

Development of novel liver retractor and retraction technique for use in  
single-port laparoscopic Nissen Fundoplication  
The TLR150 Liver Retractor

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## *Abstract*

**Background:** Laparoscopic Nissen Fundoplication has gained acceptance as the gold-standard for treating gastroesophageal reflux disease. There is a desire for a true single-port laparoscopic Nissen Fundoplication, but the liver retractor must first be replaced. In this article, we present a novel liver retractor as well as a modified retraction technique that allows for single-port laparoscopic Nissen Fundoplication to be performed.

**Materials and Methods:** A biocompatible two state Delrin 150 liver retractor with stainless steel torsional springs was constructed for use in single port Nissen Fundoplication. The TLR150 liver retractor can be converted between a deployment state for insertion through a 12 mm laparoscopic port and a retraction state to retract the outer edges of the liver left lobe.

**Results:** The mean retraction height achieved with our liver retractor was 39.72 mm, with a standard deviation of 2.35 mm (n=10). The liver retractor adequately exposed the gastroesophageal junction in an ex-vivo anatomical model.

**Conclusions:** This retractor can be inserted through the 12 mm laparoscopic port, and in combination with our modified procedure has shown potential for the retraction of the left lobe of the liver.

## *Background*

With up to 50% of the population experiencing symptoms of gastroesophageal reflux disease (GERD) at least once each month<sup>1</sup>, developing successful treatment methods for the disease is an area of intense interest. Currently, the most widely accepted treatment options include medical management (often with proton pump inhibitors) as well as open or Laparoscopic Nissen Fundoplication (LNF). Comparisons of the available treatment methods have revealed that LNF is more cost effective than medical management<sup>2</sup> and carries a lower risk of complications than open surgery.<sup>3,4</sup> These results, along with surgeons' positive perceptions of the procedure<sup>5</sup> have solidified LNF as the gold-standard for the treatment of GERD.<sup>6,7,8,9,1,10</sup>

A traditional LNF requires as many as five individual incisions (Figure 1)<sup>11</sup>. However, the reduced risk of complications associated with LNF compared to open surgery<sup>4</sup> has prompted attempts to minimize the number of incisions used, and LNFs are now routinely performed using only two incisions; one in the umbilicus where the primary port is placed, and a second located in the anterior abdomen for the Nathanson liver retractor (Figure 2). Since the benefits associated with a reduction in the incisions are significant, it is plausible that eliminating the incision for the Nathanson would provide additional improvements to patient outcomes.

The idea of a single-port Nissen Fundoplication (SPNF) is not the first attempt to perform true single-incision laparoscopic surgery. Various laparoscopic procedures have recently transitioned to the single-incision technique, including: sleeve gastrectomy, colorectal resections, transvesical simple prostatectomy and appendectomy.<sup>12,13,14</sup> In each of these cases, modifications to the surgical procedure or novel surgical tools were required to facilitate the transition to a single-port technique. These cases also bolster the argument that eliminating all unnecessary incisions is beneficial to patient outcomes. To develop a suitable protocol for SPNF, the primary hurdle is retraction of the liver without using a Nathanson liver retractor. This report documents our experience with the design and implementation of a novel liver retractor and modified surgical technique that allows for a true single-port laparoscopic Nissen Fundoplication.

## *Materials and Methods*

### *TLR150 Design*

True single incision laparoscopic upper GI surgery through the umbilicus requires a method for retracting the left lobe of the liver without creating a separate incision. One such method involves inserting a collapsible device through the 12 mm laparoscopic port that will open inside the abdominal cavity to provide optimal surface area for liver retraction. The Delrin 150 trans-umbilical liver retractor (TLR150) is a two state retractor, one state for retraction of the liver left lobe (Figure 3) and another state for deployment through the 12 mm port (Figure 4). The TLR150 consists of three connected segments: the crus arm (Supplemental Figure 1), abdominal arm (Supplemental Figure 2), and base rod (Supplemental Figure 3). Each segment was constructed from polyacetal homopolymer, Delrin 150 rods (Professional Plastics, Fullerton, CA) of 11.1 mm diameter, stainless steel torsional springs (Sparco, Millington, TN), and EPO-TEK 302-3M biocompatible epoxy (Epoxy Technology, Billerica, MA) using a mill and lathe. Delrin has been used for heart valve occluders, total hip replacements, and brain microelectrodes and does not systematically degrade from long-term exposure to biological fluids and cyclic loading.<sup>15,16,17</sup> Thus, the designed retractor is biocompatible, but is meant for one-time use due to the exposed hinge that could sequester biological fluid during sterilization processes.

