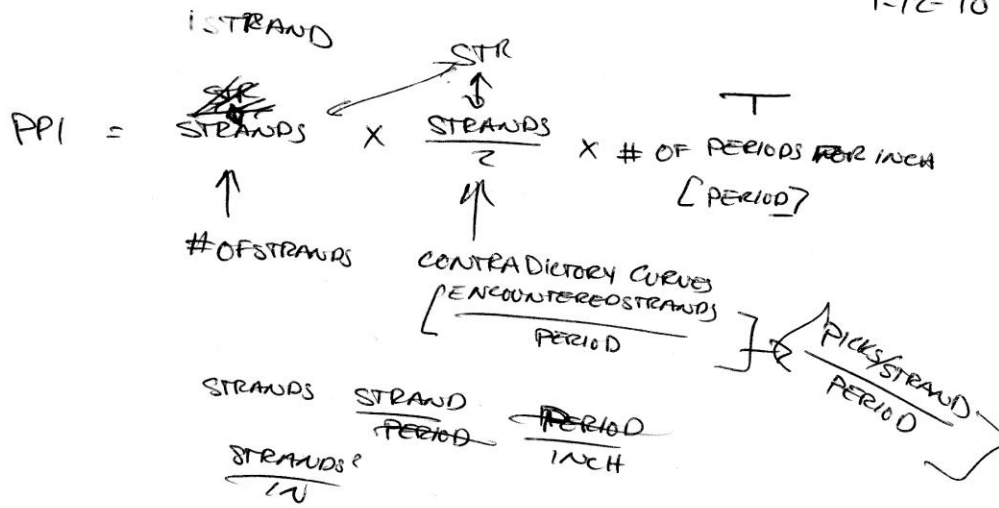
Thermal Properties	Metric	English	Comments
Heat of Fusion	11.0 J/g	4.73 BTU/lb	ASTM D3417
CTE, linear	210 µm/m-°C @Temperature -40.0 - 140 °C	117 µin/in-°F @Temperature -40.0 - 284 °F	ASTM D696
Melting Point	143.5 °C	290.3 °F	ASTM D3418
Deflection Temperature at 0.46 MPa (66 psi)	46.0 °C	115 °F	ASTM D648
Vicat Softening Point	74.0 °C	165 °F	under 1 daN; ASTM D1525

Some of the values displayed above may have been converted from their original units and/or rounded in order to display the information in a consistent format. Users requiring more precise data for scientific or engineering calculations can click on the property value to see the original value as well as raw conversions to equivalent units. We advise that you only use the original value or one of its raw conversions in your calculations to minimize rounding error. We also ask that you refer to MatWeb's disclaimer and terms of use regarding this information. [Click here](#) to view all the property values for this datasheet as they were originally entered into MatWeb.

# Appendix E - Analysis

## PPI Calculation

1-12-10



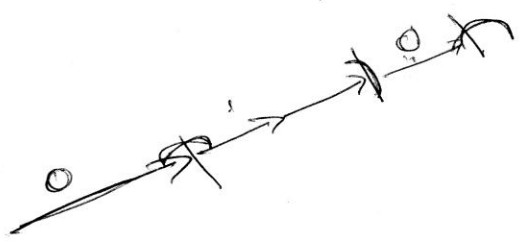
↓  
PERIODS/IN

$$PPI = \frac{STR^2}{2} T$$

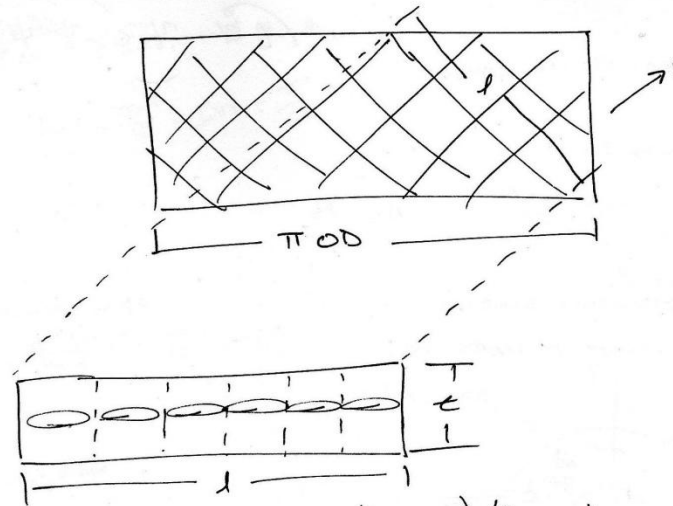
$$T = \frac{2 \times PPI}{STR^2} \left[ \frac{\text{PERIOD}}{\text{IN}} \right]$$

$$\left[ \frac{\text{PERIOD}}{\text{IN}} \right] T = \frac{1}{2} \rightarrow \left[ \frac{\text{PERIOD}}{\text{IN}} \right]$$

$$\left[ \text{IN} \right] 2 = \frac{1}{T} \frac{\text{PERIOD}}{\text{PERIOD}} \rightarrow \text{IN} \checkmark$$



# Micromechanics



$$\epsilon A_f = n A_{\text{STRAND}} = n \pi \left( \frac{D_{\text{MAJOR}}}{2} \right) \left( \frac{D_{\text{MINOR}}}{2} \right)$$

$$n = \frac{\# \text{ OF STRANDS}}{\text{DIRECTION}}$$

$$\epsilon A_f = \frac{n \pi D_{\text{MAJOR}} D_{\text{MINOR}}}{4}$$

$$D_{\text{MAJOR}} = .0128''$$

$$D_{\text{MINOR}} = .0066''$$

t = RADIAL THICKNESS OF CATHETER

$$t = \frac{.09}{2} - \frac{.04}{2} = .025''$$

$$t = \frac{.084}{2} - \frac{.04}{2} = .022''$$

$$\text{ARC LENGTH} = r\theta$$

$$r = \frac{OD}{2}$$

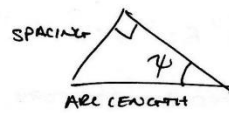
$$\theta = \frac{360}{\left( \frac{\text{STRANDS}}{2} \right)}$$

$$\text{SPACING} = \text{ARC LENGTH} \sin \psi$$

$$t = \left( \frac{\text{STRANDS}}{2} \right) \text{ SPACING} \rightarrow \text{FOR MAXIMUM LENGTH CASE}$$

FOR AREA OF PEBAX

$$A_p = t \epsilon - \epsilon A_f$$



$$\sin \psi = \frac{\text{SPACING}}{\text{ARC LENGTH}}$$

$$\psi = \text{BRAID ANGLE}$$

$$E_1^h \begin{bmatrix} \psi & -\psi & 0 & -\psi & \psi \end{bmatrix}$$

$\leftarrow E_{m_i}$

COMPUTE  $E_1$  FOR HELICAL LAYERS  
HERE ARE...

