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Improved Tissue Caliper

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Improved Tissue Caliper

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Abstract

The purpose of this project is to design an improved tissue caliper for the Research & Development department at Covidien, one of the leading companies in the medical equipment industry. One of Covidien’s most innovative products is their line of single use loading units (SULUS) which simultaneously cut and administer surgical staples. Each SULUS has a specific size staple that it delivers, which is dependent on the thickness of the tissue. An extremely thick tissue requires a longer staple to accurately close it. The long term goal of this caliper within Covidien is to establish a relationship between accurate tissue thickness and SULU and staple size to maximize the effectiveness of these products. This caliper will also be used by the Research & Development Department at Covidien to perform various other types of studies on tissues in response to different medical equipment. The tissue caliper will be used most often to be lowered down into a cavity to measure tissue on a horizontal plane.

The design created in this project will enhance the features of current devices to make it more ergonomic for all users while also increasing the accuracy and consistency of measurements taken using the device. The caliper will be used to measure the thicknesses of various tissues. It will be lightweight, ergonomic, operable ambidextrously with one hand, be able to be easily cleaned, and possess a measurement hold function.

Currently Covidien has two different types of devices that they are using to measure tissue thicknesses. Main concerns with these devices are that they exhibit extremely poor ergonomics, are heavy, and are not tailored to be used by a wide population of users. Both iterations of designs are also lacking in a functional hold feature. Many times when the caliper is being used, the screen which displays the measurement is embedded into a cavity and cannot be read. As soft tissue has a high water content and its thickness varies greatly with time, there is much variation in the measurement from the time the caliper jaws close around the tissue to when the device is removed and and the measurement able to be read. There is also much variation in the amount of time it takes each user to obtain a measurement. A hold feature will act to freeze the measurement on the screen in an attempt to mainstream measurements for repeatability.

The design created in this project will improve the ergonomics of previous designs while increasing the accuracy and repeatability of measurements. It will also offer a lightweight alternative design that can operable ambidextrously with one hand by a wide variety of users. The device will also be safe for both users and the tissue being measured.

1 Introduction

1.1 Background

The purpose of this project is to design an improved tissue caliper for the Research & Development department at Covidien, a leading company in the medical equipment industry. The design created in this project will enhance the features of the device to make it more ergonomic for all users while also increasing the accuracy and consistency of measurements taken using the device. The caliper will be used to measure the thicknesses of various tissues. It must be
lightweight, ergonomic, operable ambidextrously with one hand, be easily cleaned, and possess a measurement hold function.

Several components of our design work extremely well for our clients and exist in all of the three alternative designs. The first is the constant force magnetic spring. The clients are extremely happy with the implementation of this particular type of spring as it exerts a constant force on the tissue and removes much of the variation that occurs with the use of a traditional spring. This spring will be purchased from Linmot and exert a constant force of 22N. The use of a spring is essential to this design as it offers a comfortable amount of resistance to operate the opening and closing of the caliper with controlled precision.

The second feature that works well for our clients is the digital caliper. Previous designs used calipers that implement a pressure gauge to output the measurement, but these are difficult to read and lead to a large deviation in data. The electronic caliper chosen is the Mitutoyo 500-784, which removes part of the guesswork by displaying a measurement with +/- .001 inches of accuracy. Our clients require an accuracy of +/- .005 inches. This allowance was not able to be met using the pressure gauge but is exceeded by the Mitutoyo 500-784. The caliper is water proof which addresses the issue of any damage due to the exposure of biological fluids, and solar powered with a battery that has a lifetime warranty. Figure 1 is a picture of the device.

![Figure 1: The Final Design of the Improve Tissue Caliper](image)

Another necessity for the device is a hold feature. In many circumstances the user of the caliper has to spend a great deal of time maneuvering the device into a small crevice to retrieve a measurement. Most of the time, the screen that displays the measurement is not visible to the operator until they have removed the caliper from the aforementioned crevice. Thus, the implementation of a hold feature will keep the measurement on the screen for a specified amount of time, until the user can see the screen again and obtain the measurement. Most electronic calipers possess a chip which when connected to a wire exerts a hold function, where it will display the current measurement on the screen for a few moments. The caliper chosen in this design does not possess an externally exposed chip (as it is waterproof). As an alternative, an attachment that operates the hold feature by way of button and is enclosed in a separate compartment is available and can be clipped onto the top of the caliper. All three designs also require this mechanism. The button will be rewired to be placed in a more suitable location for the design to ensure the device is entirely operable with one hand.

A final component of all designs is a set of jaw attachments. These attachments will fit over the jaws of the caliper and possess flat surfaces to protect the tissue being measured from the sharp edges of the caliper jaws. These attachments will also be made out of aluminum and will allow the specified pressure of 8.0 +/- 0.5 grams/mm2 to be exerted on the tissue.
The current model of the tissue caliper operates using a reverse hand-trigger motion. That is, the caliper has a design similar to a gun with two handles. The front handle which the fingers hold, is stationary. The jaws of the device open by pushing the second handle, held by the thumb toward the fingers; exactly opposite of how one might operate a caulking gun, shotgun, or various other tools. In addition to the fact that this motion is unnatural, the device is also bulky and heavy.

Our three alternative designs explore other ways to hold the device that might be more comfortable and efficient for its purpose. In many situations, the device needs to be operated vertically to place the jaws in the same orientation of the tissue. Alternative designs 2 and 3, based on the concepts of a click-pen and a syringe respectively, explore mechanisms of vertical operation. The first alternative design expands on the previous design of a trigger mechanism, but reverses it so that the fingers pull toward the thumb, to create a more natural and comfortable motion.

Previous iterations of this device focus on designs similar to the reverse trigger mechanism discussed earlier. In most of these iterations, the device was held horizontally, similar to a gun. These designs seem functional and ergonomic as they are consistent with many everyday devices. However, the caliper is most often used to measure tissue with a horizontal orientation. Thus, the jaws of the caliper must be in a horizontal placement as well to measure the tissue. The caliper jaws are always perpendicular to the casing of the spring, so having the casing be horizontal positions the caliper jaws vertically, which is the opposite of what is desired. Thus, the operator must compensate for this by constantly bending their wrist at an extreme angle to orient the caliper jaws with the tissue. This exhibits extremely poor ergonomics and greatly stifles the ease of use of the tissue caliper. Our alternative designs explore mechanisms of vertical operation that offer adequate support by the hand and wrist, and a mechanism of operation that correctly orients the caliper jaws with the tissue.

1.2. Purpose of the Project

The purpose of this design is to enhance the capabilities of the research and development teams at Covidien in their production of various surgical materials by meeting their set of specifications to improve the caliper. Improved ergonomics, design, comfortability, and providing a means of reducing variability in data collection will help these teams more accurately develop and assess their equipment for sale and use in the medical industry. The device will exert a pressure of 8 g/mm2 on the tissue being measured. It will also be able to be used by a wider group of users, developing a mainstream of technique in testing and enhancing employment opportunities at Covidien.

