

# Passive-Locking Implant Retained Auricular Prosthesis Attachment

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## Function:

The client, Gregory Gion, has requested a mechanism to replace the current o-ring magnetic sleeve used to attach auricular prosthesis to the mounting pins attached at the patient's mastoid bone. The current method utilizing the o-ring housed sleeve has good attachment and rigidity but requires significant force to place and remove which causes excessive wear and tear on the prosthesis. An ideal design would maintain the already in place stable connection while refining the ease of attachment and removal.

## Client Requirements:

- Must create solid attachment of prosthetic
- Must be easily applied and removed by the patient
- Must be hypo-allergenic
- Must be low profile

## Design Requirements:

### 1. Physical and Operational Characteristics

- a. *Performance requirements*
  - i. The mechanism must firmly hold the auricular prosthetic in position.
  - ii. The mechanism must allow for ease of attachment and removal.
- b. *Safety*
  - i. The device must be made out of hypo-allergenic materials.
  - ii. The device must operate within the proper range of force tolerance so as not to compromise the mounting pins.
- c. *Accuracy and Reliability*
  - i. The device should work in all cases.
- d. *Life in Service*
  - i. The mechanism should be operational for the entirety of a prosthetic's lifespan.
- e. *Shelf life*
  - i. The mechanism should match or exceed the shelf life of the existing prosthetic.
- f. *Operating Environment*
  - i. Connects to mounting pins attached to the mastoid bone.
  - ii. Housed within an auricular prosthetic.
- g. *Ergonomics*
  - i. Must create rigid connection.
  - ii. Must be easily attached and removed.
- h. *Size*

- i. Low profile.
    - ii. Can be housed within the auricular prosthetic.
  - i. *Weight*
    - i. Light enough to avoid excessive tension on the pins caused by gravitational pull.
  - j. *Materials*
    - i. Must utilize hypo-allergenic materials.
    - ii. Final design made with client specified materials of stainless steel and titanium.
  - k. *Aesthetics, appearance, and finish*
    - i. The mechanism should be housed within the prosthetic and thus should not be seen.
- 2. **Production Characteristics**
  - a. *Quantity*
    - i. At least one proof of concept prototype.
    - ii. Ability for eventual mass production.
  - b. *Target Product Cost*
    - i. Flexible.
- 3. **Miscellaneous**
  - a. *Standards and Specifications*
    - i. Have to meet FDA health standards.
    - ii. Ideally will fit the existing three pin system.
  - b. *Customer*
    - i. Preferential use of magnet housed system.
  - c. *Patient-related concerns*
    - i. Easily sterilized between uses.
    - ii. Must be hypo-allergenic.
    - iii. Minimize force required for use.
  - d. *Competition*
    - i. Existing attachment designs include a bar system, magnetic housed o-ring system, plain magnetic attachment (Vistafix<sup>TM</sup>), and previous design project prototypes.