$$E_1^h = V_f E_f + V_m E_m$$

$$V_f = \frac{A_f}{A_c}$$

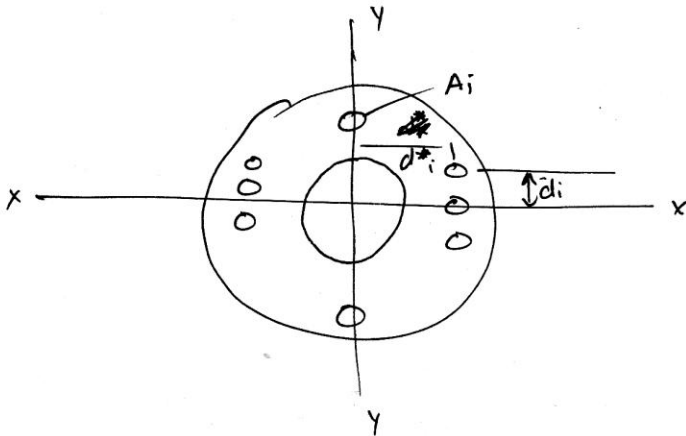
$$V_m = \frac{A_c - A_f}{A_c}$$

$$A_c = l t$$

FOR UNI LAYER

BALANCE YOUR STIFFNESS (BENDING)

$I$  IS INDEPENDENT OF COORD SYS.



$$I_{xx} = \sum \bar{I}_{xx} + \sum A_i d_i^2$$

$$I_{yy} = \sum \bar{I}_{yy} + \sum A_i d_i^* d^2$$

$$I_{xx} = I_{yy} = I_{xx}'$$

$$\text{GET } E_1^h = V_f^u E_f^u + V_m^u E_m^u$$

RUN LAMINATED PLATE THEORY FOR HELICAL / UNI LAYERS

GET COMPOSITE EFFECTIVE AXIAL MODULUS

$$E_x = \frac{1}{\sum a_{11} T} \quad \text{TOTAL THICKNESS}$$

$$P_{CR} = \frac{C E_x I}{L^2}$$

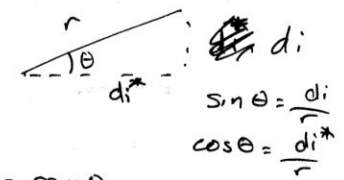
NOTE

$$E_1, E_2, \nu_{12}, G_{12}$$

FOR  $I_{XX}$   

$$I_{XX} = \sum I_{XXi} + \sum A_i d_i^2$$

$$I_{XX} = \frac{\pi r^4}{4} = I_{YY} = \frac{\pi}{64} d^4$$



$$d_i = r \sin \theta$$

$$d_i^* = r \cos \theta$$

FOR PULL WIRE

$$A = \frac{\pi}{4} d^2 = \frac{\pi}{4} (.009)^2$$

$$r_{PI} = .02 + D_{MINOR} + \frac{1}{2} D_{PULLWIRE}$$

$$r_{PI} = d_{PULL}$$

$$I_{PW} = \frac{\pi}{64} (D_{PULLWIRE})^4$$

r MUST BE LARGER THAN

$$.02 + 2 \times .0066 = .0332$$

r MUST BE LESS THAN

$$\frac{.092 - .0066}{2} = .0427$$

$$.0332 \leq r \leq .0427$$

$$I_{XX \text{ PULL WIRE}} = \frac{\pi}{64} (D_{PULLWIRE})^4 + A_{PW} \frac{\pi}{4} (D_{PULLWIRE})^2 \left( .02 + D_{MINOR} + \frac{D_{PULLWIRE}}{2} \right)^2$$

FOR 36 AWG WIRE (LINEAR FIBER)

$$A_{LF} = \frac{\pi}{4} \left( \frac{D_{MAJOR}}{2} \right) \left( \frac{D_{MAJOR}}{2} \right)$$

$$\hookrightarrow \frac{\pi}{4} (D_{MAJOR})^2$$

TREAT AS CIRCLE  
 CHANGE IF USING 40 AWG

$$d_i = r \sin \theta$$

$$r_{LF} = d_i$$

$$I_{LF} = \frac{\pi}{64} (D_{MAJOR})^4$$

$$I_{XX \text{ LF}} = \frac{\pi}{64} (D_{MAJOR})^4 + \frac{\pi}{4} (D_{MAJOR})^2 (r \sin \theta)^2$$

$$I_{XX \text{ UNI}} = 2 I_{XX \text{ PULL WIRE}} + 4 I_{XX \text{ LF}}$$

FOR  $I_{YY}$

FOR 36 AWG WIRE (LINEAR FIBER)

$$A_{LF} = \frac{\pi}{4} (D_{MAJOR})^2$$

$$d_i^* = r \cos \theta$$

$$I_{LF} = \frac{\pi}{64} (D_{MAJOR})^4$$

$$I_{YY \text{ LF}} = \frac{\pi}{64} (D_{MAJOR})^4 + \frac{\pi}{4} (D_{MAJOR})^2 (r \cos \theta)^2$$

$$I_{YY \text{ UNI}} = 6 \left( \frac{\pi}{64} (D_{MAJOR})^4 + \frac{\pi}{4} (D_{MAJOR})^2 (r \cos \theta)^2 \right)$$

FOR BALANCED DESIGN

$$I_{XX} = I_{YY}$$

VOLUME FRACTIONS FOR UNILAYER

1-18-10

$$V_f = \frac{A_f}{A_c}$$

~~FOR POLYMER~~

FOR COMPOSITE AREA

$$\begin{aligned} A_c &= \pi (r_o^2 - r_i^2) \\ &= \pi (.046^2 - .034^2) \\ &= .0036090302 \end{aligned}$$

FOR PDC WIRES

$$\begin{aligned} A_{PW} &= \frac{\pi}{4} (.009)^2 \\ &= .0000636173 \end{aligned}$$

$$V_{PW} = \frac{.0000636173}{.0036090302} = .0176272426 \times 2 = .0352544852$$

FOR LINEAR FIBERS (36 AWG)

$$\begin{aligned} A_{LF} &= \frac{\pi}{4} (.012)^2 \\ &= .0001286796 \end{aligned}$$

$$V_{LF} = \frac{.0001286796}{.0036090302} = .0356549065 \times 6 = .2139294388$$

