

Function: This device will be used to siphon excess cerebral spinal fluid from the brain in patients with hydrocephalus, reducing intracranial pressure, which can relieve symptoms and prevent brain damage.

Client requirements: The shunt should have mechanisms that compensate for cardiac pulsations and gravity to prevent over siphoning and ventricular collapse.

Design requirements

1) Physical and Operational Characteristics

- a) *Performance requirements:* The device will be implanted into many pediatric patients and should last 20 years without failing.
- b) *Safety:* The device must be biocompatible. It should also be treated and implanted in such a way as to reduce the risk of infection.
- c) *Accuracy and Reliability:* The device should have accurate threshold pressures so that CSF is not over or under siphoned.
- d) *Life in Service:* The device should last 20 years in a patient.
- e) *Shelf life:* The device should be packaged in a sterile way for storage.
- f) *Operating Environment:* The device will be implanted into patients and be in a biological environment at normal body temperature. It must resist infection and biological attack. It should be designed to avoid obstruction by biological tissue.
- g) *Ergonomics:* The device must be compatible with different aged children.
- h) *Size:* The device must fit into cerebral ventricles and long enough to drain into the appropriate body cavity.
- i) *Weight:* The device should be as light as possible.
- j) *Materials:* Industry standard materials for shunts are silicone elastomer for tubing and titanium alloy for the valves.
- k) *Aesthetics, Appearance, and Finish:* Device aesthetics are not a significant factor. The device should be made small and efficient in order to perform its function.

2) Production Characteristics

- a) *Quantity:* One prototype (for class purposes only).
- b) *Production Cost (novel valve):* \$50 (budget is flexible).
- c) *Production Cost (entire loop):* ~\$2,500

3) Miscellaneous:

- a) *Standards and Specifications:* 1.5 cm in diameter, 3cm in length
- b) *Customer:* Most customers will be young children suffering from hydrocephalus, although older children and adults may also use this product.
- c) *Patient related concerns:* Infection and ventricular collapse due to over drainage of CSF are the two main patient concerns.
- d) *Competition:* There are several companies that manufacture shunts, but this will be the first shunt with specialized valves in a nonlinear conformation to control for cardiac pulsations and gravity, two factors that can lead to over drainage.