

## Product Design Specifications

# Liver Retractor

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**Team Members:**     **Kevin Hanson**, *Team Leader*  
                              **Kara Barnhart**, *Communicator*  
                              **Dan Jonovic**, *BWIG*  
                              **Nick Ladwig**, *BSAC*

**Client:**                 **Jon Gould, MD**

**Advisor:**             **Professor Mitch Tyler**

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**Function:** This device is to be used for liver retraction during a SILS<sup>1</sup> Nissen fundoplication<sup>2</sup>.

It should retract the left liver lobe of the liver to expose the gastroesophageal junction, allowing for access to the stomach and esophagus. The device needs to be deployed and removed through a 12mm laparoscopic port

**The device should:**

- Insert through a 12mm laparoscopic port
- Deploy in under 5 minutes
- Maintain retracted position without:
  - additional incisions
  - use of an additional laparoscopic port
  - resting on the stomach or esophagus
  - obstructing the view of the gastroesophageal junction
  - changing conformation
- Retract the left liver lobe 10cm or within 1cm of the abdominal wall
- Evenly distribute the liver weight

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<sup>1</sup> SILS: Single Incision Laparoscopic Surgery

<sup>2</sup> **Nissen:** A surgical procedure that wraps a portion of the stomach around the esophagus. The procedure is performed to treat gastroesophageal reflux disease (GERD) as well as hiatus hernias.

# Design requirements

## 1. Physical and Operational Characteristics

- a. *Performance requirements:* The weight of the liver should be evenly supported by the retractor each time it is used and accommodate a variety of human liver sizes and weights.
- b. *Safety:* The device should be free of sharp edges or other protrusions that could cause internal trauma.
- c. *Accuracy and Reliability:* The device should retract the liver within 1cm of the top of the abdominal wall, about 10 cm from the lower edge of the liver. Once deployed, the device should not change conformation unless intentionally manipulated by the surgeon.
- d. *Life in Service:* The device will need to last the length of the surgery, 2 hours. It should be reusable with proper sterilization procedures<sup>i</sup>.
- e. *Shelf Life:* The device needs to be capable of being stored at room temperature in a sterile environment for at least one year.
- f. *Operating Environment:* The device should be able to withstand surgical conditions<sup>ii</sup>.
- g. *Ergonomics:* The device should be inserted, maneuvered, and retrieved using laparoscopic instrumentation.
- h. *Size:* The diameter must be less than 12mm for insertion and deploy to evenly distribute the force of the liver<sup>iii</sup>.
- i. *Weight:* The weight should be under 150g.
- j. *Materials:* Stainless steel 304 or 316 should be used whenever possible. Sutures may be used for attaching the retractor.
- k. *Aesthetics, Appearance, and Finish:* The device should appear simple to operate and smooth to not cause injury upon insertion.

## 2. Production Characteristics

- a. *Quantity:* One prototype.
- b. *Target Product Cost:* Under \$500 for a prototype but up to several thousand for a reusable commercial product.

### 3. Miscellaneous

#### a. *Standards and Specifications:*

As “a manual surgical instrument for general use”, this device is classified under general and plastic surgery devices from section 878.4800 of the FDA’s Modernization Act. This exempts it from premarket requirements as defined by the FDA Center for Devices and Radiological Health. This device falls under category of “investigational device exemptions,” unless marketed for profit.

#### b. *Customer:* Would prefer:

- Minimization of work required to deploy/retrieve device and retract liver
- Attachment of the device with sutures through the abdominal wall and left crus

#### c. *Patient-related concerns:*

This device should not be used on obese patients due to complications with high fat content around the liver. The device must adequately distribute the load of the liver to minimize pressure applied and not cause trauma to the liver. It also must not injure the patient during its use.

d. *Competition:* Cook medical supplies the Nathanson liver retractor for traditional laparoscopic Nissen procedures which requires its own incision. It is sterilizable and costs approximately \$500.

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<sup>i</sup> Sterilizing techniques include: a) moist heat by steam autoclaving, b) ethylene oxide gas, and c) dry heat.

<sup>ii</sup> The surgical environment will entail the human internal environment with 15 mmHg CO<sub>2</sub> and 37°C.

<sup>iii</sup> Average liver dimensions: greatest transverse measurement 20 to 22.5 cm, vertically 15 to 17.5 cm., greatest anteroposterior diameter 10 to 12.5 cm