1.3 Previous Work

1.3.1. Products

The Toveytron is a spring loaded device that exerts a force of 11 g/mm2 on the tissue, which is in excess of the desired pressure of 8 g/mm2. This device is long and extremely difficult to operate with one hand. The stroke of the device is also too large to be operated by a variety of users with different hand sizes. The device design also contains lots of crevices in which debris and fluid can
become lodges and impair the function of the caliper. The pressure gauge that displays the measurement is extremely inaccurate. This gauge does not meet the level of accuracy required by the device to be effective, and also leaves much room for user error when retrieving a measurement.

Last year a UConn senior design group was given a similar project to design a tissue caliper based on a slightly different set of specifications. They incorporated a few subunits into their design that work extremely well and adhere to the specifications. These include the use of a digital caliper and a constant force magnetic spring. These two subunits greatly improved the accuracy of the device and also dealt with the issue of the exertion of constant pressure on the tissue. Although these two incorporations were major improvements, the mechanism of operation of this design exhibited extremely poor ergonomics. The device operated similar to a pair of pliers, where the user pulls a trigger towards the thumb to open the caliper jaws. However, this design operated inversely, where the user would have to have their fingers remaining stationary while pushing their thumb towards the fingers to open the caliper jaws. This is an awkward and somewhat difficult motion while fighting against the 22N force of the spring. Also, they oriented their device in such a way that for operation the user would have to have their wrist pointed down at a 90° angle which is extremely uncomfortable given the weight of device and time required to retrieve a measurement. They were also not able to successfully implement a functional hold feature.

This device design focuses on improving the prototype developed by last year’s group. The mechanism of function has been changed to orient the caliper jaws in the same plane as the tissue so that the wrist will not have to be bent at an awkward angle to take measurements. The device will be smaller and lighter with the implementation of a hold feature. The device will be able to take measurements in 360° of rotation.

1.3.2. Previously Held Patents

There are several devices currently on the market that hold patents that are relatively similar to the tissue caliper being produced in this design project. The first is a skin-fold caliper that is used for measuring body fat content. Grafco holds a patent on one type of these calipers, which is also operable by a spring loaded mechanism and exhibits results on rule based on the opening of the jaws. There is a wide range of electronic calipers that have begun to replace manual gauge calipers used in the medical industry. These can range in units of measurement, and many are corrosive-resistant to water and biological materials, like the Ultra-Cal IV Digital Electronic Caliper in Fig. 2. A caliper similar to this will be implemented in the final design but will be combined with other materials and parts to meet the specifications provided by Covidien. There also exist some patented calipers for measuring deformable objects that are used in the measurement of soft objects such as tumors, although these use the traditional gauge as an output reading. There are also electronic patented calipers that are used in research for the testing of rat foot pad and mouse ear edema measurements. This device uses a constant force spring, which is similar to the idea used in this design and necessary when measuring soft biological tissue. This device is more concerned with the electronics and operates by using a button instead of a trigger motion. Although these similar devices do exist, none that are utilized in a device aimed to exert specific amounts of pressure or be
Operable with one hand are currently present in the market.

**Figure 2:** Grafco Skinfold Caliper  
**Figure 3:** Ultra-Cal Electronic Caliper

### 1.4 Map for the Rest of the Report

The remainder of this report will focus on the major subunits of the final design. Three major alternative designs will be discussed as well as an optimal design report that highlights the specifics of the current design and why they are effective for the purpose of this project. A list of technical and operation specifications will also be included. The budget for the final product is included as well as an acknowledgement of all those who have helped us succeed in the design process this year.

### 2 Design

#### 2.1 Introduction

The project design consists of a process that involves three alternative designs and an ultimate optimal design. Our three alternative designs were investigated and evaluated for effectiveness and ergonomics. Several components of our design work extremely well for our clients and exist in all of the three alternative designs. The first is the constant force magnetic spring. Our clients are extremely happy with the implementation of this particular type of spring as it exerts a constant force on the tissue and removes much of the variation that occurs with the use of a traditional spring. This spring will be purchased from Linmot and exert a constant force of 22N. The use of a spring is essential to this design as it offers a comfortable amount of resistance to operate the opening and closing of the caliper with controlled precision. Our three alternative designs explore other ways to hold the device that might be more comfortable and efficient for its purpose. The device needs to be operated vertically to place the jaws in the same orientation of the tissue. Alternative designs 2 and 3, based on the concepts of a click-pen and a syringe respectively, explore mechanisms of vertical operation. The first alternative design expands on the previous design of a trigger mechanism, but reverses it so that the fingers pull toward the thumb, to create a more natural and comfortable motion.
**Alternative Design 1:**
The purpose of this alternative design is to optimally improve the ergonomics and usability of the device. The current design features a two handle system that allows the user to operate the device with one hand. The handles are positioned along the bottom of the device in such a manner that the rear handle is free to move but the front handle acts as an anchor. The user will rest the inside of their palm on the rear handle and grasp the stationary front handle with their fingers. The user will then attempt to close their hand and the rear handle will begin to move forward, thus allowing the caliper's jaws to open. Although this design allows for a single hand operation, it is not the most optimally comfortable position to open the caliper jaws. Many pliers and other single handed tools will rely on a stationary back handle. Figure 4 below displays a pair of locking pliers that function on a freely movable front handle mechanism.

![Figure 4: Locking Pliers](image)

The user will rest their hand on the back handle as previously mention but their fingertips will control the caliper jaws. The purpose of this reversed feature is to increase the comfort level of the instrument. It is much more ergonomically practical for the user to control the opening mechanism by their fingers. The operator has more control of the force that they can exert on the handles and it can ultimately lead to a more accurate tissue measurement. Additionally, the new handle system forces the handles to be positioned closer together. The current design of the caliper has both the front and back handles spaced far apart. The distance of the handles does not allow users with small hands to easily operate the device. The new handle system will allow both men and women from the ages 20-60 to effortlessly take accurate tissue measurements.

As a result of the newly incorporated handle system, the device will feature a kick-back mechanism. Currently the caliper’s primary jaw is anchored to the housing. The back handle moves forward and back allowing the secondary jaw to open and close. In order to open and close the caliper using the newly devised front handle system, the secondary jaw must now be anchored. This reversed design will cause half of the caliper to retract backwards such as a kick-back mechanism found in a pistol. Figure 5 below shows the kick-back mechanism as a result of the operator using their fingers to trigger the device.
Although the back portion of the caliper will retract and elongate the device, it will not hinder the actual operation. The caliper will retract in the opposite direction of the tissue jaws and out of the way of the current measurement. Figure 6 below shows the new caliper design with the kick-back mechanism and front handle system.