Stainless steel torsional springs inserted inside a hollow cylinder (Supplemental Figure 4) connect each arm to the base rod and serve as the hinges for arm rotation (Figure 5). The hollow cylinders were constructed by drilling a 4.2 mm diameter hole in a Delrin rod, followed by turning down the rod the outer diameter to produce a 0.65 mm thick hollow cylinder. The two hollow cylinders were friction fit into holes drilled into each end of the base rod. The torsional spring has two legs, one on each end, with one leg secured to one of the retractor arms and the other leg secured to the base rod. Each hollow cylinder has a carved slot that allows one of the legs of a torsional spring to slide through it. An additional slot of the same size was cut into each side of the base rod for securing the same torsional spring leg. A 7 mm slot was carved into each arm rod in order to secure the opposite leg. The angular rotation of the arms was restricted to the deployment and retraction configurations by a restriction slot carved into the base rod and a peg (Supplemental Figure 5) connected to each arm and fitted into the restriction slot (Figure 5). The peg was cut from an 11.1 mm diameter Delrin rod turned down to 1.5 mm in diameter. Thus, the arm rotation requires the peg to be within the carved slot, which is set between the straight deployment configuration and 45° or 135° depending on the arm. All edges were filleted and the ends of each rod were rounded for ease of insertion through the 12 mm port and minimization of internal tissue trauma. The step-wise procedure for combination of each part follows:

1. Insert hollow cylinders into friction fit holes drilled into each end of the base rod
2. Insert torsional springs through the aligned hollow cylinder slots, with one of the spring legs sliding through the hollow cylinder and base rod slots
3. Insert restriction slot pegs into friction fit holes drilled into the arms
4. Fill slots for the torsional spring legs in the torsional arms and base rod with biocompatible epoxy
5. Align arms with the torsional springs and hollow cylinders, align pegs with the restriction slots carved in the base rod
6. Press the arms and base rod together, with the torsional spring legs in their respective arm slots and the pegs in each restriction slot
7. Clamp the arms to the base rod at each hinge; cure the biocompatible epoxy at 65°C for 3 hours.

### *Deployment Procedure*

For insertion into the abdominal cavity, a suture is first attached to the left crus of the diaphragm, pulled back out the laparoscopic port, and threaded through the suture passage of the crus arm followed by the suture passage of the abdominal arm. Next, each arm is turned in line with the base rod into a straight conformation for insertion through the laparoscopic port, increasing the torsional energy in the springs. Once inserted through the laparoscopic port, the torsional springs release the stored energy by rotating the arms back to the original retracted configuration. To deploy the retractor, the surgeon positions it under the liver and threads the suture through the abdominal wall. Outside of the abdominal cavity, the suture is pulled until the left lobe of the liver is sufficiently retracted, and the suture is clamped in place for the remainder of the surgery. Removal of the retractor from the abdominal cavity is performed at the conclusion of the procedure through the incision of the laparoscopic port after the port has been removed.

In order to validate that our retractor is able to provide sufficient retraction for SPNF to be performed, we ran tests using an anatomically accurate liver model. The suture attachment points at the left crus and abdominal wall were also modeled, and a retraction force was applied to the suture. The distance between the superior surface of the stomach and the inferior surface of the liver was measured using a digital caliper. The relative spatial distribution of the stomach, liver, left crus, and suture exit point were approximated based on observation of the deployment procedure in a pig that was used for medical student training of other surgical procedures, and not sacrificed for the purposes of this study.

### *Results*

The results from the anatomical model testing of the TLR150 can be seen in Figure 6. The mean retraction height achieved was 39.7 mm with a standard deviation of 2.35 mm (n=10). The retracted and non-retracted positions of the LTR150 in the anatomical model can be seen in Figure 7 and 8, respectively. As indicated in Figure 8, the LTR150 sufficiently retracts the liver as indicated by the exposure of the gastroesophageal junction.

### *Discussion*

As surgical techniques continue to be developed with fewer incisions than their predecessors, it is important to analyze both the additional benefits to patient outcome and the cost-effectiveness of the technique in comparison to the current gold-standard for treatment. Without cost effectiveness studies, it is easy to adopt new technologies that may not be providing additional benefits to the patients. This point is exemplified by the fact that robot-assisted Nissen Fundoplication was found to have no significant benefits over conventional LNF while adding an additional \$1310 and requiring an additional 47 minutes in surgery.<sup>18</sup> In the case of LNF, cost effectiveness studies have previously demonstrated the superiority of LNF over open surgery as well as medical management.<sup>9,7,6</sup>

Another benefit of SPNF over conventional LNF is the exclusive use of a transumbilical incision for the operation. An incision through the umbilicus<sup>19</sup>, which is composed of scar tissue, reduces the risk of incisional morbidity. The insertion of the Nathanson liver retractor also carries an elevated risk for trauma due to the location used for insertion. Trocars (or other instruments) in the anterior abdomen may result in damage to the epigastric blood vessel, which runs on either side of the midline.<sup>12</sup> Finally, SPNF improves the cosmetic outcome of the surgery, as the incisional scar is not readily visible after healing has occurred. This would improve patient perceptions following the surgery, as well as preserve self-confidence in younger individuals who receive SPNF.

