

Product Design Specifications

May 8, 2009

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Problem Statement:

To train clinicians to perform transnasal endoscopy of the larynx, a model with realistic and anatomically correct structures of the nasal passages and larynx must be developed. Currently, training is conducted on human subjects in the form of volunteers and/or patients.

Client Requirements:

- Anatomically correct model of nasal passages and larynx
- Materials should have a compliance similar to living tissue
- Costs less than \$3000
- Force against a turbinate is painful, touching the larynx causes choking, touching the tongue base causes gagging. Feedback to the user would be helpful if contact with these structures is made.

1. Physical and Operational Characteristics

a. *Performance requirements:* Needs to accurately simulate environment and obstacles involved in transnasal endoscopy. Simulate a real face as best as possible.

b. *Safety:* The model must contain non-toxic materials. The materials included may not damage the endoscope.

c. *Accuracy and Reliability:* The model must be anatomically correct for training purposes. The model should be durable.

d. *Life in Service:* 5 years

e. *Shelf Life:* No specific requirements by client, but to be determined by materials used.

f. *Operating Environment:* Office / classroom (non-sterile).

g. *Ergonomics:* Should be small enough to place on a table or desktop.

h. *Size:* Accurate in terms of anatomy.

i. *Weight:* 25 pounds so it's light enough for one person to move by hand.

j. *Materials:* Non-toxic materials.

k. *Aesthetics, Appearance, and Finish:* The outer surface should look like a face. The inner structures should be the same color and shape as the living structures.

2. Production Characteristics

- a. *Quantity*: One.
- b. *Target Product Cost*: Less than \$3000.

3. Miscellaneous

- a. *Standards and Specifications*: Model should comply with anthropometric data.
- b. *Customer*: Voice pathologists and other medical professionals working with transnasal endoscopy and its training.
- c. *Patient-related concerns*: Any material allergies such as latex need to be taken into concern. The scope needs to be cleaned after use with the model since it is not sterile.
- d. *Competition*: Existing commercial larynx models and human subjects (volunteers and/or patients).