

Design of a Wound Protector/Retractor for Thyroid Surgery

Project 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:

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

Design Requirements:

1. Physical and Operational characteristics

- Performance requirements:* The retractor must retract the skin with less damage and provide equal distribution of pressure around entire incision. Ideally it should be used more than once with sterilization.
- Safety:* The retractor should be able to insulate the skin from heat and possible burning by electrocautery. It must be biocompatible and cannot increase risk of infection.
- Accuracy and Reliability:* The retractor must be compatible with varied anatomies.
- Life of Service:* If designed for one-time use, the retractor must last length of surgery (approximately 2 to 2.5 hours). If designed for multiple uses, it must be able to withstand sterilization processes.
- Shelf Life:* The retractor must be durable enough to withstand room temperature and sterilization conditions between uses (if used in more than one surgery).
- 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 121°C for 15 to 20 minutes in a steam autoclave or exposure to 5 to 10 percent of ethylene oxide (alkylating agent) and hydrogen peroxide and ozone (oxidizing agents) for inert chemical sterilization.
- 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.
- 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.

- 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, the retractor must handle sterilization conditions.
- k. Aesthetics, Appearance, and Finish:* The retractor should have a smooth surface to avoid skin damage. If possible, it should be transparent.

2. Production Characteristics

- a. Quantity:* Two reusable or fifty single-use 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.
- b. Customer:* The client would prefer a device that is environmentally friendly, provides equal force and more natural retraction, and is easy to use.
- c. Patient-related concerns:* The retractor needs to be sterilized between uses and must be small enough to reduce visible scarring from surgery.
- 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.