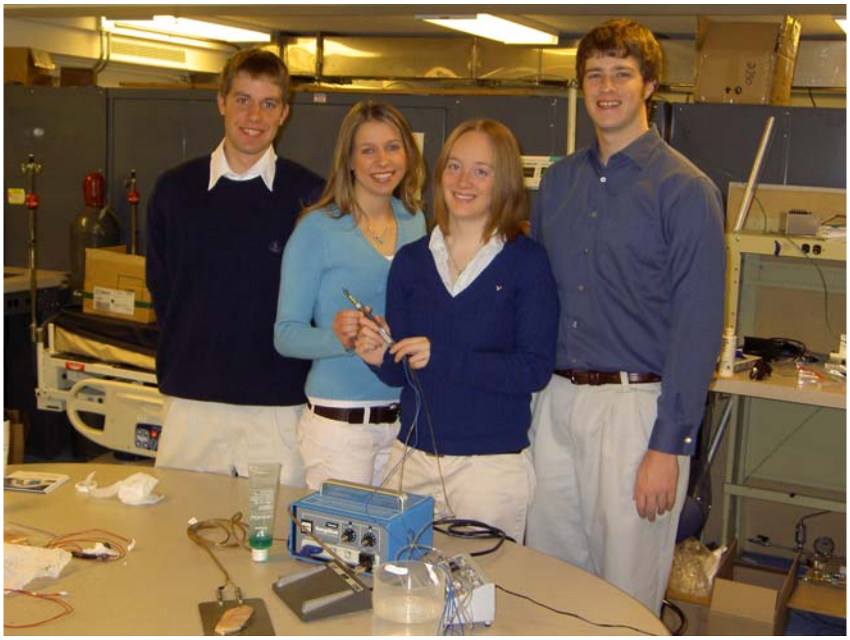
Monopolar Electrosurgical Thermal Management



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ABSTRACT

Monopolar surgical dissecting uses a pencil like device and electrical current to cut through fibrous tissue and seal off vessels. During surgery, heat is applied for coagulation, which creates collateral damage to adjacent nerves that are heat sensitive. This project is expected to develop a surgical thermal management system to protect the nerve from thermal damage during monopolar surgical dissecting in both open and laparoscopic procedures. Because of the widespread use of monopolar energy, a main goal of this thermal management system is to eliminate thermal damage to surrounding nerves, improving post-operation quality of life for patients.

EXECUTIVE SUMMARY

Electrosurgical devices have become more prevalent in recent years; however, there are inherent problems with using high temperatures in and around the body. The most common type of electrosurgery is monopolar, used for cauterizing vessels and cutting through tissue. The current that is applied to cut or coagulate produces heat. In coagulation mode, the excess heat is spread to surrounding nerves and tissues, causing collateral damage [1], which in turn can cause continence and potency problems for prostatectomy and hysterectomy patients.

To develop a device to reduce the thermal spread in monopolar electrosurgery, a set of customer requirements was analyzed and quantitative engineering specifications were created. The engineering specifications concentrated on include: the system's maximum radius from center of the original device, the additional weight increase to the device, the ease in retraction of the coolant system, and most importantly, the ability to cool the surrounding tissue during coagulation.

We have chosen a final design that combines the best properties of our initial concepts. It uses a cooling channel that runs a fluid down to the surgical surface and back up, to allow for heat dissipation. The cooling device is retractable along the body of the electrosurgical device by a single step. This pressurized, self-locking, sliding device allows the cooling channel to be used in various positions, as well as providing the ability to retract away from the surgical site and out of the surgeon's view. The cooling channel has a u-shaped hook on the end, making it versatile. Variations of the device can be used for both open and laparoscopic procedures, either by hooking the vessel with the cooling channel to apply a pressure for successful cauterization, or by pressing the bottom surface of u-shaped hook against the tissue.

We have manufactured an initial prototype of our design. Our prototype demonstrates a novel engineering approach to the presented problem. Although the prototype is not an exact replica of the design, it does allow us to validate the concepts and specifications of our design. Differences between the prototype and the actual design include materials used, dimensions, and the manufacturing processes. These, however, are limited to parts of the device that do not affect the integrity of the design. A stainless steel pipe forms the desired u-shaped hooking tip. The sliding mechanism consists of a PVC rod and a metal spring. All parts are housed in a clear PVC casing, along with electrical components from a current device.

By comparing finite element analysis to physical tests, we were able to validate that our design helps reduce thermal spread in tissue surrounding an electrode tip. Thermal management results were determined using thermistors placed at various radii around the electrosurgical tip. According to the performed analysis, with our system in place, we have achieved desired results, meeting or exceeding all of our engineering specifications.

Although our design meets or exceeds our specifications, further improvements could be made by changing the cooling channel material and exploring passive cooling systems.

INTRODUCTION

For years, monopolar electrosurgical devices have been the most commonly used equipment for tissue cutting and coagulating during surgery. The devices are easy to use, efficient, and versatile. Modern electrosurgery was first developed in the 1920's [7] and was quickly adapted for use in many different operations. Monopolar electrosurgery creates a closed circuit through the body using a generator, grounding pad, and pencil-like cauterizing device, Figure 1.

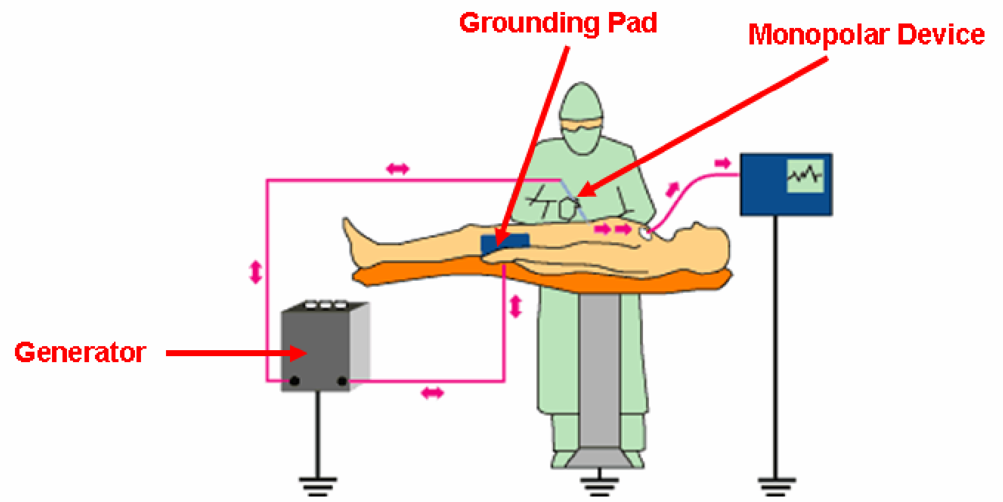


Figure 1: Diagram of Monopolar Electrosurgical Circuit where Current Flows from Generator to Monopolar Device, then through the Body to the Grounding Pad [3]

The current is focused at the tip of the pencil-like device and quickly spreads out as it travels through the body towards the grounding pad. Another concern with monopolar surgery is the precision of the pencil-like device. The energy cannot be contained at the electrode tip; therefore, undesired thermal spread occurs. This can cause collateral damage to surrounding tissue and nerves. Due to those concerns, there became a need for an alternative device. Thus, bipolar electrosurgery became a new option. In bipolar, the current flows between two poles placed close together at the tip of a tweezer like device, Figure 2, page 6. This eliminates the current traveling through the body and minimizes thermal spread. Hence, it is optimal for more delicate operations (i.e. facial). Bipolar electrosurgery, however, is much slower and more tedious. Therefore, monopolar electrosurgery still remains the most commonly used method.

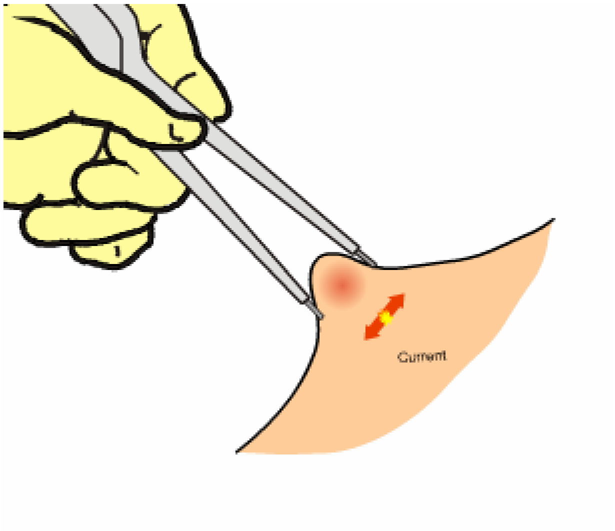


Figure 2: Bipolar electrosurgery with current running between electrodes [3]

Using monopolar electrosurgery, surgeons can cut through internal tissue and seal off vessels using two settings: cut mode and coagulation mode. Cut mode is used for quickly slicing through tissues that contain only small vessels while keeping the current constant. This setting uses a high current and low voltage which allows for quick and easy cuts through tissue [1]. Due to the applications of the cut mode, thermal management is unnecessary. The coagulation mode uses high voltage and low current. Because the device is in contact with one area of tissue for a longer period of time in coagulation mode, thermal spread is greater, and therefore, thermal management would be beneficial. This setting is used to seal off vessels to prevent excess bleeding. Currently, during coagulation, surgeons use an on-off cycle to prevent excess heating. This can also be achieved through an automatic duty cycle implemented in some newer devices [3].

Dr. James Geiger sponsored our efforts to implement a thermal management system within the coagulation mode of monopolar electrosurgery devices. The greatest impact this device will have is the reduction of thermal spread in monopolar electrosurgery, which would allow monopolar electrosurgery to be used in more operations.

CUSTOMER REQUIREMENTS AND ENGINEERING SPECIFICATIONS

Information from sponsors, background studies, and benchmarking has led us to develop and rank a set of customer requirements and engineering specifications. These were developed through the help of a Quality Functional Diagram (QFD) that can be found in Appendix A. The customer requirements that were developed for our system were related to part characteristics that we developed. This was done by comparing each customer requirement with respect to each part characteristic and assigning a ranking of 1, 3, or 9 (9 representing the highest relation) depending on how they related to each other. We were then able to rank the requirements and characteristics according to these relations and determine the importance of each. Competitive and related products were also benchmarked along with the part characteristics to determine how well they satisfied the customer requirements. From the customer requirements, we were able to determine quantifiable engineering specifications for each characteristic.

The major customer requirement for the development of this device is to prevent thermal spread in surrounding tissue, while maintaining sufficient tissue coagulation in both open and laparoscopic procedures. Since this is the most important aspect of our project, we have given it the highest normalized importance (1.0). Another customer concern is the ease of use. To make a thermal management system for monopolar electrosurgery feasible, it must be as easy to use as the current device, if not easier. If this were not the case, surgeons would opt against using the system. Also, the thermal management device must be easily retractable and extendable for quick changes between cutting and coagulation modes, while not restricting the surgeon's view. This has led us to give ease of use a high normalized importance (0.9). Once compared to the part characteristics, it was found that these are also important customer requirements. Other concerns presented by the customer include: durability, minimal size and weight, cost, and an accurate temperature monitoring system for testing purposes.

From these requirements we were able to determine the part characteristics' importance. The most important characteristic for our device will be reducing the thermal spread (22%). Other physical characteristics important to the manufacturing of the device are the system's maximum distance from the center of the surgical device and the number of steps needed to retract and extend the system, at 20% and 18%, respectively. The devices weight is also of importance. Remaining characteristics that must be taken into account include: temperature monitoring accuracy and material cost. Further research into current devices allows us to give appropriate, quantifiable specifications to these characteristics. The device radius, as well as the thermal spread reduction target, has been chosen partially based on the manufacturing feasibility of the prototype. Initial engineering specifications are shown in Table 1. We were also able to benchmark these current devices to develop a better understanding of the goals and results we are striving to achieve.

Engineering Specifications	**Target**
Increase in Tissue Temperature	At 5 mm, < 6°C (power level 4)
Temperature Monitoring Accuracy	2 % error
Additional Weight Increase	20 %
Steps from Retraction to Usable Position	2 steps
Material Cost	< $400
Maximum Radius from Device Center	5 mm

Table 1: Engineering Specifications and Targets for Monopolar Thermal Management System

There are currently many innovative systems integrating thermal management into electrosurgery. All bipolar electrosurgical devices produce less thermal spread than monopolar devices due to their bipolar nature. One patented bipolar design [19] can be seen in Figure 3. This instrument is able to clamp, seal, and cut tissue. The current is contained within the two electrodes, thus there is minimal thermal spread.

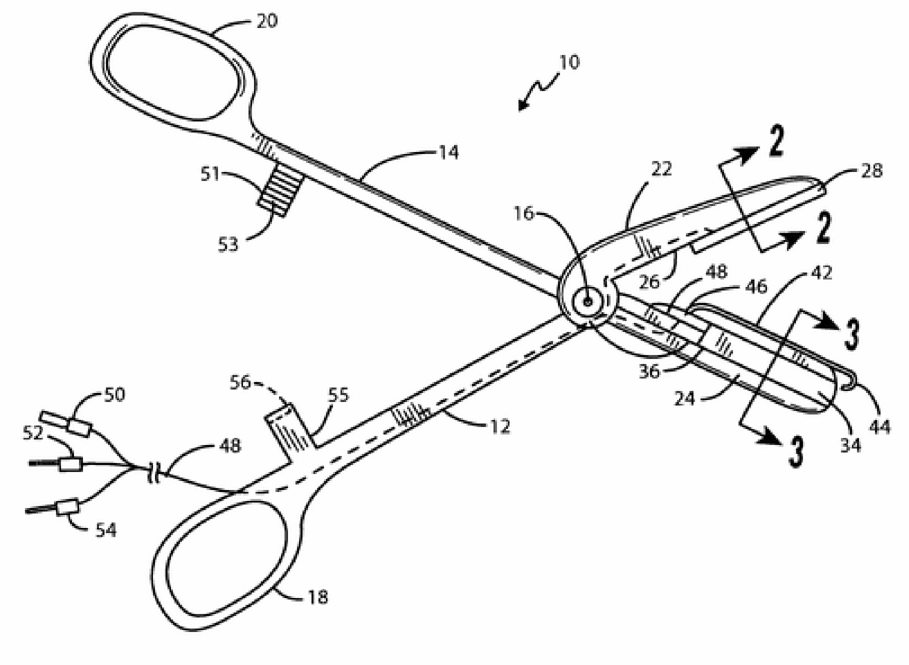


Figure 3: Patent 7,033,356 B2 Bipolar Electrosurgical Instrument for Cutting, Desiccating, and Sealing Tissue [19]

Gyrus also has a state-of-the-art bipolar instrument, PlasmaCision, which uses low temperature plasma to cut and coagulate precisely and cleanly. These conditions provide quicker healing with less pain for patients [10, 11]. PlasmaCision's J-Hook electrosurgical tip can be used for both laparoscopic and open procedures. Pictures of PlasmaCision device can be found in Appendix B. This device offers power, precision, and predictability providing surgeons with unique ways to seal, transect, coagulate, dissect, and mobilize tissue [10, 11].

Loan Cosmescu has patented an automatic fluid control system for use in laser and electrosurgery [18]. This system provides irrigation to the surgical site from an internal fluid reservoir. It is designed to allow the irrigation to be activated upon the deactivation of the actual surgical device. A suctioning device is then automatically activated upon the deactivation of the irrigation system. This device can be seen in Figure 4, page 9.

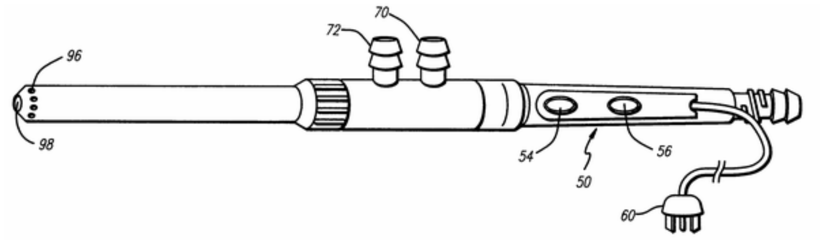


Figure 4: Patent 7,083,601 B1 Automatic Fluid Control System for use in Open and Laparoscopic Laser and Electrosurgery [18]

A monopolar electrosurgical device with cooled electrodes was patented by Ethicon Endo-Surgery, Incorporated [17]. This design, as seen in Figure 5, uses an internal heat pipe within the electrode. This heat pipe contains a heat transfer fluid which conducts thermal energy away from the end of the electrode. This reduces the charring of tissue as well as the sticking of tissue to the electrode. Megadyne has also developed a monopolar electrosurgical tip which reduces the build up of charred tissue [9]. This design uses a PTFE surface coating over the stainless steel electrode, as seen in Appendix B.

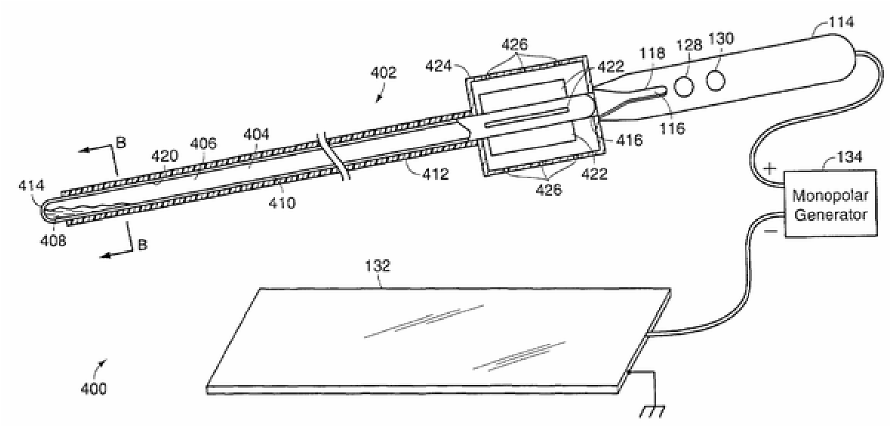


Figure 5: Patent 7,074,219 B2 Electrosurgery with Cooled Electrodes [17]

All of the above mentioned benchmarks provide insight into possibilities for a thermal management system. None, however, solve the current issue of thermal spread in tissue surrounding an electrosurgical tip.

CONCEPT GENERATION

Following generation of the engineering specifications, we were able to begin synthesizing initial concepts for a thermal management system for monopolar electrosurgery devices.

In order to determine initial concepts, our team first met as a group and discussed the engineering specifications, project goals, and possible obstacles that may be encountered. This initial discussion allowed us to ensure that we were all striving for the same objectives. During this meeting, we also created a functional decomposition for the potential device. The functional decomposition is shown in Figure 6, where Q represents heat, I – current, V – voltage, F – force, and U – potential energy that may act as inputs or outputs to the system.

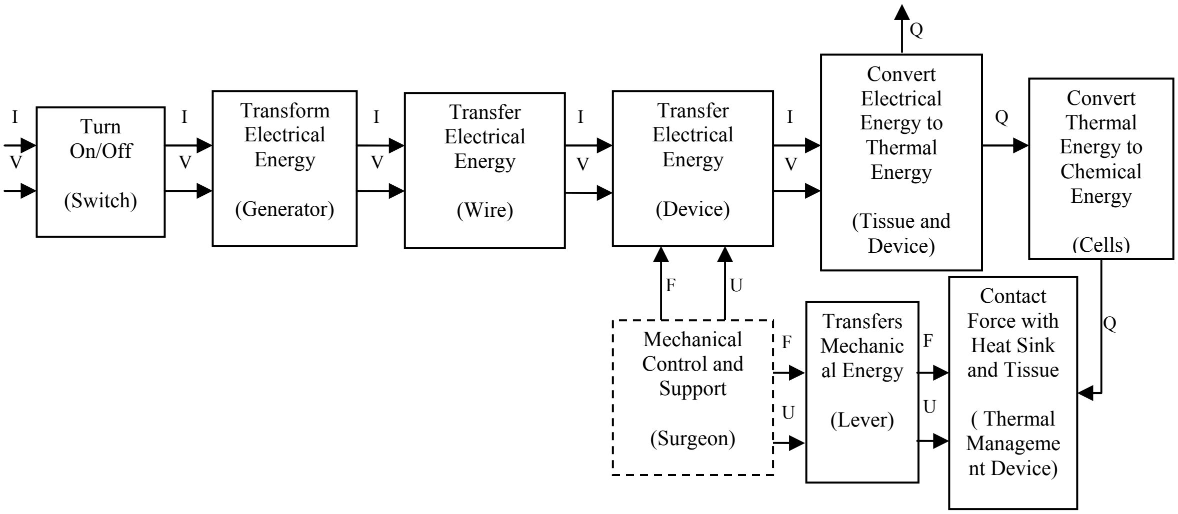


Figure 6: Thermal Management Functional Decomposition

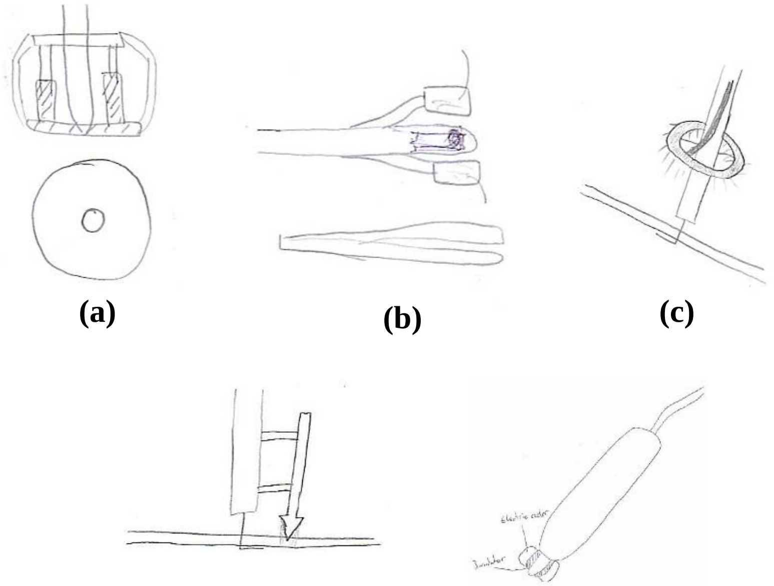
After this meeting we each developed initial concepts for the device. These initial concepts focused on creativity and innovation, and were not limited by the feasibility of the design. We then met again as a group to compare and discuss our initial ideas.

The initial concepts we developed for the thermal management system can be roughly distributed into five major categories. These categories include: separate piece devices, retractable plate devices, side attachments, wave canceling devices, and pinching devices. The initial concepts can be found in Appendix C and are categorized in Table 2 by their corresponding concept number.

Separate Piece Devices	Retractable Plate Devices	Side Attachment Devices	Wave Canceling Devices	Pinching Devices
5	1	7	13	4
8	2	11		
9	3	12		
10	6			
14				
15				

Table 2: Categories of Thermal Management Concept Designs

As a team, we determined our top five concepts using a concept selection or scoring matrix. This matrix allowed us to determine how each design fulfilled both the customer requirements and the engineering specifications. This was done by using a scoring system of +'s and –'s to signify if the concept would fulfill or not fulfill each requirement. The scoring matrix can be found in Appendix D. Analysis of the designs using the scoring matrix showed that our top five concepts were: 3, 4, 6, 7, and 11. Sketches of these concepts are shown in Figure 7 (a-e).



(a) (b) (c)

(d) (e)

Figure 7: Top Five Concept Designs and Initial Design for Thermal Management of Monopolar Electrosurgery; (a) Concept 3, (b) Concept 4, (c) Concept 6, (d) Concept 7, (e) Concept 11

Concept 3, as seen in Figure 7a, is a retractable plate design that attaches to the monopolar pencil device using a spring or hydraulic type mechanism that would allow the plate to be in constant contact with the tissue. The plate would have a coolant running through it, which would be transported down the shaft of the monopolar pencil and returned through the same process.

As seen in Figure 7b, concept 4 is a pinching device. The end of the device is similar to that of the bipolar device, except that it would have a coagulation point in the middle of two cooling plates. The vessel or tissue would be pinched between the coagulation point on one side and the two cooling pads on the other. The cooling pads would be made of a heat sink material that would reduce the thermal spread.

Concept 6, shown in Figure 7c, is a retractable ring that would eject a coolant in a circular path around the coagulation point. The coolant would run through the handle of the pencil-like device and would be pressurized leaving the cooling unit. The cooling ring would be retractable through a ratchet system along the side of the device.

Similar to concept 6, concept 7 (Figure 7d) would have a device attached to the side of the monopolar pencil that would release pressurized coolant where thermal spread posed a problem. The device could be rotated around the shaft in order to provide cooling in different areas, as well as to provide a clear view for the surgeon.

Seen in Figure 7e, page 11, concept 11 opted to change the housing of the pencil like device to insulate the device tip and use electric coolers on either side to manage the thermal spread throughout the vessel.

Figure 8 shows our initial design idea. This concept was a collaboration of the top five concepts, using a retractable side piece that will apply pressure to the coagulation location. The design, however, does not have an adequate thermal management system. The two heat sinks on either side will not provide enough heat capacity to reduce the thermal spread. The design also has a fault, in that it can only be used for open surgeries and not in laparoscopic procedures. Further modeling of this design can be seen in Appendix E.

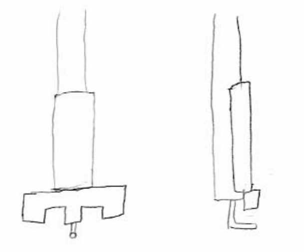


Figure 8: Initial Design with Two Heat Sinks for Thermal Management

CONCEPT SELECTION PROCESS

As explained above, using a scoring matrix found in Appendix D, our initial concepts were narrowed down to five main concepts and an initial design. Further analysis allowed us to combine these concepts into the “alpha design”, as seen in Figure 9.

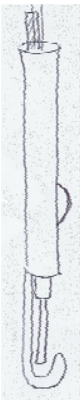


Figure 9: “Alpha Design” Sketch

The six concepts for the monopolar devices were all very different, each of which had important advantages as well as disadvantages. Concepts 1 and 3 provided the necessary pressure and cooling system; however, the size of the device may hinder the visibility of the surgeon and or limit the usability of the device. Similar problems could be found with concepts 6 and 7, which greatly increase the diameter of the device, and thus limit the usability. Another problem that arose with these concepts is that coolant was being ejected into the patient, and would therefore require a separate suction device to remove the excess fluid, unless a feasible gas, such as air, was used. An advantage of these concepts, however, is that the coolant system is retractable. Concept 4 would be ideal for vessels because it could localize the cooling to either side of the coagulation point, preventing over cooling and a reduction in coagulation. With concept 11, there is more interaction with electrical components, which can cause difficulty in manufacturing; it was also ineffective in removing heat. The initial design had many of the advantages from the top five designs; however, the disadvantages outweighed the advantages.

Considering all of these advantages and disadvantages, as well as the selection matrix, we were able to combine these concepts into the final "alpha design". The "alpha design" is compared using a selection matrix to the previously mentioned concepts. The "alpha design" scored a 6, and the next highest concepts, including the initial design, received a score of 5, shown in Table 3.

	Concept #3	Concept #4	Concept #6	Concept #7	Concept #11	Initial Design	Alpha Design
Net Score	3	5	4	-1	1	5	6
Rank	3	1	2	5	4	-	-

Table 3: Top Concepts Compared to Alpha Design

According to our QFD (Appendix A), the most important engineering specification for the device is to prevent thermal spread in surrounding tissue, while maintaining sufficient tissue coagulation in both open and laparoscopic procedures. Some additional specifications are the system's maximum radius from the device's center and the additional weight increase to the overall device. To meet these specifications, a hybrid of our top concepts must be used. Concept 7 and 11 are very close to the center of the device, which helps to satisfy these specifications. Another important specification is the number of steps to change the system from the retracted position to the usable position. Concepts 6 and 7 use a sliding, retractable motion to allow the coolant system to be easily removed from the point of contact when not in use. These allow the design to meet the retractable specification while maximizing the surgeon's visibility. The idea of applying pressure to the vessel during coagulation increased our interest in pursuing a pinching device similar to concept 4 and the initial design.

For ease of use and visibility, we incorporated the idea of a retractable cooling channel, which forms a u-shaped hook at the point of contact with the tissue, into our "alpha design". This concept allows the surgeon to place the cooling channel in any desired position, which includes: hooking a vessel, pressing the bottom of the cooling channel against the tissue and applying slight pressure, or completely retracting the device away from the surgeon’s plane of view. Each of these options makes variations of the instrument versatile for both open and laparoscopic procedures. With one hand the surgeon can apply a slight pressure to slide the device down to the surgical site, and release the pressure to secure the system into its desired location. The cooling channel must be made of an electrically nonconductive material, while still possessing a high thermal conductivity, so that the current does not arc from the electrosurgical tip to the cooling channel. For our initial testing we have chosen stainless steel, however another material may prove to be more beneficial in the future. One other disadvantage of this “alpha design” is that the pressure of the cooling channel does not occur directly aligned with the point of contact from the electrode. Optimally, the pressure applied should be flat against the tissue; however, our “alpha design” instead uses curved areas where pressure is applied. The reason for this design was to allow ease of use when sliding the device down or retracting it. Because of the minimal distance between the two points of contact, the curvature in our design should not pose any problem.

Some constraints that arose in our design process were time and budget. These constraints came from the requirements of the class. With more time, we would have further researched the possibility of different materials for the cooling channel. We would have also included a small sensing device, which would allow the surgeon to know where the cooling channel was with respect to the electrode tip. The budget was not a main concern in our design because we had many components donated and the current devices are disposable. This required us to maintain a low cost of manufacturability, and therefore we were well under our $400 budget.

SELECTED CONCEPT DESCRIPTION

The “alpha design” is comprised of a system of components. These components work together to accomplish the specified task. These were initial concepts, and therefore changes did occur before prototyping. These minor changes will be discussed in detail later.

The monopolar electrosurgical thermal management system contains a u-shaped hook tip, a sliding mechanism, and an internal securing device, all of which are integrated into a current monopolar pencil device, Figure 10, page 15.