**Figure 5: Kick-Back Mechanism in a Pistol**

**Figure 6: Alternative Design 1**

**Alternative Design 2:**

This design will require the operator to hold the tissue caliper similar to a retractable ballpoint pen. The main body of the tissue caliper will be a cylindrical tube with a plunger protruding out of the top end and the caliper will be facing downwards on the bottom end. The operator will then use his or her thumb to depress the plunger, which will open the caliper. Similarly to the previous design iteration, the tissue caliper will utilize a magnetic spring to apply a constant force to close the caliper jaws when the plunger is released. The plunger will also contain a button on the end of it to perform the hold feature. The hold feature will be implemented slightly differently from what was previously mentioned. Rather than holding the measurement as soon as the button is pressed, the hold operation is performed as soon as the button is released. This way, as the operator releases the plunger to close the jaw, the button is simultaneously released, locking the measurement. This will minimize the variation of measurements between operators since the
measurement is locked as soon as the caliper is closed and no time is taken to press the hold button separately. A CAD model of this design is shown below in Figure 7.

![Figure 7: Alternate Design 2](image)

The advantage of this design is that the device is much more streamlined. By removing the handles in the previous design, weight is removed and there are fewer crevices in which tissue can be trapped. Also, since all moving parts are internal, the outer casing of the device can be constructed out of a solid piece of aluminum. This will simplify assembly and by eliminating the need for screws to hold the case together, this design further reduce possible crevices for tissue to be trapped. Additionally, the tissue caliper is typically used by inserting it downward into a cavity to take measurements. Orienting the caliper so that is already facing downwards makes it much easier to use.

The drawback of this design is that the operator will be only using his or her thumb to open the caliper. Operators with weaker thumbs may have a little difficulty holding the caliper open for extended periods of time.

**Alternative Design 3:**

The third alternative design is based on the concept of a syringe. In mechanism, it is similar to the second design that is based on the pen. The constant force magnetic spring and electronic caliper will both still be used in this design. A small handle will be placed around the casing of the spring which can be held between two fingers, similar to the mechanism of operation of a syringe. The stroke of the spring that shoots out the back will be surrounded by a casing of appropriate material. In this design, the button that will act to hold the measurement on the screen of the caliper will be situated at the top of the device, where the thumb will rest and operate the caliper. The user will place their two fingers around the cylindrical grip and use their thumb to push the back-shoot of the spring towards their two fingers, thus opening the jaws of the caliper. The placement of the button is important in this design because since it is involved in the mechanism of operation, it helps to eliminate variation in the retrieval of measurements. Also, the mechanism of operation is
much more ergonomic and natural in function than the reverse trigger mechanism. Although the motion of operation is more ergonomic, this design is only operated using two fingers and the thumb versus designs one and two which operate using the entire hand, offering a more stable operation. This syringe-based design will require exceptionally light materials and a smaller length to be able to operate accurately. The design can be viewed below in Figure 8. Figure 8 only displays the casing of the device and is lacking the caliper and spring in the visual. The size of this design is similar to that of the other two and is based upon the length of the constant force magnetic spring. The entire device will be less than or equal to 7 inches in length. This design offers a new and innovate mechanism that will be more beneficial for the needs of the Research and Development team at Covidien.

**Figure 8: Alternative Design 3**

**Figure 9: Commercial Syringe**
2.2 Optimal Design

2.2.1 Objectives

The optimal design chosen by deliberation amongst the team and with the client is based on alternative design 2, which focuses on the mechanism of a click-pen. In this design, the user will hold the device similarly to a click pen, with their palm and fingers gripped around the cylindrical part of the device that houses the spring, and their thumb on the top of the device. To open the jaws, the user will push down on the top of the device, which will slide inside of the cylindrical casing, exactly the same as one might click a pen. The advantage of this design over previous iterations is that it allows easy use in both a vertical and horizontal orientation. While hold the tissue caliper vertically, the wrist position is very natural and no bending is necessary. Since the new tissue caliper will be cylindrical, the jaws of the caliper can be rotated a full 360°, allowing the operator to measure tissue in any direction. The previous design only allowed the caliper to be rotated about 180°. The new tissue caliper design also allows for use in the horizontal orientation without any unnatural bending in the wrist. To do this the operator would simply grasp the caliper the same way he or she would for the vertical orientation, but then turn their hand so that his or her palm is facing downward. This places the caliper in a horizontal orientation, again without any bending of the wrist. From this position the caliper can be rotated a full 360° as well. This design requires a grip by the entire hand which offers sufficient support and also maneuverability. The hold button will be positioned on the topmost part of the device, where the thumb rests. Placing the button here will ensure that all users are able to operate it effectively, and will help to decrease variability in measurements as the execution of the button will also be a natural motion. The casing of the spring will be made out of Aluminum. There will also be a lip located on the end of the casing that will cap the hand and give it some resistance to operate against when pushing the cap part down with the thumb to open the jaws. The idea is similar to the feature on a syringe, which is discussed in alternative design 3. This will prevent the hand from sliding up the device while the user is operating it.

2.2.2 Subunits

Caliper

The optimal design for this project continues to use a digital caliper due to its ease of use and readability. The specific caliper chosen for this design is a Mitutoyo 500-175-20 Digital Caliper. Mitutoyo has been selected because of its proven track record for producing high quality instruments. All previous designs of the tissue caliper have used Mitutoyo-brand calipers and thus, familiarity with the products is also another benefit. When selecting a caliper to use in the optimal design, the follow characteristics were taken into consideration: size, weight, features, accuracy, and price.

Mitutoyo manufactures digital calipers with a maximum measurement ranging from 4 inches to 80 inches. In order to keep the final product as compact as possible, the caliper would also have to be as small as possible. Since the specifications of the project only require measurement of thicknesses up to 1 inch, a digital caliper with a maximum measurement between 4 inches and 6 inches would be sufficient. Again, in order to keep the weight of the final product at a minimum, the smallest possible caliper will be used. The Mitutoyo 500-series calipers are all compatible with an
optional data hold unit, which will hold the current measurement when a button is pressed. The caliper must also be able to accurately within the 0.10 inches and 1 inch with an accuracy of ± 0.005 inches. Finally, since the budget for the entire project is limited to $2000, the caliper should also be as inexpensive as possible.

Figure 10: Mitutoyo 500-175-20 Digital Caliper

The Mitutoyo 500-175-20 Digital Caliper measures from a range 0-6 inches. Although, the sample will never exceed one inch in thickness, the caliper was modified so that the jaws could be opened to 1.25 inches. The ruler end was cut down to the 6 inch mark to reduce the overall length of the device. The Mitutoyo 500-175-20 has two sets of jaws, one set for measuring thickness, and another set for measuring the inside diameter of objects. The latter set of jaws create a very sharp points that can pose a safety hazard that can damage tissue samples, harm the operator, or possibly rip the operator's gloves. In order to prevent this, those jaws were be milled off and the edge will be smoothed out with a file or belt sander. Other modifications to the caliper included removing the thumb roller at the bottom of the caliper body, removing the depth gauge, and making a cutout and holes in the ruler end of the caliper to attach the fixation component. Some material was left on the ruler end to provide an area to attach the caliper to the spring. A 3D CAD drawing of the final modified digital caliper is shown below in Figure 2.