Additional surgical techniques such as Natural Orifices Transluminal Endoscopic Surgery

(NOTES) have gained theoretical popularity as a method of reducing incisions. It is the perception of surgeons that NOTES still carries too high a risk of severe complications to trump SPNF as the ideal surgical technique.<sup>5</sup> Additionally, it is our opinion that the observed benefits of LNF over conventional Nissen Fundoplication will be amplified through the use of SPNF.

While this report focuses on the use of a novel liver retractor to perform SPNF, it is conceivable that the device and deployment/retraction technique could be applied to other surgeries that currently involve an incision for insertion of the Nathanson liver retractor. LAP-BAND gastric banding placement, transperitoneal nephrectomy, and giant hiatal hernia repair are some of the most common operations that could benefit from the techniques outlined in this report.<sup>20,21,22</sup>

As a testament to the interest in the developing of a technique that allows SPNFs to be performed, we cite another research group who recently reported on *The Istanbul Technique*, a novel method of retracting the liver for Nissen Fundoplication without using the Nathanson retractor.<sup>13</sup> In this report, the authors utilize a similar retraction technique, but replace our novel retractor with a Penrose Drain. Additionally, the *Istanbul Technique* calls for attachment to the left triangular ligament of the liver rather than the left crus of the diaphragm. Because of the obvious similarities between the *Istanbul Technique* and the technique described in this report, their success serves as support and reaffirms our retraction technique. In addition, we theorize that the compact, standardized design of our retractor will help address the issue of additional operating time when performing a SPNF.

One major limitation of this study is the lack of in-vivo testing of the LTR150. Using the anatomical model provides validation as a proof-of-concept, but lacks many of the variables associated with performing a true SPNF. Future studies involving the LTR150 should focus on its use in a clinical setting to conclusively validate the deployment procedure and retractor design. However, the similar technique outlined in *The Istanbul Technique* partially reconciles this limitation, as it validates the major concepts behind our technique.

### Conclusions

In conclusion, the TLR150 can be successfully inserted and deployed through the 12 mm laparoscopic port. The modified retraction technique developed for the TLR150 was shown to be capable of adequately retracting the liver in an anatomical model. In the future, a retractor such as the TLR150 could be used to facilitate additional surgeries in the transition to single-port laparoscopic surgery.

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Figure Legends

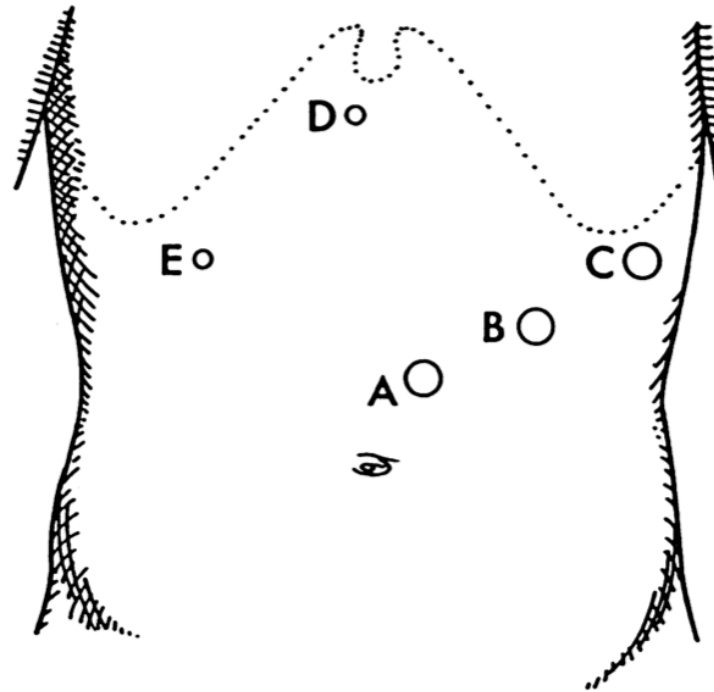
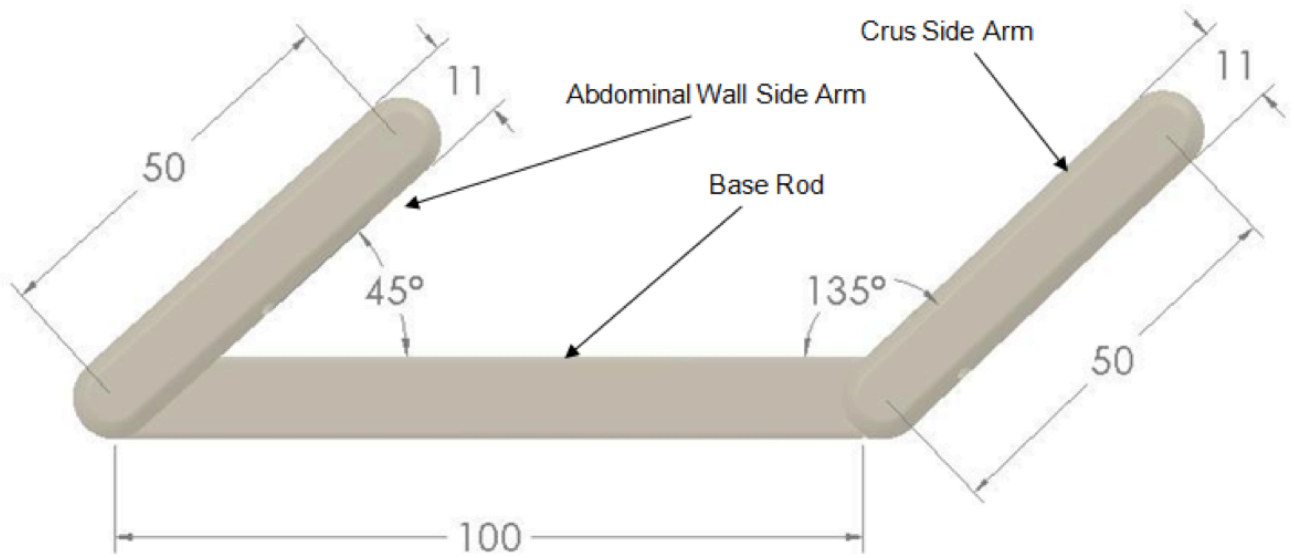


