PROJECT DESIGN SPECIFICATIONS

#36- Fixation device for laryngeal soft tissue flap for vocal fold reconstruction
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Function:
The device will secure a perichondrial tissue flap into the lamina propria layer of the vocal folds. Insertion of this flap into the vocal fold will benefit individuals with scarred and damaged vocal folds. This fixation device should endure typical laryngeal movements that may otherwise dislodge the soft tissue flap.

Client Requirements:
- Surgical procedure should involve limited rotation of the tissue flap
- Fixation must be held for one to two weeks
- Device must be able to be inserted via minithyrotomy
- Insertion must not perforate the epithelial layer of vocal folds
- Insertion must maintain vasculature of the tissue flap
- Device must cause minimal damage to surrounding tissue

Design Specifications:
1) Physical and Operational Characteristics
    a) *Performance requirements*
        i. Must effectively secure soft tissue flap and withstand typical laryngeal movements
        ii. Must remain sterile before implantation
        iii. Must maintain fixation for 1-2 weeks
    b) *Safety*
        i. No negative biological effect
        ii. Degradation products should be biocompatible
    c) *Accuracy and Reliability*
        i. Must accurately attach to desired location inside the lamina propria

    d) *Life in Service*
        i. Minimum of one week for attachment to ensure tissue regrowth
    e) *Shelf Life*
        i. Evicel can be refrigerated for up to 30 days or frozen for extended life
        ii. Once vials are opened, glue must be used within 24 hours
    f) *Operating Environment*
        i. Within thesuperficial layer of the lamina propria of the vocal fold
    g) *Ergonomics*
        i. Glue must be easily applied viaglue applicator
    h) *Size*
        i.Applicator must be less than 2 mm in diameter
    i) *Weight*

i. Weight of 1-2 drops of Evicel is negligible

j) *Materials*

i. Composed of human fibrinogen and thrombin

ii. Fibrin glue and its degradation products are biocompatible

k) *Aesthetics*

i. N/A

2) Production Characteristics

a) *Quantity*

i. 1-2 drops per procedure

ii. Multiple procedures can be performed with one vial if done within 24 hours

b) *Target Product Cost*

i. $150

3) Miscellaneous

a) *Standards and Specifications*

i. FDA approval required for glue application

ii. IRB approval required for human testing

b) *Customer*

i. Medical schools

ii. Hospitals

c) *Patient-related concerns*

i. Biocompatibility

ii. Immune response

d) *Competition*

i. Injections or implants

ii. Previous screw prototypes