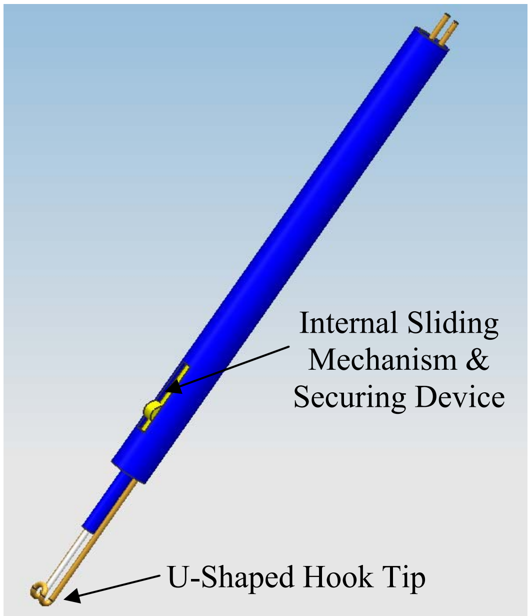


Figure 10: The U-shaped Hook Tip, Slider, and Internal Securing Device Create the Monopolar Thermal Management System

The main purpose of the above device is to cool tissue surrounding an electrosurgical tip in an open or laparoscopic procedure. We determined that using a u-shaped hook for a tip is optimal to hook a vessel and apply pressure for coagulation. As seen in Figure 11, the cooling channel is retractable. The continuous sliding mechanism allows the surgeon to place the channel in any desired location which can include: completely retracted so it does not obstruct the surgeon's view, aligned with the end of the electrode to be used as a surface cooling device, or past the electrode to hook onto a vessel in order to apply a desired pressure for coagulation.

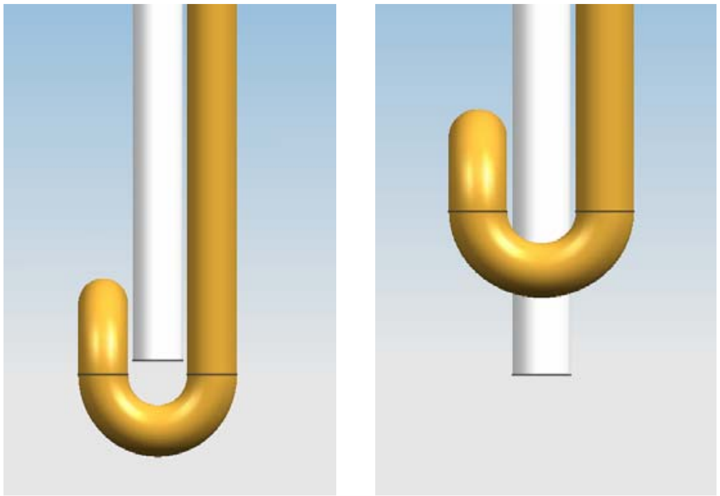


Figure 11: Tip with U-shaped Cooling Channel Used in Various Retractable Positions

Shown in Figure 12, the slider is used to move the tip up and down depending on the surgeon's need. When thermal management is not needed, the tip will be retracted out of the surgeon's view. When the need for thermal management arises, the cooling channel is extended by one handed pressure on the knob from the surgeon. When the desired placement is reached, the surgeon releases the applied pressure, which secures the device into place. The idea for the locking mechanism is to use friction caused by a thin layer of rubber placed on the internal slider, as well as a simple spring. The need for additional friction may not be necessary. If this is the case, we will simply use the spring and no additional rubber stripping.

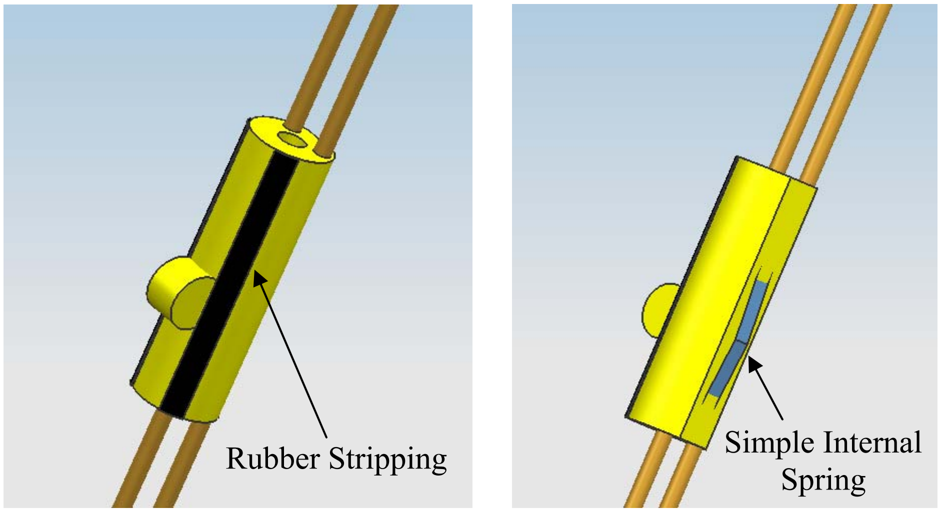


Figure 12: Internal Sliding Mechanism Views

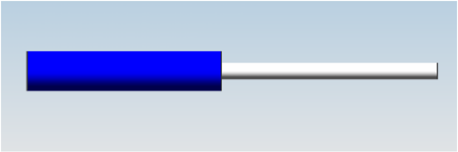
ENGINEERING DESIGN PARAMETER ANALYSIS

The specific engineering parameters for our product were determined using the existing geometry of electrosurgical devices, engineering logic, finite element analysis, manufacturability, and safety. Analysis predicts that our product will meet the desired engineering specifications.

Physical Constraints

We based the dimensions and shape of the casing and electrode for open surgery off of the geometry of existing monopolar pencils. This was done to minimize the difference in feel between our device and existing pencils. Currently, the ValleyLab E2504 Reusable pencil has a handle diameter of 12.7 mm and length of 152 mm. Therefore, we designed our casing similarly with a 12.7 mm diameter and 165 mm length. The slight increase in length provides space for the internal slider movement. The prototype outer casing will be manufacuted from PVC; however, if mass produced, the casing could be made of a injection molded polymer similar to that of current pencils. PVC was chosen because of its similar properties to the plastics currently used, its availability, and ease in manufacturing. We also designed our electrode to be 22 mm long, which is a similar length to most blade-like electrodes. The only difference is the shape of the electrode. Currently, flat-blade electrodes are used, as shown in Figure 13a. Our design, however, requires an electrode with a flat bottom surface to help apply pressure to larger vessels, thus we made our electrode in a cylindrical shape with a diameter of 1.83 mm as seen in Figure 13b.

(a)



(b)

Figure 13: Electrode Tips: (a) Flat Blade Tip [13] (b) Our Cylindrical Tip

For laparoscopic electrosurgery we have less freedom in the dimensions of the device. The ports used for this surgery are round with a 5 mm diameter, thus the maximum diameter of our laparoscopic design must be no larger than 5 mm. In addition, the device must be long enough to accommodate entrance into the body. We set the length to be 355 mm based on current laparoscopic devices. As with the open surgery device, the electrode must have a flat end, therefore a cylindrical shape was again chosen.

The dimensions of the slider were designed to fit within the outer casing of the device. The center hole of the slider is dimensioned to allow the electrical connections of the device to pass through without interference. Also, two smaller holes are present and dimensioned to the diameter of the cooling channels as seen in Figure 14. The positioning of the sliding control was chosen based on the natural position of the surgeon’s hand on the instrument. For the laparoscopic instrument, this sliding control was moved to the end of the device to allow for easy control outside the body. PVC was chosen as the material for the slider for the same general reasons as the outer casing, however, it may be made from another material for mass production.

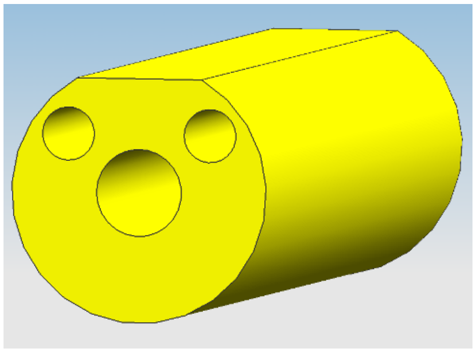


Figure 14: Slider with Holes for Cooling Channel and Electrical Connections

The optimal diameter of the cooling channels, as well as the optimal curvature of the u-shaped tip, allows the channels to fit easily into the outer casing without interfering with the electrode or electrical connections. The diameter was also constrained by the available material. We have chosen to use stainless steel piping for our prototype because of its biocompatibility and other physical properties. Further research, however, may prove another material to be more beneficial when mass produced.

The dimensions were not the only design parameters set by physical constraints. We also used this analysis to determine the force needed to control the sliding mechanism. This was analyzed and calculated through formulas by testing with known materials and masses. The slider must have enough frictional force with the outer casing to keep the cooling channel in place until movement is desired. The surgeon must also be able to press the knob down and move the slider without applying excessive force. The results show a spring force of approximately 6 N is needed to hold the slider in place. A detailed description of the calculations is shown in Appendix F.

Finite Element Analysis

We conducted finite element analysis (FEA) on the model of our device using the program COMSOL. The first step of our analysis was to simulate the current device. This was done by modeling a simple electrode and block of tissue and assigning the appropriate initial and boundary conditions to each. The electrode was modeled to provide the proper electric potential of the Valleylab monopolar generator. The bottom of the tissue was modeled as the grounding pad for the electrical conduction, while the remaining sides of the tissue were kept electrically insulated. This was done to model the concept that no electricity escapes into the surrounding atmosphere. The side and bottom surfaces of the tissue were treated as thermally insulated, while the top surface was treated as a heat flux to model that heat only escapes out of the top surface of the tissue. The physical properties of the electrode and tissue were also determined and can be found in Appendix G. The desired voltage was determined using oscilloscope readings taken from our monopolar generator. The generated voltage and current readings can also be seen in Appendix G.

Using COMSOL, we were able to generate a model of thermal spread during monopolar electrosurgrey. Figure 15, page 19, shows this thermal spread throughout the tissue, when no thermal management is in place, for a 10 second simulation.

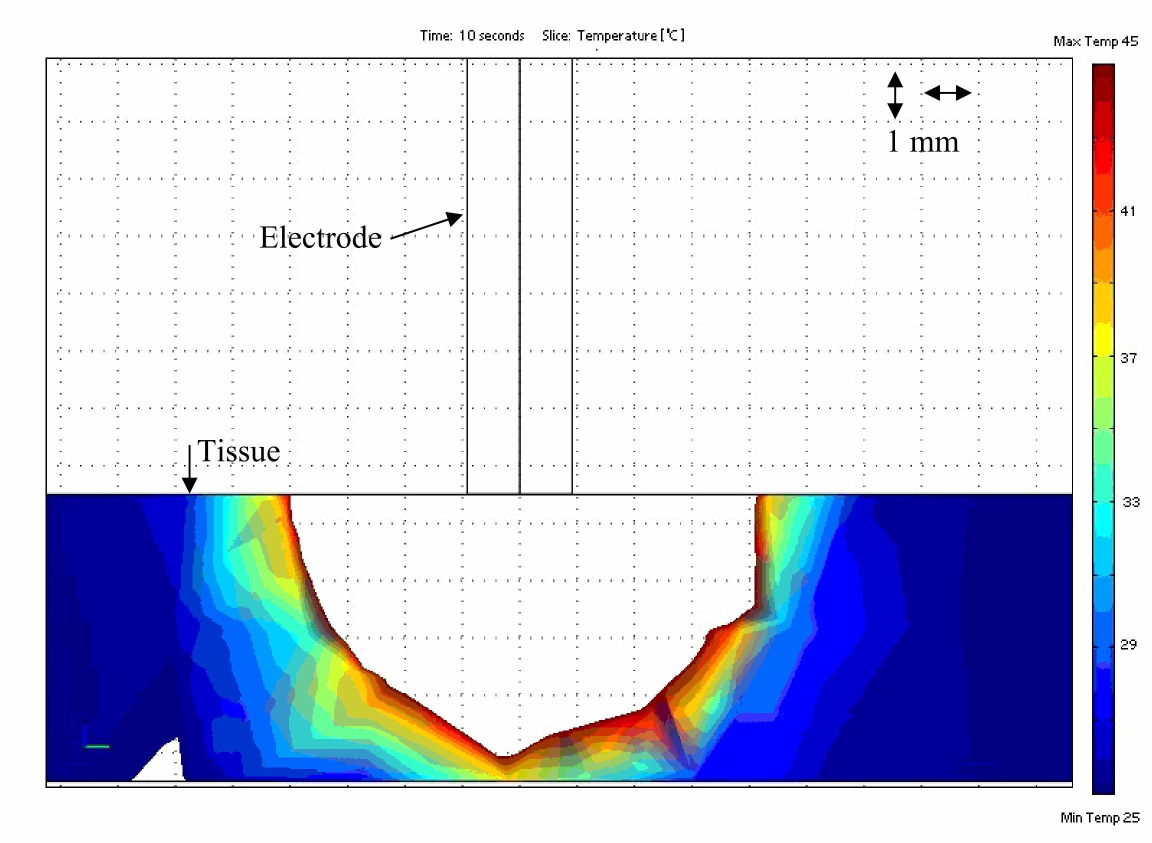


Figure 15: COMSOL Analysis of Thermal Spread from Electrode

The white area of the tissue indicates tissue that has increased by more than 6°C after the 10 second interval. This increase of 6°C correlates to our engineering specification. It is also apparent that the thermal spread in the tissue is approximately 4 mm from the center of the electrode tip.

Further analysis of the simulation can be shown by the plot in Figure 16, page 20. The starting temperature was 23.3°C with an ending temperature of 46.8°C at 6 seconds. Over the selected time interval, the data shows a steady increase in the temperature.

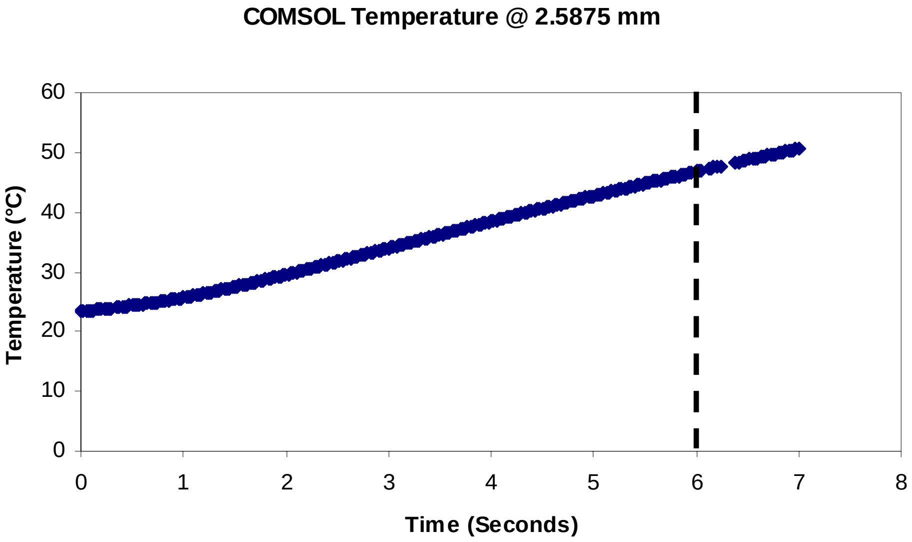


Figure 16: COMSOL Plot of Temperature vs. Time at 2.59 mm from Electrode Center

Because these are only theoretical models of the electrode and the tissue, we must validate the accuracy of these models using physical testing. We therefore conducted various tests using our monopolar generator and pencil to measure the thermal spread in the tissue surrounding the electrode tip. Pictures of tested tissue can be seen in Figure 17. From these pictures, it is apparent that thermal spread does occur when the monopolar electrosurgical device is used.

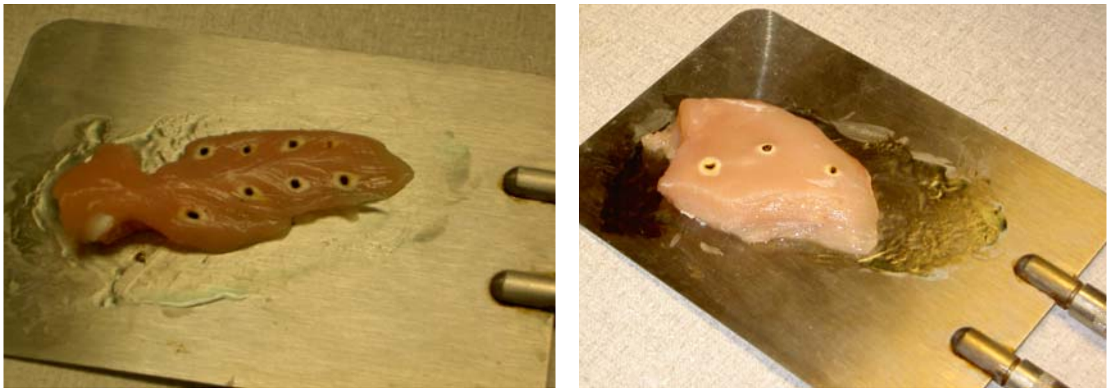


Figure 17: Tested Tissue – White Area Around Charred Tissue Indicates Thermal Spread

All temperatures were verified using a calibration curve that can be seen in Appendix H. Figure 18, page 21, shows two curves from our gathered lab data. The blue curve represents thermistor data from our actual testing. This curve is very similar to that of the COMSOL model, shown by the gold curve. At the 6 second mark, the temperatures of the COMSOL generated plot, and our physical test plots, show the same temperature within error. This data allows us to be certain that our COMSOL model is an accurate representation of a current monopolar electrosurgical system. Therefore, we are confident that our models with the cooling system in place will also be accurate.

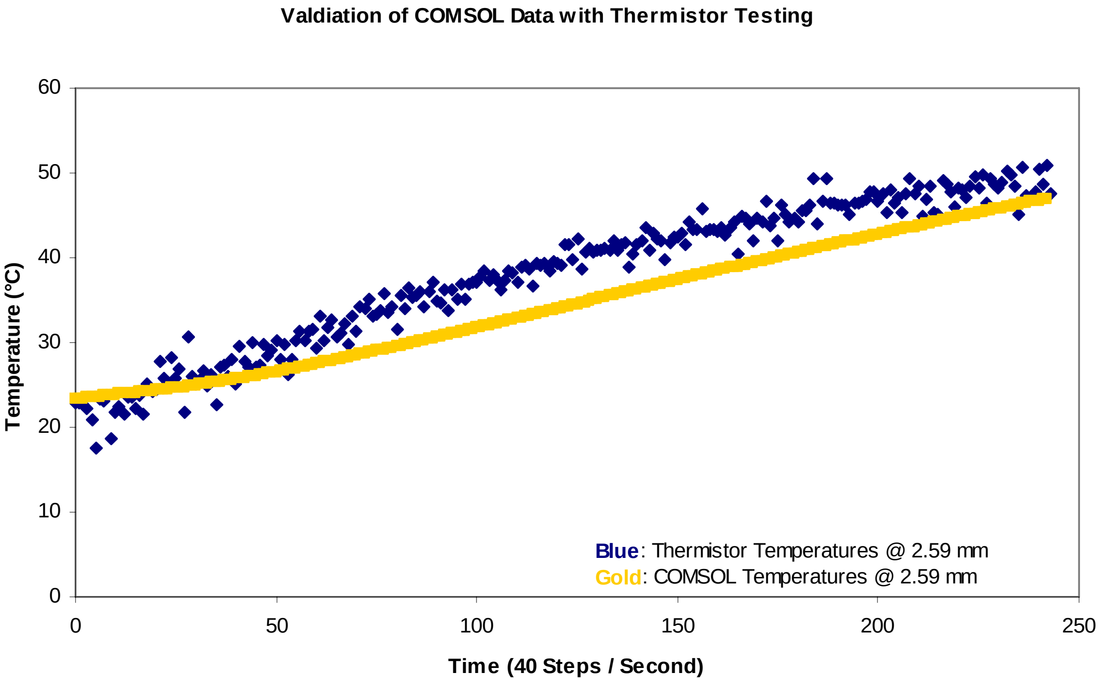


Figure 18: Comparison Plot of Temperature vs. Time at 2.59 mm from Electrode Center Determined (Thermistor vs. COMSOL)

To begin FEA of our thermal management model, the type and temperature of the coolant needed to be determined. Because water is already used in surgery, and research shows it is an ideal coolant for medical usages, we selected distilled water as our choice of coolant. We first simulated our model using cool water. Further analysis may suggest the use of a different coolant. If this is the case, we will adjust our model accordingly. The physical properties of our cooling channel and fluid can also be found in Appendix G. The model of our cooling channel was imported from our CAD model and placed in contact with the tissue surrounding the electrode. The cooling channel consists of an outer pipe made of stainless steel, which was treated as electrically insulated to prevent any current from jumping to the cooling channel instead of the grounding plate. The cooling channel was modeled as a constant temperature tube. We were able to assume this because a fast flow rate of the coolant will make the change in the water temperature negligible. The tissue and electrode were modeled the same as in the simulation of the monopolar device without thermal management.

Figure 19, page 22, is the model of the thermal spread within the tissue for monopolar electrosurgery with our operating thermal management system. As with the simulation of monopolar electrosurgery without thermal management, the heat dissipates throughout the tissue, however at a quicker rate.

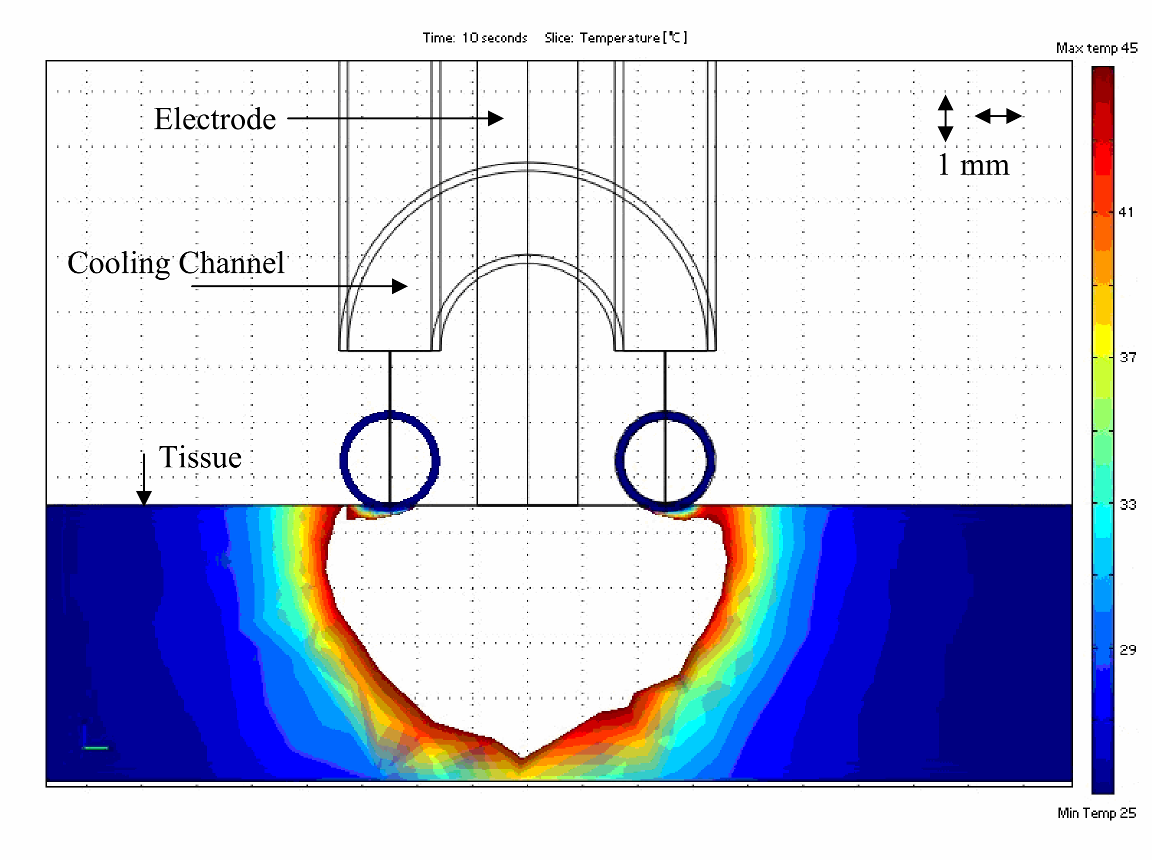


Figure 19: COMSOL Analysis of Thermal Spread from Electrode with Thermal Management System in Place

Both models, with and without the thermal management system in place, have the same temperature scale. Thus, in comparison, it can easily be seen that the applied thermal management system does reduce the thermal spread on the tissue surface by a significant amount. This can also be seen by plotting the temperature and radii of various points on the tissue for this model. As Figure 20, page 23, shows, the temperature at 5mm from the electrode tip increases less than 6°C, which validates our initial engineering specification.

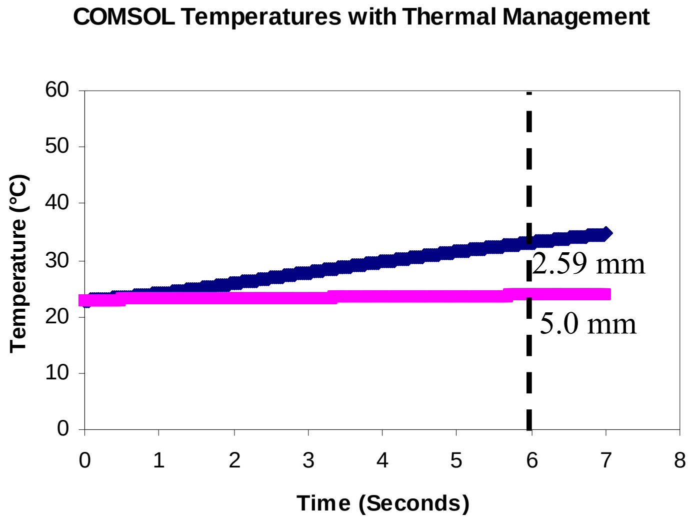


Figure 20: COMSOL Plots of Temperature vs. Time at 2.59 mm (blue) and 5.0 mm (pink) from Electrode Center with Thermal Management System

The comparison and analysis of the two simulations show that our device does provide the desired thermal management according to our engineering specifications. Also, it validates our decision to use cooled water as the chosen cooling fluid.

Manufacturing Constraints

Since our project is intended for mass production, the manufacturability of the device was considered during the design process. The major change in our design from a current device on the market, was the addition of a cooling channel. The other components of our device remained similar to the current device. This ensures that mass production would be economically feasible. As mentioned above, the materials used in mass production of our device would be the same as current devices. For prototype manufacturing, however, we have decided to use materials that are more readily available and easily machined. Although not the same, these materials have similar properties to those that will be used in mass production. The casings of the current devices are injection molded, which is beyond our capabilities. However, since the casing is not an integral part of validating our design, this will not affect our results.

Failure/Safety Constraints

The thermal management system that we have designed for a monopolar electrosurgical tool poses no major safety concerns. As stated earlier, monopolar devices are used in most surgeries. The widespread use and dependability would not be as common today, if the device had safety issues. By integrating the cooling channel into a current monopolar electrosurgical device, we have eliminated any additional risks that may be involved with the use of the device. For our prototype, the cooling channel was manufactured out of stainless steel. Stainless steel was chosen because of the widespread use in medical instruments. The coolant was also chosen (water rather than a gas such as air) based upon safety in the operating room. It is much more desirable to use distilled water rather than a gas in the operating room. Our design is expected to have the same lifetime as a current device. Some monopolar electrosurgical devices are disposable, while others can be used multiple times. For our device, with the integrated cooling channel, we would expect that the device be reused, only requiring the electrode tip to be changed.

FINAL DESIGN

Final Design Description

Our final design is very similar to the "alpha design" presented earlier. When modeling our final design we added to and modified the dimensions of the "alpha design" to best fit the needs of the surgeon, as well as the manufacturability of the design.

The final design for the monopolar electrosurgical device is comprised of five components. A list of numbered components, along with the material suggested for mass production and the material used for the prototype, is shown in Table 4.

Component	Component	Material for Mass Production	Material for Prototype
1	Outer Casing	Injection Molded Plastic	PVC Pipe
2	Curved Cooling Channel	Stainless Steel Pipe	Stainless Steel Pipe
3	Interior Slider	Injection Molded Plastic	PVC Rod
4	Locking Device	Spring	Spring
5	Electrode	Stainless Steel/Teflon	Stainless Steel/Teflon

Table 4: Final Design Component List and Corresponding Materials

Figure 21, page 25, shows an isometric view of the final design with the individual components labeled. A layout view of the final design can be seen in Figure 22, page 25.