Figure 11: Modified Digital Caliper

The caliper is very lightweight; at 168 g (approximately 0.4 pounds) it is well under the 4-pound limit for the device. The Mitutoyo 500-175-20 also has several special features on top of normal digital calipers. The Mitutoyo 500-series calipers all feature Mitutoyo's ABSOLUTE system, eliminating the need for an origin set up every time the caliper is powered on. This makes the caliper easier to operate and can eliminate operator error if he or she forgets zero the caliper before taking a measurement. The Mitutoyo 500-175-20 uses the SR44 Silver Oxide cell battery and has a rated battery life of 3.5 years with regular use. The Mitutoyo is capable of measuring accurately to 0.001 inches ± 0.0005 inches. The list price for the Mitutoyo 500-175-20 is $320.
Spring

In order to operate the tissue caliper only using one hand, there must be a mechanism to close the caliper jaws automatically. The optimal design involves using a spring that will be compressed when the caliper jaws are opened. Therefore when the caliper is released the spring will expand again, closing the jaws. The problem with conventional springs is that the force they exert varies linearly based on the length that they are extended or compressed. Therefore, the more you compress a spring, the stronger a force it will exert. This presents a problem because there will be inconsistencies when measuring tissue samples of different thickness. Using a standard spring, the tissue caliper will exert a much greater force on a 1-inch-thick sample than on a 0.10-inch-thick sample.

In order to overcome this issue, a magnetic spring will be used. A magnetic spring consists of two neodymium magnets, one static magnet (stator), and another sliding magnet (slider). By pushing on the slider, the magnetic stator applies a constant force to resist this motion throughout the entire range of motion. The magnetic spring used in the optimal design is a LinMot MagSpring (Model Number: M01-20x60/50-22). The MagSpring to be used in the final product is shown below in Figure 3.

![LinMot MagSpring](image)

Figure 12: LinMot MagSpring

Two properties were taken into consideration when choosing the correct magnetic spring model: size, and force. LinMot manufactures a range of magnetic springs ranging in sizes from 130mm to 370mm. The strength of the magnetic springs range from 11 Newtons to 60 Newtons. Similarly to the caliper, the smallest possible size would be most desirable in order to keep the tissue caliper compact. However, the total size of the spring is not the only consideration. The stroke length of the slider must be long enough to open the caliper jaws a sufficient amount (1 inch). The smallest MagSpring has a length of 130mm and a stroke of 50mm (~2 inches). Since the stroke length is sufficient, the smallest MagSpring was chosen for this optimal design. The downside of a magnetic spring is that the strength is not as variable as a normal spring. Springs are so widely available that it is easy to find a spring with almost any spring constant. The 130mm MagSpring, however, only offers three different strengths: 11N, 17N, and 22N. The previous version of the tissue caliper used a 22N MagSpring. This optimal design will continue to use the same force since it is known that approximately the correct amount of force is produced. The specifications of the MagSpring are shown below in Figure 4.
Since the client requires a very specific amount of pressure to be applied on the tissue and the MagSpring is limited to only a few strength values, the pressure can be adjusted by changing the surface areas of the jaws. The surface area of the jaws will be changed by using jaw attachments that will be explained in further detail below. Both ends of the magnetic slider have a M5x8 screw thread. We decided to take advantage of these screw threads to attach the different components of the tissue caliper together. The fixation component and top button cap were the components attached to the MagSpring slider and will be further discussed in subsequent sections. One modification that was made to the MagSpring slider was to drill a hole axially through the slider. This modification will be discussed further in the top button subunit.

Spring and Caliper Fixation Component

The optimal design for this caliper involves pushing down on the MagSpring slider, causing the front jaw to move down as well. In order to link the movement of the slider with the movement of the caliper jaw, a component must be designed to physically connect the two pieces together. The fixation component is a two-part component that was machined out of aluminum. The first part is a “sleeve” that slides over the ruler end of the digital caliper. Two holes in the sleeve align with two holes in the caliper, allowing two screws to secure the fixation component to the caliper. A 3D CAD model of the “sleeve” part of the fixation component is shown below in Figure 5.

The second part of the fixation component contains a tapped hole with a M5x8 screw thread. This allows the fixation component to be connected to the MagSpring slider with the same
screw thread. Finally, both parts of the fixation component are connected using two small screws go through the second fixation component part into the first “sleeve” part. A 3D CAD model of the second fixation component part and the full fixation component attached to the caliper are shown below in Figures 6 and 7, respectively.

![Figure 15: Fixation component, second part.](image)

![Figure 16: Fixation component attached to caliper.](image)

**Jaw Attachments**

Jaw attachments are necessary in this design to protect the tissue that is being measured. Tissue contains a lot of water and is extremely sensitive to pressure. The normal jaws of the caliper are extremely sharp and could potentially damage the tissue being measured, which will ruin all measurements. Also, because tissue is soft and responds sensitively to pressure, too great of a pressure could squeeze the tissue and yield an inaccurate measurement. The client requires a pressure of 8.00 g/mm² to be exerted on the tissue with an allowance of ± 0.005g/mm². Pressure is equivalent to force divided by area, and because the constant force magnetic spring does not have a variable force, the pressure exerted on the tissue by the device is entirely dependent on the surface area of the jaws. This was calculated from the pressure, which is first converted from g/mm² to Pascals:

\[
\frac{8.00 \text{ g}}{\text{mm}^2} \times \frac{1 \text{ kg}}{1000 \text{ g}} \times \frac{10^6 \text{ mm}^2}{1 \text{ m}^2} \times \frac{9.8 \text{ m}}{s^2} = \frac{78400 \text{ kg}}{m \cdot s^2} = 78400 \text{ Pa}
\]

The surface area of the jaw attachments in contact with the tissue is calculated by rearranging equation 1.

\[
\text{Pressure} = \frac{\text{Force}}{\text{Area}} \rightarrow \text{Area} = \frac{\text{Force}}{\text{Pressure}}
\]

**Equation 1: Pressure.**

\[
\text{Area} = \frac{22 \text{ N}}{78400 \text{ N/m}^2} = 2.806 \times 10^{-4} \text{ m}^2 = 280.6 \text{ mm}^2
\]
The surface area of the jaw attachments in contact with the jaw is in the shape of a rectangle and semi-circle shown below in Figure 8, where \( l \) is the length of the rectangular section of the jaw attachment, and \( r \) is the radius of the semi-circle.

![Figure 17: Jaw attachment surface area](image)

The length and radius dimensions of the jaw attachments can vary infinitely as long as the surface area is 280.6 mm\(^2\). We therefore arbitrarily selected a length of 30mm and solved for the radius using the quadratic equation.

\[
0 = \left( \frac{\pi}{2} \cdot r^2 \right) + (2l) \cdot r - A;
\]

\[
r = \frac{-2l \pm \sqrt{(2l)^2 - 4 \cdot \left( \frac{\pi}{2} \right) \cdot (-A)}}{2 \cdot \left( \frac{\pi}{2} \right)}
\]

**Equation 3: Solving for \( r \) using the quadratic equation**

The dimensions of the jaw attachments were calculated to be \( l = 30\text{mm} \) and \( r = 4.212 \text{ mm} \).

