

# **Ergonomic Prosthetic Ear Attachment Product Design Specifications**

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## **Problem Statement**

The purpose is to design and fabricate an attachment to augment the magnetic components that are currently in use to retain silicone auricular prostheses. The bar-clip and magnet-abutment cap techniques currently in use both have disadvantages. It is desired to retain the current magnetic attachments and the magnacaps that mount on each abutment. The objective is to incorporate a passive locking mechanism to safeguard the prosthetic ear from complete dislodgement due to a posterior or anterior applied force. Additionally, when the locking mechanism is not engaged, minimal effort should be required to remove and attach the ear to the surgical implant.

## **Client Specifications**

Prosthesis should resist unintentional dislodgement

Must be low profile

Must be contained within the prosthesis

Able to withstand considerable anterior and posterior force – approximately 5 lbs

Adaptable /scalable to current abutment sizes – 4.4 mm diameter

Should require minimal effort to remove and attach prosthesis

## **Design Requirements**

1. Physical and Operational Characteristics
  - a. Performance Requirements
    - i. Ear should stay in position throughout daily activities
    - ii. Withstand force in the posterior/anterior direction without unintentional dislodgement
  - b. Safety
    - i. Will not cause harm to compromised bone structure or remaining soft tissue when subjected to force
    - ii. Attachment should break before the bone or surgical implant is damaged
    - iii. Should be easy to clean to prevent infections
  - c. Accuracy and Reliability
    - i. Must fit previous abutment sizes (4.4 mm diameter) or be scalable to them
    - ii. Must not fail due to aging of components over the life span of the prosthesis itself
  - d. Life in Service
    - i. Approximately 3 years
    - ii. Materials should be able to withstand daily cleaning
  - e. Operating Environment
    - i. Rust and weather-proof
  - f. Ergonomics
    - i. Attachment and removal should require minimal effort
    - ii. Components should be easy to clean
  - g. Size
    - i. Attachments should fit the current abutments
    - ii. Mechanism should fit within prosthesis
  - h. Weight

- i. Device weight should not cause discomfort for user
    - ii. Patient should not feel any difference of weight due to new design (no more than 10% added weight)
  - i. Materials
    - i. Preferably composed of titanium, stainless steel
    - ii. Compatible with silicone and the body
  - j. Aesthetics
    - i. Should not be visible when attached
- 2. Production Characteristics
  - a. Quantity
    - i. One prototype
  - b. Target Product Costs
    - i. Preferably under \$500 although budget is flexible
- 3. Miscellaneous
  - a. Standards and Specifications
    - i. Materials used must be FDA approved
  - b. Customer
    - i. Should be available for patients regardless of age or ear size
  - c. Patient-related concerns
    - i. Ease of attachment and removal for users
    - ii. Cleaning process be simple
  - d. Competition
    - i. Various methods exist, but none completely satisfy the client's demands
    - ii. Existing methods include the bar-clip, magnetic, and snap-on