FOR PEGAY

$$A = .0036090302 - .0008998123 = .0027092179$$

$$V_{PEBAY} = \frac{.0027092179}{.0036090302} = .750816076$$



CASE 1

$$E_1^u = V_{PEBAK} E_{PEBAK} + V_{LF} E_{LF} + V_{PW} E_{PW}$$

$$E_{PEBAK} = 2.76 \text{ ksi}$$

$$E_{LF} = 16000 \text{ ksi} \rightarrow 16 \text{ Msi}$$

$$E_{PW} = 29000 \text{ ksi}$$

$$E_1^u = (0.750816076)(2.76 \text{ ksi}) + 0.2139244388(16000 \text{ ksi}) + 0.0352544852(29000 \text{ ksi})$$

$$E_1^u = 4447.32 \text{ ksi}$$

CASE 2

$$E_1^u = V_{LF} E_{LF} + V_{PW} E_{PW}$$

$$= 0.2139244388(16000 \text{ ksi}) + 0.0352544852(29000 \text{ ksi})$$

$$= 4445.25 \text{ ksi}$$

ASK MELLO ABOUT R IN BRAID. M

# Heat Transfer Analysis

17 12/2/04

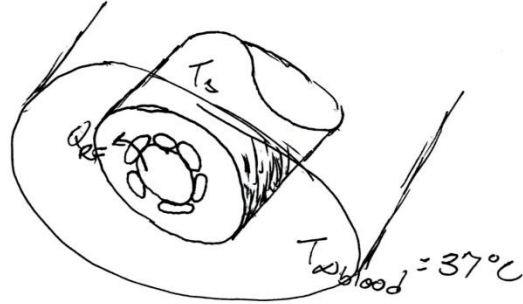
## HEAT TRANSFER ANALYSIS

14

BIOT NUMBER

to determine validity of  
lumped capacitance

$$Bi = \frac{hL_c}{k}$$



DETERMINE  $h$

$$Nu_D = \frac{hD_h}{k} \quad D_h = \frac{4A_c}{P} \leftarrow \text{wetted perimeter}$$

$$Re = \frac{VD_h}{\nu}$$

$$M_{\text{blood}} = 3 \mu\text{H}_2\text{O} + 4 \mu\text{H}_2\text{O}$$

$$\nu = \frac{\mu}{\rho} \quad \rho \approx 1000 \frac{\text{kg}}{\text{m}^3}$$

$$\nu = \frac{3(1080 \times 10^{-6} \frac{\text{N}\cdot\text{s}}{\text{m}^2})}{1000 \frac{\text{kg}}{\text{m}^3}}$$

$$\nu = 3.057 \times 10^{-6} \frac{\text{m}^2}{\text{s}} \text{ for blood @ } 37^\circ\text{C}$$

$$D_h = \frac{4\pi(D_{\text{rein}}^2 - D_{\text{cath}}^2)}{\pi(D_{\text{rein}} + D_{\text{cath}})} = \frac{D_{\text{rein}}^2 - D_{\text{cath}}^2}{D_{\text{rein}} + D_{\text{cath}}}$$

$$D_h = \frac{(4.5 \text{ mm})^2 - \left[0.04 \text{ in} \left(\frac{2.54 \text{ cm}}{1 \text{ in}}\right) \left(\frac{10 \text{ mm}}{1 \text{ cm}}\right)\right]^2}{4.5 \text{ mm} + 0.04 \text{ in} \left(\frac{2.54 \text{ cm}}{1 \text{ in}}\right) \left(\frac{10 \text{ mm}}{1 \text{ cm}}\right)}$$

$$D_h = 7.214 \text{ mm} \Rightarrow .007214 \text{ m}$$

$$Re = \frac{VD_h}{\nu}$$

$$= \frac{30 \frac{\text{cm}}{\text{s}} \left(\frac{2 \text{ m}}{100 \text{ cm}}\right) (.007214 \text{ m})}{3.057 \times 10^{-6} \frac{\text{m}^2}{\text{s}}}$$

$$Re = 707.95 \leftarrow \text{Laminar Flow } < 2300$$

$$\Rightarrow Nu_D = \text{constant} = 4.36$$

Assume: Fully Developed Laminar Flow

## HEAT TRANSFER ANALYSIS

(15)

$$Nu_D = \frac{hD_n}{k} \Rightarrow h = \frac{Nu_D k_{\text{blood}}}{D_n} \quad k_{\text{blood}} \approx .5 \frac{\text{W}}{\text{m}\cdot\text{K}}$$

$$h = \frac{4.36 (.5 \frac{\text{W}}{\text{m}\cdot\text{K}})}{.007214 \text{ m}}$$

$$h = 302.14 \frac{\text{W}}{\text{m}^2\cdot\text{K}}$$

$$Bi = \frac{hL_c}{k}$$

$$L_c = \frac{V}{A_s} = \frac{\frac{\pi}{4}(D_o^2 - D_i^2) \ell_{\text{cath}}}{\pi D_o \ell_{\text{cath}}}$$

$$L_c = \frac{D_o^2 - D_i^2}{4D_o} = \frac{(.09 \text{ in})^2 - .05 \text{ in} (.0632 \text{ in})^2}{4(.0632 \text{ in})}$$

$$L_c = 0.010 \text{ in} \left( \frac{2.54 \text{ cm}}{1 \text{ in}} \right) \left( \frac{1 \text{ m}}{100 \text{ cm}} \right) = 4.13 \times 10^{-4} \text{ m}$$

$$Bi = \frac{302.14 \frac{\text{W}}{\text{m}^2\cdot\text{K}} (4.13 \times 10^{-4} \text{ m})}{0.18 \frac{\text{W}}{\text{m}\cdot\text{K}}} = .693 > .1$$

Lumped Capacitance invalid

## APPENDIX F - Coding

### Braid Geometry

```
function [circ_d] = Medtronic_Helix_Code(totalstrands, ppiG, ODG, location,
wirenumber)
clc

%strands = 8;           %number of strands
strands = totalstrands;
OD      = 0.0844;       %Outer Diameter of Braid
dm      = 0.0066;       %Minor Diameter of Strand
d_avg   = OD - dm;      %Nominal Diameter of Braid
res     = 4;           %# Points/Degree
%ppi    = 60;          %input picks per inch
ppi     = ppiG;
picsperperiod = strands;
periods = ppi/picsperperiod;%# of periods per inch
h       = 1/periods;    %height of 1 period
d_major = 0.0128;
%user_s = 1;           %electrical strand picked by user
user_s  = wirenumber;

%cut_length = 43;      %prompted to user later on
%distance along shaft for desired exposure point
in inches
cut_length = location;

%cath_OD    = 0.09;     %prompted to user later on
%outer diameter of fully made catheter
cath_OD    = ODG;

%maybe prompt to user later on

pts        = 361*res;   %total number of data points
i = 1;       %sets point index to 1
s = 1;       %strand index variable
s_test = s;   %strand index for test condition
counter = 0;
jumpflg = 0;
count = 0;

x = zeros(pts-(res-1),strands);
y = zeros(pts-(res-1),strands);
z = zeros(pts-(res-1),strands);
angle = zeros(pts-(res-1),strands);

%fills x,y,z coordinates of each strand

for s = 1:strands
    for theta = 0:1/res:360
```

```

phi = 360/strands*(s-1);      %phase shift of each strand
if rem(s,2)                   %counterclockwise for odd # strands

    angle(i,s) = phi+(i-1)/res;

    x(i,s) = d_avg/2*cosd(theta+phi);
    y(i,s) = d_avg/2*sind(theta+phi);
    z(i,s) = (i-1)*h/pts;      %point evenly along shaft length...
                                %starting from 0

else                           %clockwise for even # strands

    angle(i,s) = phi-(i-1)/res;

    x(i,s) = d_avg/2*cosd(angle(i,s)); %cos and sin 90 deg out of
phase
    y(i,s) = d_avg/2*sind(angle(i,s));
    z(i,s) = (i-1)*h/pts;

end
i = i + 1;
end
i = 1;
end

x_jump = x;
y_jump = y;
z_jump = z;

chord = sqrt((x(2,1)-x(1,1))^2+(y(2,1)-y(1,1))^2+(z(2,1)-z(1,1))^2) %find
distance for a chord from pt to pt
psi = atand(chord/(z(2,1)-z(1,1)))
%calculate braid angle

theta_data = xlsread('Medtronic','Modified','a1:a43');      %load in
data for jump profile
delta_r = dm*xlsread('Medtronic','Modified','b1:b43');
xtol = 1e-4;

for s = 1:strands
    if rem(s,2)
        jumpflg = 0;
    else
        jumpflg = 1;
    end
    for i = 1:pts-(res-1)
        for s_test = 1:strands      %compare one strand to all other
strands
            if s ~= s_test
%                if x(i,s) == x(i,s_test) && y(i,s) == y(i,s_test) %finds
intersection points that need to be altered
                    if ( norm( [x(i,s)-x(i,s_test) y(i,s)-y(i,s_test)] ) <= xtol )
                        counter = counter + 1;
                        d_theta = round((d_major/sind(psi)+dm)/(d_avg/2)*180/pi);
%arc = r*theta, 180/pi to put in degrees