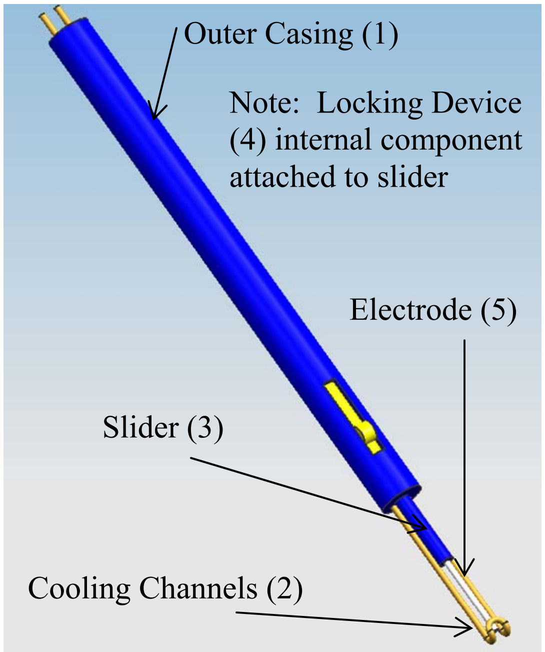


Figure 21: Final Design for Open Surgery With Labeled Components

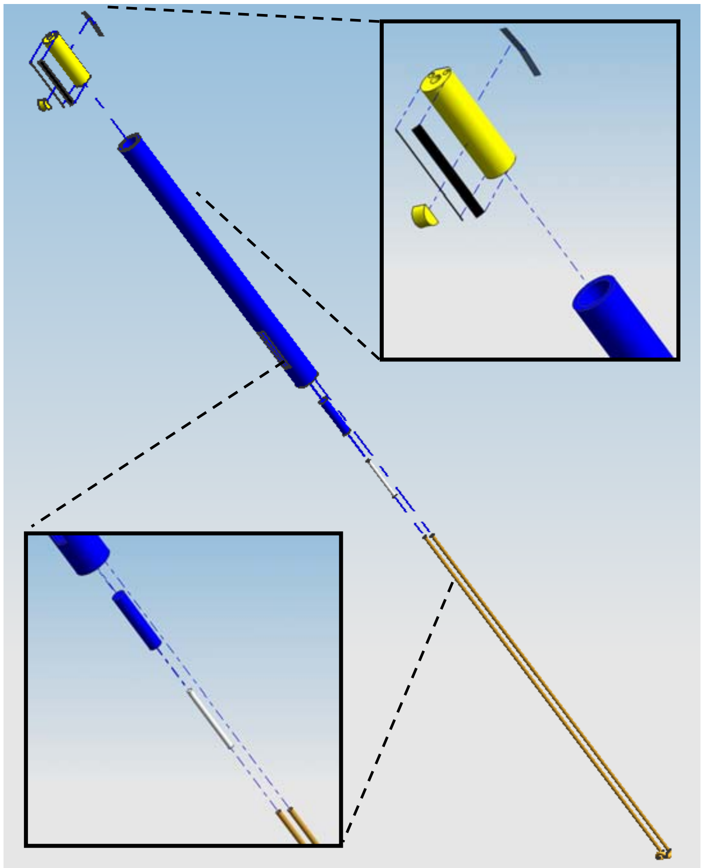


Figure 22: Final Design Layout View

The innovative portion of our design is the curved cooling channel that winds around the electrode tip area as shown in Figure 23. This tube will be made of stainless steel, with cool water flowing through it, extracting the excess heat from the tissue.

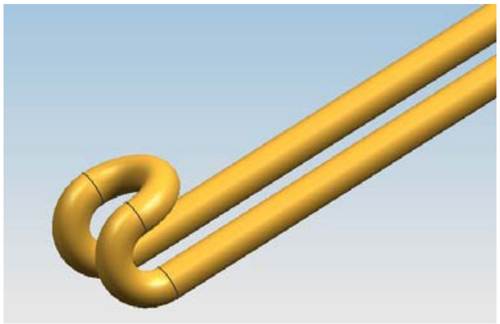


Figure 23: Cooling Channel

The cooling channel can be slid up and down in three basic positions. When the channel is up and away from the electrode tip, as shown in Figure 24 (a), it is out of the surgeon's line of sight. This position is desired when thermal management is not necessary, such as while in cutting mode. The second position is when the cooling channel is slid down so the end of it is even with the electrode tip as seen in Figure 24 (b). This position allows the curved channel to come into contact with the tissue, so that the excess heat can be extracted by the fluid. The third position is used for cauterizing vessels of 1 - 2 mm diameter. In this position, the cooling channel slides past the vessel then retracts back, pinching the vessel between its surface and the electrode tip as seen in Figure 24 (c).

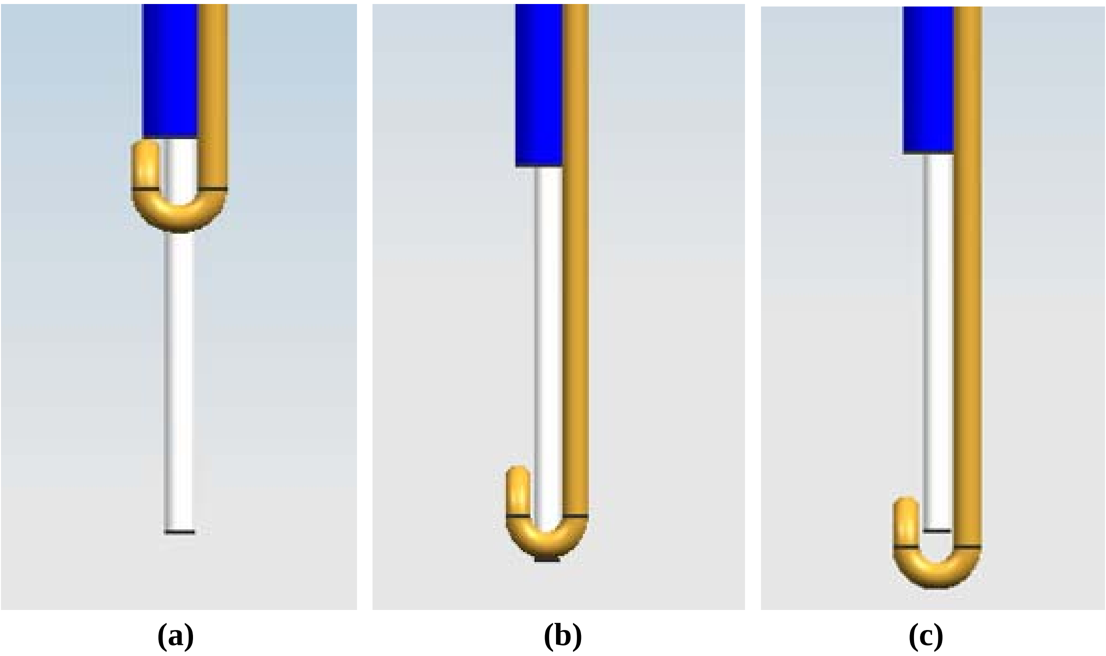


Figure 24: Three Desired Positions for the Cooling Channel

Although the sliding mechanism has three basic positions, it is continuous and therefore can be locked at any desired position along the electrode.

The remaining components are used to encase and control the curved cooling channel. The insulating casing is the part of the monopolar pencil that the surgeon holds during surgery. This was made from PVC pipe for the prototype, and is shown in Figure 25. For mass production the casing would most likely be made of injection molded plastic similar to that used for current monopolar pencils. The slider, and most of the cooling channel, are encased inside this insulating tube, along with the wire that conducts the current to the electrode tip.

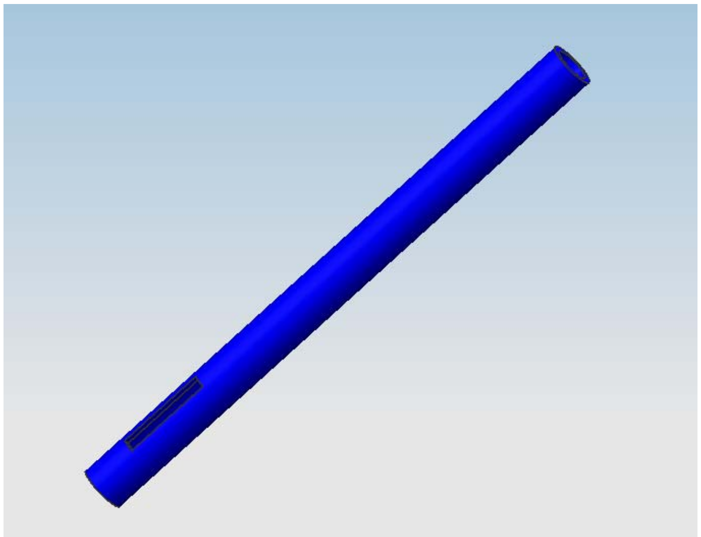
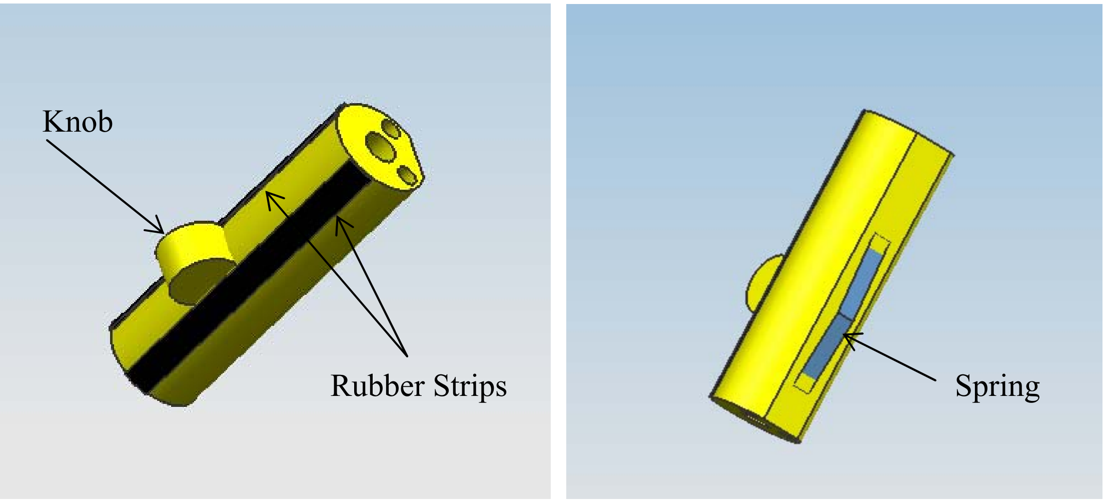


Figure 25: Insulating Casing of Monopolar Pencil

The slider is rigidly attached to the cooling channel, and slides within the insulating casing. The slider can be seen in Figure 26, page 28. A knob is attached to the front side of the slider, which allows the surgeon to retract and extend it. If additional friction is necessary between the insulating tube and the slider, two rubber strips will be attached to the front of the slider. The back side of the slider has a flat metal spring that applies a force to the slider toward the knob. This force creates friction, which keeps the slider in place. The surgeon will apply pressure to the knob when movement is desired. This applied pressure separates the rubber part of the slider and the insulating casing, which reduces the friction, and allows for movement of the slider. There are also three holes in the slider. Two outer holes for the rigidly attached cooling channel and a center hole for the electrical wire to pass to the electrode.



(a) **(b)**

Figure 26: Interior Slide with Components

There are many different electrode tips used during monopolar electrosurgery. Our design uses a stainless steel cylinder with a 1.83 mm diameter and a flat end, which would be coated in Teflon to reduce tissue sticking to the electrode. The flat end is used so the vessel can be pinched between the electrode and the cooling channel. Due to the manufacturability of the cylindrical electrode we will use a current electrode tip for the prototype. Refer back to Figure 13, page 17, for a comparison between this electrode and other common electrodes used.

Detailed dimensioned drawings for each component of the open surgery design are shown in Appendix I.

Our original task also included designing a thermal management system for laparoscopic surgery. The design discussed in the previous section (Figure 22, page 25) is only suitable for open surgery; however, the possibility of manipulating the concepts used to work in laparoscopic surgery does exist. Ideally, the design would be scaled to the dimensions of current laparoscopic monopolar devices. Because of our limited manufacturing processes, we will not be able to manufacture a prototype of the laparoscopic device. We have, however, modeled the laparoscopic design using Unigraphics as seen in Figure 27, page 29.

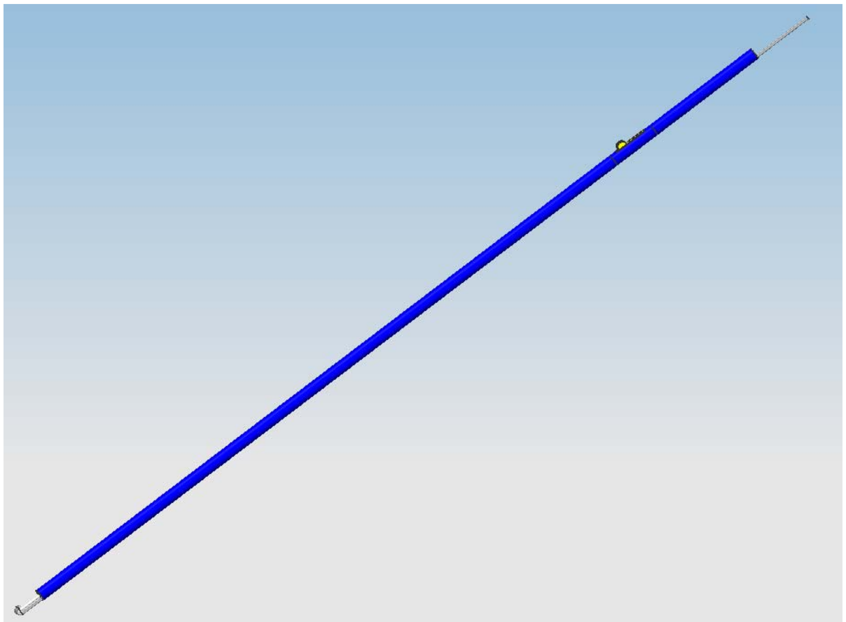


Figure 27: Laparoscopic Monopolar Device Design

The mechanisms used in the laparoscopic device are the same as in the open device; however, many of the dimensions vary. The major variations occur in the length of the device, the radii of the tubing and electrode, and the length of the electrode. We also adjusted the placement of the sliding control to the opposite end of the casing to allow the tubing to enter the body without restricting use of the device. Detailed dimensioned drawings of the laparoscopic device can be found in Appendix J. Because the laparoscopic device is similar to the open surgery device, we can assume that by validating the open device, the laparoscopic device will perform similarly

Prototyping for Validation

Our manufactured prototype is not a final product, but it does allow us to validate our final design and the concepts that it is based upon. The goals of our final prototype were to prove the possibility of thermal management in monopolar electrosurgery, as well as, to present our final design and its feasibility. As shown in the design parameter analysis, our engineering logic and mathematical analysis predicted that our concept should provide proper thermal management in monopolar electrosurgery to meet our engineering specifications. Further testing of the prototype device allowed us to physically test these concepts, showing that our device provided proper thermal management.

As mentioned in the final design description not all of the aspects of the final design were produced in the prototype, however, these changes are limited to aspects of the device that are not essential to the operation of the cooling device (such as the elimination of the rubber strips since no additional friction was necessary). Because the cooling channel in the prototype is the same as the final design, we can use the prototype to validate the concepts of the device.

Validation Procedure

If a design doesn't successfully fulfill its engineering specifications, then it is a failed design, or needs to be partially redesigned. Thus, the experimentation and validation of a design are critical to providing a successful product.

In order to validate our design, we had to show that the concepts and designs we used meet the original engineering specifications that were set. The single, most important engineering specification was to keep the increase in tissue temperature at a 5 mm radius from the surgical tip to no more than 6°C. This temperature increase reflects the temperature that would minimize the amount of damage from thermal spread to the tissue. In order to validate that our design meets this specification we first tested the temperature increase at a 5 mm radius without the cooling system in place. After these tests were complete, we repeated the test with the cooling channel in place. This allowed us to compare the results of both to our original specification, as well as the current devices.

Although the change in temperature was the most important specification, we also had to determine whether our device met the other specifications. The next specification evaluated was the increase in the weight of our device compared to the current device. This was tested by weighing the original device, as well as the prototype. However, since the prototype was not made from the same materials as if mass produced, we considered that the device would be unchanged with the only additional mass coming from the cooling channel. In order to determine this projected increase in weight, we weighed the cooling channel. We also tested the accuracy of the thermistors used for testing. This was done by testing known temperatures of boiling water and ice water, and creating a calibration curve. For the specification of the number of steps from use to non-use our design validated this by using a simple sliding motion. The final specification was the cost for manufacturing which was set at $400. This was validated by our Bill of Materials.

MANUFACTURING

Prototype Manufacturing

In order to begin the manufacturing process for our prototype we first created a Bill of Materials (BOM), Appendix K. This allowed us to determine all necessary materials and equipment along with the cost and availability of each. Initial materials used for testing are not included.

We determined that the optimal material for creating our thermal management cooling channel is stainless steel, due to its biocompatibility, as well as its thermal conductivity properties in and around the body. In order to create the initial bend we sought outside resources, who helped to create a small cylindrical device (with the desired bend radii), which in turn was used along with a mill (rotated by hand) to slowly bend the initial u-shape in the tip (Appendix L). This same device was then used to create the other bends.

Because of the size of the device we were unable to bend both of these at the same time which left them slightly uneven. The shape of the final cooling channel can be seen in Figure 23, page 26.

The outer casing of the monopolar device prototype was made from a clear PVC pipe. This pipe was purchased with dimensions similar to those of our original design, however, due to limitations in availability, cost, and machining limitations we used a pipe with a slightly larger diameter than the original design. We then cut the pipe to the desired length using a cut off tool on the lathe. Once the desired length was achieved we used a 3/16 inch end mill to mill the slot in the casing for the slider.

To manufacture the slider we used the appropriate sized drill bits to drill the required cooling channel and electrical connection holes. We started with a ½ inch diameter PVC rod which was lathed down to the desired diameter. The rod was then milled using a ½ inch end mill to create the flat side for the spring. We were then able to cut off the slider to the correct length again using the cut off tool on the lathe. The final piece of the slider was the control knob, which was created using the excess PVC rod. The rod was again lathed to the desired diameter and then cut off to the correct thickness. This was then milled down to the half circle shape of the knob. From the rod we were also able to create both end caps, which were made from a similar process for the slider excluding the milling of the flat side.

The final component was the spring for the sliding mechanism. We used a simple flat spring from an existing Exacto knife. This spring was modified in length by using a sheet metal shear.

Once all of the components were manufactured, assembly could begin. A layout view of this assembly is shown in Figure 28, page 32. The first piece to be assembled was the end cap, which connects to the electrode. Since we were using an electrode and electrical connection from an existing device, this had to be integrated into our prototype system. The electrical connection consisted of the wire as well as the as the actual connection, which also acted as a support for the electrode. This was attached to the end cap using super glue. A key concern with this attachment was to prevent the glue from getting into the electrical connector and preventing a proper connection.

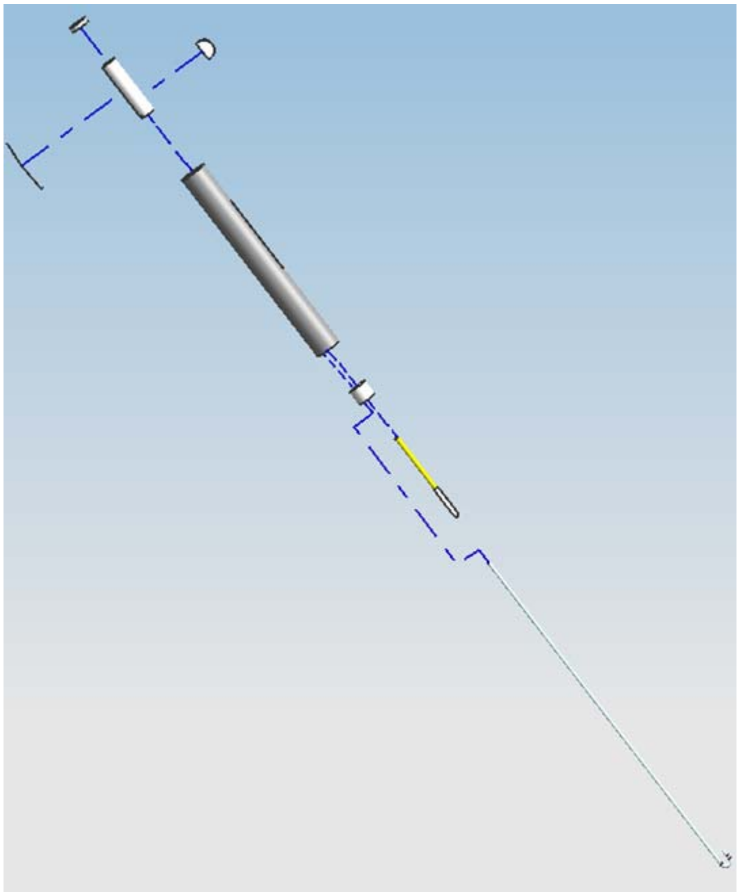


Figure 28: Prototype Layout View

The spring also needed to be attached to the slider, which was accomplished by placing a small groove in the flat side of the slider. The end of the spring was then bent slightly to fit into this slot and super glue was applied to hold the spring in place. This connection is shown in Figure 29, page 33.

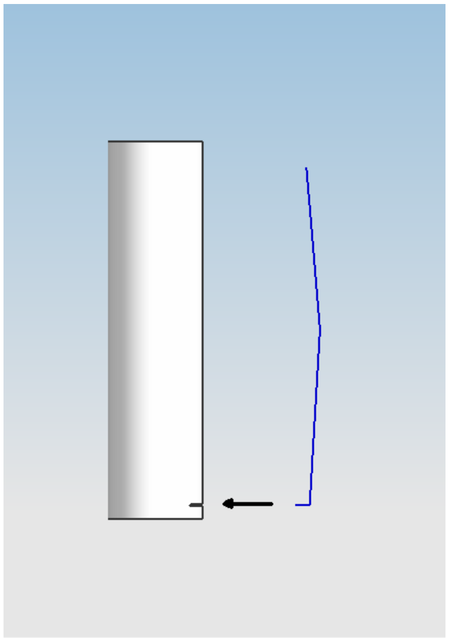


Figure 29: Internal Slider and Spring Assembly

The next step was to connect the end cap/connector piece and the slider to the cooling channel. Since the cooling channel needed to move freely with respect to the end cap, the cooling channel was fed through the end cap. The slider, on the other hand, needed to be rigidly attached to the cooling channel; therefore, super glue was placed on the cooling channel prior to sliding it into place. This part of the assembly can be seen in Figure 30.

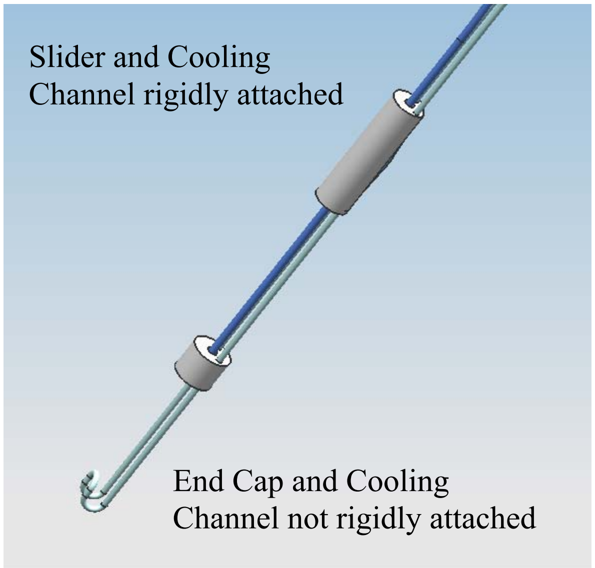


Figure 30: Internal Slider, End Cap, and Cooling Channel Assembly

Once these pieces were combined, they needed to be attached to the outer casing. The major concern with this was to make sure the spring was lined up directly opposite the slot for the knob. Once the entire system was slid into the outer casing, the end caps were glued in place with the electrical wiring running through the predrilled center holes. Lastly, the knob was attached to the slider. The final assembled prototype, as well as a view of the slider integrated into the casing can be seen in Figures 31 and 32, respectively.

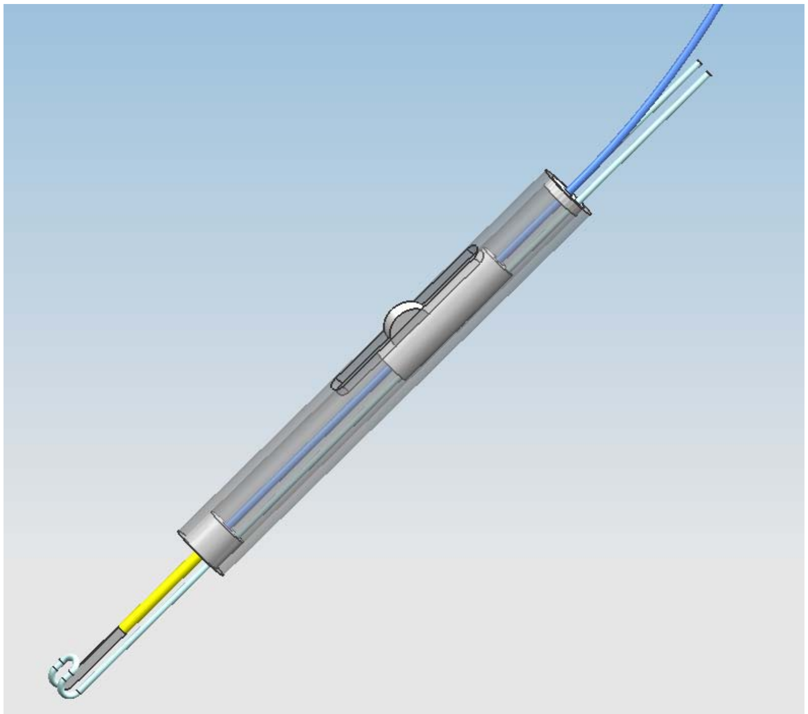


Figure 31: Assembled Prototype

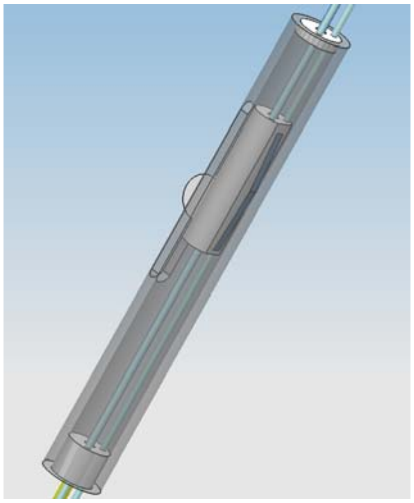


Figure 32: Sliding Mechanism of Final Prototype

The final step in assembling the device was to attach the pump. This was done using three pieces of plastic tubing which ran between a beaker of cool water and the inlet of the pump, the outlet of the pump and the inlet to the cooling channel, and the outlet of the cooling channel back to the beaker of cool water. A schematic drawing of this setup is shown in Figure 33.

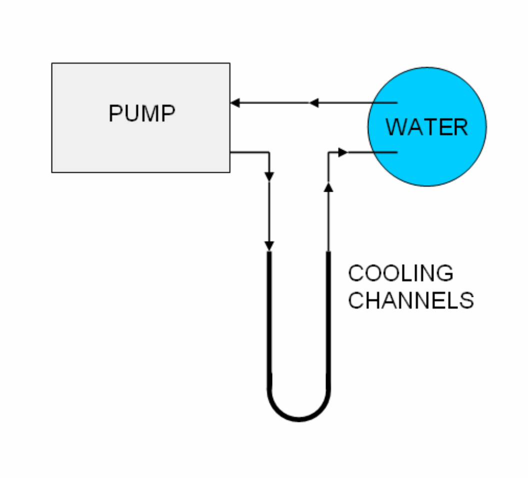


Figure 33: Flow of Water through Cooling System

The only remaining pieces were the generator and electrode, which remained intact from the current device and were simply integrated into our system. A close up view of the electrode attached to the end cap can be seen in Figure 34.

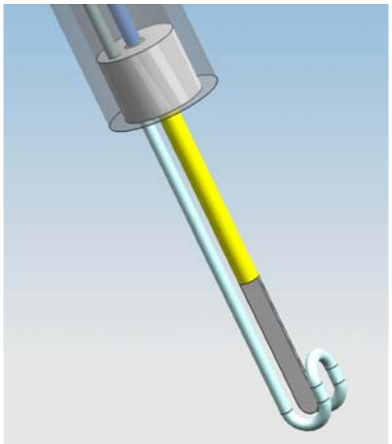


Figure 34: Electrode Attached to End Cap

Detailed, dimensioned drawings of the final prototype can be seen in Appendix M. These pictures are similar to those seen in Appendix I, however, vary slightly in certain dimensions based upon the manufacturing constraints we had. The process plan sheets, which detail the manufacturing steps of each individual component can be seen in Appendix N.

Mass Production Manufacturing

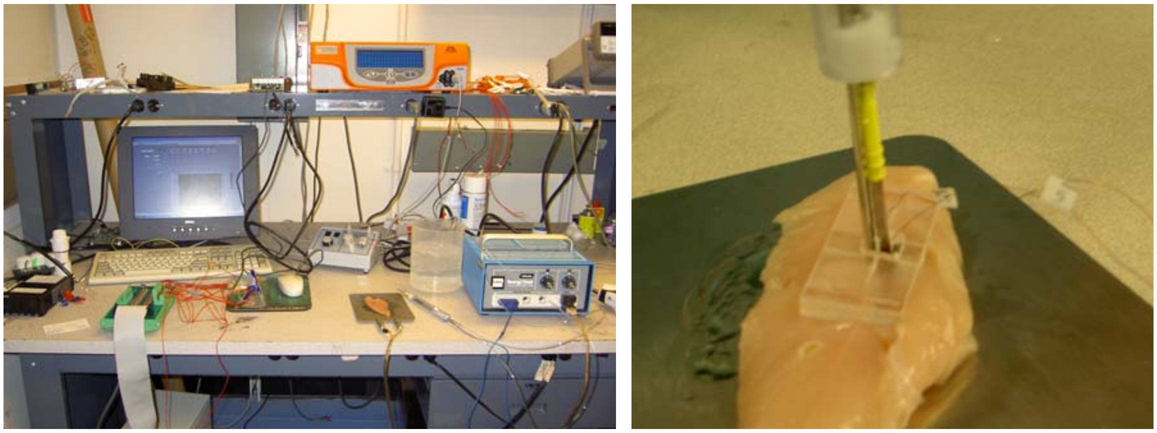
Many current monopolar pencils are disposable and highly inexpensive; because of this, in order to be competitive in the market, we must strive to obtain a similar cost of manufacturing to current devices. The major obstacle to this is the bending of the tubes fro the cooling channel. This is a very delicate and timely process in comparison to the mainly injection molded pieces in current devices. In order to manufacture the bent tubing parts of our device for mass production, the material used may need to be adjusted. A more ductile material would allow for a simpler bending process. For the other components of the device, mass production would be similar to the production for current devices, mainly using injection molding.

