

Tracheotomy Security Device Product Design Specifications

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Function: In patients who have had a tracheotomy performed, a major post surgery problem is discomfort from the tracheotomy collar. The collar must be secured tightly to keep the tracheotomy tube in place so the patient can breathe. However, if the collar is kept at the proper tension, it can cause ulcers on the patient's skin. Our goal is to design a tracheotomy strap that is comfortable, easy to clean and equipped with monitoring devices to ensure that proper pressure is exerted on the neck.

Client requirements:

- Wider, more comfortable strap around the back of the neck.
- Adjustment monitoring system for placement of straps
- Balloons filled with air or gel to increase comfort and adjustability of pressure on the back of the neck.
- Easy to maintain.
- Last for 5-7 days.

Design requirements:

1. Physical and Operational Characteristics

- Performance requirements:* One time use, for 5-7 days. Cleanliness must be easy to maintain while device is stable.
- Safety:* Must keep tracheotomy tube secured within the trachea.
- Accuracy and Reliability:* Pressure must be determined within 1mmHg, to maintain tracheotomy strap pressure. Position of securing straps on front should be monitored within 1mm.
- Life in Service:* Disposable, life span of 5-7 days.
- Shelf Life:* There are no degradable components to our design. Theoretically the device should have an indefinite shelf life when properly sealed.

f. *Operating Environment*: The device should be impervious to blood, sweat and other human secretions. The device should also allow air flow to the back of the patient's neck.

g. *Ergonomics*: 30mmHg pressure applied around the patient's neck.

****LOOK UP NECK DIMENSIONS****

h. *Size*: Adult necks are generally categorized into two sizes: 12-16 inches and 16-20 inches.

i. *Weight*: n/a

j. *Materials*: hypoallergenic materials, no skin irritants.

k. *Aesthetics, Appearance, and Finish*: Aesthetically pleasing; no rough edges as it will be in direct contact with human skin.

2. Production Characteristics

a. *Quantity*: 1-2 deliverables, eventual mass production.

b. *Target Product Cost*: below \$20

3. Miscellaneous

a. *Standards and Specifications*: FDA approval required

b. *Customer*: Optimal comfort; the strap shouldn't bunch and should aerate the back of the neck.

c. *Patient-related concerns*: The device will need to be sterilized so it needs to be easy to clean daily. After 5-7 days the device can be disposed.

d. *Competition*: The tracheostomy collar is currently used to secure the tracheotomy tube after surgery. It is manufactured by Marpac. The current model has many disadvantages that we hope to improve upon with our design.