# Breast Pedicle Protector

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**Abstract**

During breast reduction surgery, the surgeon requires an assistant to hold the breast in place while he/she cuts away the excess breast tissue. Working around the assistant while maintaining the breast position and ensuring both breasts are reduced evenly is difficult and time consuming. The goal of this project is to design a device that will hold the breast in place during surgery and protect the breast pedicle, the tissue that supplies blood and nerves to the nipple. The device will surround the breast pedicle with needles that serve as a guide for the surgeon to cut along. The device should adjust to fit each patient. The use of this device will eliminate the need for an assistant and thus increase the surgeon's precision and decrease the time required to complete the procedure.

## Product Design Specifications

The final design needs to meet several physical and operational requirements. The device needs to adjust to each patient. The width should adjust between 5 cm and 10cm. While it would be acceptable for the length to be a fixed 8 cm, it would be desirable to have the length cover a range from 6 cm to 12 cm. The adjusting mechanisms should be accurate within 5-10 mm. The needles protruding from the device should be approximately 10 cm long and be placed no more than 1 cm apart. The needles should be 3-4 mm in diameter to easily penetrate the breast tissue and not deform due to forces applied during surgery. The tip of the needle should be rounded similar to a knitting needle to avoid excessive tissue damage. Ideally, the device will be made entirely of stainless steel. Finally, the device needs to be operable by one person.

## Background

### *Need For Breast Reduction Surgery*

Breast reduction surgery is not generally a cosmetic procedure. Surgery is needed to improve the physical, developmental, social and emotional problems that excessively large breasts cause. These symptoms are usually pressing enough to be covered under a woman's health insurance, and therefore not treated as cosmetic surgery. The abnormally large breasts are usually not created under normal conditions. The women that seek breast reduction surgery are usually entering puberty, coming out of a pregnancy, or going through menopause, which indicates that hormones usually play some role in the disorder.

The physical symptoms troubling these women vary by age. If the breasts become very large during the start of puberty, patients are diagnosed with virginal

hypertrophy (see figure 1). Girls at this age are usually between the ages of 11 and 15 and most negatively impacted by the effect the breasts have on body image, social adjustment, and self-confidence. Doctors should also be concerned about how the girls' posture develops. Women with heavier breasts, no matter what age, may also be afflicted by shoulder grooving, neck and back pain, thoracic curvatures, and upper extremity neurological symptoms due to compression of the brachial plexus. Additionally, pendulous breasts lead to issues with moisture, intertrigo, and other dermatoses due to the skin-on-skin contact.

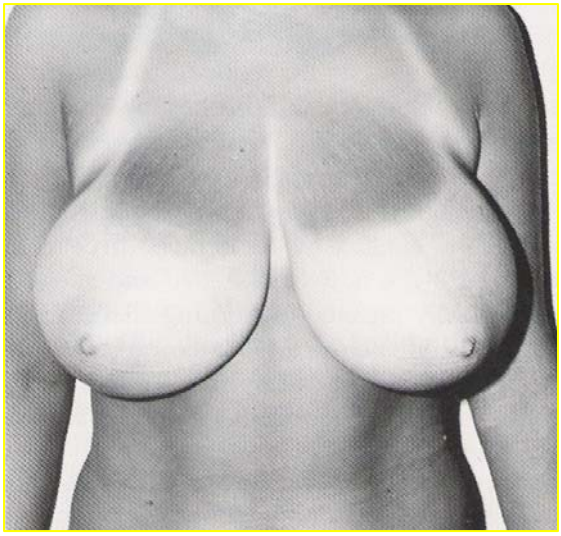

**Fig 1: candidate for breast reduction surgery, virginal hypertrophy**

Not all impairments of large breasts are immediately apparent, but some are more obvious, such as being larger than what is considered attractive at the time, appearing heavier than she actually is, or trouble finding clothing that fits properly. Furthermore, the impact of embarrassment and lack of self-worth and other such issues on a woman's psyche should not be forgotten. Larger breasts also impair physical functioning in activities such as running, golf, or tennis.