Figure 1 - Location of laparoscopic ports for Nissen Fundoplication. Large circles indicate 10 mm ports, small circles indicate 5 mm ports. (Taken from Jamieson, et al.)



Figure 2 - Nathanson Liver Retractor used for two-port LNF. (Cook Medical Inc.)



*Figure 3 - Retraction configuration used to move the left lobe of the liver out of the surgeon's field of view.*



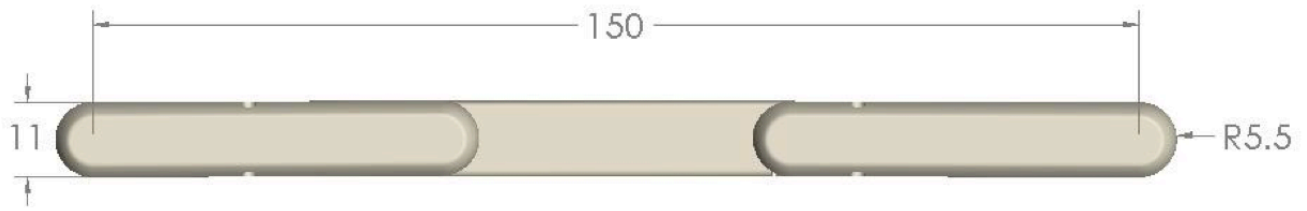


Figure 4 - Deployment configuration. Arms are rotated into linear pattern for insertion through the laparoscopic port.

