Product Design Specification

Auto Suture Device

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Problem Statement:

Our goal is to develop a device which will automatically deploy a purse-string suture to close an incision created on one or both sides of the septum during nasal surgery. The most common operations in which this device will be used are the septoplasty, the correction in the deviation of the septum separating the two nostrils, for improved breathing, and the rhinoplasty, the plastic surgery performed to improve the appearance of the nose. The traditional suturing procedure is done by hand which is tedious and time consuming, often taking 15 minutes or more. Our client would like to develop a device that will consistently deliver sutures to the desired location in a systematic and reproducible manner while maintaining the safety of the surgeon and patient. The device will deploy a series of sutures that go through the septum, back and forth, delivering a purse string which is usually absorbable by the body.

Client Requirements:

- √ Device should be accurate and reliable: The client requires a device that replicates the current suturing procedure that includes about 10 passes of the suture in an area of 2 cm x 2.5 cm where the lining is stripped from the septum. For the device to be effective, the device should close the area in less time than it takes to do manually. Reliability indicates that the device will not fail during the procedure and accuracy indicates that lining of the septum will be secured.
- √ Safety of patient and surgeon should be maintained: The device must contain proper safety features to ensure that the needle does not puncture the patient or surgeon while using. Also, the device should only close the desired area and not inflict any additional injury.
- √ Materials must be auto-clavable and/or be able to be sterilized: Because the device is used in a medical procedure, it must be sterilizable. Either a material that can withstand the high temperature of the autoclave (121ºC) or Ethylene oxide sterilization is acceptable which can include plastics.
- √ Can cost as much as $500 per device: The cost of operating rooms is at least $60/min. The current manual suturing of the nose takes 10-15 minutes, costing$600-$900. The device must reduce the time it takes to suture manually so there is incentive to buy the product and in turn save money spent on the operating room.

1. Physical Requirements:

a. *Performance:*

i. Either a one time device or a reusable device is acceptable
ii. The device must reduce the manual suturing time

b. *Safety:*

i. Unnecessary sharp end or edge must be avoided. The suture needle should be the only sharp edge on the device so no harm to the surgeon or patient is accidentally induced.
ii. If the device is automated, a lock should exist to prevent slipping of needle before the auto suture is activated so the suture doesn't puncture an area that it is not supposed to. If the device is semi-automatic or manual, the surgeon will have control over the placement of the needle.
iii. Suitable grip to prevent slipping should be included so the surgeon does not drop the device and inadvertently puncture the patient.

c. *Accuracy and Reliability:*

The device should be accurate in the sense that the sutures are deployed in the same manner as manually. The device should be reliable in that it can not fail during a surgery. In general, the device should be as accurate and reliable as the surgeon.

d. *Life in Service:*

i. If disposable, one use only.
ii. If reusable, the device should last for 5 years, or a maximum number of surgeries as to be determined by the performing surgeon.

e. *Shelf Life:*

Device will be kept in operation room at room temperature (25˚C)

f. *Operating Environment:*

i. Device should only be used within the operating room
ii. Function is performed in the nasal area, therefore must not be porous or contaminated. After the surgery, the device must be sterilized.

g. *Size*:

i. Grip: Suitable size for comfortable gripping (8 – 10cm)
ii. Tip: Maximum length should fit in the nose (2.0-2.5cm)
iii. Suture size: one absorbable suture is used and each pass varies between 3-5mm in length; suture passes in and out of cartilage approximately 10 times in a circular pattern.

h. *Weight:*

Must not exceed 2 lbs

i. *Materials:*

Materials compatible with sterility: plastic or surgical stainless steel grade 420 with a tempering temperatures between 204˚C and 650˚C
Must be disposable or autoclavable (must withstand 121˚C).

2. Operational Requirements:

a. *Quantity:*

One prototype

b. *Target Production Cost:*

i. Up to $300 for a disposable device that can be used on one patient only.
ii. Up to $1500 is acceptable for a re-usable device that could have a small, inexpensive disposable part.

3. Miscellaneous:

a. *Standards and Specifications:*

i. Most likely our device would fall into an FDA Class II category. This would mean before we could sell our product, we would submit a Pre-Market Approval form. Our device would then be reviewed by a panel of scientists for qualities such as meeting the devices stated standards, local and/or systemic toxicity after use, and irritation and sensitization, among other concerns. All of these can be found by visiting the FDA site. Since our device will consist of (mainly) a needle, as long as our device has a safeguard where the needle always enters and exits the skin where it is placed and there is little or no chance of accidental stabbing, there shouldn't be too much concern about meeting these standards.

b. *Patient-related concerns:*

i. The device must be sterile, either coming from a new package if disposable, or be able to withstand standard hospital sterilization techniques. These techniques can either be chemical or pressure and heat induced. Therefore, the material must be able to withstand chemical degradation along with pressures of up to 15 psi and temperatures up to 121 ^{o}C.

ii. The device must also have a safeguard (most likely a covering for the needle) where the patient or physician will not get accidentally punctured.

c. *Competition:*

i. Research of similar products has yielded devices that perform sutures automatically. These devices, though, have been designed for specific surgeries and are not able to be adapted easily to perform the sutures required by our client in the confined area of the nasal cavities. As such, our device would be fulfilling a need that could not be performed by devices currently on the market.