```

```

        [x_jump, y_jump, jumpflg] = data_change(x_jump, y_jump,...
        i, s, res, jumpflg, angle, theta_data,...
        delta_r, strands, d_theta);    %call data_change
function
    end
    end
    end
    end
    jumpflg = 0;        %set jumpflg to 0 before starting new strand
end

    figure(2)
    %for s = 1:strands
        s = 2;
        hold on
        plot3(x_jump(:,s),y_jump(:,s),z_jump(:,s))
        xlabel('X')
        ylabel('Y')
        zlabel('Z')
    %end

hold off

counter;
                                %calculate cut position
num_periods = cut_length/h
pos_len = (num_periods - floor(num_periods))*h;
i = 1;
while z(i,user_s) < pos_len
    i = i + 1;        %finds point just above desired position along shaft
end
if i > 1
    pt_i = (1/(z(i,user_s)-z(i-1,user_s)))*(pos_len-(z(i-1,user_s)))+i-1;

    x_return = (x_jump(i,user_s)-x_jump(i-1,user_s))*(pt_i-(i-1))+x_jump(i-
1,user_s); %returns interpolated x, y and angle coordinates
    y_return = (y_jump(i,user_s)-y_jump(i-1,user_s))*(pt_i-(i-1))+y_jump(i-
1,user_s); %of strand at distance z along shaft
    angle_return = (angle(i,user_s)-angle(i-1,user_s))*(pt_i-(i-1))+angle(i-
1,user_s);
else
    x_return = x_jump(1,user_s);
    y_return = y_jump(1,user_s);
    angle_return = angle(1,user_s);
end

circ_d = (cath_OD/2)*angle_return*pi/180; %circumferential distance from datum
if circ_d > pi*cath_OD/2
    circ_d = -(pi/2*cath_OD-(circ_d-pi/2*cath_OD));
end
circ_d
end

```

```

function [x_jump,y_jump,jumpflg] = data_change(x_jump, y_jump, i, s, res,
jumpflg, angle, theta_data, delta_r , strands, d_theta)

    OD      = 0.0844;           %outer diameter of braid
    dm      = 0.0066;           %minor diameter of strands
    d_avg   = OD-dm;
    m = 1;                       %initialize jump curve index
    theta_int = angle(i,s);      %store theta position of intersection

    j = 1;
    d_beta = 180/(d_theta*res);  %change in angle through excel sheet
    beta = 0;                    %initialize jump curve angle
    phi = 360/strands*(s-1);     %calculate phase shift

    if jumpflg == 0              %test to see if strand has just had a jump
        if rem(s,2)
            if i > round(d_theta*res/2) && i < 361*res - round(d_theta*res/2)
                %for pts where full data range applies

                i = i - round(d_theta/2*res); %move index to starting index at
                %beginning of jump

                for theta = (angle(i,s)):1/res:(angle(i,s)+d_theta)

                    angle_diff = abs(theta_int - theta);

                    while theta_data(j) < beta %finds proper spot in excel data to
                    interpolate data
                        if j<43
                            m = j+1;
                            j = j+1;           %find proper point to interpolate in
                    excel data
                        else
                            m = j;
                            beta = 180;
                        end
                    end
                    if m == 1 || m == 43 %avoids interpolation of end points of data

                        d_r_rel = delta_r(m)*sind(beta); %project onto theta_int
                    vector
                        d_r      = d_r_rel/cosd(angle_diff); %project onto theta(i,s)

                    else

                        d_r_rel = (delta_r(m-1)+((delta_r(m)-delta_r(m-1))/...
                    %interpolate data for designated beta angle
                        (theta_data(m)-theta_data(m-1))*(beta-theta_data(m-1))))...
                    %project onto theta_int vector
                        *sind(beta);
                        d_r      = d_r_rel/abs(cosd(angle_diff));

                    end
                end
            end
        end
    end

```

```

coordinates
    d_x_jump = d_r*cosd(theta);           %convert to rectangular
    d_y_jump = d_r*sind(theta);

    x_jump(i,s) = x_jump(i,s) + d_x_jump;   %add jump distance
    y_jump(i,s) = y_jump(i,s) + d_y_jump;   %to original data

    beta = beta + d_beta;
    i = i + 1;
end

beta = 0;
m = 1;
jumpflg = 1;
j = 1;
else if i >= 361*res - round(d_theta*res/2) %for pts near end of period

    i = i - round(d_theta/2*res);           %move index to starting index
at beginning of jump
    pts = 361*res-(res-1) - i;             %finds pts available
for change

    %for theta = (angle(i,s)):1/res:angle(i+pts,s) %step back to change
to 43 excel points
    for i = i:(i+pts)
        angle_diff = abs(theta_int - theta);

        while theta_data(j) < beta
            m = j;
            j = j+1;
        end
        if m == 1 || m == 43 %avoids interpolation of end points of data
            d_r_rel = delta_r(m)*sind(beta);
            d_r      = d_r_rel/cosd(angle_diff);

        else
            d_r_rel = (delta_r(m-1)+((delta_r(m)-delta_r(m-1))/...
                (theta_data(m)-theta_data(m-1))*(beta-theta_data(m-1))))...
                *sind(beta);
            d_r      = d_r_rel/abs(cosd(angle_diff));
        end

        d_x_jump = d_r*cosd(theta);
        d_y_jump = d_r*sind(theta);

        x_jump(i,s) = x_jump(i,s) + d_x_jump;
        y_jump(i,s) = y_jump(i,s) + d_y_jump;

        beta = beta + d_beta;
        %i = i + 1;
    end
beta = 0;
m = 1;
jumpflg = 1;

