Device to Secure Endotracheal Tube in Prone Patient (PDS)

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Problem Statement:
Our project's goal is to develop an easy to use endotracheal tube securing device. The device fixes the tube in place in the mouth. Before surgery, an endotracheal tube can be inserted into the trachea to administer anesthetics or improve airflow to the lungs. During surgery, internal forces from the airway and external forces from surgical environment can move the tube in and out or side to side in the mouth. This device would prevent any unexpected movement of this kind and allow for control of movement that is required for adjustment. The device must be versatile enough to function even if the patient is on their side or face-down.

Client requirements:

- Must be compatible with all current types of endotracheal tubes of varying diameters.
- Must not restrict accessibility to the mouth or face.
- Must be sterile.
- Must apply adequate force to maintain position of endotracheal tube.
- Must be made of biocompatible materials.
- Must be easily manufactured in large quantities.

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements*: This device will have to be able to perform throughout the full length of a surgery and remain in the correct position the entire time. The device must apply adequate force towards the trachea and a stabilizing force to keep the tube in the sagittal plane. The device will also be able to hold all endotracheal tubes of 2mm-9mm inner diameters.

b. *Safety*: The device must be made of biocompatible, non-toxic materials. It is also important to make sure that the device will not cause asphyxiation or any damage to the airway. The device must comply with current FDA standards for Class 1 medical devices. It must also be able to resist chemical and physical degradation.

c. *Accuracy and Reliability*: Once in place, the device must not move more than 5 mm in or out of the airway and not more than 1.5 cm from side to side. The device will consistently hold the endotracheal tube in place for the duration of the surgery.

d. *Life in Service*: The device will be single-use and disposed of afterwards. It will function for a maximum of ten hours.

e. *Shelf Life*: Sterile packaging will be used for storage of this device. It will be stored in a hospital environment at room temperature (21˚C), normal atmospheric pressure (1 atm), and normal humidity (30-50%). The device should be able to maintain its sterility and stability in storage for five years.

f. *Operating Environment*: The device must be able to function at 37˚C and at 90% humidity in the mouth of the patient. It must be able to withstand the force applied to keep the endotracheal tube in place and must also be adjustable to be moved slightly by the surgeon for proper access to the mouth. In the case of possible jaw movement, the device must withstand 700 N of bite force. It must be compatible with water and sterilizing liquids, such as ethyl alcohol and chlorhexidine.

g. *Ergonomics*: The device must not interfere with surgery and must be easily adjustable. The set-up of the device with the endotracheal tube must be user-friendly and not require longer than five minutes.

h. *Size*: The device must be large enough to hold endotracheal tubes with inner diameters of 2mm-9mm, yet small enough to fit easily within a mouth.

i. *Weight*: The device should not weigh more than 2 ounces.

j. *Materials*: Materials used must be hypoallergenic and non-toxic.

k. *Aesthetics, Appearance, and Finish*: The shape must be cohesive with the shape of the mouth. The material should be smooth to ensure comfort for the patient and easy maneuverability.

2. Production Characteristics

a. *Quantity*: One prototype delivered, with the possibility of mass manufacturing.

b. *Target Product Cost*: The budget for this project is $100, but the target cost for the individual product is under $20.

3. Miscellaneous

a. *Standards and Specifications*: FDA Class 1 approval is required. The materials used must comply with the international ASTM plastic standards for the environment(s) described above.

b. *Customer*: The client would like the device to take up as little space as possible and fit in the mouth, allowing the face to be completely accessible.

c. *Patient-related concerns*: The device must be completely sterile upon introduction to the patient's mouth, but may be disposed of after use. Ideally, the device will cause the patient no physical discomfort and will keep the endotracheal tube in a safe position.

d. *Competition*: There are several devices currently on the market that perform a similar function. However, the facial attachment methods currently used are not ideal for our client's needs. These devices restrict access to the face and/or mouth during surgery and may not properly hold the endotracheal tube in place in the range of positions specified by our client.