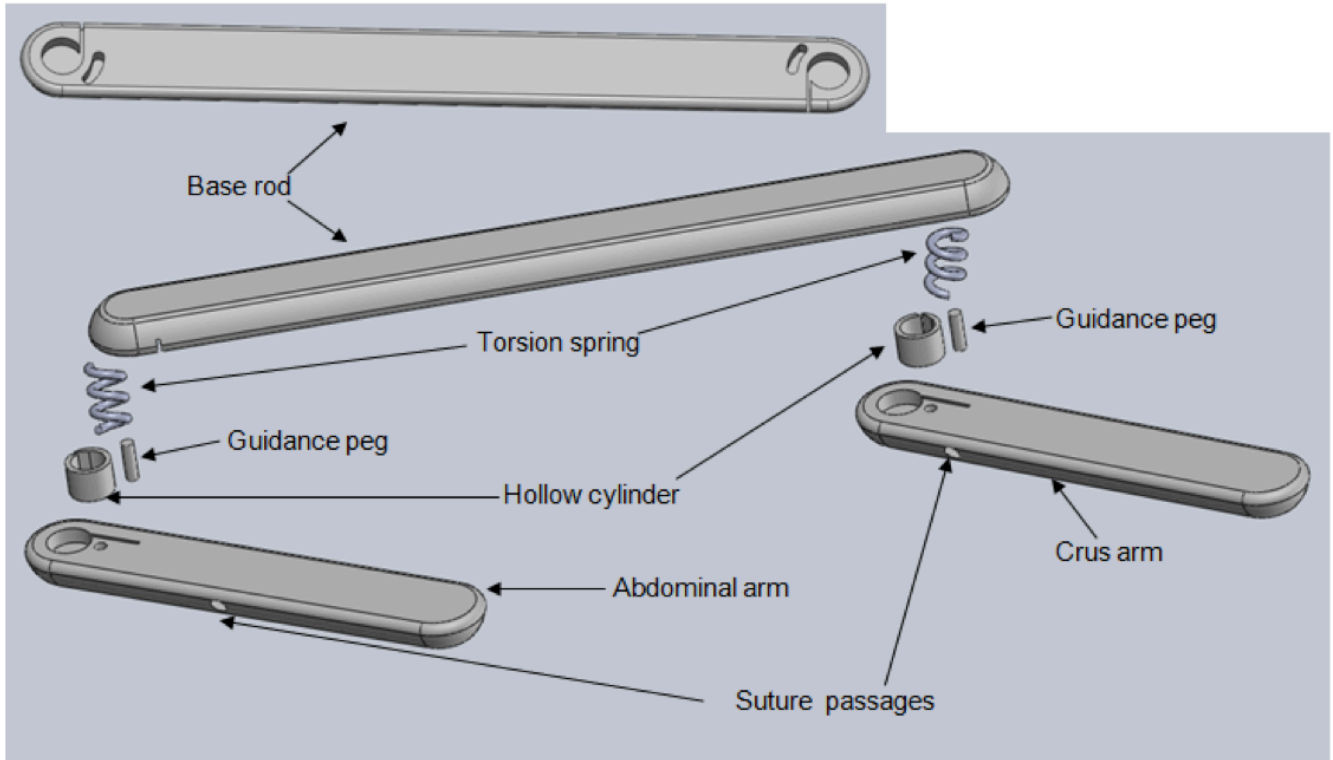


Figure 5 - Exploded Solidworks representation of each component of the retractor.

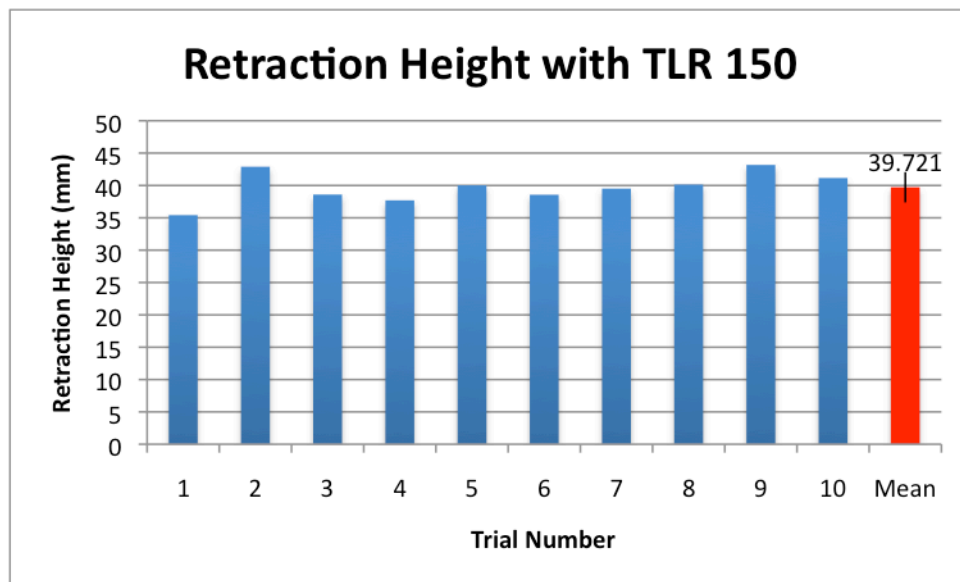


Figure 6 - Retraction height using TLR 150 as measured from superior face of stomach to inferior face