Lastly, overly full breasts prevent a timely diagnosis of tumors. The overall size reduces the area in which a cancerous tumor would be easily seen or felt. Therefore, large and advanced cancerous masses may grow without medical attention.

*Breast Reduction Procedure*

The most commonly used technique for breast reduction surgery is the inferior-pedicle technique. This procedure is used for breasts that are wide, pendulous, or just large (600 to 2000 g). It is also used for moving the nipple upwards in an otherwise normally sized breast. The technique can reduce the mass by as much as 800 g, and move the nipple-areolar complex vertically as much as 8 cm.

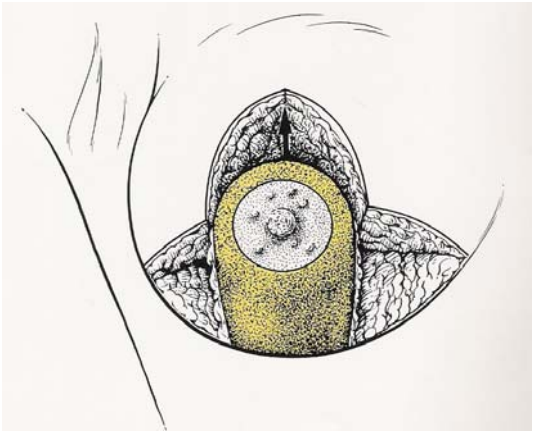

**Fig 2: where tissue will be removed**

The surgery removes adipose tissue that is directly superior, medially-inferior and laterally-inferior to the nipple-areolar complex (see figure 2). The tissue that is directly inferior is preserved. This section of tissue is known as the central pedicle and must be retained as it brings blood and nerves to the nipple and areola. Harming this region can lead to loss of feeling, lactation, and in the worst case the nipple dies and falls off. The purpose of the proposed device is to prevent any damage to the central pedicle.

The surgery begins by removing the skin around and inferior to the areola. In figure 3, the skin has been removed to reveal the central pedicle. At this stage, the device would be placed onto the pedicle to protect the blood vessels, nerves and mammary glands contained within it. The device also needs to provide a straight edge to cut against when removing the medial and lateral

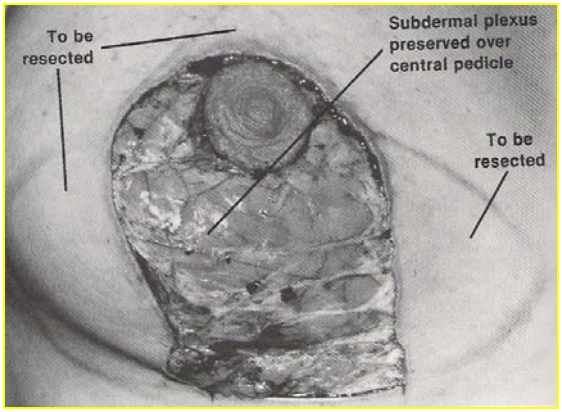


**Fig 3: central pedicle, skin removed**

inferior tissue. The current procedure involves a second pair of hands to hold the breast in place while all cuts are being made. Figure 4 shows the removed tissue and from what area of the breast the tissue came from.