```



```

j = 1;

else                                     %for pts near beginning of period
pts = i - 1;                             %# of points away from intersection point
i = 1;
pt_shift = (round(d_theta*res/2)-pts);
beta = d_beta*pt_shift;

for theta = (angle(i,s)):1/res:(angle(i,s)+(d_theta-pt_shift/res))
%step back to change to 43 excel points

    angle_diff = abs(theta_int - theta);

    while theta_data(j) < beta
        m = j;
        j = j+1;
    end
    if m == 1 || m == 43 %avoids interpolation of end points of data

        d_r_rel = delta_r(m)*sind(beta);
        d_r      = d_r_rel/cosd(angle_diff);

    else

        d_r_rel = (delta_r(m-1)+((delta_r(m)-delta_r(m-1))/...
            (theta_data(m)-theta_data(m-1))*(beta-theta_data(m-1))))...
            *sind(beta);
        d_r      = d_r_rel/abs(cosd(angle_diff));

    end

    d_x_jump = d_r*cosd(theta);
    d_y_jump = d_r*sind(theta);

    x_jump(i,s) = x_jump(i,s) + d_x_jump;
    y_jump(i,s) = y_jump(i,s) + d_y_jump;
    beta = beta + d_beta;
    i = i + 1;
end
end

beta = 0;
m = 1;
jumpflg = 1;
j = 1;

end

else                                     %repeat of above code for counterclockwise
strands
    if i > round(d_theta*res/2) && i <= 361*res - round(d_theta*res/2)
%for pts where full data range applies

```

```

        i = i - round(d_theta/2*res); %move index to starting index at
beginning of jump

        for theta = (angle(i,s)):-1/res:(angle(i,s)-d_theta) %counter
clockwise strands count down since

%drawn in opposite direction
        angle_diff = abs(theta_int - theta);

        while theta_data(j) < beta %finds proper spot in excel data to
interpolate data
            if j<43
                m = j+1;
                j = j+1;
            else
                m = j;
                beta = 180;
            end
        end
        if m == 1 || m == 43 %avoids interpolation of end points of data

            d_r_rel = delta_r(m)*sind(beta);
            d_r      = d_r_rel/cosd(angle_diff);

        else

            d_r_rel = (delta_r(m-1)+((delta_r(m)-delta_r(m-1))/...
(theta_data(m)-theta_data(m-1))*(beta-theta_data(m-1))))...
*sind(beta);
            d_r      = d_r_rel/abs(cosd(angle_diff));

        end

        d_x_jump = d_r*cosd(theta);
        d_y_jump = d_r*sind(theta);

        x_jump(i,s) = x_jump(i,s) + d_x_jump;
        y_jump(i,s) = y_jump(i,s) + d_y_jump;

        beta = beta + d_beta;
        i = i + 1;
        %j = 1;
    end

    beta = 0;
    m = 1;
    jumpflg = 1;
    j = 1;

    else if i > 361*res - round(d_theta*res/2) %for pts near end of period

        i = i - round(d_theta/2*res); %move index to starting index at
beginning of jump

```

```

        pts = 361*res - (res-1) - i;           %finds pts available
for change

%       for theta = (angle(i,s)):-1/res:(angle(i+pts,s)) %step back to
change points within d_theta
    for i = i:i+pts

        angle_diff = abs(theta_int - angle(i,s)); %theta);

        while theta_data(j) < beta
            m = j;
            j = j+1;
        end
        if m == 1 || m == 43 %avoids interpolation of end points of data

            d_r_rel = delta_r(m)*sind(beta);
            d_r      = d_r_rel/cosd(angle_diff);

        else
            d_r_rel = (delta_r(m-1)+((delta_r(m)-delta_r(m-1))/...
                (theta_data(m)-theta_data(m-1))*(beta-theta_data(m-1))))...
                *sind(beta);

            d_r      = d_r_rel/abs(cosd(angle_diff));
        end

        d_x_jump = d_r*cosd(angle(i,s)); %go back to theta if doesn't
work
        d_y_jump = d_r*sind(angle(i,s));

        x_jump(i,s) = x_jump(i,s) + d_x_jump;
        y_jump(i,s) = y_jump(i,s) + d_y_jump;

        beta = beta + d_beta;
%       i = i + 1;
    end
    beta = 0;
    m = 1;
    jumpflg = 1;
    j = 1;

    else %for pts near beginning of period
        pts = i - 1;
        i = i - pts;

        for theta = (angle(i,s)):-1/res:(angle(i+pts,s)) %step back to change
to 43 excel points

            angle_diff = abs(theta_int - theta);

            while theta_data(j) < beta
                m = j;
                j = j+1;
            end

```

```

if m == 1 || m == 43 %avoids interpolation of end points of data

    d_r_rel = delta_r(m)*sind(beta);
    d_r      = d_r_rel/cosd(angle_diff);

else

    d_r_rel = (delta_r(m-1)+((delta_r(m)-delta_r(m-1))/...
        (theta_data(m)-theta_data(m-1))*(beta-theta_data(m-1))))...
        *sind(beta);

    d_r      = d_r_rel/abs(cosd(angle_diff));
end

d_x_jump = d_r*cosd(theta);
d_y_jump = d_r*sind(theta);

x_jump(i,s) = x_jump(i,s) + d_x_jump;
y_jump(i,s) = y_jump(i,s) + d_y_jump;

beta = beta + d_beta;
i = i + 1;
end
end
beta = 0;
m = 1;
jumpflg = 1;
j = 1;
end

end
else
    jumpflg = 0;
end
end