TEST RESULTS

Once our prototype was manufactured, we then had to validate our design and earlier finite element analysis by demonstrating that our design satisfies our engineering specifications. The most important engineering specification was to allow a tissue temperature increase of no more than 6°C at a radius of 5 mm during monopolar electrosurgery, and thus this validation was the focus of our testing.

Experimentation

Through the aid of Robert Dodde, we developed a simple experiment to test and evaluate our design. The overall goal of the experiment was to be able to measure surface temperatures of chicken tissue at pre-determined radii from the electrode. Thus, first we had to establish a temperature measuring system. We used thermistors in coordination with the LabView program to accomplish this, as seen in Figure 35, page 37. In order to place the thermistors at the pre-determined locations, we created a physical template (from Plexiglas) to place on the chicken tissue, Figure 36, page 37. This template was machined to allow the electrode and cooling channel of our device to be in contact with the chicken tissue at the point of coagulation, which would be the center point of our template. Six small holes were then drilled at radii of 5 mm to 15 mm, in 2 mm increments, from the center point. These distances were chosen based on our engineering specifications. These holes were drilled to the diameter of the thermistors we would be using to measure the tissue temperatures. The temperatures measured by the thermistors were recorded by LabView using a time step of 40. For this testing, we only used the radii of 5 mm to 9 mm, because the temperature change beyond the 9 mm point was determined to be negligible. A dimensioned model of the thermistor holder can be seen in Appendix O.



(a) **(b)**

Figure 35: (a) Entire Computer (LabView) Setup
(b) Close-Up View of Thermistors and Chicken Tissue

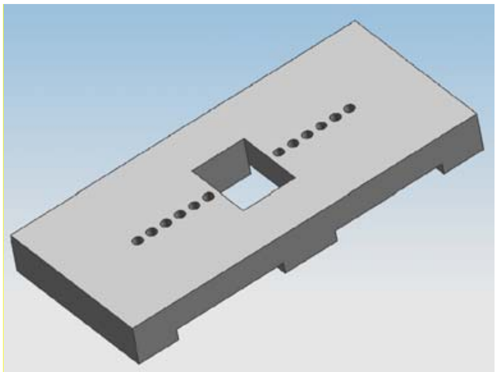


Figure 36: Physical Template for Holding Thermistors

In order to ensure accurate temperature measurements, the thermistors needed to be calibrated. The thermistor measured temperatures were taken in both ice water and boiling water, which we know to have an actual temperature of 0°C and 100°C, respectively. A calibration curve for each of the three thermistors was created, shown in Figure 37, page 38. The average of the recorded temperatures was used to determine the calibration. The equation of each calibration curve was then found and used to correct all of our temperature data used in our analysis. Equations 1, 2, and 3 (page 38) refer to the 5 mm, 7 mm, and 9 mm thermistors, respectively.

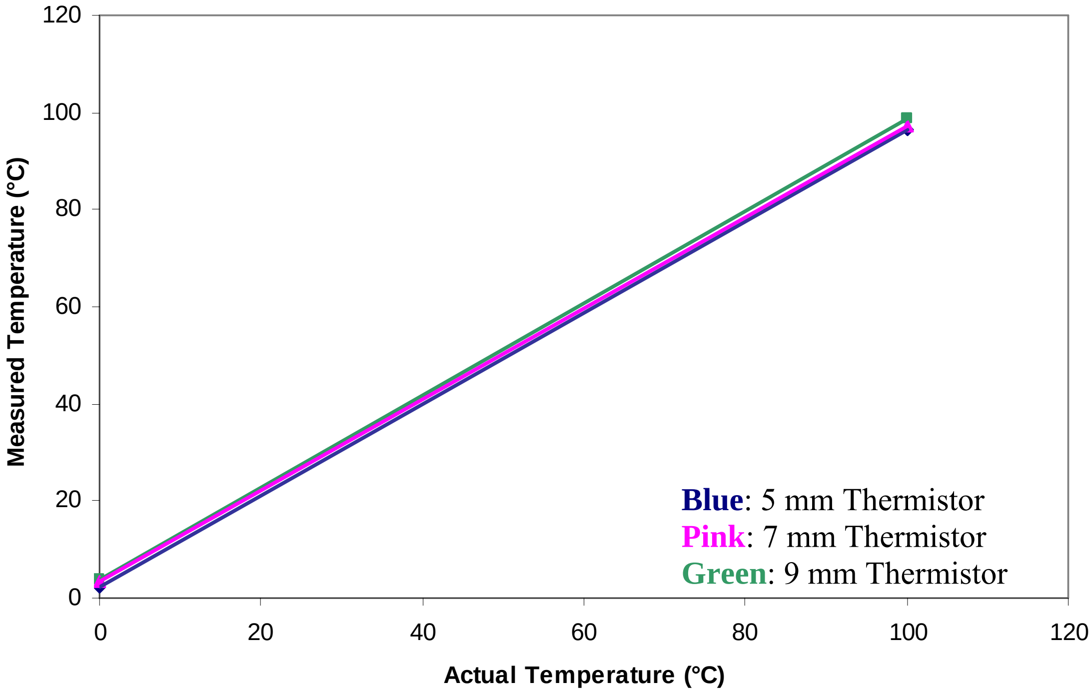


Figure 37: Calibration Curve for the Three Thermistors Used throughout Experimentation

$$y = 0.9414x + 2.3867 \qquad \textbf{Eq. 1}$$

$$y = 0.9393x + 3.3659 \qquad \textbf{Eq. 2}$$

$$y = 0.9511x + 3.6951 \qquad \textbf{Eq. 3}$$

In order the see the difference in tissue surface temperature between the current monopolar electrosurgical device and our device, we ran two sets of experimental trials. The first set was to represent the current device. In order to do this, we used our design, with the cooling system slid up and out of the surgical site. This would mean that no thermal management was taking place. The second set represented our newly designed device with our thermal management system. The cooling channel was slid down, even to the tip of the electrode, to allow a surface contact between the tissue and cooling channel. Multiple trials of each setup were conducted with all temperatures being recorded.

Results of Experimentation

Once the temperature readings from the three thermistors were recorded, they were calibrated according to each thermistor's calibration curve. Every 20 data points were then averaged into one data point, allowing for a more concise graph. A graph of time versus temperature was created for each trial. These were then examined to see if any errors had occurred regarding specific trials. Any erroneous or outlier trials were then discarded. These errors included: allowing the cooling channel to cool the tissue before coagulation was started, uneven coagulation, and inconsistent pressure at the coagulation site.

The first set of testing was to simulate current monopolar electrosurgery devices with no thermal management system. Graphs were created from the recorded data for two trials as seen in Figures 38 and 39 (page 39 and 40, respectively). The three curves per graph represent each of the three thermistor's temperature readings at the given locations. Thus, the two trials are shown on separate graphs, with the same scale, to allow temperatures at different radii to be shown. The solid red line across the graph represents the temperature that is 6°C above the initial temperature of the 5 mm thermistor. This represents our engineering specification of no more than a 6°C increase of tissue temperature at a radius of 5 mm from the electrode. As each graph shows, the temperature recorded by the thermistor at a radius of 5 mm increases to beyond this 6°C threshold. Even though the temperatures at 7 mm and 9 mm do not reach the 6°C threshold, they still increase with time. This does agree with our finite element analysis shown earlier. Accordingly, we should see that once the thermal management system is used, the temperature recordings should not increase beyond the 6°C threshold at a distance of 5 mm, and at a distance of 7 mm and 9 mm the temperature increase should be minimal, if any at all.

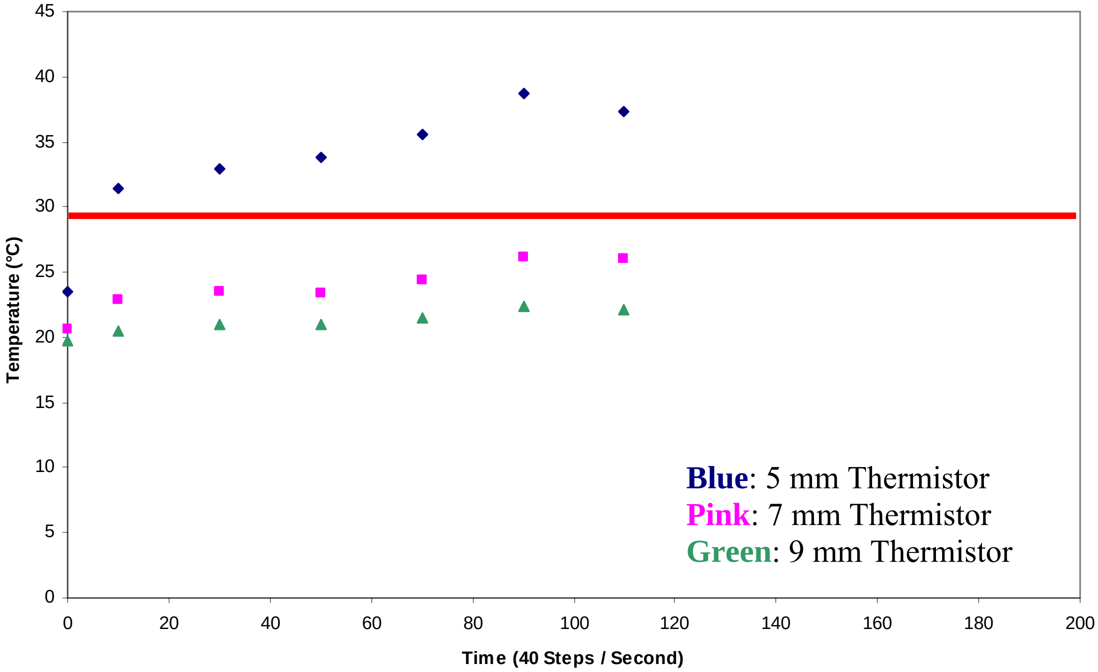


Figure 38: Graph of Recorded Temperatures while Simulating No Thermal Management System, Trial 1

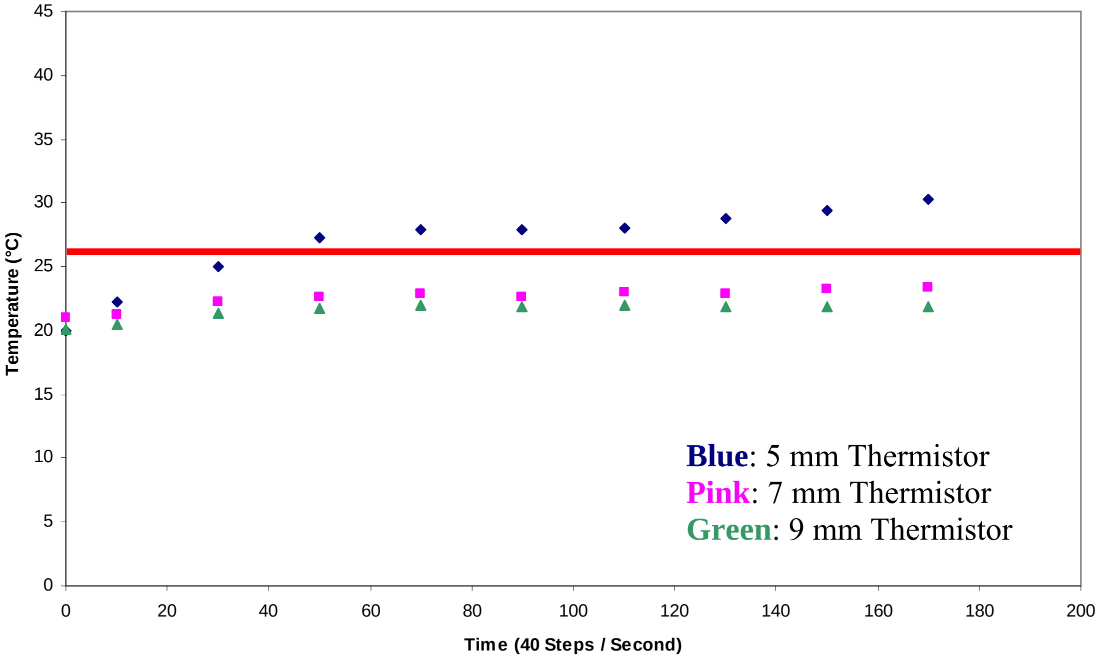


Figure 39: Graph of Recorded Temperatures while Simulating No Thermal Management System, Trial 2

The second set of testing attempted to validate our design for a thermal management system for monopolar electrosurgery. The recorded data from trials with the cooling system in use was analyzed and placed into graphs using the same process as the uncooled data, as shown in Figures 40, 41, and 42 (pages 41 and 42). As with the previous graphs, each thermistor radii is represented by a curve, as well as the 6°C threshold being represented by the solid red line for the thermistor with a radius of 5 mm. Again, trials are shown on separate graphs to allow the three thermistor distances to be seen clearly. All trials conducted with the thermal management system in place show that no temperature recorded outside of a radius of 5 mm increases beyond the 6°C threshold. In fact, in general, there is no tissue surface temperature increase at any of the three distances.

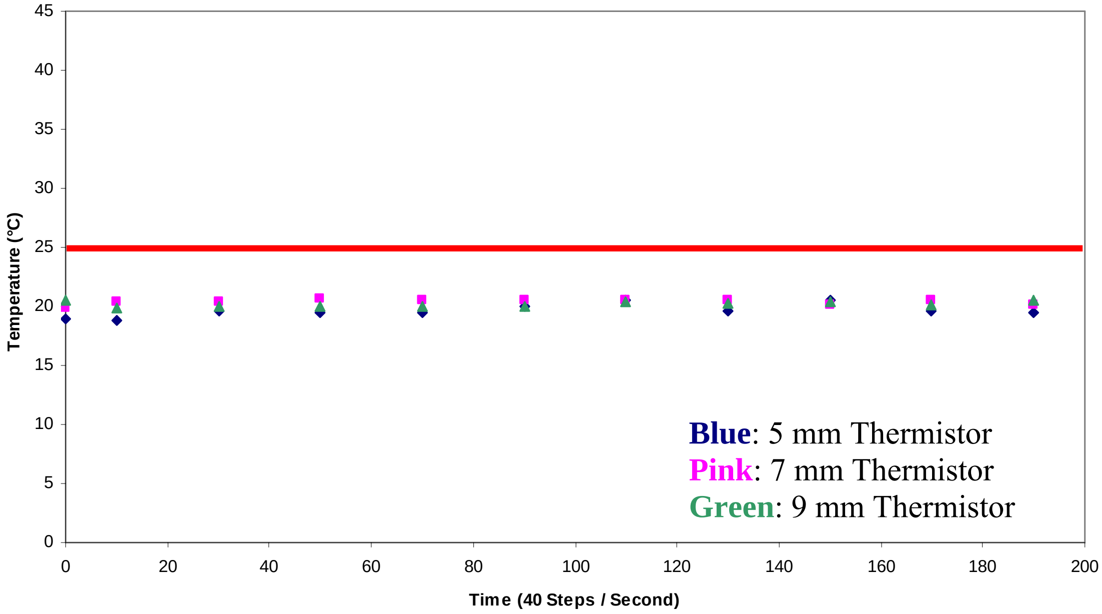


Figure 40: Graph of Recorded Temperatures while using the Thermal Management System, Trial 1

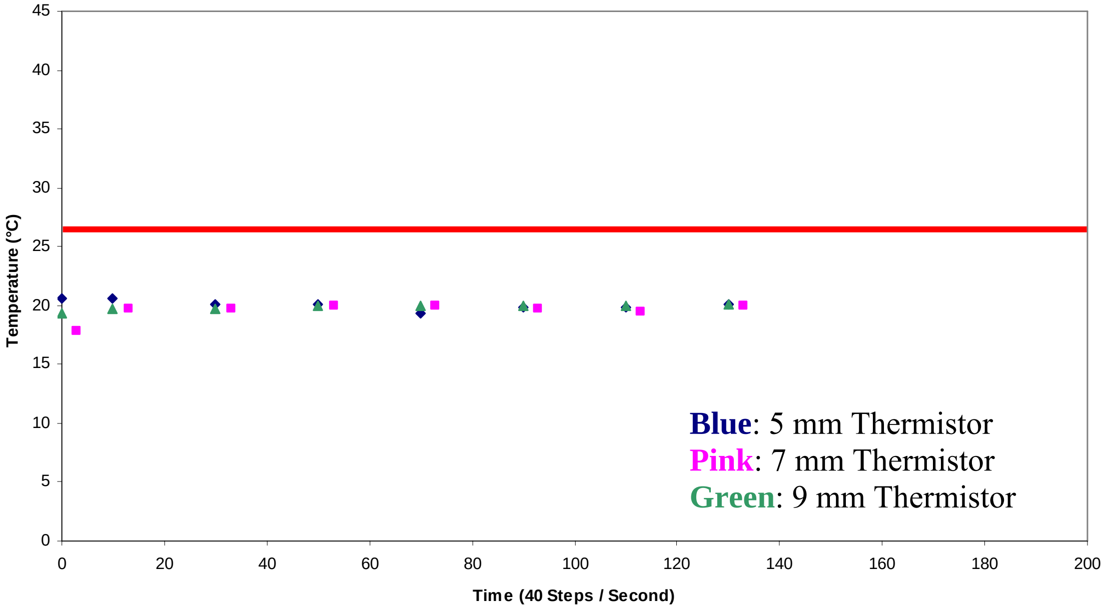


Figure 41: Graph of Recorded Temperatures while using the Thermal Management System, Trial 2

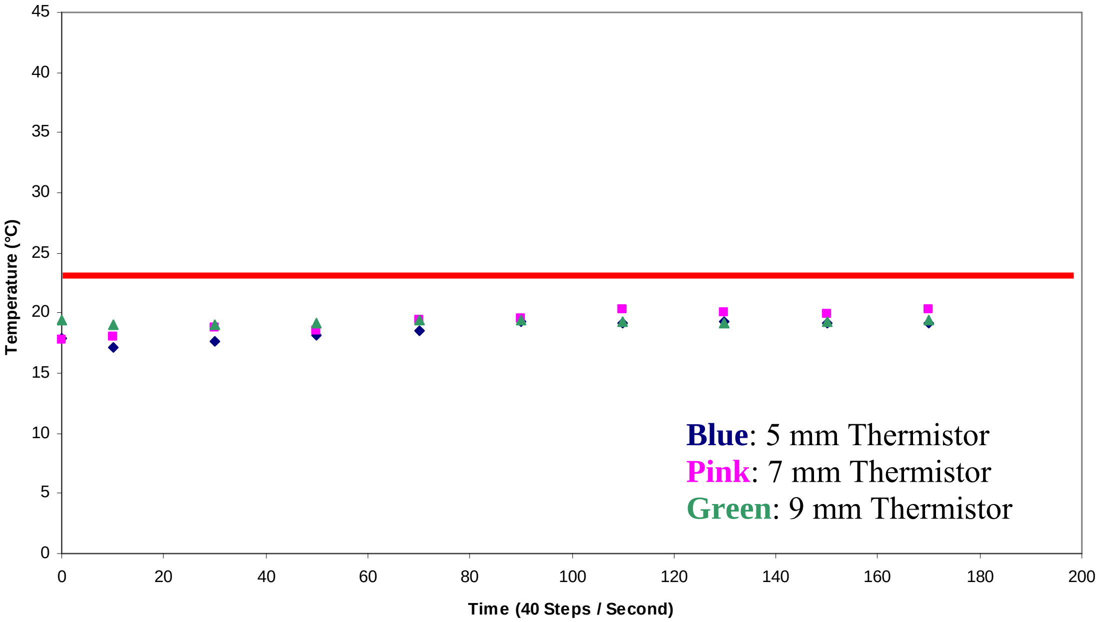


Figure 42: Graph of Recorded Temperatures while using the Thermal Management System, Trial 3

The major goal of our design was to decrease the tissue temperature during monopolar electrosurgery. We decided that the engineering specification we would need to meet to accomplish this was to allow for no more than a 6°C increase at or beyond a distance of 5 mm from the electrode. The testing without a thermal management system does allow temperatures to reach beyond the specification, meaning that it was a reasonable specification to set. Also, as Figures 38 and 39, page, show, the temperature of the tissue at distances of 7 mm and 9 mm also increases. Once our thermal management system was added, the tissue temperature at 5 mm not only remained below our engineering specification throughout experimentation, but hardly increased at all. Also, there was minimal noticeable increase in the temperatures at distances of 7 mm and 9 mm. Thus, all test data shows that our thermal management system is successful. A picture of the tested chicken tissue can be seen in Figure 43, page 43. From this picture you can see the visible difference in thermal spread with and without the cooling channels present.

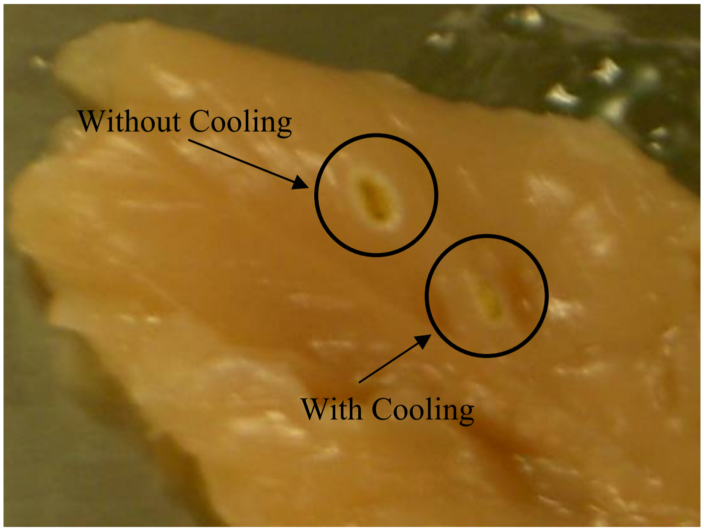


Figure 43: Tested Chicken Tissue Showing the Reduced Thermal Spread when Cooling is Present

COMSOL Simulation

Further analysis and validation of our design can be done using COMSOL, our finite element analysis program. COMSOL was used earlier to model the earlier stages of our design and simulate monopolar electrosurgery with and without our thermal management system. Now that the prototype has been built, we adjusted the COMSOL model to match the dimensions and design of the prototype with our thermal management system. Simulating our COMSOL model for the same time frame and initial temperatures as our actual experimentation, we found a very close match between the simulation and actual results. Figure 44, page 44, shows the temperature versus time plot of the COMSOL simulation. As you can see, there is a minimal increase in tissue temperature at a radius of 5 mm from the electrode. This minimal increase does stay well below our 6°C threshold. Also, modeled temperatures at distances of 7 mm and 9 mm are shown on the plot. It can be seen that there is no noticeable increase in tissue temperature at these distances.

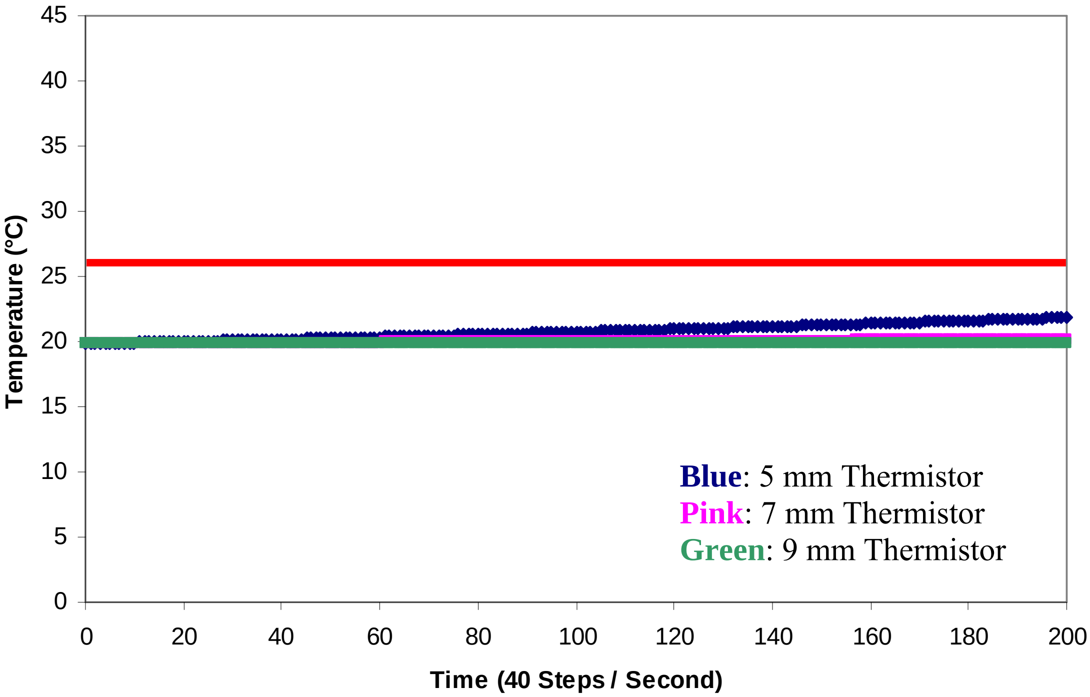


Figure 44: COMSOL Model shows 5 mm Temperature below 6°C Threshold, and Minimal Increase for Temperatures at 7 mm and 9 mm

Validation of Specifications

The COMSOL Simulation, Figure 44, can be compared to the plots of our actual thermal management system (Figures 40, 41, and 42, pages 41 and 42). The recorded temperatures of these trials over the 5 second (200 steps) time frame very closely match the temperatures produced by the COMSOL model of our system. This comparison shows that our COMSOL model and actual design are very closely related and that our COMSOL model can be used to make predictions about our design with a great deal of accuracy. All of these plots, the actual tests, and the COMSOL model, show that the tissue temperature at a distance of 5 mm is well below the 6°C threshold that was set as our engineering specification. In addition, the temperature recordings at 7 mm and 9 mm remain mostly constant at the initial tissue temperature. The combination of our actual testing results along with our COMSOL simulation results shows a validation of our design that not only meets our most important engineering specification, but widely surpasses it.

We also validated the other engineering specifications using the procedures explained earlier. As seen in Table 5, page 45, the results of our testing showed that all specifications were either met or exceeded.

Engineering Specifications	Target	Results
Increase in Tissue Temperature	At 5.0 mm, < 6°C (power level 4)	At 5.0 mm < 2°C (power level 4)
Temperature Monitoring Accuracy	2 % error	2 % error
Additional Weight Increase	20 %	14 %
Steps from Retraction to Usable Position	2 steps	1 step
Material Cost	< $400.00	$45.83
Maximum Radius from Device Center	5.0 mm	4.3 mm

Table 5: Targets and Results of Engineering Specifications, Showing all Specification Met or Exceeded

ENGINEERING CHANGES NOTICE

There are some aspects of our monopolar pencil and thermal management system that have changed from our final design to our prototype. The majority of these changes are dimensions, where the new dimensions can be found in Appendix M. These changes are due to material availability and manufacturability. For example, the outer tube in our final design had an outer diameter of 12.7 mm and an inner diameter of 9.5 mm. A standard size for clear PVC tubing, however, has an outer diameter of 17.3 mm and an inner diameter of 12.2 mm. We used the standard size for our prototype due to its availability. Other component dimensions also changed slightly based upon the casing changes.

Other than the dimensions changing, we changed the slider and electrode for our prototype. These changes are documented in Appendix P.

DISCUSSION

Every design has its strengths and weaknesses, as well as aspects that may need to be changed in future applications. Since our design is still a work in progress, this is especially true. Overall, our design performed well in testing and showed signs of progress towards the goal of achieving thermal management with monopolar electrosurgery, but there are still many weaknesses as well.

Strengths

The major strength of our design was that it showed that the concept of thermal management in monopolar electrosurgery was possible. Our design was simple and integrated well with current devices as well as maintaining a similar overall design to current devices. This would allow for an easier transition into the market if the device was to be mass produced. Another advantage is the way the cooling channel is integrated into the device. Because it remains so close to the center of the device, it has a very small impact on the surgeon’s line of sight. Also, because it is adjustable, it can easily be removed when unnecessary. Finally our testing has shown that the device still maintains the necessary coagulation.

Weaknesses

The major weakness in our design is the manufacturability of the bent tubing for the cooling channel. Because current devices are usually disposable, manufacturing costs must be very low. The cost of manufacturing our cooling channel would make it infeasible to market our current design as a disposable device. Another weakness is in the possibility of the current arcing from the electrode to the cooling channel; this was not found to be a huge problem in our testing unless the electrode got bent out of alignment during testing. Since this is a possible situation during an operation this would also be a major concern with continuing development of our design. Another weakness is the addition of the pump and cool water to the device. This adds more things for the surgeons and nurses to deal with during surgery as well as increasing the cost of the device.

Improvements

Many of the weaknesses mentioned above may be able to be improved with further adjustments to the design. For the issues with the cooling channel, including the manufacturing cost and the current arcing, a change of material may reduce the impact of these problems. Problems with the pump and tubing may be reduced by combing the tubes and wiring into a single cable running from the device.

RECOMMENDATIONS

From our finite element analysis and physical tests, we have shown that the theory of our cooling system will work in reducing thermal spread. However, our current prototype is not perfect.

There is a possibility of the electrical current arcing from the electrode to the stainless steel cooling channels if the electrode deflects toward them. We recommend different materials be researched to see if there are any that are still biocompatible, but also are less electrically conductive. Another possible solution to this problem could be placing thin strips of insulation on the inside of the cooling channel to prevent arcing of the current. Both the different material and insulating strips should be researched further.

We also recommend developing a thinner way to package the entire system. Our prototype has a larger diameter than the current monopolar pencils. This was done due to material availabilities as well as the need to hold the tubes, slider, and electrical wire all within the outer tubing. A smaller diameter system would be easier for the surgeon to adjust to because they currently use pencils with smaller diameters.

