Product Design Specifications

Liver Retractor

February 6, 2009

Team Members:	**Kevin Hanson**, *Team Leader* **Kara Barnhart**, *Communicator* **Dan Jonovic**, *BWIG* **Nick Ladwig**, *BSAC*
Client:	**Jon Gould, MD**
Advisor:	**Professor Mitch Tyler**

Function: This device is for use in a single incision surgery such as Nissen fundoplication – a process 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. It should retract the left liver lobe to expose the gastroesophageal junction, allowing for free access to the stomach and esophagus. It needs to be capable of being both safely deployed and removed through a 12mm laparoscopic port.

Client requirements (itemize what you have learned from the client about his / her needs):

- Deployment
  - In the human body (i.e. no attachments through the umbilicus / port}
  - Setup in under five minutes (current devices take one minute)
    - Should be easy due to limited mobility of instruments in the abdomen
  - Cannot rest upon the stomach or esophagus
  - Liver should be retracted within 1cm of the abdominal wall (10cm from stomach)
  - Fits through a 12mm laparoscopic port
- Materials
  - The use stainless steel or aluminum is ideal
  - Must withstand up to 15 mmHg in abdomen
  - The use of silk sutures is available
- Human considerations
  - The liver weight needs to be evenly distributed due to fragility
  - The procedure is much more difficult in the obese
  - View of the esophagus cannot be obstructed
  - A variety of liver sizes need to be considered

Design requirements

1. Physical and Operational Characteristics

a. *Performance requirements*: The device may be either single use or reusable. If reusable, it should be available for use after sterilization. The weight of the liver should be supported evenly by the retractor each time it is used. It also must accommodate a variety of human and liver sizes and weights.

b. *Safety*: The device needs to be non-toxic to humans and biocompatible as it will go inside the body. It needs to satisfy all relevant FDA standards including appropriate labeling (name, address and qualifier for manufacturer, intended use, directions for use, net quantity, warning statements of safety hazards, and contain the phrase "CAUTION Investigational device. Limited by Federal (or United States) law to investigational use"). The device also needs to be free of sharp edges that would cause significant internal trauma (including puncturing the chest cavity).

c. *Accuracy and Reliability*: The device needs to retract the liver to the top of the abdominal wall, which is an approximate distance of 10 cm from the lower edge of the liver depending on the person. This needs to be done once during the surgery, and can be within 1 cm of the top of the abdominal wall.

d. *Life in Service*: The device will need to last the length of the surgery, which is about 2 hours. The device can either be a disposable device made for one-time use or, preferably, can be reusable.

e. *Shelf Life*: The device needs to be able to be stored at room temperature in a sterile environment for at least one year.

f. *Operating Environment*: The device should be able to:

- Withstand an environment high in CO_2 at15 mmHg
- Be used at body temperature (37^o C)
- Withstand sterilizing conditions (either steam and heat or sterilizing gas and IR)
- Be held by surgeons
- Withstand corrosion from body fluids and air

g. *Ergonomics*: The device should be easily maneuverable during deployment and removal using laparoscopic instrumentation.

h. *Size*: The device must attach to a deploying tool that together fit through a 1.2 cm diameter laparoscopic port and reach from the umbilicus to the liver. Inside the abdominal cavity, the deployed, self-supporting device must be large enough to evenly distribute retracting force on the liver without being in the way of the surgeon's tools and line of view. 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.

i. *Weight*: The weight of the self-supporting device inside the patient should not cause trauma to internal organs and tissues.

j. *Materials*: Must be biocompatible, non-toxic, and durable to the specified operating environment. Titanium, sutures, red rubber robinsons, and stainless steel are acceptable materials.

k. *Aesthetics, Appearance, and Finish*: Device material in contact with the liver and internal tissue must be smooth to not cause injury upon friction. Device shape must be compatible with 1.2 cm diameter laparoscopic port and human anatomy in order to fit inside abdominal cavity and extend from the umbilicus to the liver.

2. Production Characteristics

a. *Quantity*: For prototype, only one necessary. If reusable, less need to be produced than if single-use.

b. *Target Product Cost*: If reusable product, target price is in the thousands. If single-use, target is in the hundreds.

Initial budget for production: ~$500

3. Miscellaneous

a. *Standards and Specifications*:

Because this item is a "manual surgical instrument for general use," under section 878.4800 of the FDA's Modernization Act, this device (classified under general and plastic surgery devices) appears to be exempt from premarket requirements as defined by the FDA Center for Devices and Radiological Health. Initially, device also falls under category of "investigational device exemptions," but if marketed for profit will no longer qualify.

b. *Customer*: Would prefer:

- Minimize work after placing device inside patient
- Open to coupling device with sutures in abdominal wall
- Open to using falciform ligament for device attachment

c. *Patient-related concerns*:

Device must be safe and cause no damage to patient during its use. With fatty livers, the liver becomes heavier, increasing the risk of "sawing" through liver with improper support from device, requiring our device to adequately distribute the load to relieve liver pressure. The operation is not usually performed on obese patients due to complications with fat deposits.

d. *Competition*:

- Nathanson Liver Retractor
    - Retracts liver during laparoscopic GI surgery
    - Requires separate incision for insertion

    - Intended for sterilization and reuse
    - ~$500/ea
    - www.cookmedical.com
- Pediatric Liver Retractor
    - US Patent #7300400
    - Supports liver to make room for surgical procedures
    - Requires separate incision for insertion