```

## GUI Code

```
function varargout = Medtronic_GUI1(varargin)
% MEDTRONIC_GUI1 M-file for Medtronic_GUI1.fig
%   MEDTRONIC_GUI1, by itself, creates a new MEDTRONIC_GUI1 or raises the
existing
%   singleton*.
%
%   H = MEDTRONIC_GUI1 returns the handle to a new MEDTRONIC_GUI1 or the
handle to
%   the existing singleton*.
%
%   MEDTRONIC_GUI1('CALLBACK',hObject,eventData,handles,...) calls the
local
%   function named CALLBACK in MEDTRONIC_GUI1.M with the given input
arguments.
%
%   MEDTRONIC_GUI1('Property','Value',...) creates a new MEDTRONIC_GUI1 or
raises the
%   existing singleton*. Starting from the left, property value pairs are
applied to the GUI before Medtronic_GUI1_OpeningFcn gets called. An
%   unrecognized property name or invalid value makes property application
stop. All inputs are passed to Medtronic_GUI1_OpeningFcn via
varargin.
%
%   *See GUI Options on GUIDE's Tools menu. Choose "GUI allows only one
instance to run (singleton)".
%
% See also: GUIDE, GUIDATA, GUIHANDLES

% Edit the above text to modify the response to help Medtronic_GUI1

% Last Modified by GUIDE v2.5 04-Mar-2010 19:45:36

% Begin initialization code - DO NOT EDIT
gui_Singleton = 1;
gui_State = struct('gui_Name',       mfilename, ...
                  'gui_Singleton',  gui_Singleton, ...
                  'gui_OpeningFcn', @Medtronic_GUI1_OpeningFcn, ...
                  'gui_OutputFcn',  @Medtronic_GUI1_OutputFcn, ...
                  'gui_LayoutFcn',  [] , ...
                  'gui_Callback',    []);
if nargin && ischar(varargin{1})
    gui_State.gui_Callback = str2func(varargin{1});
end

if nargout
    [varargout{1:nargout}] = gui_mainfcn(gui_State, varargin{:});
else
    gui_mainfcn(gui_State, varargin{:});
end
% End initialization code - DO NOT EDIT

% --- Executes just before Medtronic_GUI1 is made visible.
function Medtronic_GUI1_OpeningFcn(hObject, eventdata, handles, varargin)
```

```

% This function has no output args, see OutputFcn.
% hObject    handle to figure
% eventdata  reserved - to be defined in a future version of MATLAB
% handles     structure with handles and user data (see GUIDATA)
% varargin   command line arguments to Medtronic_GUI1 (see VARARGIN)

% Choose default command line output for Medtronic_GUI1
handles.output = hObject;

% Update handles structure
guidata(hObject, handles);

% UIWAIT makes Medtronic_GUI1 wait for user response (see UIRESUME)
% uiwait(handles.figure1);

% --- Outputs from this function are returned to the command line.
function varargout = Medtronic_GUI1_OutputFcn(hObject, eventdata, handles)
% varargout  cell array for returning output args (see VARARGOUT);
% hObject    handle to figure
% eventdata  reserved - to be defined in a future version of MATLAB
% handles     structure with handles and user data (see GUIDATA)

% Get default command line output from handles structure
varargout{1} = handles.output;

function totalstrands_Callback(hObject, eventdata, handles)
% hObject    handle to totalstrands (see GCBO)
% eventdata  reserved - to be defined in a future version of MATLAB
% handles     structure with handles and user data (see GUIDATA)

% Hints: get(hObject,'String') returns contents of totalstrands as text
%        str2double(get(hObject,'String')) returns contents of totalstrands
%        as a double

% --- Executes during object creation, after setting all properties.
function totalstrands_CreateFcn(hObject, eventdata, handles)
% hObject    handle to totalstrands (see GCBO)
% eventdata  reserved - to be defined in a future version of MATLAB
% handles     empty - handles not created until after all CreateFcns called

% Hint: edit controls usually have a white background on Windows.
%       See ISPC and COMPUTER.
if ispc && isequal(get(hObject,'BackgroundColor'),
get(0,'defaultUiControlBackgroundColor'))
    set(hObject,'BackgroundColor','white');
end

function ppi_Callback(hObject, eventdata, handles)

```

```

% hObject    handle to ppi (see GCBO)
% eventdata  reserved - to be defined in a future version of MATLAB
% handles    structure with handles and user data (see GUIDATA)

% Hints: get(hObject,'String') returns contents of ppi as text
%         str2double(get(hObject,'String')) returns contents of ppi as a
double

% --- Executes during object creation, after setting all properties.
function ppi_CreateFcn(hObject, eventdata, handles)
% hObject    handle to ppi (see GCBO)
% eventdata  reserved - to be defined in a future version of MATLAB
% handles    empty - handles not created until after all CreateFcns called

% Hint: edit controls usually have a white background on Windows.
%         See ISPC and COMPUTER.
if ispc && isequal(get(hObject,'BackgroundColor'),
get(0,'defaultUicontrolBackgroundColor'))
    set(hObject,'BackgroundColor','white');
end

function OD_Callback(hObject, eventdata, handles)
% hObject    handle to OD (see GCBO)
% eventdata  reserved - to be defined in a future version of MATLAB
% handles    structure with handles and user data (see GUIDATA)

% Hints: get(hObject,'String') returns contents of OD as text
%         str2double(get(hObject,'String')) returns contents of OD as a double

% --- Executes during object creation, after setting all properties.
function OD_CreateFcn(hObject, eventdata, handles)
% hObject    handle to OD (see GCBO)
% eventdata  reserved - to be defined in a future version of MATLAB
% handles    empty - handles not created until after all CreateFcns called

% Hint: edit controls usually have a white background on Windows.
%         See ISPC and COMPUTER.
if ispc && isequal(get(hObject,'BackgroundColor'),
get(0,'defaultUicontrolBackgroundColor'))
    set(hObject,'BackgroundColor','white');
end

% --- Executes on button press in Go.
function Go_Callback(hObject, eventdata, handles)
% hObject    handle to Go (see GCBO)
% eventdata  reserved - to be defined in a future version of MATLAB

```

```

% handles      structure with handles and user data (see GUIDATA)
ODG = str2double(get(handles.OD, 'String'));
location = str2double(get(handles.location, 'String'));
ppiG = str2double(get(handles.ppi, 'String'));
wirenumber = str2double(get(handles.wirenumber, 'String'));
totalstrands = str2double(get(handles.totalstrands, 'String'));
[circ_d] = Medtronic_Helix_Code(totalstrands, ppiG, ODG, location,
wirenumber);
axes(handles.Plot)
theta = 0:.5/180*pi():2*pi();
x = ODG/2*sin(theta);
y = ODG/2*cos(theta);
hold on
plot(x ,y);
xp = (ODG/2)*sin(circ_d/(ODG/2)); %find coordinates of cut point around
circle
yp = (ODG/2)*cos(circ_d/(ODG/2));
temp = xp;
if circ_d<0
    for i=1:20
        xline(i) = temp;
        temp = temp - xp/20;
    end
else
    xline = 0:xp/20:xp;
end
yline = yp/xp*xline;
plot(xline,yline,'r')
hold off
set(handles.display,'String',circ_d);
guidata(hObject, handles);

function location_Callback(hObject, eventdata, handles)
% hObject      handle to location (see GCBO)
% eventdata    reserved - to be defined in a future version of MATLAB
% handles      structure with handles and user data (see GUIDATA)
% Hints: get(hObject,'String') returns contents of location as text
%            str2double(get(hObject,'String')) returns contents of location as a
double

% --- Executes during object creation, after setting all properties.
function location_CreateFcn(hObject, eventdata, handles)
% hObject      handle to location (see GCBO)
% eventdata    reserved - to be defined in a future version of MATLAB
% handles      empty - handles not created until after all CreateFcns called

% Hint: edit controls usually have a white background on Windows.
%           See ISPC and COMPUTER.
if ispc && isequal(get(hObject,'BackgroundColor'),
get(0,'defaultUiControlBackgroundColor'))
    set(hObject,'BackgroundColor','white');
end

```



```

function wirenumber_Callback(hObject, eventdata, handles)
% hObject    handle to wirenumber (see GCBO)
% eventdata  reserved - to be defined in a future version of MATLAB
% handles    structure with handles and user data (see GUIDATA)

% Hints: get(hObject,'String') returns contents of wirenumber as text
%        str2double(get(hObject,'String')) returns contents of wirenumber as
a double
e = str2double(get(hObject,'String'));

% --- Executes during object creation, after setting all properties.
function wirenumber_CreateFcn(hObject, eventdata, handles)
% hObject    handle to wirenumber (see GCBO)
% eventdata  reserved - to be defined in a future version of MATLAB
% handles    empty - handles not created until after all CreateFcns called

% Hint: edit controls usually have a white background on Windows.
%        See ISPC and COMPUTER.
if ispc && isequal(get(hObject,'BackgroundColor'),
get(0,'defaultUicontrolBackgroundColor'))
    set(hObject,'BackgroundColor','white');
end

function display_Callback(hObject, eventdata, handles)
% hObject    handle to display (see GCBO)
% eventdata  reserved - to be defined in a future version of MATLAB
% handles    structure with handles and user data (see GUIDATA)

% Hints: get(hObject,'String') returns contents of display as text
%        str2double(get(hObject,'String')) returns contents of display as a
double

% --- Executes during object creation, after setting all properties.
function display_CreateFcn(hObject, eventdata, handles)
% hObject    handle to display (see GCBO)
% eventdata  reserved - to be defined in a future version of MATLAB
% handles    empty - handles not created until after all CreateFcns called

% Hint: edit controls usually have a white background on Windows.
%        See ISPC and COMPUTER.
if ispc && isequal(get(hObject,'BackgroundColor'),
get(0,'defaultUicontrolBackgroundColor'))
    set(hObject,'BackgroundColor','white');
end