In addition to tuning the applied pressure on the tissue to the correct value, the jaw attachments serve another purpose of protecting the tissue sample and operator. The digital caliper jaws contain sharp edges and points that may damage the tissue sample or tear the operator’s gloves. The jaw attachments have rounded edges to prevent any damage. They also fit tightly enough around the caliper jaws to remain stationary and intact during measurements, but not impossible to remove and exchange with different sized attachments. A 3D CAD model of the jaw attachment is shown below in Figure 9.

![Figure 18: CAD of Jaw Attachment](image)
Button/Hold Feature

One of the most important aspects of this improved design is the button and hold feature. Although the electronic caliper is a huge improvement from previous versions of this device, there is still much variability in the retrieval of measurements. In certain circumstances, the operators may be attempting to get a measurement for up to 15 minutes, trying to maneuver the caliper into crevices and achieve the correct orientation. All users vary in the time it takes them to actually read the screen, and in some cases the caliper is positioned in a way that makes it impossible to read the measurement on the screen until the caliper is removed from the tissue. Thus, our clients require a hold feature on the device that will display the measurement on the screen until the user is able to retrieve it. Most electronic calipers come with chips that possess a hold feature. Mitutoyo offers an attachment that can be purchased separately to execute this function. This device can be seen in Figure 10 below. This attachment clips onto the upper right hand corner of the caliper body, and possesses a red button that activates the hold feature by depressing it.

![Figure 19: Mitutoyo Data Hold Unit.](image)

Although the hold feature is extremely important, there still exists much room for variability in when the user actually chooses to execute the hold function. In this design, the attachment will remain on the caliper body, but the hold feature will be re-wired to a button at the extreme opposite end of the device, where it can be activated by the operator’s thumb. This allows for easy access to the button that activates the hold feature and the operator will not have to reach into a tissue cavity to activate the hold feature. To operate the hold feature using a secondary button, the data hold unit module had to be cut open to expose the internal circuitry. The figure below shows the circuit board within the data hold unit.

![Figure 20: Exposed circuit board of data hold unit.](image)
Pushbutton and End-Cap

The secondary button used to activate the hold feature is an SPST Pushbutton Switch shown below in Figure 21.

Figure 21: SPST Pushbutton Switch

To connect the pushbutton switch to the data hold unit, wires were soldered to the two contacts shown above in Figure 11. The wires then connect to the two contacts on the bottom of the button. The switch is a normally closed, momentary pushbutton. In other words, the button activates when it is released, not when it is pressed.

The pushbutton is seated in hollow cylinder referred to as the end-cap. This button cap is attached to the MagSpring slider opposite the fixation component. This way when the operator pushes down on the top button, he or she will push down on the end-cap, which pushes down on the MagSpring slider and opens the caliper jaws. The end-cap is designed so that as the operator opens and closes the caliper jaws, he or she does so while simultaneously activating the pushbutton switch. As the operator gradually releases the button, his or her thumb will lift off pushbutton switch as soon as the caliper jaws close around the tissue sample. As stated earlier, the hold feature is activated as soon as the pushbutton is released. This improves the consistency of measurements since there is no delay or variation between the time the caliper jaws close and the time measurement is held. A 3D CAD model of the end cap is shown below in Figure 22.

Figure 22: End-cap.

The wire connecting the pushbutton to the data hold unit will be threaded through the hold and screw connecting the end-cap to the MagSpring. The wire will run through the center of the entire
device. As discussed earlier, this is the reason why the center of the MagSpring slider had to be drilled out. Additionally a hold had to be drilled through the screws between the MagSpring and the fixation component and end-cap. The holes through the screws were drilled using a laihe and a 0.098-inch drill bit.

**Housing**

The main purpose of the housing is to contain and protect all of the internal mechanics of the tissue caliper. The foundation behind the pen mechanism relies on the user to hold the device on the distal end of the shaft away from the caliper jaws. The housing is a cylinder made out of Delrin and secures the MagSpring in place. The spring is placed into the cylinder through the top end and rests on an internal step. The step's location allows the spring to reach optimal extension of around 1.25". Additionally, the caliper housing is used to realign the internal mechanisms of the device. The spring fits inside the housing and the slider is located exactly at the housings center. The slider is responsible for attaching to the fixation component, which drives the caliper jaws open. If the housing was to be unsymmetrical there would be severe alignment issues internally and potentially a smaller jaw extension.

![Figure 23: Cross Sectional View of Housing](image)

Although the caliper housing is functionally important, it is essential for the device to be ergonomically comfortable for the user. The physical housing is designed in a cylindrical shape so that both left and right-handed users have equivalent comfort. The current Toveytron is made specifically for right-handed users. The analogue dial on the Toveytron is positioned on the left side and therefore it is medial to a right-handed user. A left-handed user simply cannot see the caliper's dial when taking a measurement. The current design can be used by both types of users and makes it very advantageous in the lab for repeatable measurements between users.

The housing is constrained in many ways because it must remain safe for the user. The casing is rounded in a cylindrical shape to eliminate sharp edges from harming the operator. Additionally, the housing is made out of Delrin because it is a much lighter plastic when previous designs mentioned aluminum as the primary material. Delrin is much easier to handle for the user and it is still very easy to clean with medical sanitary wipes. The operator should find no difficulty in controlling and operating the device for an extended period of time.
Nose Cone

The nose cone is a threaded cylinder made out of Delrin that is connected to the housing. The nose cone is responsible for aligning the track of the caliper. There is a slit made in the center of the nose cone face that the caliper slides through. The caliper is placed through the nose cone before it is screwed together with the housing. The caliper body then stops against the front face of the nose cone. The nose cone ultimately allows for the entire device to be assembled. Additionally, the nose cone acts as a hard stop for the fixation component. The fixation component is sliding back and forth inside the housing. Once the fixation component has moved all the way forward it will bump into the nose cone and that point will yield the maximum extension of the caliper jaws. The last function of the nose cone is that it acts as a point of attachment for the anchor. The anchor is placed into its respective slots on the caliper body during assembly and then secured to the nose cone.

![Figure 24: Nose Cone](image)

Anchor

The anchor piece is a stainless steel clip used to secure the caliper body to the housing. The anchor originated as a flat piece of sheet metal that was bent into an “S” shape. There are two small legs that slide into respective slits on the caliper body. The legs hold the caliper body to the nose cone. There is an additional point of attachment along the face of the nose cone where one screw secures the two components together. The union between the anchor and the nose cone allows the device to extend and retract. When the MagSpring puts force on the caliper body it will extend both jaws. The purpose of the anchor is to isolate and secure one of the jaws to the housing so the MagSpring is only moving one jaw. By securing one jaw the device is able to keep consistent measurements. It was essential to customize the anchor piece and ensure a tight fit to prevent any discrepancies in measurements between users.