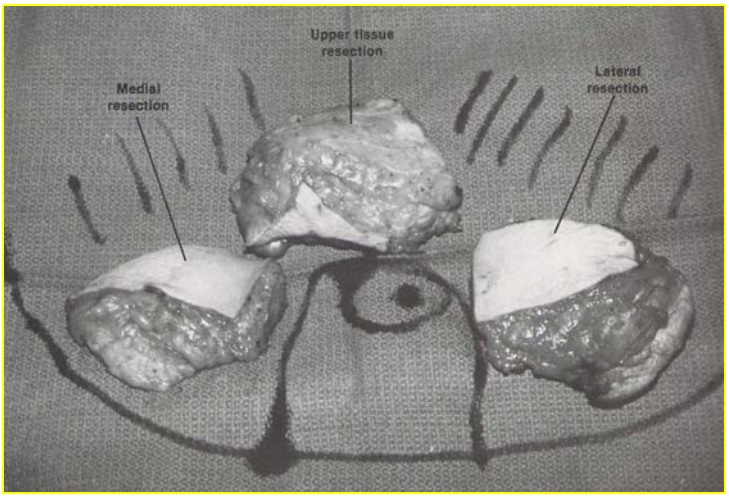


**Fig 4: dissected tissue**

## Design Alternatives

*Design 1: No Moving Parts*

The first design consists of fixed width, length, and height (see figure 5). The length and height are 8 cm and 10 cm, respectively. A length of 8 cm will fit most patients, and a height of 10 cm will cover a wide range of breast thicknesses. Width, however, must vary between 5 cm to 10 cm depending on the patient. This problem can be solved by making six devices; the first device will have a width of 5 cm and each subsequent device will increase in width by 1 cm. The two bridges that connect the two rows of needles can be used as a handle during the surgery. The opening between the bridges gives the surgeon a clear view of the areola during surgery. Since this design is simple and contains no moving parts, it is easy to construct and there is no risk of the device accidentally adjusting during surgery. It is also easy to sterilize because there are few places for debris to get trapped. Having multiple devices, however, requires more storage space and the risk of losing a device is increased. This design also does not allow for adjustment more precise than 1 cm.

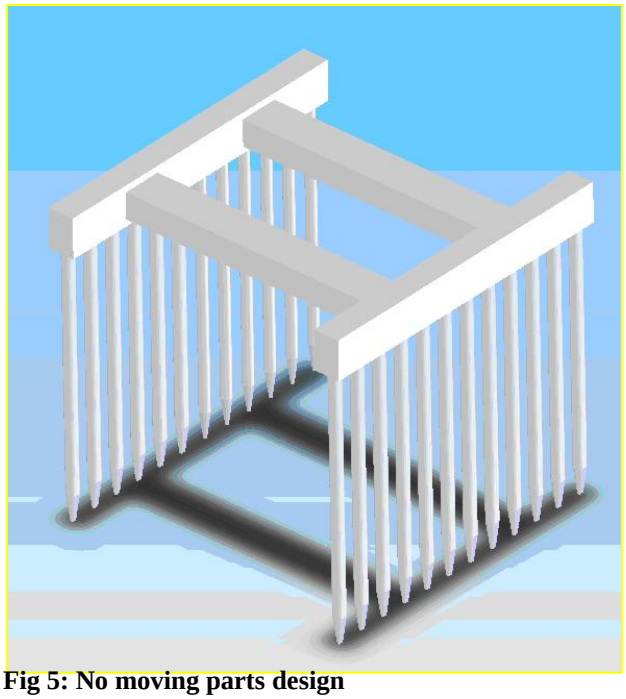

**Fig 5: No moving parts design**

*Design 2: 2D Adjustable, Snap-on Pieces*

The second design adjusts both width - and length –wise (see figure 6). The width adjusts with a sliding track and locks with a simple screw mechanism. It has a range of 5-10 cm. The sliding track is created by having the bridge on one row of needles fit inside the bridge on the other row of needles. Two of these mechanisms will be needed as the two rows of needles are connected by two adjusting bridges. The track is marked with a ruler so the surgeon can easily adjust the device to the correct dimension. The length of the device adjusts by snapping on extra needles. The main device has a length of 6 cm. Each extra snap-on needle adds a length of 1 cm giving the length a range of 6-12 cm. Making the extra pieces in 1 cm intervals allows the needles to remain less than 1 cm apart. This device is more complicated to construct than the first design, but it allows the surgeon to adjust the device more specifically to each patient. This design also requires the user to keep track of extra pieces.