```

## MatLab Wire Tracking GUI Instructions

1. Before opening MatLab, make sure the files Medtronic\_Helix\_Code.m, Medtronic\_GUI1.fig, Medtronic\_GUI1.m, and Medtronic.xls are in the same folder
2. Open Matlab
3. Enter “guide” into the command line
4. Click on “Open Existing GUI” tab
5. Navigate to and select Medtronic\_GUI1.fig
6. On the opened GUI template, press the green run button. If a pop-up window opens
7. Enter in the parameters for the catheter and press GO
  - **Wire Number:** The number of the signal wire of interest. Wires are number from 1 to 8 clockwise around the cross section of the catheter with 1 being the topmost wire. All odd numbered wires are braided counterclockwise and even numbered wires are braided clockwise.
  - **Connecting Wires:** The number of signal wires in the braid structure. (8 for the designed TVAC)
  - **PPI:** The designated braid density of the signal wire braid in picks per inch. (30 for the designed TVAC)
  - **Cather OD:** The out diameter of the catheter steering section. (0.09 for the designed TVAC)
  - **Location along Shaft:** The distal location where the electrode is to be attached measured from the proximal end of the catheter.
  - **Location of Cut:** The circumferential distance around the surface of the catheter where the signal wire should be accessed measured from the top of the catheter in inches. A positive value indicates measurement in a clockwise direction and a negative value indicates measurement in a counterclockwise direction.
8. A graphical representation of the radial position of the signal wire at the desired distal location will appear on the axes on the right

NOTE: The GUI assumes that the topmost signal wire on the proximal end is braided in a counterclockwise orientation so the tested catheter must be oriented in the same way.

## Composite Analysis

```
%  
% Simple CLT File  
% This one includes hygrothermal  
%  
% this things has plots and pauses hit return play with scaling factors  
%  
  
clear all  
close all  
  
%set up a diary file  
diary Braid.dat  
  
%units are US customary (lb, in, E in psi)  
  
% total laminate definition in matrix below  
% [ply angles, thicknesses, matl. #]  
  
%Set up for two materials  
  
% Data in there now is  
%1-Uni Layer  
%2-Helix Layer  
  
psi = 52.25  
  
%Laminate is defined in this matrix l (sorry it looks like a one)  
% [ angle thick matl #]  
l=[  psi    .0422-.02    2;  
    -psi    .0422-.02    2;  
      0     .046-.0311    1;  
    -psi    .0422-.02    2;  
     psi    .0422-.02    2];  
  
% this is the total laminate  
% cut, paste, edit above to study your laminate of choice  
  
%delta temp  
DT = 0.1;  
  
% size command to get number of plies  
n = size(l,1);  
  
%      Lamina Properties  
  
%For Helix Layer volume fraction  
vfh = (1.991e-4)/((.2651*sind(psi))*0.0222)  
vmh = ((.2651*sind(psi)*0.0222-(1.99e-4))/(.2651*sind(psi)*0.0222))  
Epebax = 2760; %psi  
Efiber = 16e6; %psi
```

```

Elh = vfh*Efiber+vmh*Epebax;
%      matrix for engineering constants
%      E1      E2      v12      G12      a11      a22
E = [4.445e6  815.4  .30  815.4  0.0e-6  0.0e-6; %Uni Layer
     Elh      815.4  .30  815.4  0.0e-6  0.0e-6] %Helix Layer
% a's are CTE's

%intitialize the ply distance and ABD matrices
NT = zeros(3,1);
MT = zeros(3,1);

h = zeros(n+1,1);
A = zeros(3);
B = zeros(3);
D = zeros(3);
% Form R matrix which relates engineering to tensor strain
R = [1  0  0;
     0  1  0;
     0  0  2];

% find the total thickness
total = sum(h);
thick = total;

% locate the bottom of the first ply
h(1) = -thick/2.;
imax = n + 1;
%loop for rest of the ply distances from midsurf
for i = 2 : imax
    h(i) = h(i-1) + l(i-1,2);
end

%loop over each ply to integrate the ABD matrices
for i = 1:n

    %ply material ID
    mi=l(i,3);
    v21 = E(mi,2)*E(mi,3)/E(mi,1);
    d = 1 - E(mi,3)*v21;

    %Q12 matrix
    Q = [E(mi,1)/d      v21*E(mi,1)/d      0;
         E(mi,3)*E(mi,2)/d  E(mi,2)/d      0;
         0                0                E(mi,4)];

    %ply angle in radians
    a=l(i,1)*pi/180;

    %Form transformation matrices T1 for ply

```

```

T1 = [(cos(a1))^2      (sin(a1))^2      2*sin(a1)*cos(a1);
      (sin(a1))^2      (cos(a1))^2      -2*sin(a1)*cos(a1);
      -sin(a1)*cos(a1)  sin(a1)*cos(a1)  (cos(a1))^2-(sin(a1))^2 ];

%Form Qxy
Qxy = inv(T1)*Q*R*T1*inv(R);

% build up the laminate stiffness matrices
A = A + Qxy*(h(i+1)-h(i));
B = B + Qxy*(h(i+1)^2 - h(i)^2);
D = D + Qxy*(h(i+1)^3 - h(i)^3);

%load alphas into and array
a=[E(mi,5); E(mi,6); 0.0];

%transform cte's mult by DT to get thermal strain exy
exy = (R*inv(T1)*inv(R)*a)*DT;
%build up thermal load as well now
NT = NT + Qxy*exy*(h(i+1)-h(i));
MT = MT + .5*(Qxy*exy*(h(i+1)^2 - h(i)^2));

%end of stiffness loop
end

%change the display format for compliance matrix
format short e

A = 1.0*A;
B = .5*B;
D = (1/3)*D;

%
%
%Braid Tube Meas Radius
Ro=.045;
Ri=.02;
%
% Stiffness Terms for Braid Tube Analysis
ac=inv(A);
%Axial Stifness for P/A type problem
Ex=1/(ac(1,1)*thick) %psi
%
%Bending Effective EI
EI=(pi*(Ro^3-Ri^3)/ac(1,1))/144 %lb*ft^2
%
%Tube Torsion effective G
G=1/(ac(3,3)*thick) %psi

K = [A, B;

