Design of a Wound Protector/Retractor for Thyroid Surgery

Product Design Specifications

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Function:

Because of the risks of scarring, smaller incisions are being used in thyroid surgery. These small incisions still require retractors to keep the site visible, but most traditional retractors are incompatible with the smaller incisions. The currently used metal retractors distribute pressure unevenly across the incision site, which can cause ischemic trauma to the local tissues. On the other hand, our client tested round, flexible wound retractors used for abdominal surgery, and requests a similar device for thyroid surgery. The goal is to construct a device that is precise, provides a comfortable fit, and is capable of evenly distributing pressure across the site of incision.

Client Requirements:

Our client wants a retraction device that meets the following requirements:

- Delocalizes pressure over a large contact area
- Is compatible with varying anatomies
- Opens the wound in an "eye" shape (ellipse with pointed edges)
- Minimizes damage to tissue
- Is compatible with electrocautery (i.e. insulating)
- Ideally reusable

Design Requirements:

1. **Physical and Operational characteristics**

   a. Performance requirements: The retractor must retract the skin for a variety of anatomies with less damage and provide equal distribution of pressure around entire incision. Uneven distribution of force causes localized damage to the tissue which results in bruising and scarring. The incision should be held open by the retractor in a football shape or reasonable close (ie oval). Ideally the device should be used more than once with sterilization (see *1.f. Operating Environment*). The device also should be easily insterted and removed (see *1.g.Ergonomics*).

   b. Safety: The retractor should be able to insulate the skin from heat and possible burning by electrocautery (see *f. Operating Environment).* It must be biocompatible and cannot increase risk of infection.

   c. Accuracy and Reliability: The device should be able to maintain retraction under normal surgical conditions. The retractor must be compatible with varied anatomies. The factor safety must account for the wide range of anatomies that the device will be used with. Ideally the retractor could be used

in other surgical procedures.

d. Life of Service: If designed for one-time use (ie revised Alexis designs), the retractor must last length of surgery (approximately 60 to 90 minutes). If designed for multiple uses (ie metal spring retractor design), it must be able to withstand sterilization processes (see *1f. Operating Environment)*.

e. Shelf Life: The retractor must be durable enough to withstand room temperature and sterilization conditions (see 1*f. Operating Environment)* between uses (ie metal spring retractor design).

f. Operating Environment: While in the operating room, the retractor will be exposed to electrocautery which creates frequency upwards of 100 kHz and power of 120 watts. While being sterilized, the device will be exposed to a pressure of 15 psi and a temperature of 121oC for 15 to 20 minutes in a steam autoclave or exposure to 5 to10 percent of ethylene oxide (alkylating agent) and hydrogen peroxide and ozone (oxidizing agents) for inert chemical sterilization.

g. Ergonomics: The retractor must be easily handled by one person and apply enough pressure to hold incision open but not enough pressure to damage tissues. One person must be able to not only insert and remove the retractor at the start of the operation but also adjust the view throughout the operation. The retractor should slow down or inhibit the standard course of events in the operating room. In addition, the device should not have excess bulk as to obscure the surgical field (see *1.h. Size, 1.i. Weight*).

h. Size: The retractor must fit in 3.5 to 4 centimeter incision and have a depth of 2 to 4 centimeters. It cannot obstruct access or view of surgical field. The rings for the revised Alexis designs must be 5 by 6 centimeters. The spring constant of the metal spring retractor design must be minimized to cause the least amount of trauma.

i. Weight: The specific weight was not specified by client. The device, however, should not have excessive weight to damage tissues (approximately 8 ounces).

j. Materials: Materials must be biocompatible. If reusable (ie revised Alexis designs), the retractor must handle sterilization conditions (see *1.f. Operating Environment)*. Ideal materials provide desired device safety features (see *1.b. Safety).*

k. Aesthetics, Appearance, and Finish: The retractor should have a smooth surface to avoid skin damage. If possible, it should be transparent. The spring metal retractor must not have sharp edges that will penetrate the skin.

2. **Production Characteristics**

a. Quantity: Two reusable (ie revised spring metal retractor) or three single-use (ie revised Alexis design) retractors should be made.

b. Target Product Cost: Total budget should not exceed $500. Individual retractors should not exceed $100 per unit.

3. **Miscellaneous**

a. Standards and Specifications: The retractor must meet FDA requirements

for clinical trials. IRB approval is required for testing in animals. The device must be able to function in a tissue breast model.

b. Customer: The client would prefer a device that is easy to use and provides natural retraction with equal force. The device would ideally be reusable but not at the cost of functionality. A revised metal retractor is a last resort as countless other similar devices already exist.

c. Patient-related concerns: The retractor needs to be sterilized between uses (see *1.f. Operating Environment)* and must be small enough to reduce visible scarring from surgery (see *1.a. Performance Requirements)*. Also, the retractor must be compatible with a wide range of anatomies (see *1.c.Accurarcy and Reliability)*.

d. Competition: The Alexis O Wound Retractor and the Gelpi retractor are two products currently used in thyroid surgery. Neither is ideal; the Alexis device is too long, and the Gelpi retractor is too damaging.