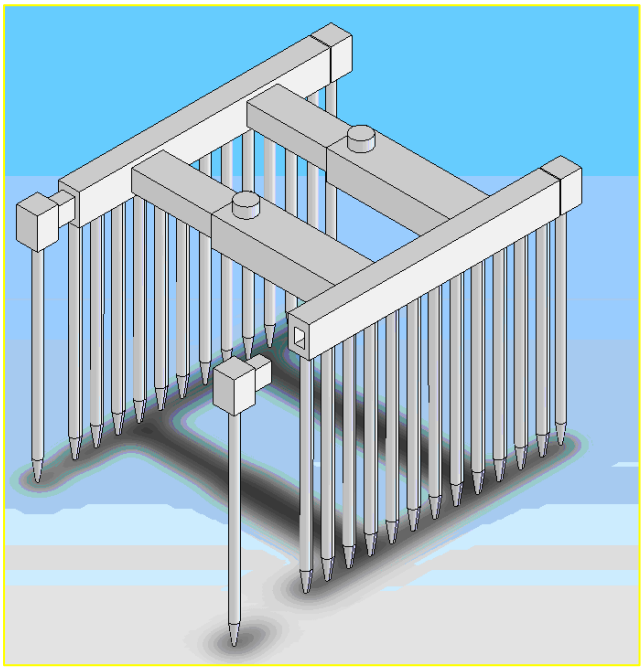

**Fig 6: 2D adjustable, snap-on pieces design**

*Design 3: 2D Adjustable, Spring Mechanism*

The third design (see figure 7) is similar to design 2, but utilizes different adjustment mechanisms. The width will be adjusted using the same track described in design 2, but it uses a spring loaded push-button mechanism as a lock instead of a screw.

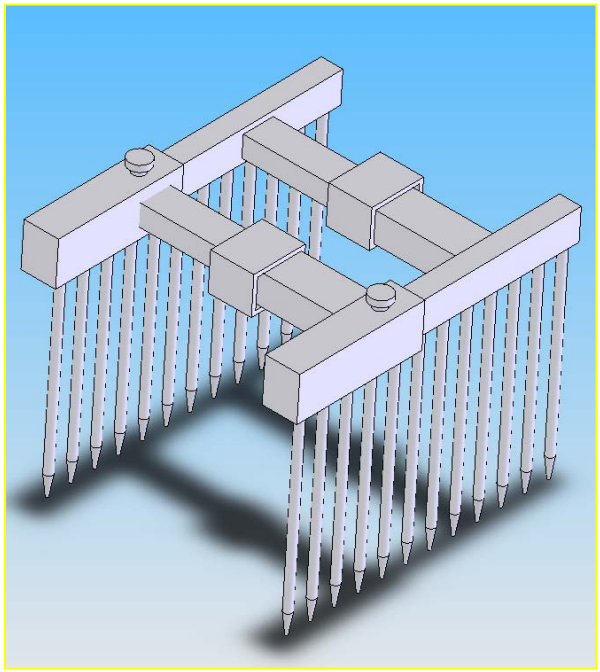

**Fig 7: 2D adjustable, push-button design**

Instead of a smooth track like design 2, the track is notched. When the button is pushed down, a spring is compressed and a tab is pushed out of the notches that serve as the locking mechanism. When the button is released, the tab falls back into the notches. The width adjusts within a 5-10 cm range. The buttons on the bridges face away from the device (towards the head and feet of the patient). This will make it possible for surgeon to push both buttons at the same time with one hand and use other hand to slide the device to the desired width. The length of this device uses a modified screw mechanism described in design 2. Within the bars running length-wise, the needles are spaced by compressed springs. When the screw is released and the length is adjusted, the springs will compress or lengthen to accommodate the 1 cm needle spacing requirement. The construction of this design is more complicated than designs 1 and 2, but it allows the surgeon even more accuracy when adjusting the device to fit the patient. This design also does not require storage of extra pieces.