![Figure 25: Anchor](image)
**Button Cap**

The button cap is a customized protective shield that is composed out of SLA. The geometric complexity of the button cap allows for a tight fit seal while still maintaining a streamlined appearance. The first half of the component is a simply box that is used to house the chip and protect it. During testing, the device will be exposed to blood, tissue fluid, water, etc. It is essential to seal the chip from any outside fluids that may cause potential harm to the circuitry. Additionally, the button cap is used to protect the exposed wires. There is a recessed step under the button cap where the wires are channeled through to prevent them from being pinched. If the wires were to get caught on anything or even become worn, there would be a short in the circuit. It was critical to maintain a streamlined wire that would not be exposed to any hazards. The second half of the button cap is a designed to fit the contour of the nose cone. There is a half circular component that sits flush to the nose cone and a through hole that aligns with the same screw used for the anchor. Ultimately the button cap clips onto the top of the chip but it is screwed through the anchor and nose cone. The button cap is secured at two points in order to prevent any chance of loosening and thus exposing the actual circuitry to tissue.

![Figure 26: Button Cap](image)

**2.2.3 Prototype**

The team went through several iterations of prototypes before reaching the final design. The design work was accomplished mostly in Solidworks, and parts were rapid prototyped in SLA both at UConn and Covidien. Most prototypes were used for proof-of-concept purposes, as well as to experiment with the ergonomics of various measurements of parts. Images of the prototypes can be seen below.

Figure 27 is a prototype of the housing. The housing was initially designed with a step inside of it to hold the magnet of the spring so that the slider is isolated and able to move with the caliper without moving both parts of the MagSpring. The housing did not undergo many changes throughout the design process. The team experimented with lengths and outer diameters to find optimal ergonomics. The final product has a slightly increased wall thickness to compensate for the threads. It is very difficult to thread SLA parts, especially thin pieces, therefore none of the SLA parts were threaded, while the final design does have threads.
The fixation component also underwent several design iterations. Many of these iterations were done in CAD and the parts were not printed in SLA. The size of the fixation component depending on the housing, and changes were made to it as changes to the wall thickness and outer diameter of the housing were made. Figure x below shows the final design of the fixation component. The two small screw holes are where the ruler part of the caliper is screwed into the fixation component. The hole on the end of the fixation component is where the set screw resides to attach the MagSpring to the fixation component. The final design of the fixation component has the same dimensions as the SLA piece here, but it was manufactured in two separate pieces for machining purposes.

Below are two iterations of the nose-cone piece. The team experimented with various shapes for the nose cone that varied with the shape of the metal anchor piece. The bottom nose cone piece was the final SLA part and is almost exactly the same as the final piece.
The metal anchor piece needed to be tested for proof of concept before any CAD work was done. The team created this piece in the machine shop at UConn out of a piece of scrap aluminum. Originally, this piece was bent into an 'L' shape instead of an 'S' shape. Once again, some experimentation and testing with which shape was optimal for the design ultimately ended in the 'S' shaped anchor.

The UConn senior design team from last year that worked on the tissue caliper gave all of their old pieces to this year's team. The model of the caliper was the same in both designs. The team needed to do modifications on the prototype caliper for proof of concept. In the machine shop at UConn, the depth gauge was removed and the ruler part of the caliper was cut. The modified caliper that the team used in their prototype can be seen below.

There were several button cap prototype iterations. Before the team found the momentary button, they were experimenting with switches similar to a light switch or the power switch on a power strip. They were also experimenting with the positioning of buttons. All of the designs would screw into the spring as the current button cap does, but the height and accessibility of the button varied. Ultimately this design was too bulky and the positioning of the button was not ideal. Figure 32
shows the final prototype of the button cap. It is the same dimensions and design of the final design piece.

![Figure 33: Button Cap Prototype](image)

The team visited Covidien with a finalized prototype to ensure that the length, weight, and mode of operation were satisfactory. After conformation, the final dimensions were established and specs prepared accordingly.

## 3 Realistic Constraints

The purpose of this project is to design, manufacture, and validate an improved tissue caliper that will be used to measure various thicknesses of tissue and media. In order to successfully construct a device that will be approved by Covidien, a series of constraints must be met.

### Health and Safety:

A realistic constraint of the device is the health and safety of both the tissue and the operator. The instrument must properly function in the lab without causing any harm to the tissue. Due to the hydraulic nature of tissue, the device should not exert an excessive amount of pressure on the sample, thus causing the tissue to release fluid. If the tissue was to be held in the clamped position for an extended period of time, the tissue could be permanently tarnished and very detrimental for repeating measurements. The device’s spring should be able to retract with minimal strain on the tissue to prevent this problem from occurring. The tissue caliper must be designed in such a manner that it does contain any sharp or rigid edges. The elimination of any sharp edges will lower the possibility of potential injury to the tissue. Additionally, any rigid corners of the device could lead to the tearing of the user's gloves and ultimately exposing their bare skin to tissue fluids. Other possible safety risks to the user are the potential strains acting on the operator's hand. During the use of the instrument, the operator will be holding the device in the opened position for an extended period of time. It is important for the design to limit the amount of strain a person will have on their hand when operating the device. Both men and women from the ages 20-60 years old must have the ability to accurately record tissue measurements with minimal strains on their hands.

### Sustainability:

The instrument should not be made of a material that will breakdown or corrode due to tissue
fluid exposure. Also, the device should not be composed of a material that will become damaged over time due to exposure of medical sanitary wipes. The materials used must not only be strong and resilient but should not affect the accuracy of the tissue measurements in anyway.

Manufacturability:

The purpose of this project is to not only draft an improved model, but to actually build and manufacture the design. Although the device will not be manufactured on a large scale it must be easy to assemble and interchange parts. The device must be made with proper geometric dimensions and tolerances for this purpose. Therefore, the hardware chosen should be selected using standard screw and dowel sizes. During the assembly of the device, the tolerances of each part must allow for a tight secured fit. If the device is to be designed using small holes and open crevices it could pose as potential risks for tissue to get trapped in. Tissue that cannot be cleaned, could cause additional problems in the breakdown of the material. Manufacturing the device also comes into play with the disassembly of the device and replacement of internal parts. It is important to have multiple jaw attachments that can be universally interchangeable on the same caliper. Various jaw attachments allow the user to exert different amounts of pressure on tissue. Additionally, if there was a potential malfunction with the electronics of the caliper or spring, the operator must be able to access the internal parts easily. Lastly, the mechanism of the trigger may wear down over time so the user must be able to disassemble the casing in order to apply addition grease and lubrication fluids to ensure minimal resistance within the measuring process.

Economic:

Financial constraints are an extremely large factor in the development of the improved tissue caliper. The foundation of the budget relies strictly on a simple electronic caliper, a constant force magnet spring, and a casing used to house both components. The device must be constructed using an affordable material that can withstand maximum exposure to tissue fluids and sanitary medical chemicals. The purpose of the budget is to find a suitable material that is not overly expensive but still allows for maximum comfort and functional accuracy. A larger budget would allow for the group to implement a more advanced and accurate caliper that will be able to handle exposure to various environmental conditions.