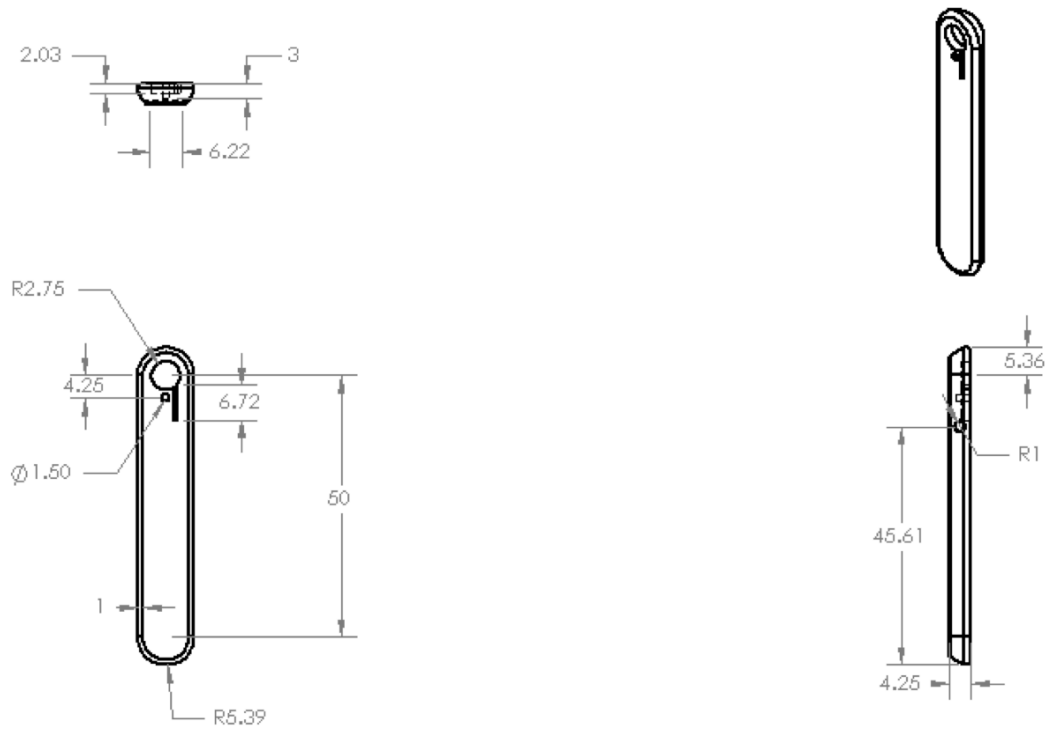
*of liver in anatomical model.*



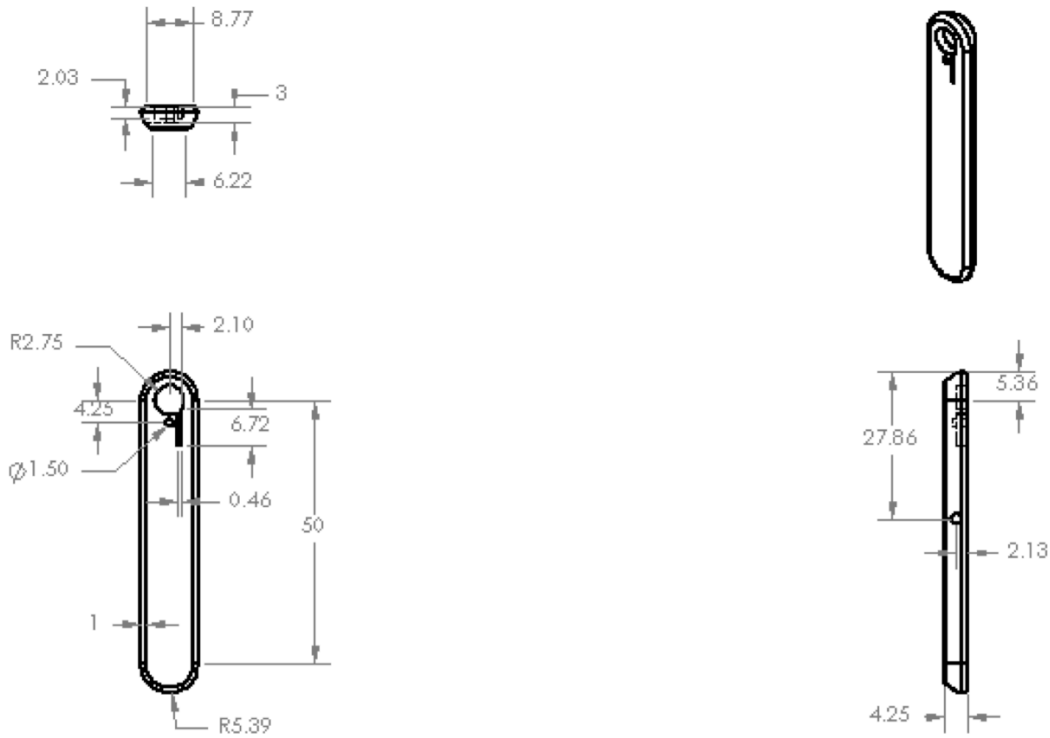
*Figure 7 - Non-retracted position of TLR150 in anatomical model.*