We also recommend researching a passive way to cool the tissue. Observations of our device without the pump running show the possible reduction in thermal spread without the coolant. With our prototype, we need a pump, and cool water for our system to work. These would both need to be added to the operating room for electrosurgery. Ideally, we would like the cooling channel to be able to cool the tissue passively so no new items need to be added to the operating room. To determine whether the cooling channel could cool enough using a passive heating method such as a heat pipe, we recommend researching and testing other methods.

CONCLUSIONS

Electrosurgical devices have become more and more common in today's operating rooms; however, the technological advances of these products have not allowed for optimal functionality in all operations. The most common electrosurgical device is monopolar, which transfers current from a pencil-like device through the body to a grounding pad. Two settings exist on monopolar devices: cut and coagulate. Due to the nature of cutting, thermal management is not necessary. However, monopolar electrosurgical devices lack the ability to monitor and control thermal spread during coagulation mode. Thermal spread can cause collateral damage to tissue and nerves surrounding the coagulation site. The goal of our project is to implement an integrated thermal management system into existing monopolar devices to reduce this excess damage. Speaking to our sponsors and gathering information from biomdical corporations have been the major sources of background information on thermal management in monopolar devices. As mentioned above, the major customer requirement is to reduce thermal spread while maintaining adequate tissue coagulation. To achieve this, the major engineering specifications we derived were the shape and material of the coolant system.

From generated concepts, functional decompositions, and analogical thinking, we were able to develop an "alpha design" which led us to our final design. This design consists of a fluid running through a cooling channel, integrated within a PVC casing. The bottom of the channel is curved upward, forming a u-shaped tip, to allow for a hooking motion. This system can be easily retracted and extended along the body of the monopolar handle, allowing the surgeon to use the thermal management system in any desired location along the electrode.

To determine if our design is beneficial, we have used finite element analysis. Through these simulations and physical testing, we have been able to confirm that our design will decrease the thermal spread to within 5 mm of the electrosurgical tip. We have explored various dimensions and materials to allow us to integrate the best results into our final design.

We have developed and manufactured a prototype to validate our design. All this was accomplished according to the Gantt Chart, as seen in Appendix Q. The prototype represents a novel engineering approach to the presented problem of thermal spread in monopolar electrosurgery. Manufacturing of the prototype began with the bending of the stainless steel tube to create our cooling channel. This was then rigidly attached to the sliding mechanism, which was secured within the outer casing using two end caps. Our prototype differs from a mass produced version of our final design by using PVC for all plastic components instead of using injection molding, as in current mass produced monopolar pencils.

Validation shows that all previously set engineering specifications were either met or exceeded by our design. Most importantly, the thermal management system reduces the increase in temperature at a 5 mm radius to less than 6°C. This was shown by both physical testing and computer modeling using finite element analysis. Before the thermal management was in place the temperature at a 5 mm radius increased well beyond the 6°C threshold. Once our thermal management system was added to the modeling, the temperatures at a 5 mm radius not only remained below the 6°C, the temperatures remained within a 2°C threshold. This testing shows that we well surpassed the engineering specification regarding tissue temperature. All other engineering specification targets, including: temperature monitoring accuracy, weight increase, steps for retraction, material cost, and device radius, were either met or surpassed by our design.

Although our device meets and surpasses our engineering specifications, there is room for improvement. A more efficient means of creating the stainless steel cooling channel would be beneficial for mass production. We successfully manufactured our prototype cooling channel by bending it around a manufactured jig as seen in Appendix L; however, this is not economically feasible for mass production. Also, a more compatible material for the cooling channel could be researched. Stainless steel was chosen for our prototype because of its biocompatibility and thermal conductivity, but it is also electrically conductive, which could result in current arcing. We would also recommend further research into a passive thermal management system, such as a heat pipe. This could reduce the need for excess material in the operating room. This, along with the combination of tubing and wiring into a single system, would allow for a much simpler and easy to use device.

ACKNOWLDGEMENTS

We would first like to thank our professor, Albert Shih, for his support throughout the semester, along with our sponsors Dr. James Geiger, for his guidance and insight into the world of medicine, and Robert Dodde for his expertise and use of his lab and testing equipment throughout this project. We would also like to thank the General Motors Weld Tool Center for their assistance in bending the stainless steel tube for our cooling channel and the Crosby Neurosurgery Research Center for providing us with a monopolar generator. Finally we would like to thank Bob and Marv for their assistance in the University of Michigan student machine shop.

INFORMATION SOURCES

Gathering background information and technical specifications is a major part of this project. We had to understand how monopolar eletrosurgery works and when it is used before we could get technical specifications to improve the thermal management. Interviews with Professor Albert Shih [4] and Dr. James Geiger [1] gave us a good understanding of the benefits and downsides of monopolar electrosurgery. We acquired pictures and videos of monopolar electrosurgery, along with its dangers to the patient through Valleylab [3]. We have also researched a monopolar electrosurgical tip from Megadyne [9]. SurgRX has a state of the art bipolar device, therefore we have used it as a benchmark for bipolar electrosurgery [5]. Gyrus' form of bipolar electrosurgery, PlasmaCision, uses low temperature plasma to cut and coagulate precisely and cleanly, providing the conditions needed for less pain and quicker healing for patients [10, 11]. Suturing is another alternative to monopolar vessel sealing, which was compared to bipolar vessel sealing in research conducted by Dr. Barbara Levy [6]. Various patents pertaining to existing electrosurgical designs have also been researched [17, 18, 19].

One important source of information was physically watching a surgery. We viewed a surgery at Mott Children's Hospital where monopolar cautery was used. This gave us a good idea of how the surgeon interacts with the monopolar system. We also saw different types of tips used during surgery, from a small, sharp point to a larger, blunt tip, and talked about the hook-shaped tip. We were also able to see different sized and shaped grounding pads. We discovered how precise the surgeons are during the surgery. From this, we verified our concept to have a mechanism small enough, so that it does not block the surgeon's vision.

Currently, we have determined that stainless steel piping will work best for the prototype of our cooling channel due to its thermal conductive and electrical non conductive properties [2]. Given more time we would have researched further into the use of other materials. With more time we would also continue researching methods for bending the cooling channel tube, in order to make it easier for mass production.

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APPENDIX A – Quality Functional Diagram

Quality Functional Diagram (QFD): relates customer requirements to our device characteristics, and compares current benchmarks. Shows that the increase in tissue temperature is most important customer requirement.

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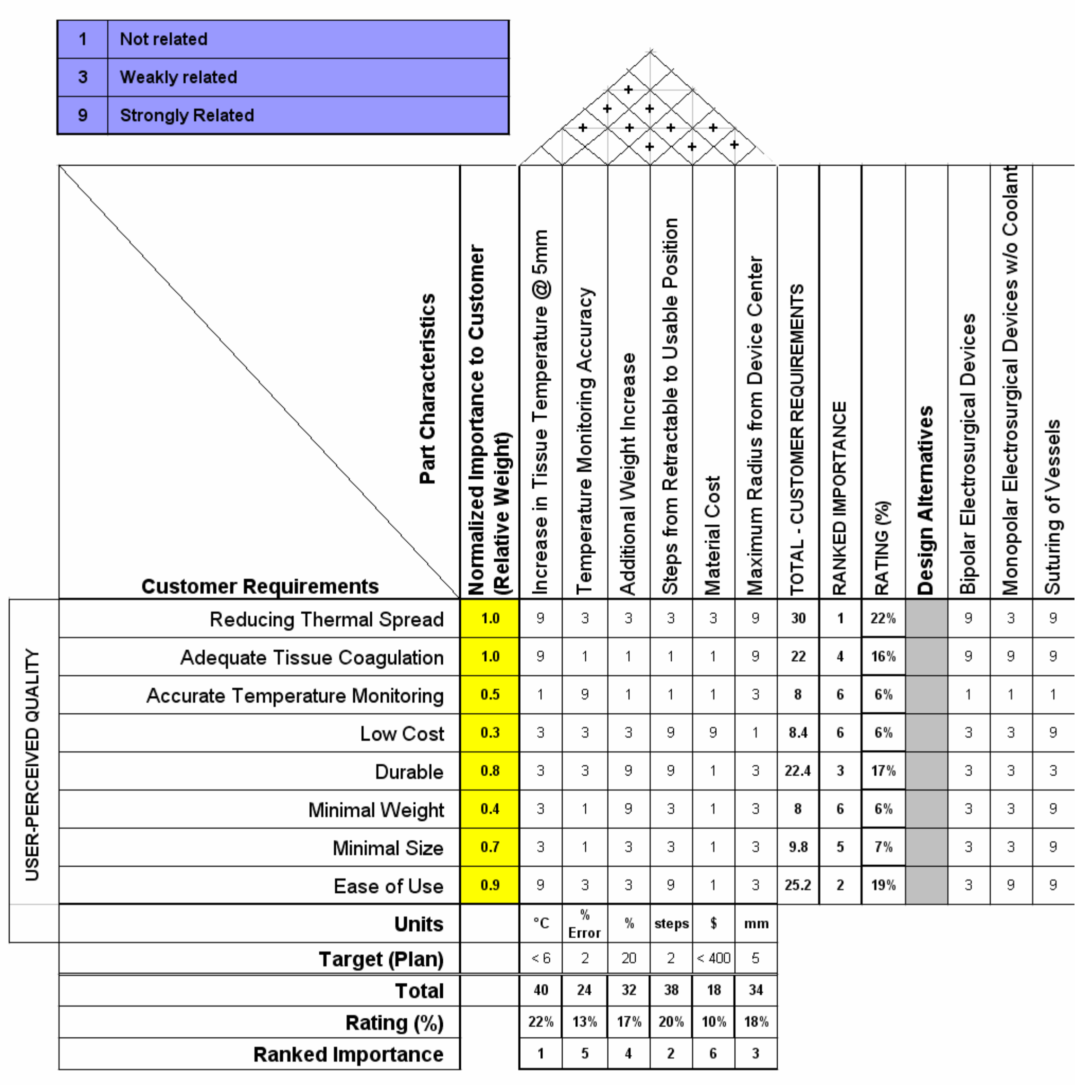

1	Not related
3	Weakly related
9	Strongly Related

	Part Characteristics Customer Requirements	Normalized Importance to Customer (Relative Weight)	Increase in Tissue Temperature @ 5mm	Temperature Monitoring Accuracy	Additional Weight Increase	Steps from Retractable to Usable Position	Material Cost	Maximum Radius from Device Center	TOTAL - CUSTOMER REQUIREMENTS	RANKED IMPORTANCE	RATING (%)	Design Alternatives	Bipolar Electrosurgical Devices	Monopolar Electrosurgical Devices w/o Coolant	Suturing of Vessels
USER-PERCEIVED QUALITY	Reducing Thermal Spread	1.0	9	3	3	3	3	9	30	1	22%		9	3	9
	Adequate Tissue Coagulation	1.0	9	1	1	1	1	9	22	4	16%		9	9	9
	Accurate Temperature Monitoring	0.5	1	9	1	1	1	3	8	6	6%		1	1	1
	Low Cost	0.3	3	3	3	9	9	1	8.4	6	6%		3	3	9
	Durable	0.8	3	3	9	9	1	3	22.4	3	17%		3	3	3
	Minimal Weight	0.4	3	1	9	3	1	3	8	6	6%		3	3	9
	Minimal Size	0.7	3	1	3	3	1	3	9.8	5	7%		3	3	9
	Ease of Use	0.9	9	3	3	9	1	3	25.2	2	19%		3	9	9
	Units		°C	% Error	%	steps	$	mm							
	Target (Plan)		< 6	2	20	2	< 400	5							
	Total		40	24	32	38	18	34							
	Rating (%)		22%	13%	17%	20%	10%	18%							
	Ranked Importance		1	5	4	2	6	3							

APPENDIX B – Benchmarking

Benchmarks from Megadyne and Gyrus, which show current electrosurgical tips and other electrosurgical devices used in the operating room today.

TAKE A SAFETY TIP FROM US!

WHEN IT COMES TO ELECTROSURGICAL SAFETY AND EFFICIENCY,
THE LEADER IS MEGADYNE – CLEANER, FASTER, SAFER.

ESCHAR BUILD-UP ON STAINLESS STEEL CAUTERY TIPS INCREASES RESISTANCE – REQUIRING HIGHER POWER SETTINGS AND INCREASING THE RISK OF THERMAL NECROSIS. REMOVAL INVOLVES SCRAPING WHICH TAKES TIME AND PROMOTES EVEN MORE ESCHAR BUILD-UP DURING SURGERY.

MEGADYNE E-Z CLEAN CAUTERY TIPS FEATURE A PATENTED HIGH-TECH PTFE COATING WHICH REDUCES ESCHAR BUILD-UP DURING SURGERY AND THE NEED FOR HIGHER POWER SETTINGS. E-Z CLEAN TIPS CAN SIMPLY BE WIPED CLEAN ON A STERILE SPONGE AND LAST AN ENTIRE CASE.

DURING ELECTROSURGERY, it's the passing of electrical current through tissue which causes hemostasis. Obviously, the higher the wattage, the greater the risk for unwanted **thermal necrosis**.

Eschar build-up on electrodes during surgery increases electrical resistance, creating the need for higher power settings. But **higher power settings makes electrosurgery less efficient** and potentially more dangerous.

The non-stick patented high-tech PTFE coating of an **E-Z CLEAN Cautery Tip** from **MEGADYNE**, reduces unwanted eschar buildup and the need for higher power settings.

Lower power settings deliver advantages to both the surgeon and the patient. The **cut** of our **coated electrode is cleaner** and **not as deep**. And since there is less thermal necrosis, **healing is enhanced**.

Another advantage of an **E-Z CLEAN** blade is, without eschar build-up, time-consuming scraping and inconvenient delays are a thing of the past – saving both time and money. A coated **E-Z CLEAN** electrode from **MEGADYNE** can simply be wiped clean on a sterile sponge. **MEGADYNE** is the leader in non-stick electrodes, giving surgeons a more **consistent and cleaner cut at lower power settings**. With more than two dozen Tip configurations and sizes available, **E-Z CLEAN Tips** are the choice of thousands of safety-conscious surgeons. Tips include **Blade**, **Needle** and **Ball Electrodes** in a variety of lengths. To order **E-Z CLEAN** Electrodes, contact **MEGADYNE** or your local distributor.

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Figure B1: Megadyne's E-Z Clean Electrosurgical Tips [9].

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FOR THE OTOLARYNGOLOGIST

PlasmaCision precision is now available in a new device for tonsillectomy, the jPlasmaKnife.

PlasmaCision is a PK Technology that uses low temperature plasma to cut and coagulate precisely, cleanly, hemostatically and safely, providing the conditions needed for more accurate surgery, less pain and quicker healing.

Rapid sequential switching between plasma cut and bipolar coag phases provides a PlasmaBlend™ output that delivers:

- *Clean, blade-like incisions*
- *Superior visualization*
- *Hemostatic performance*
- *Controllable thermal margins*
- *Less tissue damage*

jPlasmaKnife Features:

Concentric suction • Multi-functional convex-concave shape

GYRUS ACMI

Figure B2a: Gyrus' jPlasmaKnife [10].

PLASMACISION

PK TECHNOLOGY
Powerful. Precise. Predictable.

jPlasmaKnife

The jPlasmaKnife tip design has both convex and concave surfaces. The convex surface provides a low profile edge to gently separate tissue planes. The concave side provides the familiar #12 blade shape for accurate dissection.

PlasmaCision leverages the electrically conductive properties of tissue fluid to form a tightly-defined, low-temperature plasma field over the active pole of the unique PlasmaKnife triode tip. In PlasmaCision cut phase, this plasma field precisely divides tissue.

The ratio of cut to coag in the PlasmaBlend cutting output can be altered to optimize dissection performance in different tissue types, allowing the surgeon to minimize the degree of collateral thermal damage at the incision margin. In pure coag mode, the PlasmaKnife delivers bipolar tissue desiccation for effective hemostasis.

THE POWER TO TREAT.

PlasmaCision uses Gyrus ACMI'S proprietary PK Technology, provided by the G3 WorkStation, to give you the ability to hemostatically cut with precise control of the thermal margin. It does this by generating a minute, blade-like, plasma mediated bipolar field.

jPLASMAKNIFE SPECIFICATIONS

- 40W CUT MAXIMUM, ADJUSTABLE
- 40W COAG MAXIMUM, ADJUSTABLE
- PLASMABLEND RATIO ADJUSTABLE 5% - 95%
- BOTH CUT AND COAG
- NOMINAL 100-120, 220-240 V

ORDERING INFORMATION

Catalog Number	Description
7035-3001	G3 WorkStation
7035-3002	Footswitch for G3 WorkStation
720-1009-01	Powercord USA
7035-3006	jPlasmaKnife

Manufactured for:
Gyrus ENT, L.L.C.
2925 Appling Road
Bartlett, TN 38133
TEL 901-373-0200
FAX 800-757-2942

Sales Locations:
USA
Gyrus ACMI, L.P.
6655 Wedgwood Rd, Ste 160
Maple Grove MN 55311
TEL 763-416-3000
FAX 763-463-1200

Canada
ACMI Canada, Inc.
200 Bond Street West, Unit 104
Oshawa, Ontario L1J 2L7
Canada
TEL +1 (905) 432-9802
FAX +1 (905) 571-4044

UK
Gyrus International Ltd.
410 Wharfedale Road
Winnersh Triangle
Berkshire RG41 5RA
United Kingdom
TEL +44 (0) 1189-219700
FAX +44 (0) 1189-219800

Australasia
Gyrus Australasia Pty Ltd
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Port Melbourne
Victoria 3207
Australasia
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FAX +61(0) 3-9279-7699

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800.262.3540
For order inquiries call 800.773.4301
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GYRUS ACMI

THE VISION TO SEE.
THE POWER TO TREAT.

REV 7/06 7060-8046

Figure B2b: Gyrus' jPlasmaKnife [10].

Figure B3a: Gyrus' Plasmacision [11].

Latest Advancement within PK Technology

FOUR UNIQUELY DESIGNED PLASMACISION INSTRUMENTS FOR ALL YOUR SURGICAL NEEDS.

PLASMA TRISSECTOR™
- Simultaneously seals and cuts
- Primary and secondary hemostasis from one instrument
- Curved tip cuts with exceptional precision
- For laparoscopic and open procedures

PLASMA J-HOOK™
- Provides rapid hemostatic cutting
- Simultaneously cuts and coagulates
- Excellent for skeletonization and mobilization
- For laparoscopic and open procedures

PLASMASEAL™ OPEN FORCEPS
- Rapid sequential sealing and cutting
- 2-in-1 instrument – saves time by reducing instrument exchanges
- Minimal thermal spread
- For open surgical procedures

PLASMASPATULA™
- Provides rapid, controlled cutting
- Excellent for spot coagulation
- For laparoscopic and open procedures

Figure B3b: Gyrus' Plasmacision [11].

Clinically Proven Performers

SEVEN CLINICALLY PROVEN INSTRUMENTS COMPLETE THE PK TECHNOLOGY FAMILY OF PRODUCTS.

PKS CUTTING FORCEPS
Offers effective blunt tissue dissection, coagulates, securely grasps, mechanically transects and retracts tissue.

PKS NEEDLE
Provides precise, efficient cutting. Features extendable sheath for tissue dissection.

PKS LYONS™ DISSECTING FORCEPS
Uniquely designed for secure grasping, dissecting, retracting and pinpoint or broad coagulation.

PKS L-HOOK
Efficiently dissects, coagulates and transects. Features extendable sheath for tissue dissection.

PKS MOLly® FORCEPS
Unique jaw design for concentrated energy delivery that grasps, coagulates and retracts tissue.

PKS LP SCISSORS
Multifunctional device for mechanical cutting and coagulation.

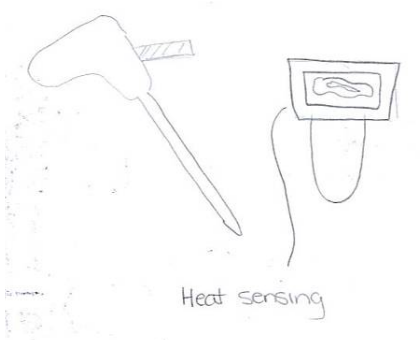
PKS SEAL™ OPEN FORCEPS
Seals a wide range of tissue types and vessels including and up to 7 millimeters, eliminating the need for most sutures, clips or staples.

Figure B3c: Gyrus' Plasmacision [11].

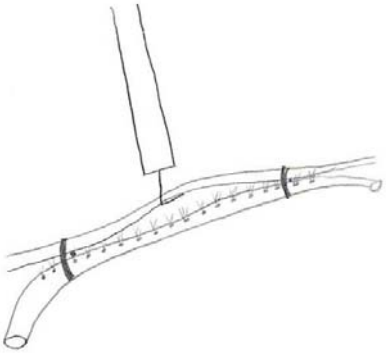
APPENDIX C – Concept Designs

Initial 15 concepts generated by each P.I.G. team member, divided into 5 major categories. These initial concepts helped direct us towards our "alpha design".

Category 1: Separate Piece Devices



Concept #5



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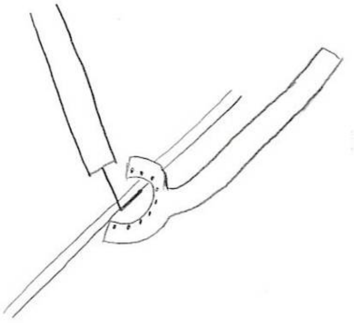

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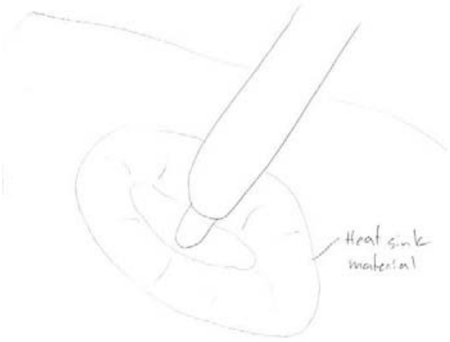
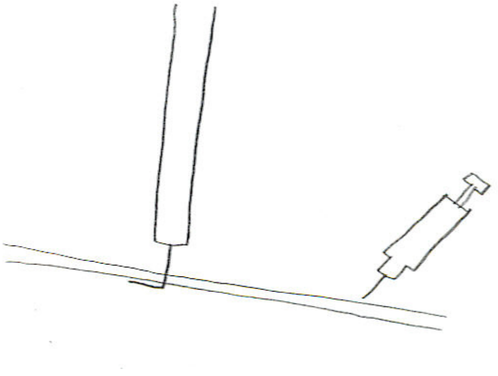


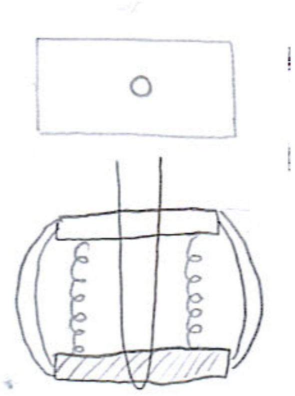
Concept #14



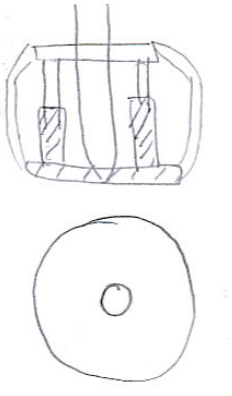
Concept #9

Concept #15

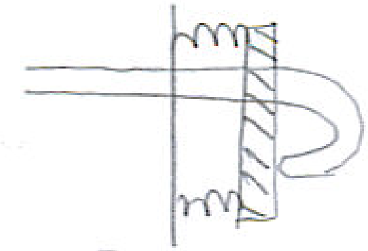
Category 2: Retractable Plate Devices



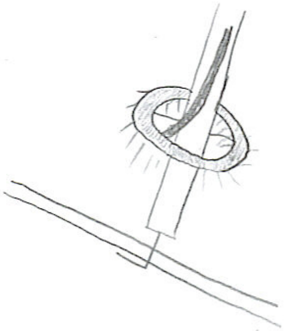
Concept #1



Concept #3

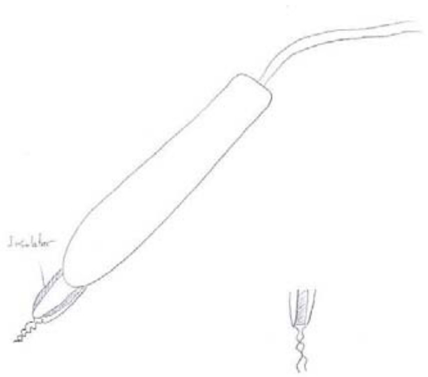


Concept #2



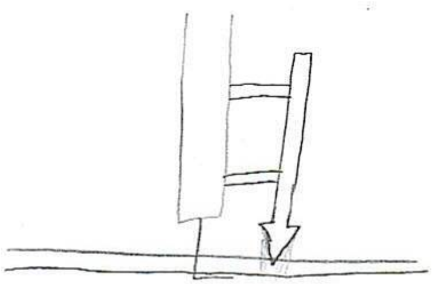
Concept #6

Category 3: Wave Cancelling Devices



Concept #13

Category 4: Side Attachment Devices



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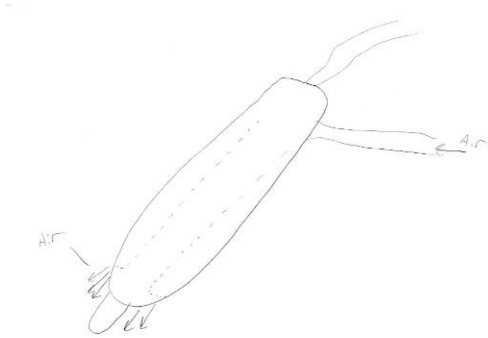
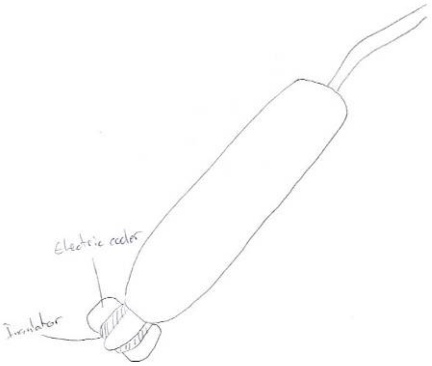
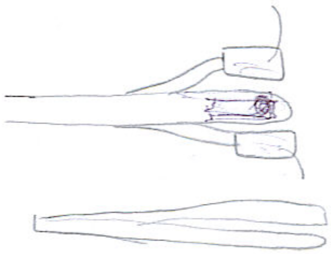


Concept #12



Concept #11

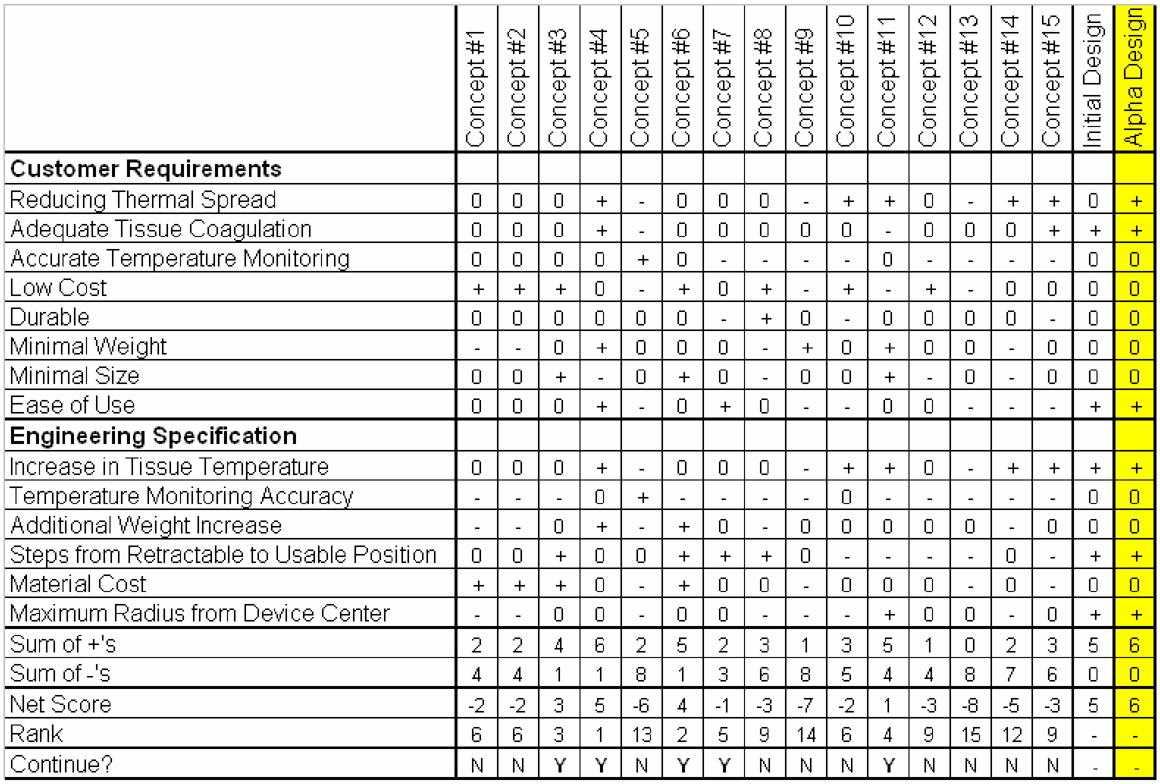
Category 5: Pinching Devices



Concept #4

APPENDIX D – Concept Scoring Matrix

Scoring Matrix ranking our top 15 concepts, initial design, and "alpha design". This shows the overall rating of our "alpha design" according to customer requirements and engineering specifications.