**Design Matrix**

In order to choose a design to pursue, we constructed a design matrix (see figure 8). We decided the most important criterion was being able to easily adjust to the patient. We also accounted for ease of use, ease of construction, ease of sterilization and cost. Each design was scored on a weighted scale of 1 (worst) -5 (best).

| | **Weight** | **Design 1:No moving parts** | **Design 2: Snap-on pieces** | **Design 3: Push-button** |
|---|---|---|---|---|
| **Ability to adjust to patient** | **0.4** | 1 | 4 | 5 |
| **Ease of use** | **0.25** | 4 | 4 | 3 |
| **Ease of Construction** | **0.2** | 4 | 3 | 3 |
| **Ease of sterilization** | **0.1** | 5 | 4 | 4 |
| **Cost** | **0.05** | 3 | 3 | 3 |
| **Total** | **1.0** | 2.85 | 3.75 | 3.9 |

**Fig 8: Design matrix**

After carefully weighing the design constraints, cost and available time, we decided to pursue design 3: 2D Adjustable, Spring Mechanism. Although this design involves complicated mechanisms, the width and length of the device can be adjusted without any extra components, such as snap-on pieces.

**Future Work**

After choosing the final design, there is a great deal of work to be done. The final components of the adjusting mechanism have to be confirmed. Component parts, such as stainless steel for the frame and springs for the adjustment mechanism, have to be ordered and a prototype needs to be built. Further testing of the protector will be done with animal adipose tissue before our client uses the device during an actual breast reduction surgery. As there is no similar product on the market, our client is very interested in pursuing a patent.

**References**

Bostwick, J. Aesthetic and Reconstructive Breast Surgery. Mosby. St. Louis. 1983. pp. 138-143, 156-158, 184-188.

Spear, S.L. (editor). Surgery of the breast. v. 2. 2006.

# APPENDIX 1: Product Design Specifications

**Team Name**
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**Problem Statement:**
Our goal is to design a device that will hold the breast pedicle, which supplies blood and nerves to the nipple, in place during breast reduction surgery. The device will also protect the pedicle by surrounding it with spikes that mark where the surgeon will cut to remove the breast tissue.

**Client Requirements:**
- Device should be able to be adjusted for each patient
- Device should be accurate and reliable
- Device should perform current standard procedure
- Safety of patient and surgeon should be maintained
- Device should be able to be sanitized or disposable

**Design Requirements:**

**1. Physical and Operational Characteristics**

a. Performance Requirements
- Very light loading capacity
- 100-150 surgeries performed per year

b. Safety
- Sharp enough to pierce breast tissue but not harm ribs or internal organs
- Storage should cover sharp spikes
- Able to be sterilized

c. Accuracy and Reliability
- Absolute accuracy not needed
- 5-10 mm accuracy

d. Life in Service
- Unknown at this point
- Account for dulling of spikes

e. Shelf Life
- Unknown at this point
- Need some sort of container for storage and safety (sharp spikes)
- General storage container okay

f. Operating Environment
- Used by a surgeon in a surgical environment

g. Ergonomics
- Should be able to be operated by one person
- Handle/gripper needed

h. Size
- Width adjustable between 5 cm and 10 cm

- Length adjustable between 6 cm and 12 cm or non-adjustable 8 cm to 10 cm
- Height approximately 10 cm
- Spikes 3-4 mm in diameter
- Spikes approximately 1 cm apart

i. Weight
- Light enough to be handled easily by surgeon
- Heavy enough to stay in place while surgeon makes cuts
- No specific requirement

j. Materials
- Stainless steel
- Minimize dulling of spikes
- Entire device should be same material (preferably)

k. Aesthetics
- Used in surgery so aesthetics are not a major concern

**2. Production Characteristics**

a. Quantity
- One prototype

b. Target Product Cost
- Actual product cost unknown
- Project budget ideally under $500, under $1000 okay

**3. Miscellaneous**

a. Standards and Specifications

b. Customer
- Would like two working devices on hand

c. Patient-related concerns
- Device sterilized between surgeries
- Needles preferably stop at muscle, but it is acceptable to stop at ribs

d. Competition
- No similar device on market