

# The Product Design Specifications (9/18/08)

## Larynx Model

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### Function:

Currently, silicone facial prostheses are removed at night, cleaned and stored in makeshift containers such as gift boxes, travel soap containers, etc. Sometimes they are damaged by children or pets, inadvertently discarded in hospitals or if mailed or transported glued surfaces or delicate elements such as eyelashes become disturbed from tumbling because they are somewhat difficult to secure. Anaplastologists often spend considerable time creating methods to suspend the device in a disposable container. A standardized container with modifiable inner element for orbital, nasal, or auricular prosthesis to stabilize and safeguard the prosthesis upon closure and perhaps have an antimicrobial element and/or vacuum environment would be desired by thousands of prosthesis wearers.

### Client Requirements:

- The chamber must offer UV protection for the prosthetic
- The longevity of the chamber must be at least 4 years
- The finished chamber must have an attractive appearance

### Design Requirements:

#### 1. Physical and Operational Characteristics

##### a. *Performance requirements:*

The chamber must be able to secure the prosthetic so that it is not disturbed when the chamber is being carried. It must be able to withstand everyday use including removing and placing the prosthetic inside.

##### b. *Safety:*

The antimicrobial effect of the chamber must not harm the user. Also the chamber should not be able to cause any damage to the prosthetic or user when they are removing or inserting the prosthetic.

##### c. *Accuracy and Reliability:*

The chamber must hold the prosthetic in the same orientation during its entire use.

##### d. *Life in Service:*

The chamber must be durable enough to be used everyday and also be able to hold a prosthetic for long storage if needed while keeping it clean and undamaged. The chamber should last at a minimum the life of the prosthetic.

##### e. *Shelf Life:*

The chamber should not be damaged while be carried or shipped and should not degrade while being stored.

f. *Operating Environment:*

Temperature: Must be able to function optimally at room temperature (20 -30 °C). It should be able to withstand warm temperatures of up to 60°C and cold temperatures as low as -30 °C. Humidity: Must be resistant to in-door and out-door humidity (up to 100%). Dirt or Dust: May accumulate dirt or dust on the outside but should not collect inside the chamber. Corrosions from fluid/handling: Must not react with cleansing agents such as alcohol or water. It should also be used to frequent handling. Operators: The box/container will be used by prosthetic products consumers. Durability: Must be unbreakable if dropped accidentally on hard surfaces. Life-Span: Must last at least 4 years.

g. *Ergonomics:*

Chamber contents should not cause harm to operator's fingers when placing prosthetic in box/container and should be easy for an elderly person to open and close.

h. *Size:*

Exact dimensions have not been discussed but the smaller the box/container the better (as long as the prosthetic fits in box/container). The box/container could have three standardized sizes to accommodate different sizes of prosthetics.

i. *Weight:*

Weight parameters have not been finalized but the lighter the box, the better.

j. *Materials:*

Box/Container: Material has not been finalized but we have several different options currently. These are Carbon fiber, steel alloys, hollow titanium, polypropylene, Lexan and Plexiglas.

k. *Aesthetics, Appearance, and Finish:*

Final product should be a dark colored box that is not lustrous.

## 2. Production Characteristics

a. *Quantity*

One prototype for use by our client. Further production of additional models will be determined by the client.

b. *Target Product Cost:*

The model should have a production cost of less than \$1500.00

## 3. Miscellaneous

a. *Standards and Specifications:*

Since this product will house a facial prosthesis, FDA approval may be required if manufactured on a large scale. The device needs to be non-toxic, user-friendly, and environmentally safe as well.

b. *Customer:*

The customer would prefer a discrete, small, transportable container to house a facial prosthesis. The container should be small enough so a spare prosthesis can easily be carried and durable enough to prevent any damage to the prosthesis.

c. *Patient –related concerns:*

The device will need to be cleaned periodically but should have anti-microbial properties to prevent bacteria build-up. The device will need to be built to house its contents securely and prevent any damage.

d. *Competition:*

The need for this device arose due to lack of a functional facial prosthesis storage chamber. A search of the USPTO's patent database did not yield any similar devices with patents. A google search showed a patent (United States Patent 5201411) for a prosthesis cleaning device, however, our facial prosthesis chamber is designed with storage in mind, not cleaning.