	Concept #1	Concept #2	Concept #3	Concept #4	Concept #5	Concept #6	Concept #7	Concept #8	Concept #9	Concept #10	Concept #11	Concept #12	Concept #13	Concept #14	Concept #15	Initial Design	Alpha Design
Customer Requirements																	
Reducing Thermal Spread	0	0	0	+	-	0	0	0	-	+	+	0	-	+	+	0	+
Adequate Tissue Coagulation	0	0	0	+	-	0	0	0	0	0	-	0	0	0	+	+	+
Accurate Temperature Monitoring	0	0	0	0	+	0	-	-	-	-	0	-	-	-	-	0	0
Low Cost	+	+	+	0	-	+	0	+	-	+	-	+	-	0	0	0	0
Durable	0	0	0	0	0	0	-	+	0	-	0	0	0	0	-	0	0
Minimal Weight	-	-	0	+	0	0	0	-	+	0	+	0	0	-	0	0	0
Minimal Size	0	0	+	-	0	+	0	-	0	0	+	-	0	-	0	0	0
Ease of Use	0	0	0	+	-	0	+	0	-	-	0	0	-	-	-	+	+
Engineering Specification																	
Increase in Tissue Temperature	0	0	0	+	-	0	0	0	-	+	+	0	-	+	+	+	+
Temperature Monitoring Accuracy	-	-	-	0	+	-	-	-	-	0	-	-	-	-	-	0	0
Additional Weight Increase	-	-	0	+	-	+	0	-	0	0	0	0	0	-	0	0	0
Steps from Retractable to Usable Position	0	0	+	0	0	+	+	+	0	-	-	-	-	0	-	+	+
Material Cost	+	+	+	0	-	+	0	0	-	0	0	0	-	0	-	0	0
Maximum Radius from Device Center	-	-	0	0	-	0	0	-	-	-	+	0	0	-	0	+	+
Sum of +'s	2	2	4	6	2	5	2	3	1	3	5	1	0	2	3	5	6
Sum of -'s	4	4	1	1	8	1	3	6	8	5	4	4	8	7	6	0	0
Net Score	-2	-2	3	5	-6	4	-1	-3	-7	-2	1	-3	-8	-5	-3	5	6
Rank	6	6	3	1	13	2	5	9	14	6	4	9	15	12	9	-	-
Continue?	N	N	Y	Y	N	Y	Y	N	N	N	Y	N	N	N	N	-	-

APPENDIX E – Initial Design

Initial design that was developed from our top 15 concepts. This design was altered to produce our final "alpha design".

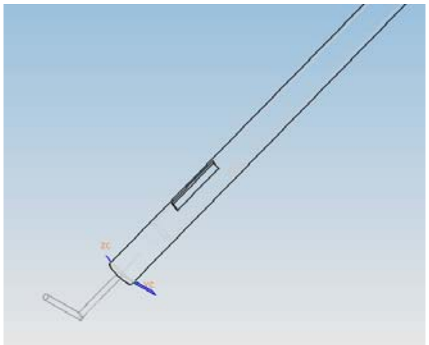


Figure E1: Original Monopolar Electrosurgical Pencil (Laparoscopic)

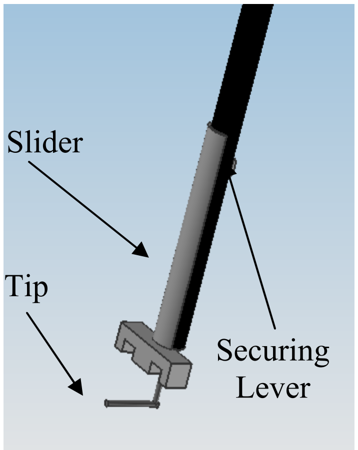


Figure E2: Initial Design With Slider, Tip, and Securing Lever

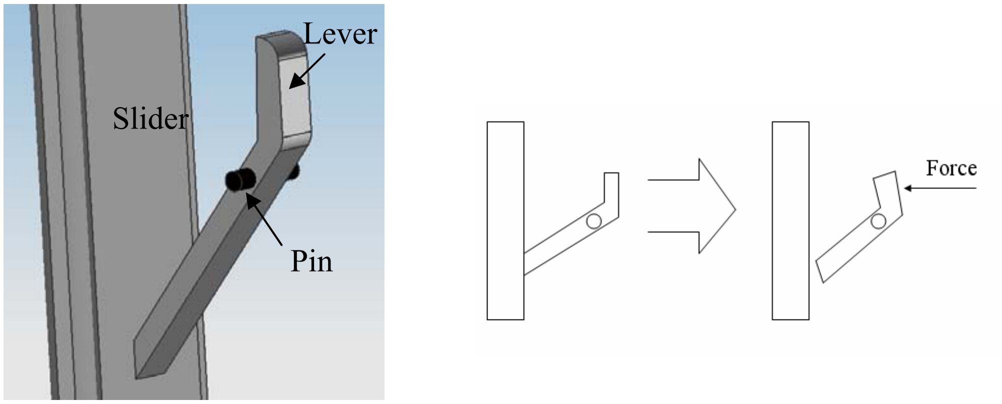
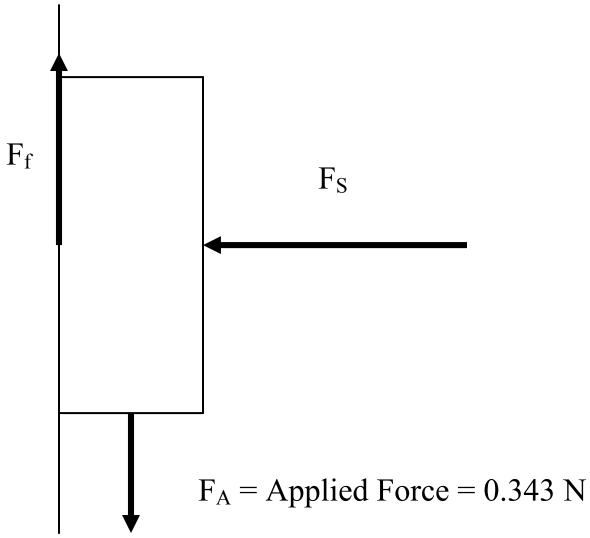


Figure E3: Locking Mechanism with Pin and Lever

APPENDIX F – Spring Force Calculations

Calculations for desired spring force:



F_f = Frictional Force

F_S = Spring Force

F_N = Normal Force

$\mu = F_f / F_N$

Calculations

$F_N = F_S = .035\ (kg) * 9.8\ m/s^2 = 0.343$ N

$F_A = F_f = 0.20874$ N

$\mu = F_f / F_N = 0.20874 / 0.343 = 0.609$ (for rubber on polymer)

Desired Force to hold Cooling channels = 4.165 N = F_f

Then $F_N = F_S = F_f / \mu = 4.165 / 0.609 = 6.84$ N

So we want a spring force of 6.84 N

APPENDIX G – COMSOL Inputs

Oscilloscope reading from physical tests using our monopolar generator, as well as a table of constants that were used for finite element analysis in COMSOL simulations.

Figure G: Oscilloscope Readings from Monopolar Generator

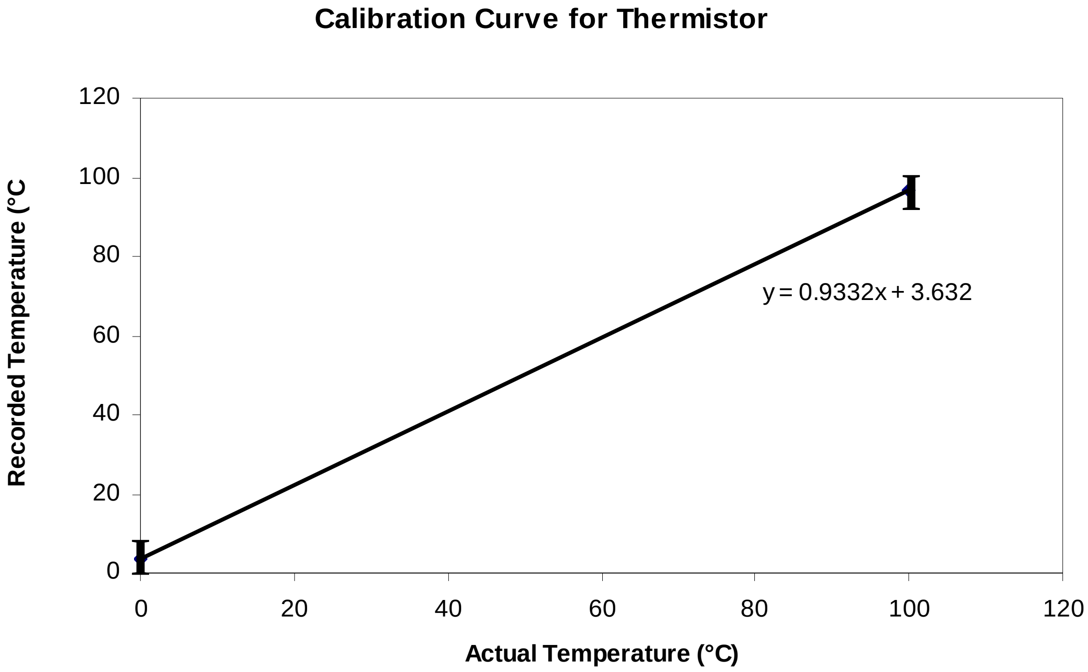
rho_pr	9.8e2	prostate tissue density
c_pr	3.85e3	prostate tissue specific heat
k_pr	4.9e-1	prostate tissue thermal conductivity
sigma_pr	0.55	prostate tissue electrical conductivity
rho_e	7900	electrode density
c_e	477	electrode specific heat
k_e	15	electrode thermal conductivity
sigma_e	1.4e6	electrode electrical conductivity
V0	53.7	electrode voltage potential
T0	298	initial system temperature
htc	25	heat transfer coefficient

rho_cpipe	8933	copper pipe density
c_cpipe	385	copper pipe specific heat
sigma_cpipe	5960	copper pipe electrical conductivity
k_cpipe	401	copper pipe thermal conductivity
rho_sspipe	7900	stainless steel pipe density
c_sspipe	477	stainless steel pipe specific heat
sigma_sspipe	1.4e6	stainless steel pipe electrical conductivity
k_sspipe	15	stainless steel pipe thermal conductivity
rho_w	1000	water density
c_w	4186	water specific heat
k_w	0.590	water thermal conductivity
sigma_w	0.667	water electrical conductivity

Table G: Constants used for FEA in COMSOL [2, 14, 15, 16]

APPENDIX H – Thermistor Calibration Curve

Calculated calibration curve for physical testing, showing recorded temperature equals the actual temperature within error.



APPENDIX I – Final Design: Open Surgery

Our design of an open surgery monopolar electrosurgical device with all dimensions labeled. Detailed drawings of each component are also included.

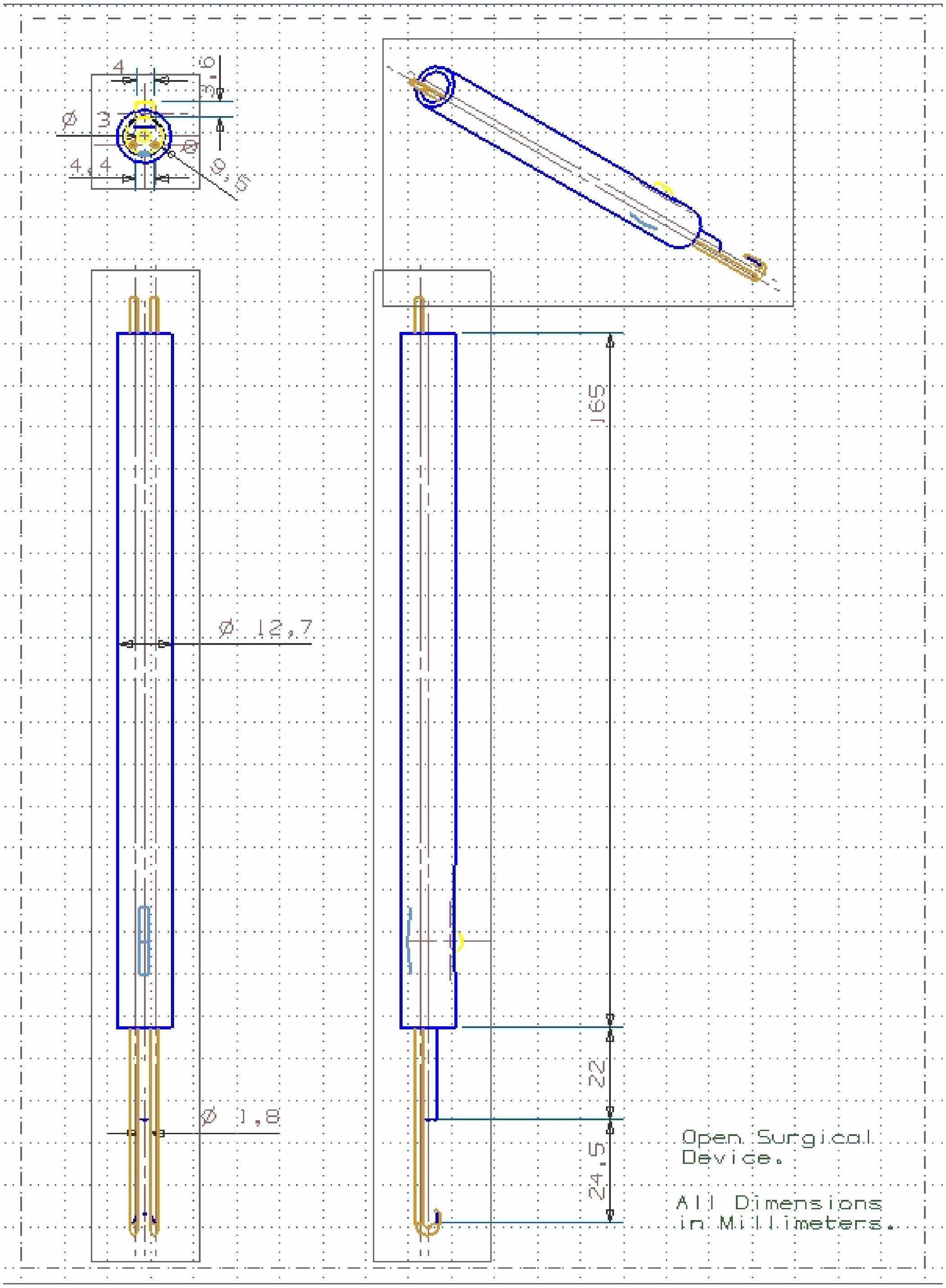


Figure I1: Open Surgery Monopolar Electrical Device Dimensioned Drawings

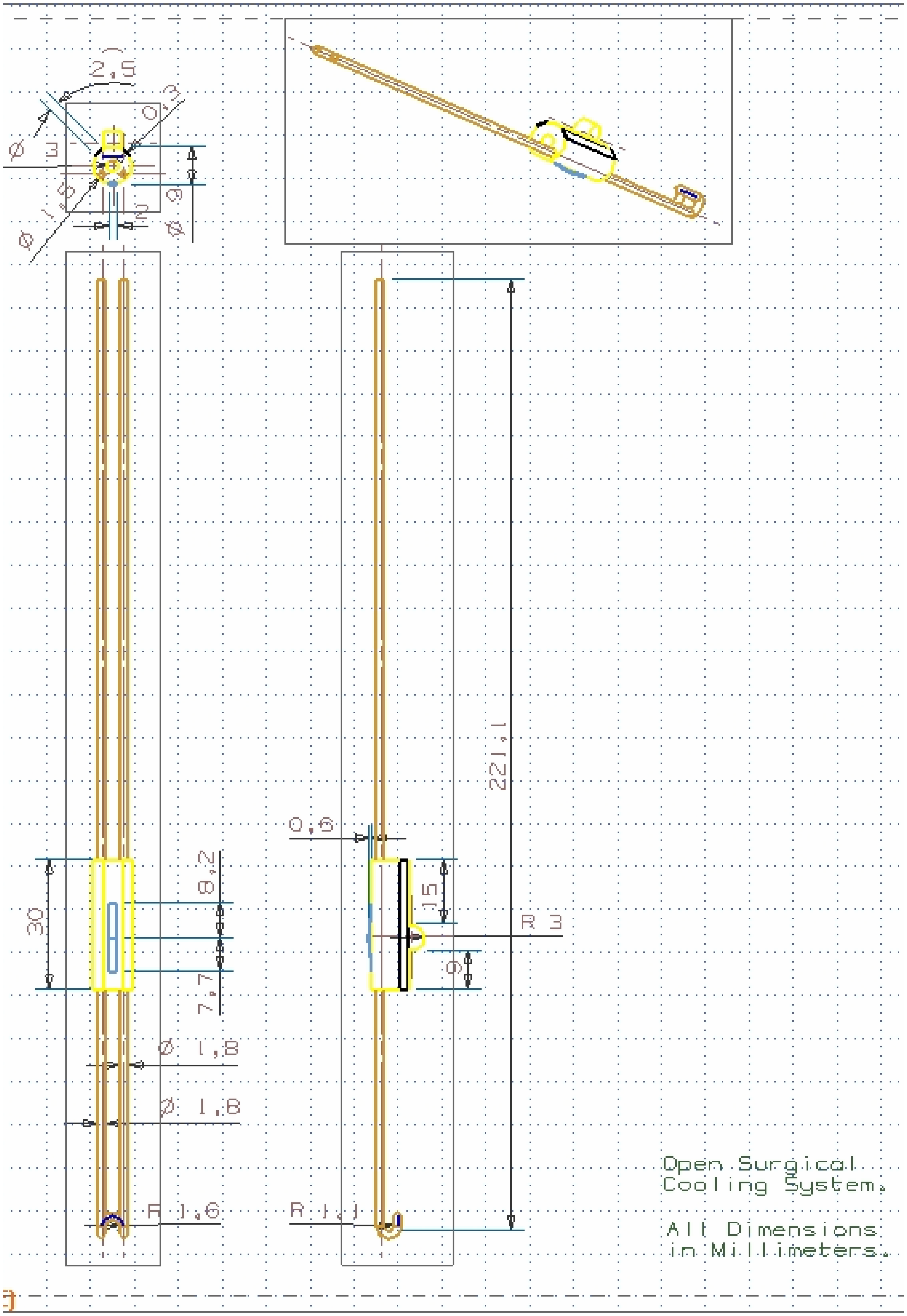


Figure I2: Open Surgery Monopolar Electrical Device Dimensioned Drawings

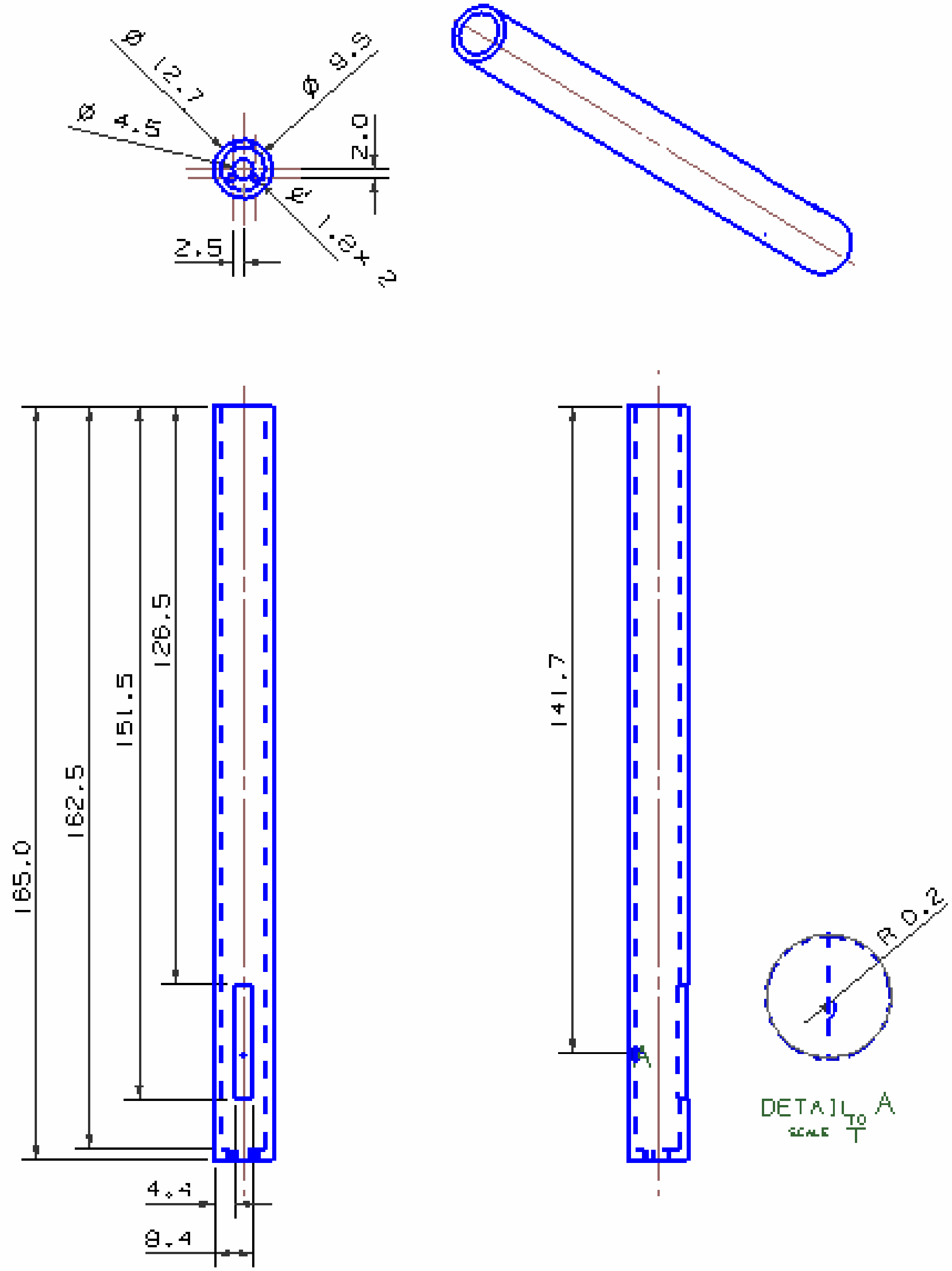


Figure I3: Open Surgery Outer Tubing Dimensioned Drawings (all dimensions in mm)

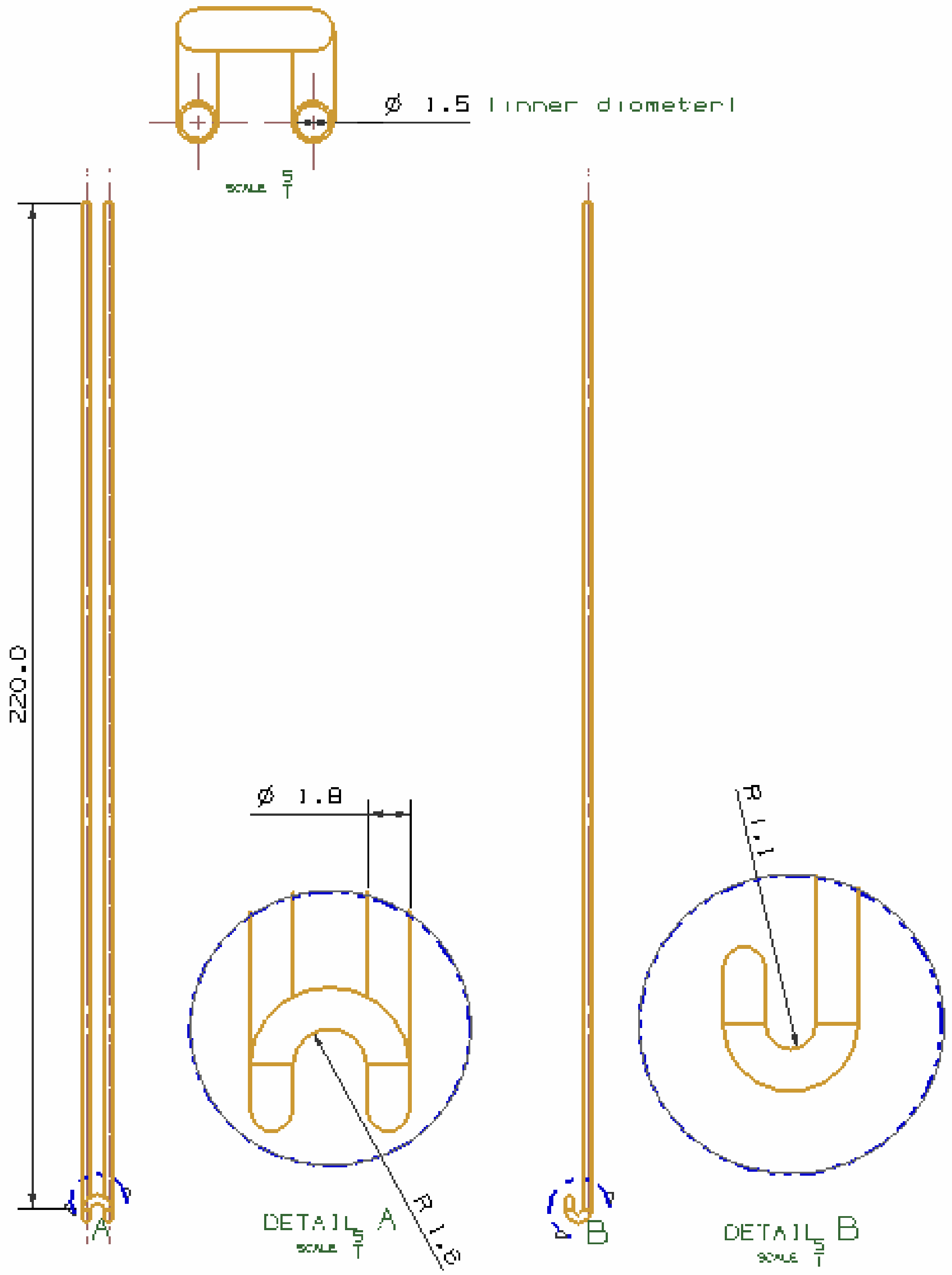


Figure I4: Open Surgery Cooling Channel Dimensioned Drawings (all dimensions in mm)

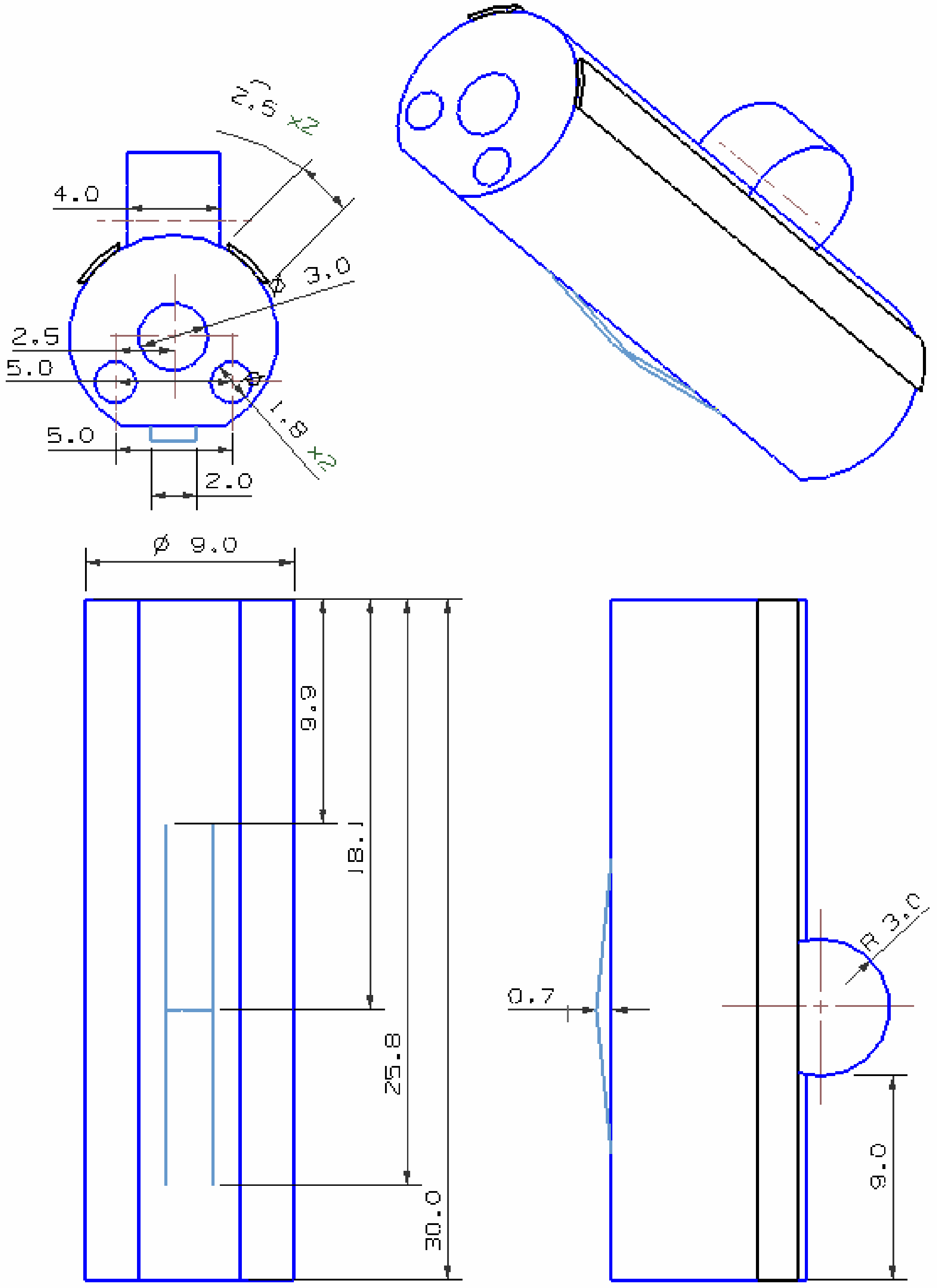


Figure I5: Open Surgery Slider Dimensioned Drawings (all dimensions in mm)

APPENDIX J – Final Design: Laparoscopic Surgery

Our design for a laparoscopic surgery monopolar electrosurgical device with all dimensions labeled. Detailed drawings of each component are also included..

