

Product Design Specifications

Team Name

Kuya Takami, Laura Bagley, Nathan Werbeckes, Joseph Yuen

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