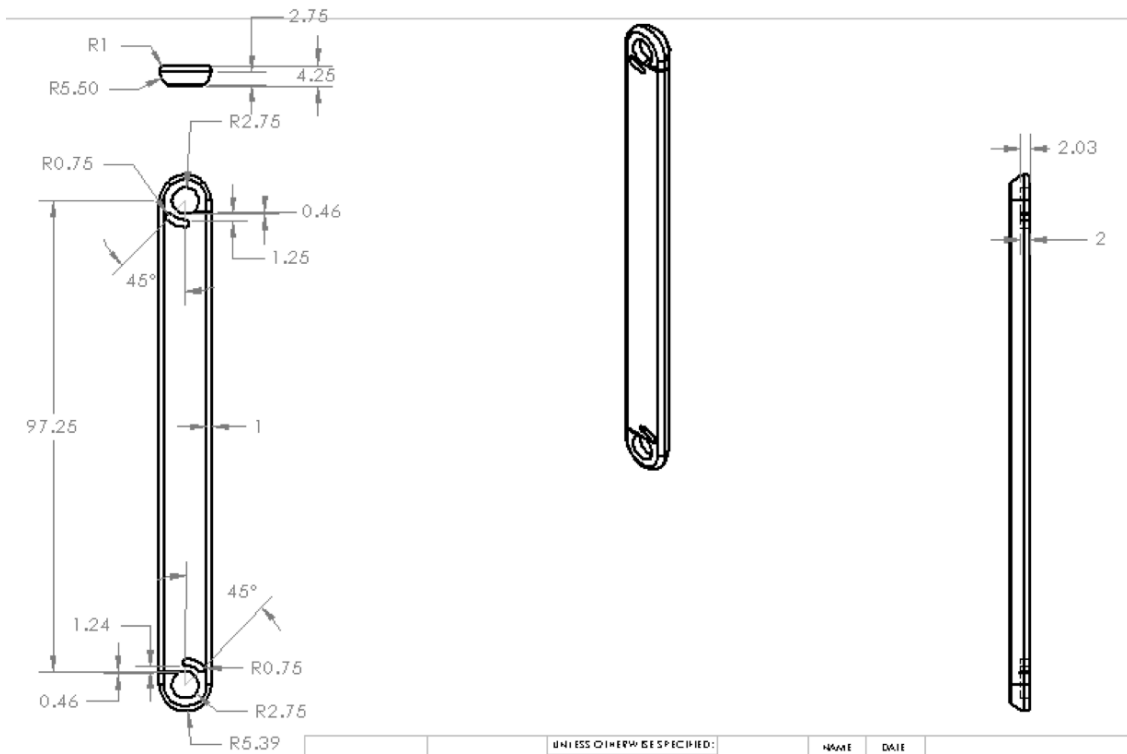
Figure 8 - Retracted position of TLR150 in anatomical testing. Note the exposure of gastroesophageal junction.



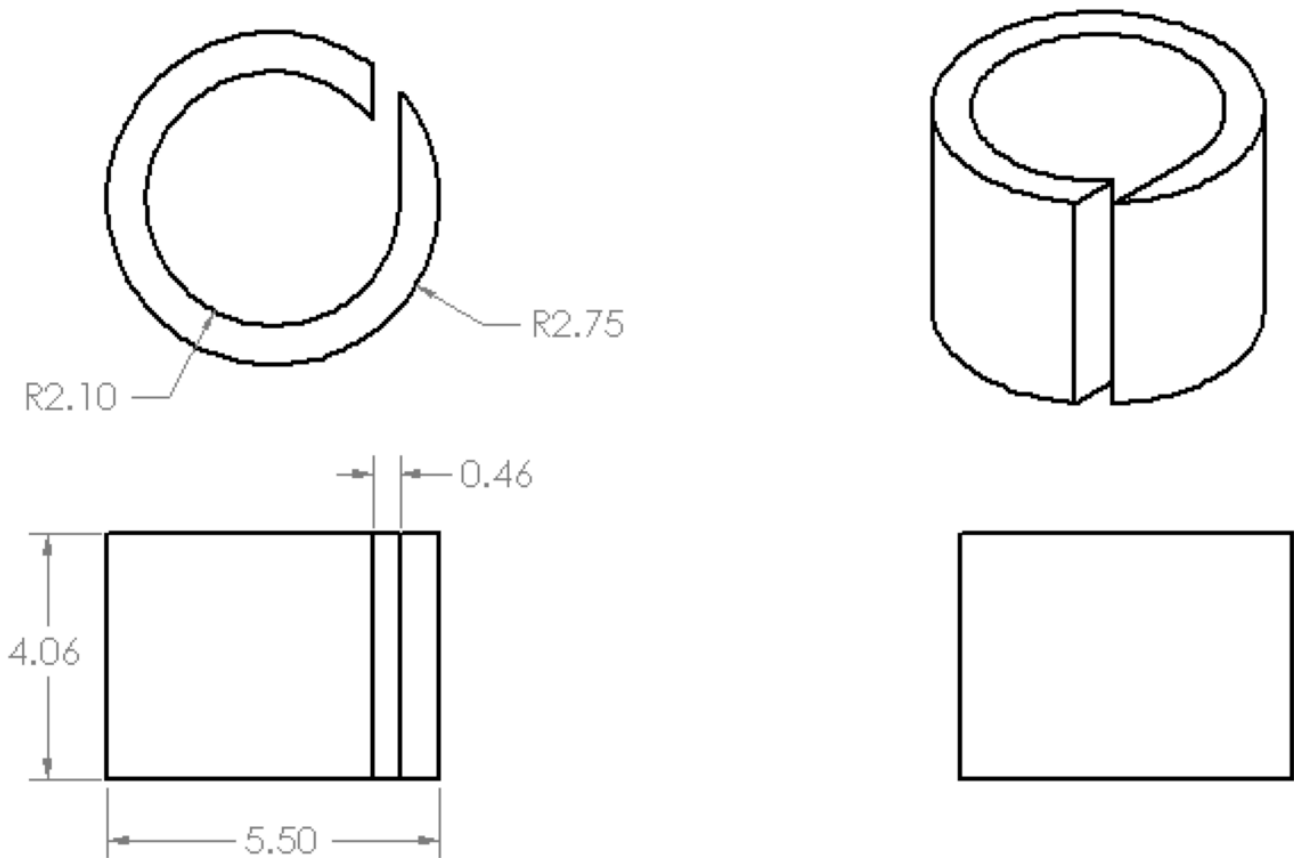
Supplementary Figure 1 - Crus arm four-view dimensioned drawing with precision to the hundredth of the mm. Hidden lines are represented as dashes.



