

The Product Design Specifications (10/22/08)

Facial Prosthetic Longevity Chamber

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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:

- **Aesthetics:** The chamber should reflect the value of the prosthetic while being attractive to a range of patients.
- **Variety of Prosthetics:** The chamber should accommodate different models of facial prosthetics.
- **Reproduced Easily:** Our client must be able to reproduce the chamber with little technical know-how and relative ease.
- **Safeguard and Stabilization:** The prosthetic should be stabilized to prevent any damage that may result either during everyday storage or shipping.
- **Antimicrobial Element:** The chamber should include a form of antimicrobial protection.

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 shipping and 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 every day 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 (3 years).

e. *Shelf Life:*

The chamber should not be damaged while be carried or shipped and should not degrade while being stored (>3 years).

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. Sunlight: Must be able to withstand U.V rays from sunlight. Humidity: Must be able to resist build up of humidity inside the chamber. 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 hydrophilic cleansing agents such as alcohol or water or hydrophobic (silicon) adhesive glue. It should 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:*

It should not cause harm to the operator's fingers when placing prosthetic in box/container. The operator should be able to place and remove prosthetic with ease.

h. *Size:*

The interior of the container should at least 4"x4"x4". The box/container for our design is 13.0 cm X 16.8 cm X 10.4 cm.

- i. *Weight:*
Weight parameters have not been finalized but the lighter the box, the better. The box/container for our design weighs 14.8 oz.
- j. *Materials:*
Box/Container: polycarbonate called Lexan. Stabilizing Base: polyurethane foam. Attachment method: Velcrow.
- k. *Aesthetics, Appearance, and Finish:*
Final product should be a dark colored box that is not lustrous, such as a matte finish. Should reflect the value of the prosthetic.

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. United States Patent 5201411 is for a prosthesis cleaning device; however, our facial prosthesis chamber is designed with storage in mind, not cleaning. Other anaplastologists offices (Medical Art Resources) offer their patients orthodontic retainer cases.