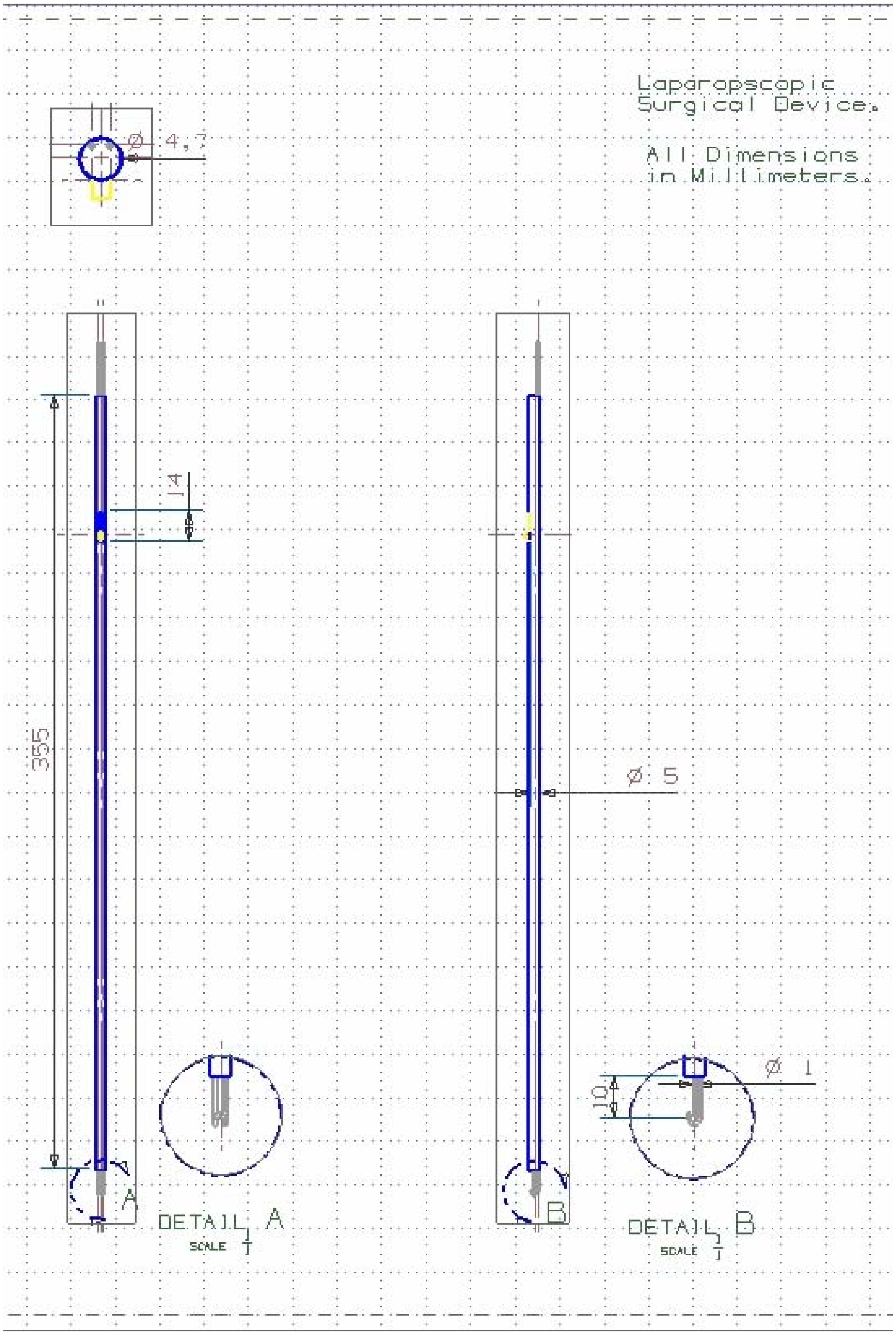


Figure J1: Laparoscopic Surgery Monopolar Electrical Device Dimensioned Drawings

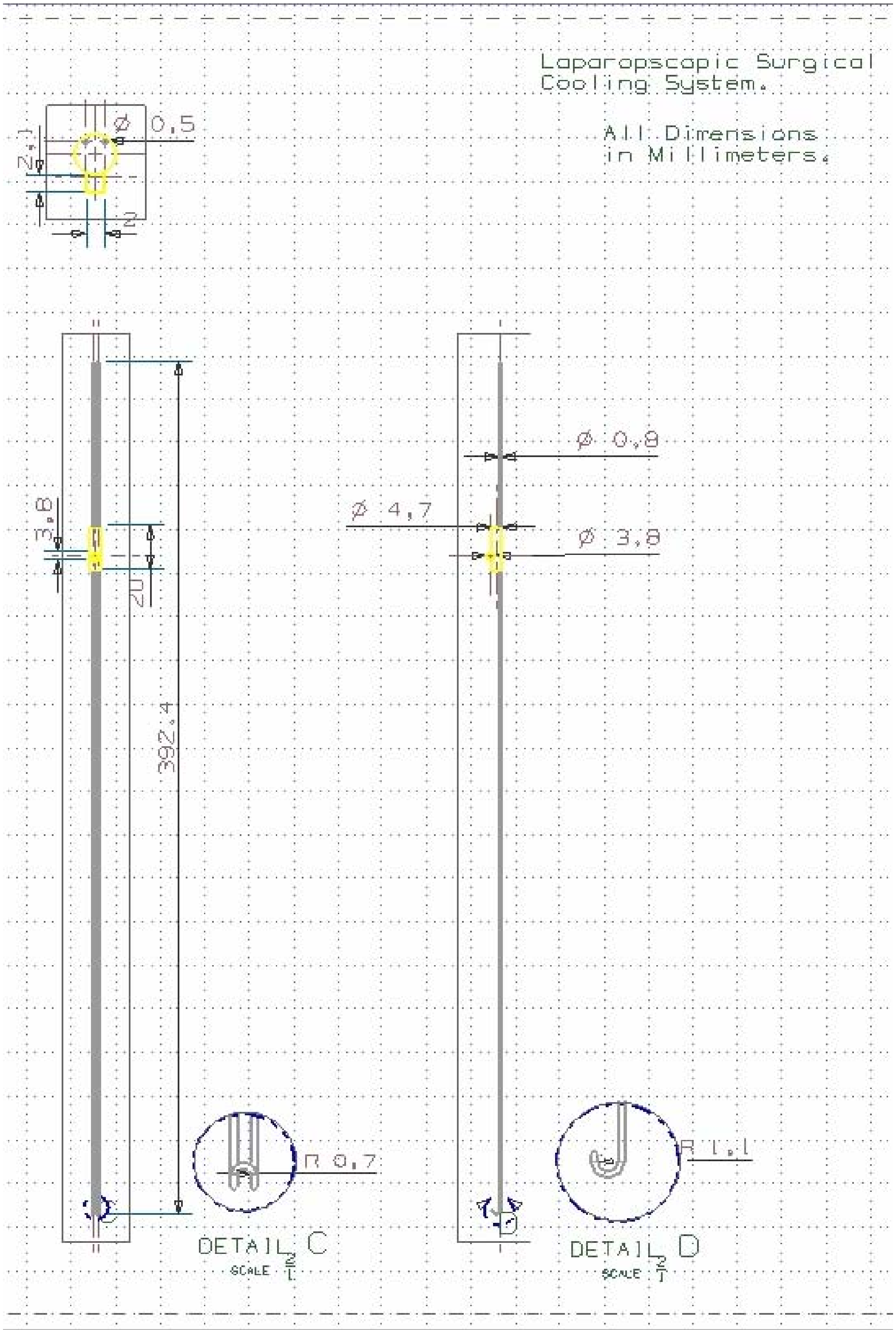


Figure J2: Laparoscopic Surgery Monopolar Electrical Device Dimensioned Drawings

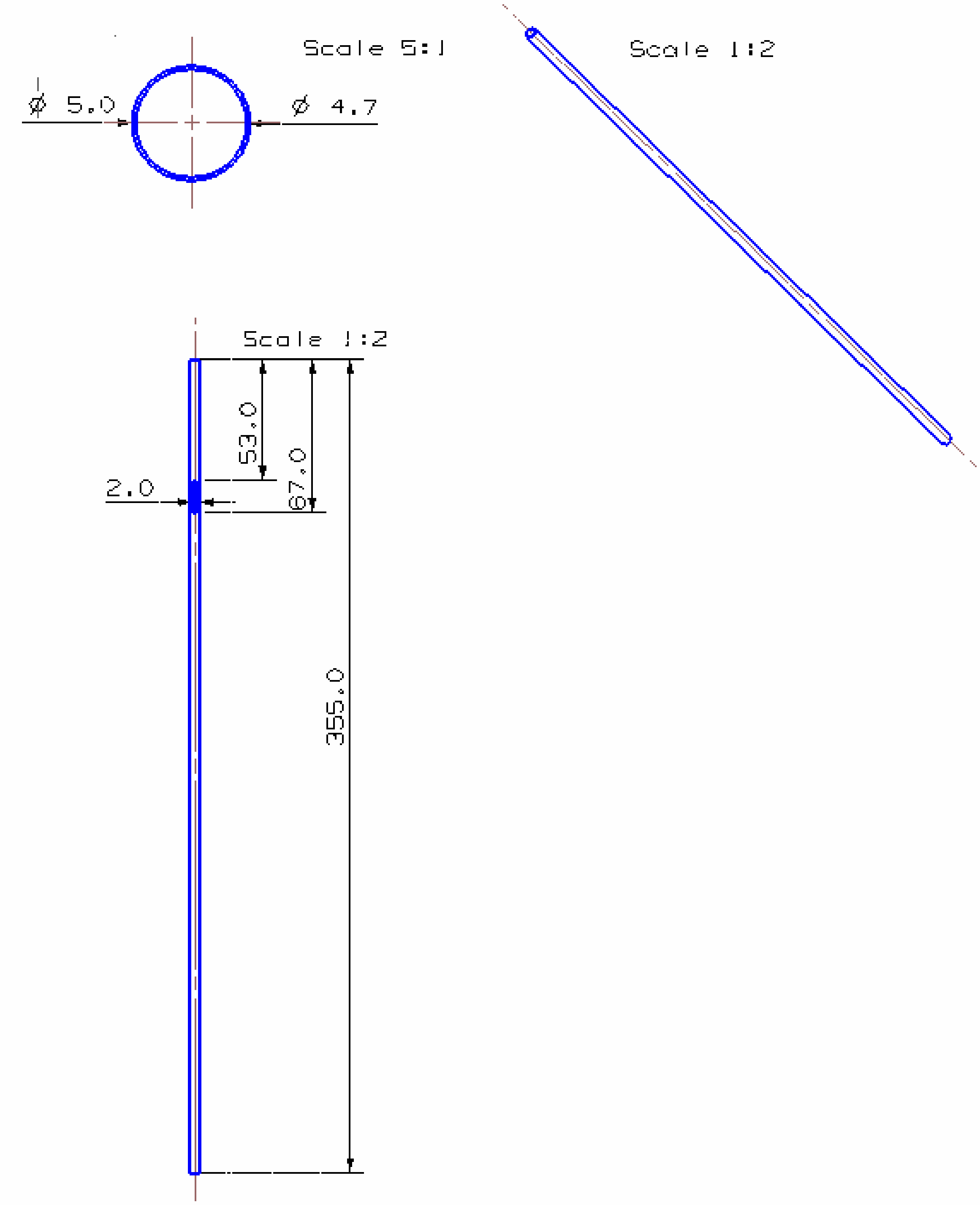


Figure J3: Laparoscopic Surgery Outer Tubing Dimensioned Drawings (all dimensions in mm)

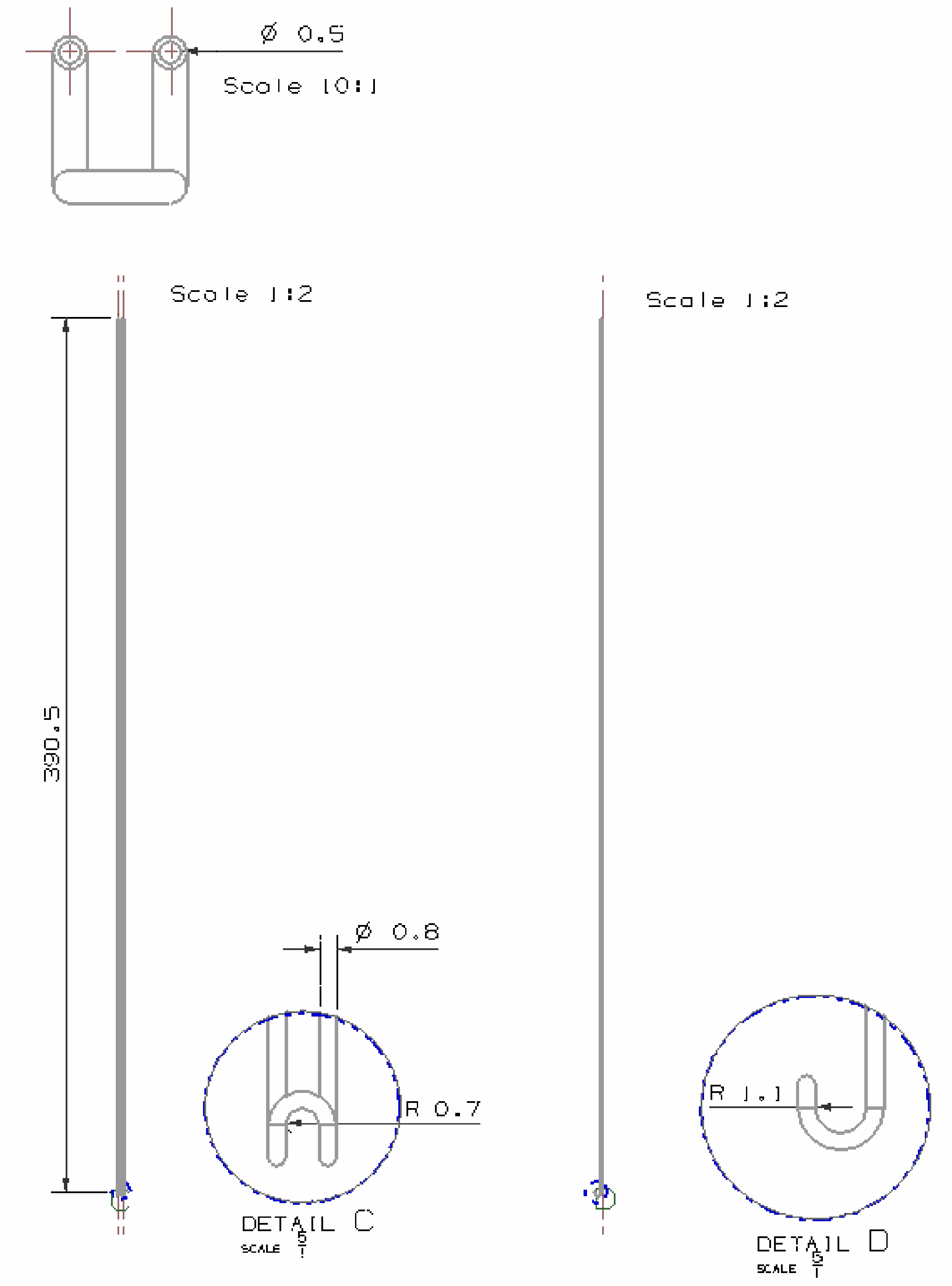


Figure J4: Laparoscopic Surgery Cooling Channel Dimensioned Drawings (all dimensions in mm)

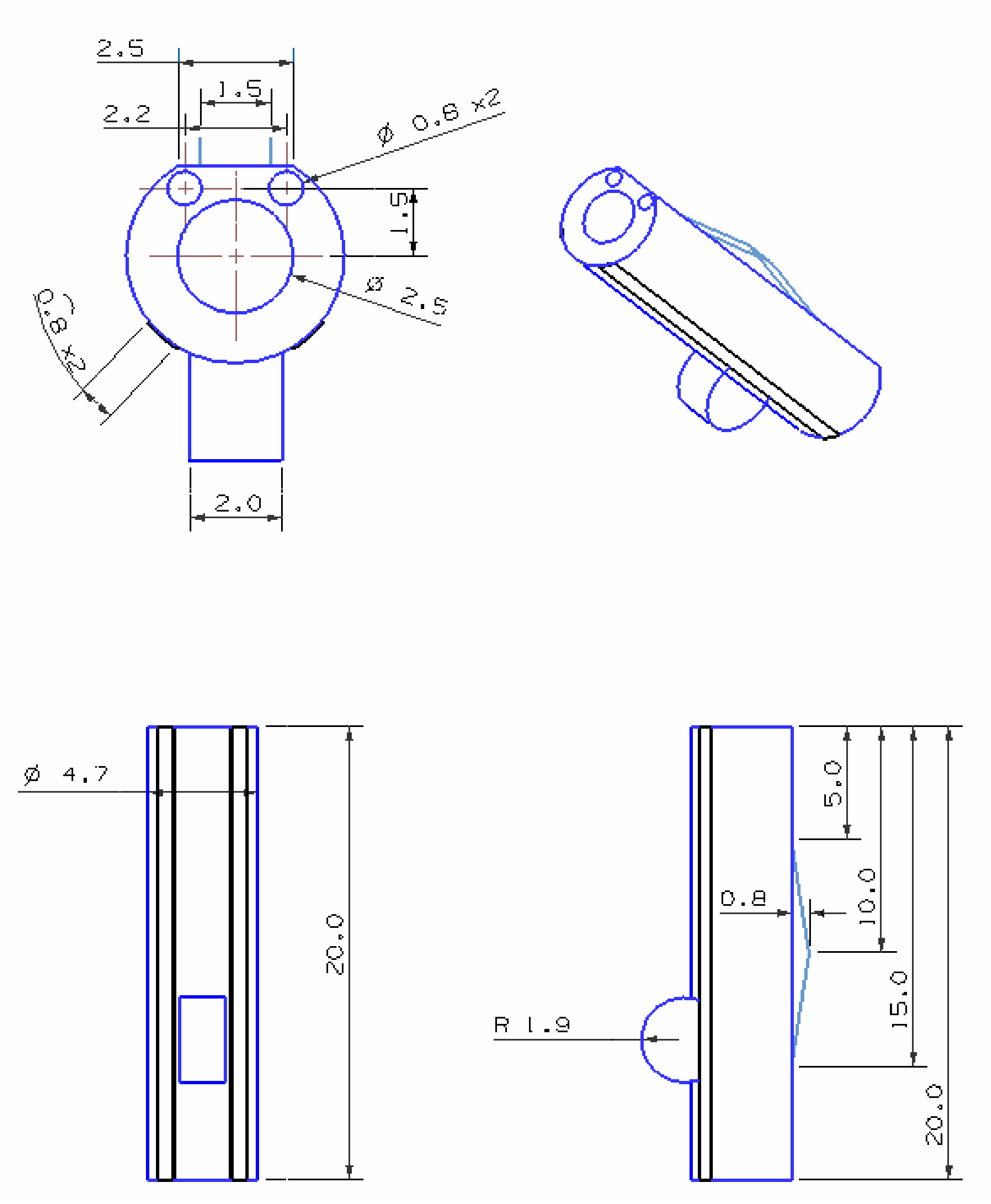


Figure J5: Laparoscopic Surgery Slider Dimensioned Drawings (all dimensions in mm)

APPENDIX K – Bill of Materials

The following Bill of Material shows the parts, quantities, sources, and prices for each component needed for our functional prototype.

Quantity	Part Description	Purchased From	Part Number	Price (each)
1	3’ 304 Stainless Steel Tubing (0.07” OD, 0.061” ID)	McMaster-Carr*	8987 K516	$14.86
1	10’ PVC Pipe (0.68” OD, 0.48” ID)	Alsco Industrial**	1395-003	$8.50
1	1’ PVC Rod (0.50” D)	University of Michigan		$0.00
1	Spring	Lowes		$3.98
1	Super Glue	University of Michigan		$0.00
1	10’ Polyurethane Tubing (0.125” OD, 0.066” ID)	McMaster-Carr*	5648 K226	$1.70
1	Electrical Components	Valleylab***	E2504	$0.00
1	Electrode	Valleylab***	E2504	$0.00
1	Pump	University of Michigan		$0.00
	Gallon of Water	University of Michigan		$0.00
1	Monopolar Generator	Crosby Neurosurgery Research Center		$0.00
15	Chicken Tissue	Kroger		$16.79

Total = $45.83

*	http://www.mcmaster.com
**	http://www.alscoind.com
***	http://valleylab.com

APPENDIX L – Tube Bending Fixture

The following picture shows the jig that was manufactured to aid in the bending of the stainless steel tube.

Figure L: Manufactured Cylindrical Jig Used in the Bending of the Stainless Steel Cooling Channel

APPENDIX M – Prototype Drawings

Our prototype dimensions for an open surgery monopolar electrosurgical device with detailed drawings and all dimensions labeled.

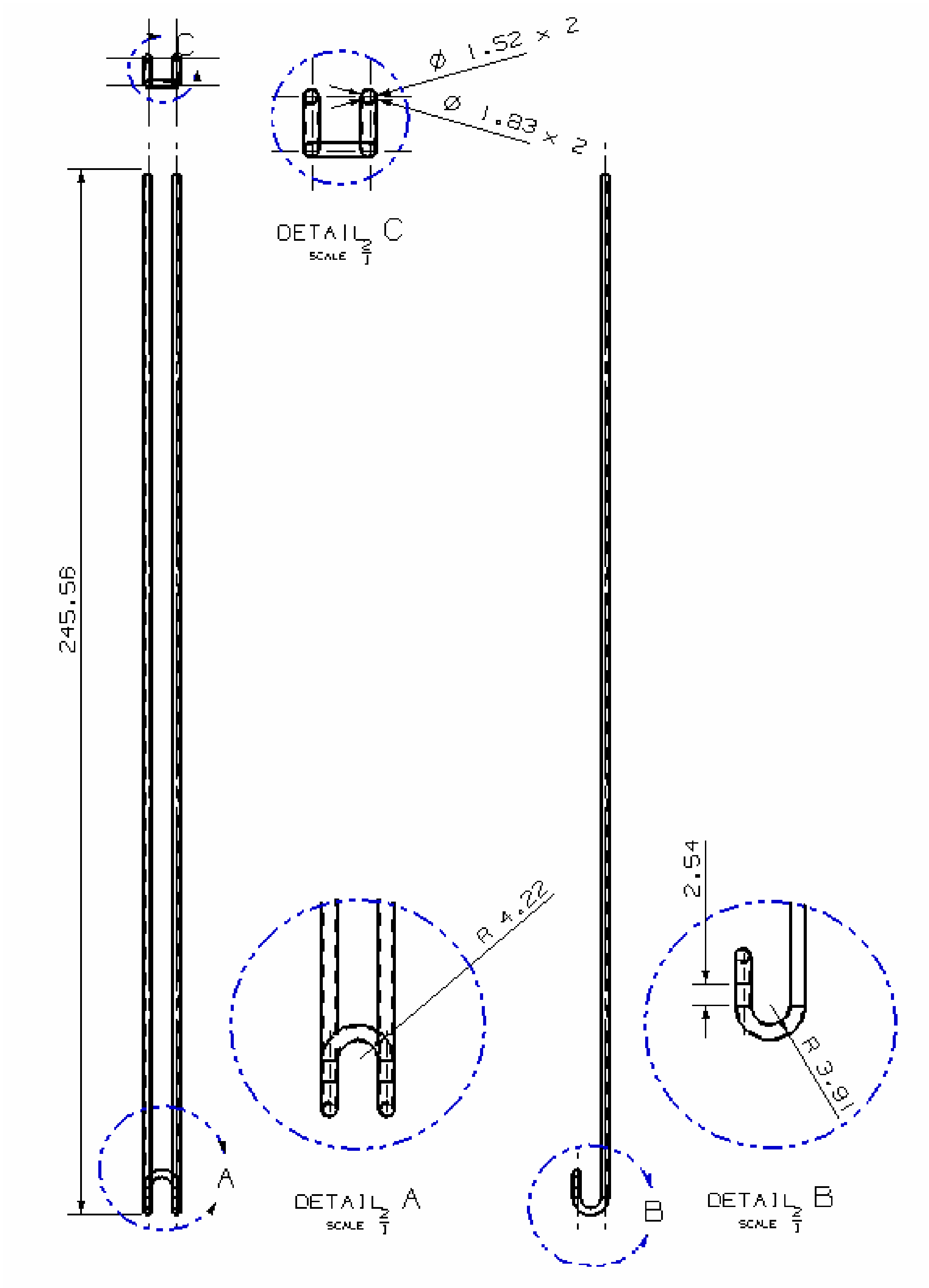


Figure M1: Prototype Cooling Channel Dimensioned Drawings (all dimensions in mm)

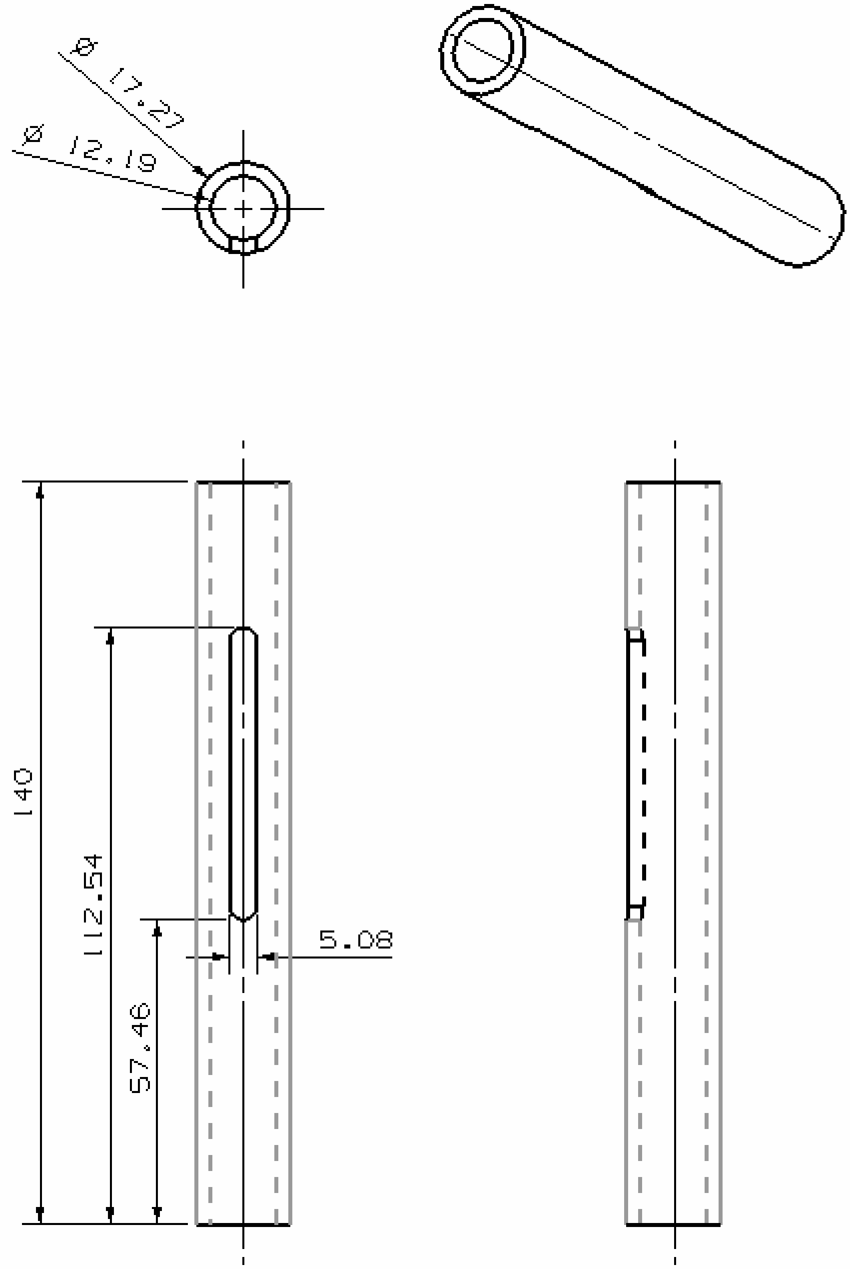


Figure M2: Prototype Outer Casing Dimensioned Drawings (all dimensions in mm)