Environmental:

The device must be created using materials that will not be harmful to the environment. This constraint does not pose a larger problem for this particular project because the device will be mostly composed of metal such as aluminum or steel. It is important to make sure that any finishing coating or paint will not be hazardous to the user or tissue. A major concern would be if the coating were to fade and wear off due to excessive tissue exposure and saturation in tissue fluid.
4 Safety Issues
A major concern in the development of the device is to create an instrument that is both safe for the user and the specimen. In order to take accurate tissue readings, the user must feel safe and confident using the instrument. The device should be designed with smooth edges and rounded corners that will limit any cutting or tearing of the operator's gloves. An operator will not want to use a device that poses injury to their hand or risks their exposure to tissue fluids. Also, they are responsible for holding the caliper open for an extended period of time. It is important to maximize the comfort level so the user can function the device without experiencing any strain on their hand. A device that is extremely uncomfortable or heavy could result in the user dropping the device, which poses potential harm to either themselves or other people. Both men and women from the ages 20-60 should have no problems controlling the device. An older woman with small hands will not have the same strength as a younger man but is still responsible for recording the same accurate tissue measurements. The ball-point pen mechanism allows people of all hand sizes to easily grasp the caliper housing and effortlessly open the caliper jaws.

The caliper cannot be harmful to the tissue because it will severely affect the results of the repeated tissue measurements. The smooth edges and rounded corners are not only implemented into the design to protect the user but to safeguard the tissue specimens. A tissue that is ripped or torn will release excessive fluid and ultimately hinder the desired measurements. Additionally, the tissue caliper jaws cannot exert a force greater than 8.0 g/mm^2. If the tissue was to be continuously clamped down at extreme forces, the caliper would not be accurate. Lastly contamination of the caliper can be prevented by building the device out of non-corrosive materials. If the device was to degrade overtime, it would damage the characteristics of the tissue thus leading to an additional cause of inaccurate measurements.

5 Impacts of Engineering Solutions
The tissue caliper is not intended to be sold as an independent commercial product, but it could still have a strong global, economic, environmental, and societal impact in an indirect way. The tissue caliper is intended to be used exclusively by Covidien’s employees in the research and development department. Covidien is a leading innovator and developer of surgical devices. Some of Covidien’s newest developments include a Tri-Stapler and Single Use Loading Units (SULUs). Since different gauge staples can be used, it is important to measure tissue thicknesses accurately in order to select the correct gauge.

By providing Covidien with an accurate and easy to use digital tissue caliper, the improved tissue caliper can have indirect global impacts by allowing Covidien to continue to develop new surgical devices as well as improve existing ones. Covidien’s surgical staple devices are used in hospitals around the world and Covidien’s continued success as a major medical equipment supply company can lead to breakthroughs in new technologies that can have a significant global impact.

Should Covidien decide to develop a commercial tissue caliper, this optimal design can provide a foundation on which Covidien can base their designs. The use of a tissue caliper could be desirable in many markets outside of the medical field. Laboratories conducting research on tissues or any other fragile material may see a caliper that can exert a constant specific pressure as
desirable. Students and universities are another potential market for a caliper that is easy to use and can be operated using one hand. By developing a new product with such a large potential market, Covidien can position itself not only as a leading medical device company, but potentially expand into other related fields.

A new, highly desirable product can also influence the economy. Large scale manufacturing and distribution of a commercial tissue product can increase global trade and create new jobs. A majority of the device will be manufactured out of aluminum. By using a recyclable material for the casing of the tissue caliper, the manufacture of this device will have a minimal environmental impact.

6 Life-Long Learning

Working on this design project has provided members of Team 13 with new skill sets and many important lessons that will be valuable in the field of engineering after graduation. On a smaller scale, members of Team 13 have learned specific skills that can be useful in the future. For example, members of Team 13 have become more familiar using tools and machines in a machine shop. Knowledge of how to properly use different machinery is not only helpful while designing a product, but it is essential to ensure safe use and to prevent injury. This senior design process has allowed members of Team 13 to learn how to use various types of software such as Dreamweaver and Pro/ENGINEER. In this information age, almost every company has a website where people can visit and learn more about the company or their products. Knowing how to develop and implement a website is becoming an increasingly useful skill for anyone to have. Team 13 members have also become much more familiar with using CAD programs, specifically Pro/ENGINEER. The use of CAD drawings is an integral step in almost any engineering design process. By being able to design and modify models digitally, a lot of time and money is saved by fixing any flaws in the design before a prototype is even built. Pro/ENGINEER is one of the industry standard 3D CAD programs and is an extremely powerful tool for engineering design.

On a broader scale, this project has introduced members of Team 13 to new lessons that are vital for success in the workforce. The first, and arguably most important concept that Team 13 learned is how to work on a budget. This is the first time in any engineering class that required members of Team 13 to work within a specified budget. This involves researching components required for the final tissue caliper, allocating an appropriate amount of funds for different components of the project, and determining how to design the best product while minimizing cost. This is one of the most useful skills to have in the workforce. Although an engineer may have a great idea, it does not matter if the company cannot afford to build it.

Another valuable lesson was how to work effectively with a client. In order to build a product that the client will like, communication is essential throughout the entire design process. Since Covidien’s employees have the most experience using the tissue caliper, it is important to listen to their feedback on previous iterations to correct any flaws. Although one design may seem like a good idea, using the caliper in a lab environment may prove otherwise.

Finally, members of Team 13 have learned about the design process as a whole. The design process involves more than just drawing models in a CAD program. The design process includes...
researching existing devices, determining materials and components, and making multiple prototypes and testing them. Also important in the design process is creating a timeline to set short-term goals and deadlines to keep the project on task.

While specific skills such as how to use different engineering-related software is useful, the more general skills of how to work effectively as a team and with a client, and how to go through the design process properly to create an effective device within the allocated budget are more important for the success of members of Team 13 in the future.

7 Budget

Our client, Covidien, has provided Team 13 with a budget of $2000 to design and develop our tissue caliper. The costs for our project include: a digital caliper, a linear magnetic spring, the circuitry required to create a hold button for the digital caliper, and raw materials to fabricate the body of the tissue caliper.

Currently there are several existing digital calipers on the market that fall within our required specifications. The caliper we purchased was a Mitutoyo 500-784. Unfortunately, due to some misinformation, this caliper was not compatible with the Data Hold Unit. As a result we had to purchase a second caliper, the Mitutoyo 500-175-20. The Mitutoyo 500-784 cost $183 and the Mitutoyo cost $320. In total, $503 has been spent on calipers for this project.

The client has specified that the tissue caliper must allow for single-handed operation and exert a specific amount of pressure on the tissue sample. Therefore our design must incorporate a mechanism for closing the jaws of the caliper automatically. It has been decided that a magnetic spring will be best suited to perform this function. The LinMot MagSpring M01-20x60/50 was selected for this project. The cost of MagSpring was $126.

The client has also expressed a desire to implement a hold button for the digital caliper. By pressing the hold button, the instantaneous measurement will be locked, allowing the operator to record the tissue thickness at that instant. Mitutoyo offers a Data Hold Unit, which is a small module that attaches to the top of compatible calipers. The cost of the Data Hold Unit was $20.

