

Product Design Specification

Auto Suture Device

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Members:

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Problem Statement:

Our goal is to develop a device which will automatically deploy a close up of an incision to a specific region of the nose which is commonly detached in two common nasal surgeries, rhinoplasty and septoplasty. The traditional closing up procedure is tedious and time consuming for the performing surgeon, often taking 15 minutes or more. Our client would like to develop a device which will automatically close up the desired location with minimal surgeon involvement. This will cut down on surgeon's error, and make a more effective suture.

Client Requirements:

- Device should be accurate and reliable
- Device should perform current standard procedure
- Safety of patient and surgeon should be maintained
- Materials must be autoclavable and be able to be sterilized
- Can cost as much as \$300 per device

1. Physical Requirements:

a. Performance:

- i. Either a one time device or a reusable device is acceptable
- ii. Methods of loading a new suture cartridge can be addressed

b. Safety:

- i. Unnecessary sharp end or edge must be avoided
- ii. Lock should exist to prevent slipping
- iii. Suitable grip to prevent slipping

c. Accuracy and Reliability:

Comparable accuracy and reliability should be achieved by the device.

d. Life in Service:

- i. If disposable, one use only.

- ii. If reusable, a maximum number of surgeries should be performed with a single device based on further research.

e. Shelf Life:

Device will be kept in operation room at room temperature

f. Operating Environment:

- i. Device should only be used within the operating room
- ii. Function is performed in the nasal area.

g. Size:

- i. Grip: Suitable size for comfortable gripping (8 – 10cm)
- ii. Tip: Maximum length should fit in the nose (2.0-2.5cm)

h. Weight:

Must not exceed 1 lb

i. Materials:

Materials compatible with sterility: plastic, surgical stainless steel
Must be disposable or autoclavable.

2. Operational Requirements:

a. Quantity:

One prototype

b. Target Production Cost:

\$300

3. Miscellaneous:

a. Standards and Specifications:

If successful, federal standards will need to be addressed.

b. Patient-related concerns:

Must be new or sterilized before use.

c. Competition:

There are auto-suture devices but none for nasal surgery.