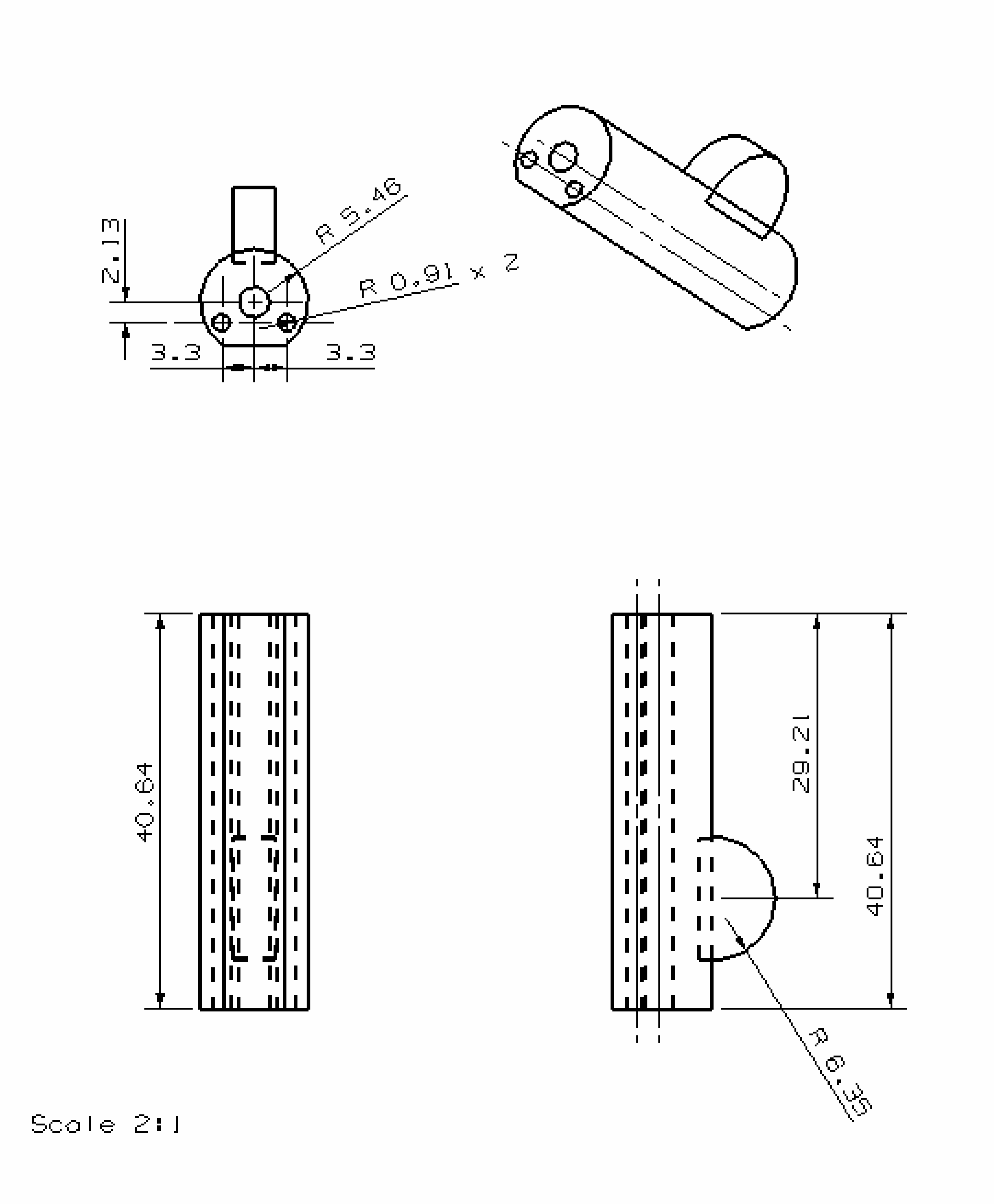


Figure M3: Prototype Slider Dimensioned Drawings (all dimensions in mm)

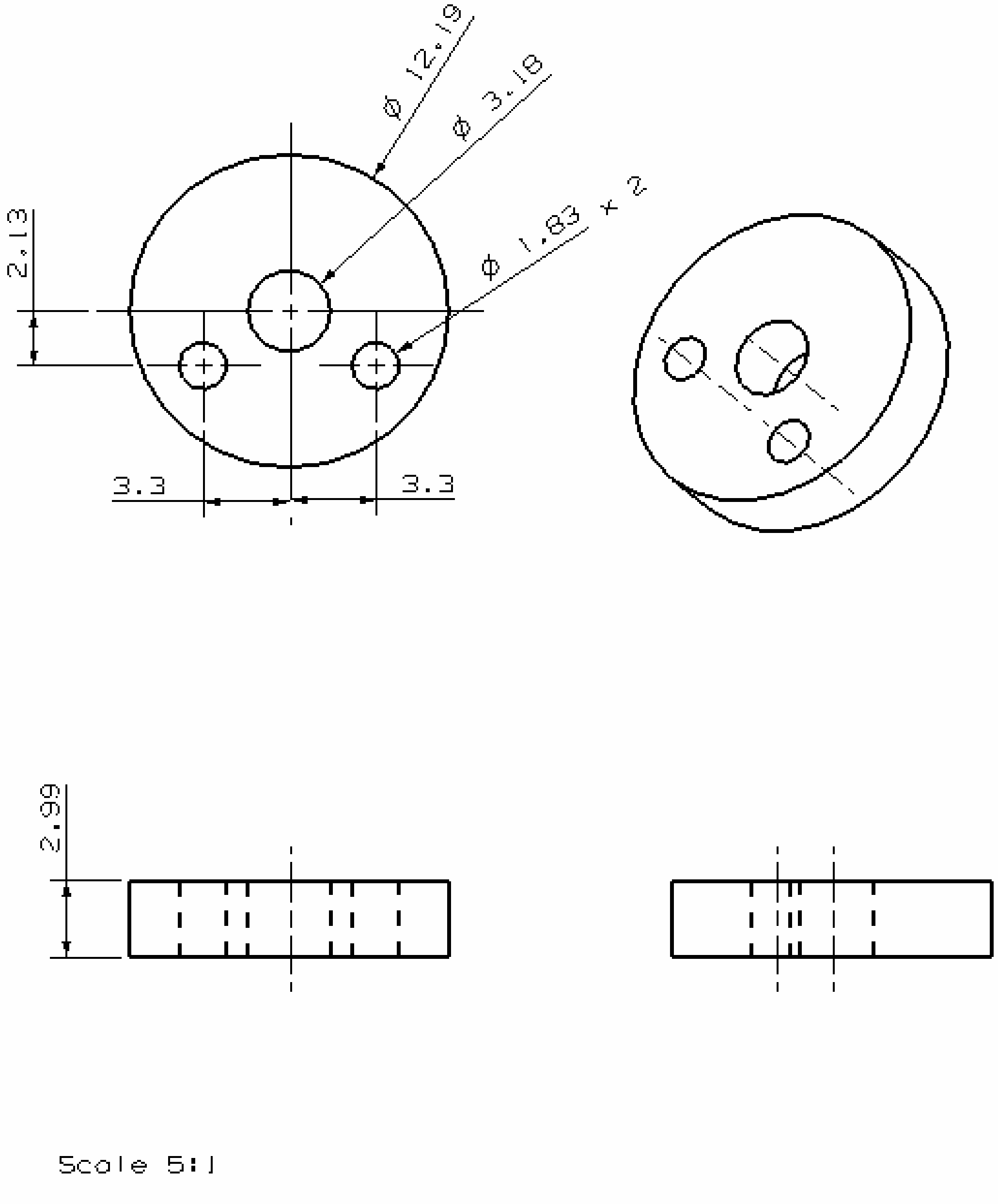


Figure M4: Prototype Top End Cap Dimensioned Drawings
(all dimensions in mm)

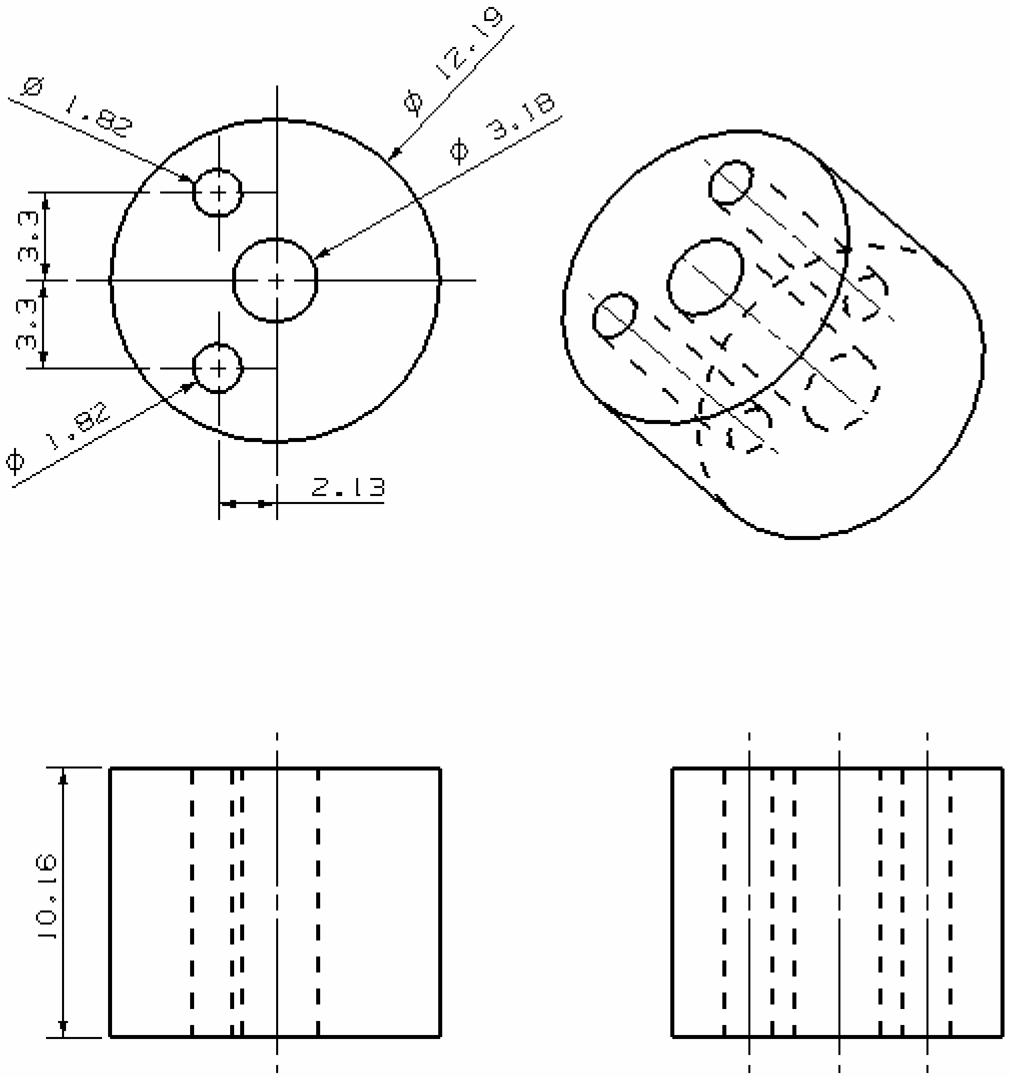


Figure M5: Prototype Bottom End Cap Dimensioned Drawings
(all dimensions in mm)

APPENDIX N – Process Plan Sheets

Process Plan Sheets for all prototype components can be seen here. Detailed descriptions are included.

Part Name: Cooling Channel
Raw material stock: 304 Stainless Steel Tubing – 0.07" OD, 0.061" ID

No.	**Process Description**	**Machine**	**Speed (rpm)**	**Tool**	**Fixtures**
1	Cut part to desired length (18")	Hand Saw			Vise
2	Hand bend tube around 3mm radius	Mill	Hand rotation	Jig seen in Appendix L	
3	Hand bend u-hook curve around 2mm radius	Mill	Hand rotation	Jig seen in Appendix L	

Part Name: Outer Casing
Raw material stock: Clear PVC Pipe – 5' length; 0.68" OD, 0.48" ID

No.	**Process Description**	**Machine**	**Speed (rpm)**	**Tool**	**Fixtures**
1	Saw part to 1' length	Band Saw	3000 fpm		
2	Square edges	Mill	2500	Φ 1/2 End mill	Vise, Parallels
3	Mill slot for slider	Mill	2500	Φ 3/16 End mill	Vise, Parallels
4	Cutoff to desired length (5.5")	Lathe	1000	Cutoff tool	Collet

Part Name: Slider
Raw material stock: PVC Rod – 1’ length; 0.50” D

No.	Process Description	Machine	Speed (rpm)	Tool	Fixtures
1	Drill center hole for electrical connection	Mill	2500	Φ 1/8 Drill	Vise
2	Drill cooling channel holes	Mill	2500	Φ 0.08 Drill	Vise
3	Face off to desired diameter (0.41”)	Lathe	1000	Cutting tool	Collet
4	End mill flat surface for spring attachment	Mill	2500	Φ 1/2 End mill	Vise, Parallels
5	Cutoff to desired length (0.65”)	Lathe	1000	Cutoff tool	Collet
6	Cut slot for spring attachment	Hand Saw			Vise

Part Name: Knob
Raw material stock: PVC Rod – 1’ length; 0.50” D

No.	Process Description	Machine	Speed (rpm)	Tool	Fixtures
1	Cutoff to desired length (0.17”)	Lathe	1000	Cutoff tool	Collet
2	End mill to half circle	Mill	2500	Φ 1/2 End mill	Vise, Parallels

Part Name: End Caps (2)
Raw material stock: PVC Rod – 1’ length; 0.50” D

No.	Process Description	Machine	Speed (rpm)	Tool	Fixtures
1	Drill center hole for electrical connection	Mill	2500	Φ 1/8 Drill	Vise
2	Drill cooling channel holes	Mill	2500	Φ 0.08 Drill	Vise
3	Face off to desired diameter (0.47”)	Lathe	1000	Cutting tool	Collet
4	Cutoff to desired lengths (0.4” & 0.2”)	Lathe	1000	Cutoff tool	Collet

APPENDIX O – Thermistor Fixture

Our thermistor fixture for physical testing of our monopolar thermal management system, including all dimensions labeled.

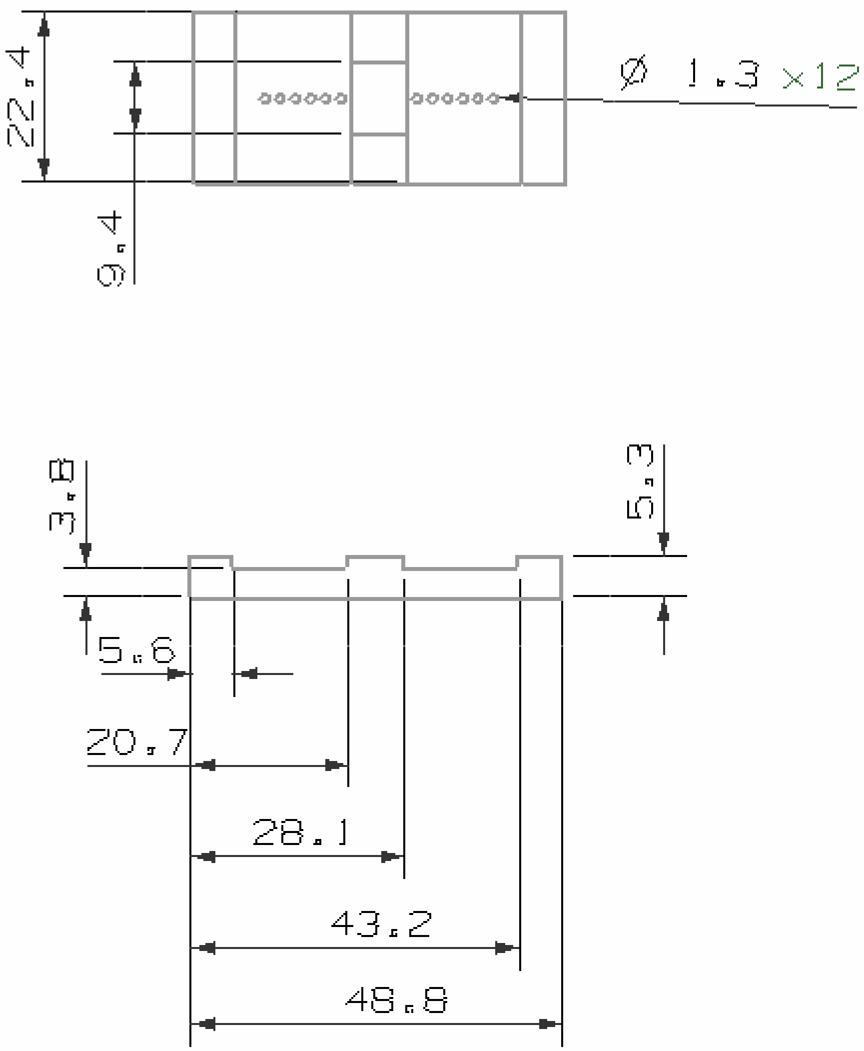
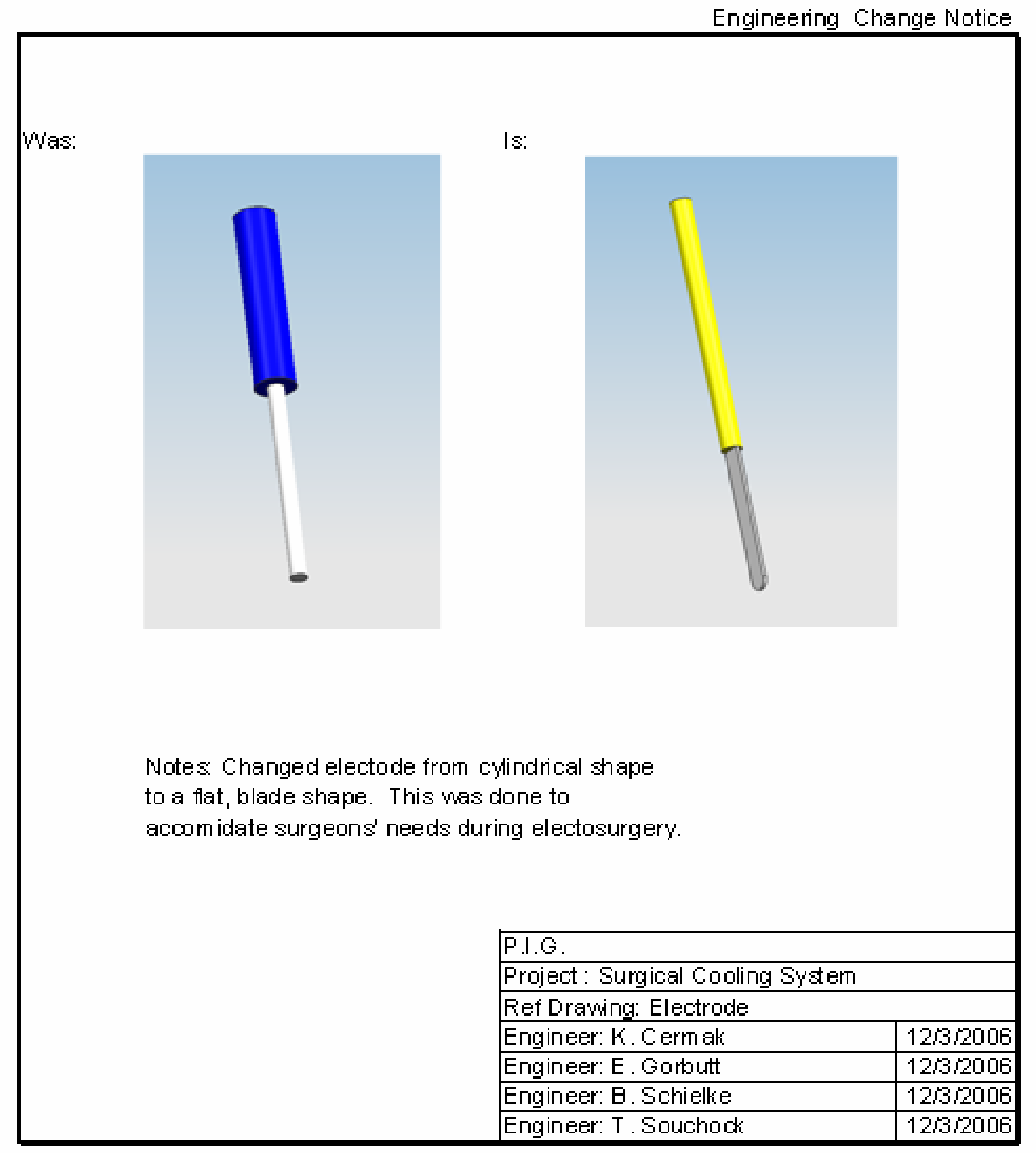


Figure O: Thermistor Fixture Dimensioned Drawings (all dimensions in mm)

APPENDIX P – Engineering Change Notices

Engineering Change Notices for all parts that have been changed during the design process. These indicate major changes beyond dimensional, which include: change in the shape of the electrode and the deletion of rubber strips on the internal slider.



Engineering Change Notice

Was:

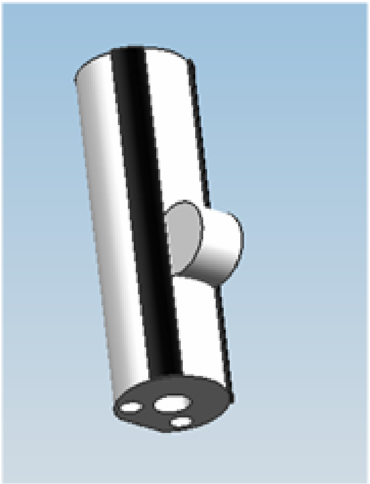
Is:

Notes: Changed electode from cylindrical shape
to a flat, blade shape. This was done to
accomidate surgeons' needs during electosurgery.

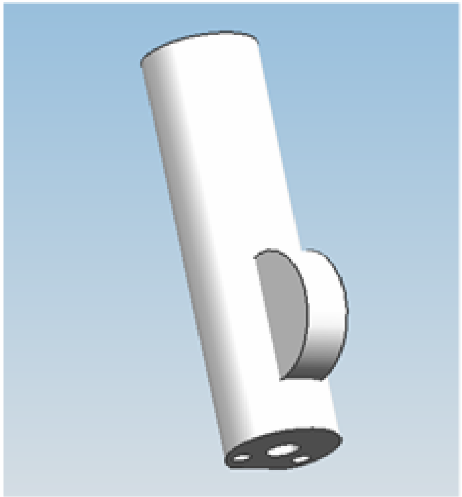
P.I.G.	
Project : Surgical Cooling System	
Ref Drawing: Electrode	
Engineer: K. Cermak	12/3/2006
Engineer: E. Gorbutt	12/3/2006
Engineer: B. Schielke	12/3/2006
Engineer: T. Souchock	12/3/2006

Engineering Change Notice

Was:



Is:

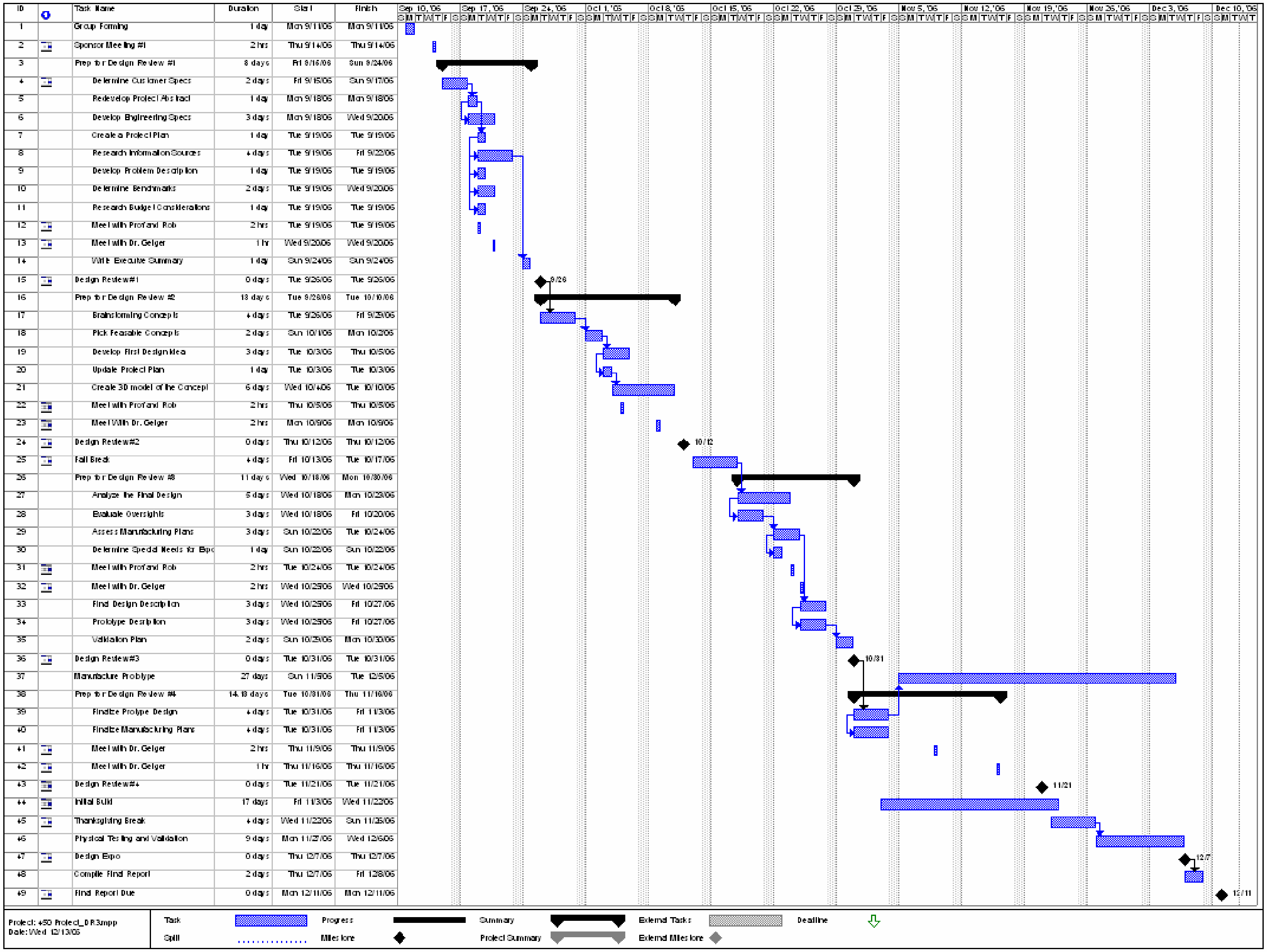


Notes: Took off rubber strips to decrease friction and reduce diameter of slider. Increased size of knob for easier sliding.

P.I.G.	
Project : Surgical Cooling System	
Ref Drawing: Slider	
Engineer: K. Cermak	12/3/2006
Engineer: E. Gorbutt	12/3/2006
Engineer: B. Schielke	12/3/2006
Engineer: T. Souchock	12/3/2006

APPENDIX Q – Gantt Chart

Gantt Chart detailing a timeline for projected milestones and deadlines.



ID	ⓘ	Task Name	Duration	Start	Finish
1		Group Forming	1 day	Mon 9/11/06	Mon 9/11/06
2	▦	Sponsor Meeting #1	2 hrs	Thu 9/14/06	Thu 9/14/06
3		Prep for Design Review #1	8 days	Fri 9/16/06	Sun 9/24/06
4	▦	Determine Customer Specs	2 days	Fri 9/15/06	Sun 9/17/06
5		Redevelop Project Abstract	1 day	Mon 9/18/06	Mon 9/18/06
6		Develop Engineering Specs	3 days	Mon 9/18/06	Wed 9/20/06
7		Create a Project Plan	1 day	Tue 9/19/06	Tue 9/19/06
8		Research Information Sources	4 days	Tue 9/19/06	Fri 9/22/06
9		Develop Problem Description	1 day	Tue 9/19/06	Tue 9/19/06
10		Determine Benchmarks	2 days	Tue 9/19/06	Wed 9/20/06
11		Research Budget Considerations	1 day	Tue 9/19/06	Tue 9/19/06
12	▦	Meet with Prof and Rob	2 hrs	Tue 9/19/06	Tue 9/19/06
13	▦	Meet with Dr. Geiger	1 hr	Wed 9/20/06	Wed 9/20/06
14		Write Executive Summary	1 day	Sun 9/24/06	Sun 9/24/06
15	▦	Design Review#1	0 days	Tue 9/26/06	Tue 9/26/06
16		Prep for Design Review #2	13 days	Tue 9/26/06	Tue 10/10/06
17		Brainstorming Concepts	4 days	Tue 9/26/06	Fri 9/29/06
18		Pick Feasable Concepts	2 days	Sun 10/1/06	Mon 10/2/06
19		Develop First Design Idea	3 days	Tue 10/3/06	Thu 10/5/06
20		Update Project Plan	1 day	Tue 10/3/06	Tue 10/3/06
21		Create 3D model of the Concept	6 days	Wed 10/4/06	Tue 10/10/06
22	▦	Meet with Prof and Rob	2 hrs	Thu 10/5/06	Thu 10/5/06
23	▦	Meet With Dr. Geiger	2 hrs	Mon 10/9/06	Mon 10/9/06
24	▦	Design Review#2	0 days	Thu 10/12/06	Thu 10/12/06
25	▦	Fall Break	4 days	Fri 10/13/06	Tue 10/17/06
26		Prep for Design Review #3	11 days	Wed 10/18/06	Mon 10/30/06
27		Analyze the Final Design	5 days	Wed 10/18/06	Mon 10/23/06
28		Evaluate Oversights	3 days	Wed 10/18/06	Fri 10/20/06
29		Assess Manufacturing Plans	3 days	Sun 10/22/06	Tue 10/24/06
30		Determine Special Needs for Exp	1 day	Sun 10/22/06	Sun 10/22/06
31	▦	Meet with Prof and Rob	2 hrs	Tue 10/24/06	Tue 10/24/06
32	▦	Meet with Dr. Geiger	2 hrs	Wed 10/25/06	Wed 10/25/06
33		Final Design Description	3 days	Wed 10/25/06	Fri 10/27/06
34		Prototype Desription	3 days	Wed 10/25/06	Fri 10/27/06
35		Validation Plan	2 days	Sun 10/29/06	Mon 10/30/06
36	▦	Design Review#3	0 days	Tue 10/31/06	Tue 10/31/06
37		Manufacture Prototype	27 days	Sun 11/5/06	Tue 12/5/06
38		Prep for Design Review #4	14.13 days	Tue 10/31/06	Thu 11/16/06
39		Finalize Protype Design	4 days	Tue 10/31/06	Fri 11/3/06
40		Finalize Manufacturing Plans	4 days	Tue 10/31/06	Fri 11/3/06
41	▦	Meet with Dr. Geiger	2 hrs	Thu 11/9/06	Thu 11/9/06
42	▦	Meet with Dr. Geiger	1 hr	Thu 11/16/06	Thu 11/16/06
43	▦	Design Review#4	0 days	Tue 11/21/06	Tue 11/21/06
44	▦	Initial Build	17 days	Fri 11/3/06	Wed 11/22/06
45	▦	Thanksgiving Break	4 days	Wed 11/22/06	Sun 11/26/06
46		Physical Testing and Validation	9 days	Mon 11/27/06	Wed 12/6/06
47	▦	Design Expo	0 days	Thu 12/7/06	Thu 12/7/06
48		Compile Final Report	2 days	Thu 12/7/06	Fri 12/8/06
49	▦	Final Report Due	0 days	Mon 12/11/06	Mon 12/11/06

Project: 450 Project_DR3.mpp
Date: Wed 12/13/06