To activate the Data Hold Unit, we used an SPDT Pushbutton Switch that allows us to activate the hold feature from the other end of the caliper, as well as activate the hold feature upon release. The total cost for the pushbutton switch is $13.

All of the parts of the tissue caliper were manufactured in Covidien’s machine shop. We printed many prototype components using SLA, with the cost of SLA totaling to $450. The metal components and hardware used in the final design cost a total of $300. The cost of labor and machine time in the machine shop cost $325. A total of $1737 was spent on this project, leaving $263 left in our budget. A summary of all the expenses in our project is shown below in Table 1.
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| **Total Expenses**            | $1,737 |
| **Remaining Budget Left**     | $263   |

**Table 1: Total Expenses**

8 Team Member Contributions to the Project

*Team Member 1: Lindsay Gaedt*

Lindsay was responsible for researching different calipers at the beginning of the project. She also did research on current similar products. She was responsible for figuring out some of the circuitry that was involved with the hold feature, and did extensive research on a bonus feature that may be added to the device at a later date. She was responsible for alternative design 3 in the beginning of the project, and the design of some early button cap iterations. She dimensioned the metal anchor piece. She completed two dimensional drawings and other components of the final print package for the model shop at Covidien. She set up the website as well.

*Team Member 2: Kenneth Hung*

Kenneth researched the digital caliper and Mitutoyo Data Hold Unit to be used in this project. Kenneth was also responsible for developing alternative design 2, which was ultimately selected to be the optimal design for this project. Kenneth designed the fixation component and made the 3D CAD models for the fixation component as it went through multiple revisions. He also measured the dimensions of the SPST Pushbutton switch and designed built the 3D CAD model of the end cap that the pushbutton was seated in. Once it was decided that the data hold unit and the pushbutton switch would be connected with a wire that was threaded through the MagSpring slider, Kenneth was responsible for making the hollow setscrews. This was accomplished by removing the head from a normal M5x8-thread bolt and then drilling through the center of the setscrew with a lathe 0.098-inch drill bit. Kenneth determined all of the dimensions for the fully modified caliper ruler and jaws. In addition to making a 3D CAD model, he made 2D engineering drawings indicating where the caliper ruler should be cut and where the holes should be drilled so that Covidien's
machine shop could modify the caliper. Kenneth also performed all of the calculations necessary to determine the proper spring force and jaw attachment sizes. Additionally he has been responsible for keeping track of the team’s budget. Funds spent were recorded in an excel spreadsheet that automatically totaled the funds spent and funds remaining. Finally, Kenneth made the 3D Solidworks assembly of the final device as well as the exploded view for presentation and verification that all the components fit together properly.

Team Member 3: Steven Plachtyna
Steven contributed many of his ideas in the design process of the project. He had originally created many of the Solidworks drawings for the alternative designs and collaborated with the group to create the Solidworks drawings for the optimal design. He was personally responsible for creating the housing design and constructing both the housing and the nose cone on Solidworks. Additionally, he helped create the final print package that would be sent to the machine shop at Covidien. The final print package included all of the 3D Solidworks drawings, 2D prints, and a full assembly. Steven also helped incorporate the hold button feature by implementing a normally closed momentary switch. The switch is the key component to holding a measurement at the point of release. Lastly, Steven designed the button cap used to protect the hold feature on top of the caliper housing. The button cap was a tight fit seal to circuitry and still remained streamline with the rest of the device.

9 Conclusion
The device designed in this project will provide Covidien with an accurate and efficient way to measure tissue in various different environments. It will greatly improve upon the devices that are currently in use by the company. The improved ergonomics will allow a wide range of persons to use the device with repeatable accuracy. The measurements taken with this device will allow the Research and Development Department at Covidien to establish important relationships between tissue thickness and staple size, as well as many other important tissue reactions in response to various types of equipment. The design will be safe to both the user and the tissue and exhibit less crevices than existing designs to avoid accumulation of biological function.

Overall this device will prove crucial to the Research and Development department at Covidien and provide them with an accurate and easy way to obtain measurements of soft tissue thicknesses.
10 References


11 Acknowledgements

The team would first like to thank Dr. John Enderle and teaching assistant Sarah Brittain for their weekly help and guidance with the design process throughout the semester. We would also like to thank our sponsors Mike Ingmanson and Kelly Valentine at Covidien Inc., for their feedback and contributions throughout the design process. Other people we would like to thank Terrance Smith, Jennifer Whiffen, John Pantazis, Tony Calderoni, Thomas Wingardner, Matt Chowaniec, Lou Stabile, Ryan McEvoy, George L. Assard II, Peter Glaude, Serge Doyon, and Thomas Mealy.

12 Appendix

12.1. Updated Specifications

Physical

Material: 316 Stainless Steel, or 6061 Aluminum

Mechanical

Weight: ≤ 4 pounds Maximum Measurable Sample Thickness: 1 inch Minimum Measurable Sample Thickness: 0.10 inches Measurement Accuracy: ± 0.005 inches Pressure Exerted on Sample: 8.0 ± 0.5 grams/mm2 Mode of Operation: Single-handed Ambidextrous Use

Environmental

Operating Environment: Indoor, Lab, Exposure to Biological Fluids

Safety

Holding the caliper open for prolonged periods of time may cause user fatigue. The device should not contain sharp edges that could potentially cut/tear either the operator or the tissue samples.

Maintenance

The caliper will be cleaned after use with a sanitary medical wipe.

Design

The design should be comfortable to hold and operate for a variety of users. The
design should be able to be used by both left and right handed persons, and 95% of the population including both men and women between the ages of 20-60 years.

12.2 Linmot Constant Force Magnet Spring Data Sheet

![Diagram of MagSpring and Mechanical Spring](image)

**Working Range**

In the relaxed state, the slider is approximately centered in the slider, while the working end of the slider extends approximately out of the end of the slider. Fundamentally, however, both ends of the slider can be used to mount loads. From this rest position, the slider can be pulled or pushed out of the slider in both directions. The force in the slider passes from zero to the nominal force within a minimum length. The working stroke then continues with a constant force. This span position (SP) describes the distance between the working end of the slider and the end of the slider at the beginning of the constant force range.

**Mounting**

The slider can be mounted via the screw thread, or with a clamp, as desired. There are appropriate mounting flanges for both sides. When attaching the slider to the load fixture, care should be taken that any backlash error can be compensated for with a flexible coupler.

**Combination with Helical Spring**

The above illustration shows a vertical arrangement of an HSP load guide together with a MagSpring. The MagSpring provides a load at the reacting force. The weight load is balanced by the MagSpring and the linear motor thus bears less load. If the electrical power supply is interrupted, the MagSpring supports the load, or moves it into a stable position.

**Materials**

- **Slider**
  - Chromium-Nickel Steel K14351
- **Ears**
  - Iron: electrosav hard plated
- **Bearings**
  - POM based