```

```

    B, D];

%put in mechanical loads here
%mech loads
    Nx=1.0;
    Ny=0.0;
    Ns=0.0;
    Mx=0.0;
    My=0.0;
    Ms=0.0;
%
% superimpose mech and thermal loads
load = [ NT(1) + Nx;
        NT(2) + Ny;
        NT(3) + Ns;
        MT(1) + Mx;
        MT(2) + My;
        MT(3) + Ms];

C = inv(K);
%
%compute the strains = compliance times load
e = C*load;
%
% calc radii of curvature
Rx = 1/e(4);
Ry = 1/e(5);
Rxy= 1/e(6);

%
% Now calc stress and strain and failure index using Max strain
%
% reduction factor for ultimate (pseudo A-basis use .80
RF=.80;
%
%
% allowable strains reduced to account for ultimate strength after impact
% row1 is carbon
% row2 is E-glass
% transverse prperties assumed same
% load allowable strains into array
%
%      ELU      ELUP      ETU      ETUP      ELTU
ea = [RF*.014    RF*.012    RF*.007    RF*.031    RF*.0296;
      RF*.02     RF*.018    RF*.0067   RF*.031    RF*.0296];
%
%
%zero out results array
ERES = zeros(2*n,6);
SRES = zeros(2*n,6);

% loop over each ply and calculate strain
for i=1 : n;
    %loop over top and bottom of each ply
    for j=1 : 2;

```

```

% one is bottom two is top for loc
ply = i;
loc = j;

z = h(i-1+j);

%ply strain from midplane strain
e1= [ e(1)+z*e(4); e(2)+z*e(5); e(3)+z*e(6) ];

%ply material ID
mi=l(i,3);
v21 = E(mi,2)*E(mi,3)/E(mi,1);
d = 1 - E(mi,3)*v21;

%Q12 matrix
Q = [E(mi,1)/d      v21*E(mi,1)/d      0;
     E(mi,3)*E(mi,2)/d  E(mi,2)/d      0;
     0                0                E(mi,4) ];

%
%ply angle in radians
a1=l(i,1)*pi/180;

%Form transformation matrices T1 for ply
T1 = [(cos(a1))^2      (sin(a1))^2      2*sin(a1)*cos(a1);
      (sin(a1))^2      (cos(a1))^2      -2*sin(a1)*cos(a1);
      -sin(a1)*cos(a1)  sin(a1)*cos(a1)  (cos(a1))^2-(sin(a1))^2 ];

% load alpha for the ply
a=[E(mi,5); E(mi,6); 0.0];

% tranform to 1,2
% subtract off alpha delta T to get mech strain that causes stress
ep = R*T1*inv(R)*e1 - a*DT;

%calculate stress in 1,2 coords
sp = Q*ep;

%failure index now looks at two different materials

if ep(1) > 0.0;
    FI = ep(1)/ea(mi,1);
    FIF=FI;
elseif ep(1) < 0.0;
    FI = abs( ep(1) )/ea(mi,2);
    FIF=FI;
end

if ep(2) > 0.0;
    F1 = ep(2)/ea(mi,3);
elseif ep(2) < 0.0;
    F1 = abs( ep(2) )/ea(mi,4);
end
%

```

```

if F1 > FI;
    FI = F1;
end
%
%
    F1 = abs( ep(3) )/ea(mi,5);
if F1 > FI ;
    FIe = F1;
elseif F1 < FI;
    FIe = FI;
end

%load the results array
% note top and botom of every ply!

%strain results, FI based on Max Strain
%angle,eps1,eps2,gamma12,FI, FIfiber
    ERES(2*i+j-2,1)=l(i);
    ERES(2*i+j-2,2)=ep(1);
    ERES(2*i+j-2,3)=ep(2);
    ERES(2*i+j-2,4)=ep(3);
    ERES(2*i+j-2,5)=FIe;
    ERES(2*i+j-2,6)=FIF;

%stress results, FI based on max strain
%angle,Sigma1,Sigma2,Taul2, FI, FIfiber
    SRES(2*i+j-2,1)=l(i);
    SRES(2*i+j-2,2)=sp(1);
    SRES(2*i+j-2,3)=sp(2);
    SRES(2*i+j-2,4)=sp(3);
    SRES(2*i+j-2,5)=FIe;
    SRES(2*i+j-2,6)=FIF;

end
%
end
ERES=ERES*1;
SRES=SRES*1;

diary off
%
%
```



## Unilayer Moment of Inertia Balance

"Unilayer Balance"

"Created 1-14-10"

"By: Am and Kasim atis, Ryan Razzari"

"Constants"

$D\_PW = .009$

$D\_CL = .04$

$D\_Minor = .0066$

$D\_Major = .0128$

$\{r = .04$

$\{\theta = 30$

"Diameter of Pullwire, [in]"

"Diameter of Center Lumen, [in]"

"Minor Diameter of Braid Wire, [in]"

"Major Diameter of Braid Wire, [in]"

"Radial Distance to Linear Fibers, [in]"

"Angle to Linear Fibers, [deg]"

"For XX Direction"

"4 Linear Fibers and 2 Pullwires Contribute"

"For Pullwires"

$A\_PW = (\pi/4) * D\_PW^2$

$d\_i\_PW = D\_CL/2 + D\_Minor + .5 * D\_PW$

$I\_PW = (\pi/64) * D\_PW^4$

"Area of Pullwire, [in<sup>2</sup>]"

"Distance from axis to Pullwire, [in]"

"Moment of Inertia for Pullwire, [in<sup>4</sup>]"

$I\_xx\_PW = I\_PW + A\_PW * d\_i\_PW^2$   
[in<sup>4</sup>"]

"Total Moment of Inertia for Pullwire,

"For Linear Fibers"

$A\_LF = (\pi/4) * D\_Major^2$

$d\_i\_LF = r * \sin(\theta)$

$I\_LF = (\pi/64) * D\_Major^4$

[in<sup>4</sup>"]

"Area of Linear Fiber, [in<sup>2</sup>]"

"Distance from axis to Linear Fiber, [in]"

"Moment of Inertia for Linear Fiber,

$I\_xx\_LF = I\_LF + A\_LF * d\_i\_LF^2$   
[in<sup>4</sup>"]

"Total Moment of Inertia for Linear Fiber,

$I\_xx\_Uni = 2 * I\_xx\_PW + 4 * I\_xx\_LF$   
XX direction"

"Total Moment of Inertia for Unilayer for

"For YY Direction"

"6 Linear and 0 Pullwires Contribute"

"For Linear Fibers"

$d\_istar\_LF = r * \cos(\theta)$

"Distance from axis to Linear Fiber, [in]"

$I\_yy\_LF = I\_LF + A\_LF * d\_istar\_LF^2$   
[in<sup>4</sup>"]

"Total Moment of Inertia for Linear Fiber,

$I\_yy\_Uni = 6 * I\_yy\_LF$   
YY direction"

"Total Moment of Inertia for Unilayer for

Balance =  $I\_yy\_Uni - I\_xx\_Uni$  "Will be zero for balanced design"

# Appendix G – Gantt Chart

