

Breast Retractor

(02.03.06)

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Function: The goal of this project is to develop a breast retractor that will allow doctors to use both their hands during surgery. Currently, breast retractors are in the shape of a horse shoe forcing the doctor to always apply an upwards pressure against the patients skin. The breast retractor allows the surgery to be done through an incision of only about 3-4cm which pleases the patient by producing a small scar. Our client would like us to create a breast retractor that stands on its own while providing a constant upward force to the pocket, a light, and a suction source into the breast cavity. The light allows the doctor to see where he/she is cutting away tissue and the suction is to remove smoke produced from the electrocautery tool. The retractor's blade should be able to be "jacked" or "ratcheted" up so that it stays in a free-standing set position. The total traveling height will increase by increments of 0.5-1.0cm to a total height of 10.5cm. The light should be able to shine in multiple directions and the suction ports should be spread around the retractor to clear smoke out quicker. The blade should be blunt as not to slice through the rib muscle and not break any ribs when being ratcheted.

Client Requirements:

The retractor must:

- ★ Be self-standing
- ★ Be autoclavable
- ★ Contain multiple light sources
- ★ Contain multiple suction ports
- ★ Be "jacked up" to a height of 10.5cm in 0.5-1.0cm increments
- ★ Work for an inframammary operation.

Design Requirements:

1. Physical and Operational Characteristics

A. Performance Requirements – The retractor should be self-standing but have a large base surface area to prevent breaking rib bones. It must contain a light source in which light is spread around the entire cavity and multiple suction ports that are not too convoluted. The retractor should be able to be "jacked up" to 10.5cm with 0.5-1.0cm step size.

B. *Safety* – Using an electrocautery tool next to a metal retractor could cause burning undesired tissue. The force of the skin acting on the retractor should be spread across a wide base in order to prevent breaking rib bones or puncturing through rib bones and into the ribs. The retractor blade should have smooth edges and insulated in a way that prevents accidental grounding of the electrocautery tool resulting shocking of the patient and doctor. This insulation should be disposable or autoclavable. Sterilization of the device is necessary in order to keep operating site free of infection.

C. *Accuracy and Reliability* – The ratcheting mechanism must be precise within a range of 5-10%. The lights should always work and the majority of suction ports remain clear throughout each procedure.

D. *Life in Service* – The retractor should have a lifetime of up to 5 years. The light source may become out of date before the function of the retractor is compromised.

E. *Shelf Life* – The shelf life of the retractor should be 5-10 years.

F. *Operating Environment* – The retractor will be stored and operated at room temperature (~20°C). While in operation the environment will be sterile, also requiring the retractor to be sterile. Retractor must withstand autoclave temperatures of 121°C.

G. *Ergonomics* – The design of this device is to eliminate the doctor from holding onto the device. The handle should be modeled like others currently on the market.

H. *Size* – A handheld device that has a blade that can fit through an incision that is 3-4cm long that can be stretched 2-3cm wide.

I. *Weight* – The total weight of the retractor should be less than 2kg, but of course the goal is to be as light as possible.

J. *Materials* – The retractor should be made of a non-porous material. Medical grade plastic, titanium, and stainless steel are possibilities. It should also be autoclavable.

K. *Aesthetics, Appearance, and Finish* – A shiny handle that is of different material than the blade (i.e. brass) which will complement the dull steel blade. The blade should not be shiny in order to reduce glare from the light source.

2. Production Characteristics:

A. *Quantity* – Only one prototype is requested at this time.

B. *Target Product Cost* – The cost should be kept to a minimum, but a budget of \$200 is provided by the client.

3. Miscellaneous:

A. *Standards and Specifications* – The only standard at this time is requiring the blade to be constructed out of surgical grade titanium or stainless steel. The device may not cause additional harm outside of their intended use.

B. *Customer* – The client would prefer that the handle on the retractor that activates the jacking mechanism be like a brake handle on a bike. This will allow for an easy motion for the doctor to perform during surgery.

C. *Patient-related Concerns* – The retractor will need to be autoclaved between uses in patients.

D. *Competition* – ASSI Gram and Sheffmed are companies that make current devices which are very similar to what our client is requesting.