

Blinking Orbital Prosthesis

Product Design Specifications

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Summary: Orbital prostheses are removable silicone restorations of the eyeball, the lids, and surrounding tissues. Current prostheses match the unaffected eye in a normal gaze but have no life-like movement. Adding life-like movement to the eye would greatly help boost the patients confidence. Advances have already been made by previous UW students toward creating a blinking mechanism. The goal of this project is to develop a design that maintains the favorable aspects of current prostheses: lightweight, small, and durable; but also incorporates a blinking mechanism that is synchronized with the other eye.

Client requirements:

- The designed mechanism must have less noise and vibration compared to the last group's prototype.
- The designed mechanism must be small enough to fit into the eye socket.
- The design should be easy and quick to fix/maintain.
- The design should be able to create a lifelike blink (300-400 milliseconds per blink).

Design requirements:

1. Physical and Operational Characteristics

- a. *Performance requirements:* The device must be able to handle at least 12 hours a day for an entire year.
- b. *Safety:* Since the mechanism needs to be inside the eye socket, everything needs to be encased in a biocompatible material.
- c. *Accuracy and Reliability:* The mechanism must be able to power a blink at a realistic speed, which is around 300-400 milliseconds. It also must blink every time the other eye blinks to keep the look consistent with a realistic blink.
- d. *Life in Service:* The mechanism should be maintained on a yearly basis. The device will be used daily for at least 12 hours a day. Also any necessary power source must be easily replaced/recharged.

- e. *Shelf Life*: The shelf life of individual components should be around 1 year.
- f. *Operating Environment*: The device will be located in a patient's eye socket and will need to be able to withstand those conditions. It also must be able to work correctly during normal activities.
- g. *Ergonomics*: The device must be easily useable. This includes lubrication (if necessary), insertion into the eye socket, recharging, and, if necessary, sterilized.
- h. *Size*: The device should be able to fit into the eye socket.
- i. *Weight*: The device should be light enough to not affect the patient during normal use.
- j. *Materials*: All materials in possible contact with the patient need to be biocompatible and non-allergenic.
- k. *Aesthetics, Appearance, and Finish*: The mechanism should be able to create a realistic looking blink.

2. Production Characteristics

- a. *Quantity*: The quantity will be 1 mechanism per prosthetic eye.
- b. *Target Product Cost*: The budget for the prototype is \$1000.

3. Miscellaneous

- a. *Standards and Specifications*: FDA class 1 approval is required for orbital prosthetics. The mechanism should be able to fit into class 1 as well.
- b. *Customer*: The product should be easy to affix to the aesthetic portion of the prosthetic eye and be easy to repair.
- c. *Patient-related concerns*: The device must work properly in creating a timely blink. Also, the device needs to be quiet and produce minimal vibrations.
- d. *Competition*: Currently orbital prosthetics that are currently publicly available do not have a blinking mechanism.