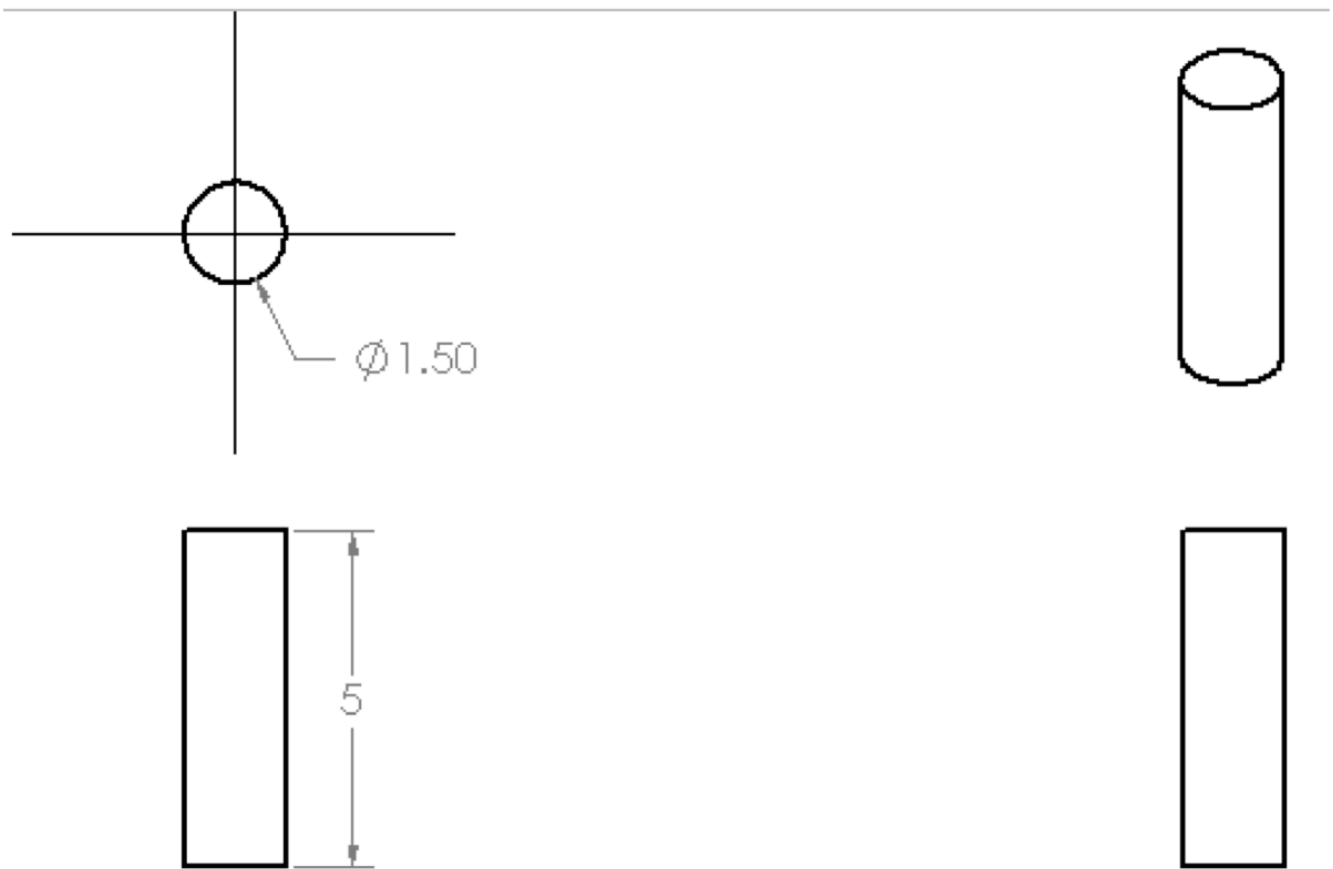
Supplementary Figure 2 - Abdominal arm four-view dimensioned drawing with precision to the hundredth of a mm. Hidden lines are represented as dashes.



Supplementary Figure 3 - Base rod four-view dimension drawing with precision to the hundredth of a mm. Hidden lines represented as dashes.



*Supplementary Figure 4 - Hollow cylinder four-view dimensioned drawing with precision to the hundredth of a mm. Torsional spring fits inside of cylinder with one leg passed through the cylinder's cut slot.*



*Supplementary Figure 5 - Guidance peg four-view dimension drawing with precision to the hundredth of a mm. Peg fits inside of guidance channel carved into the base rod to guide arm rotation between the deployment and retraction configurations.*

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