Product Design Specifications

Hydrocephalus Shunt Valve

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Function: The device will function as a valve controlling the expulsion of cerebrospinal fluid (CSF) from inside the blood-brain barrier to the abdomen in patients suffering from hydrocephalus. The device will be of a minute enough size to avoid irritation in patients when implanted underneath the chin or behind the ear. Additionally, the device is anticipated to stray away from currently applied electronic-based valve mechanisms, functioning on a purely mechanical basis. This is to avoid encountering circuitry problems as well as electronic failure. CSF is released from the skull of the patient by tubing inserted through a surgical incision. CSF then flows through the tubing to the device. Flow is blocked until sufficient pressure opens the valve to drain the CSF into the abdomen where it is reabsorbed.

Client requirements:

- Prevent debris from entering system
- Self-regulating
    - Maintain a form of homeostasis with ambient pressure
        - Openings in shunt allow it to regulate with surrounding tissue
        - Openings in shunt to environment will be $\leq 3\mu m$
        - Placed under flaccid skin (either behind chin or ear)
    - No electronic components
- Address increased pressure due to heartbeat
- Increase longevity of device

Design requirements:

- Biocompatibility (all components)
- Resistance to repeated strain (relevant components)
- Flexibility or rigidity (depending on component)
- Sealed (does not allow leakage outside the catheter system)
- Does not become clogged by tissue ingrowth
- Responds to changes in ambient **and** intracranial pressures--must safely remove CSF fluid when necessary without over draining
- Small size (described as about the size of a half dollar coin)

1. Physical and Operational Characteristics

a. **Performance requirements:** The device will need to last a lifetime, because ideally after implantation, it will never need to be removed. The shunt should also be able to remove excess fluid from the skull at approximately 1 ml/min, and should be designed so tissues do not clog the valve within the shunt. In order to properly displace excess pressure in the skull, the device should be designed to incorporate the use of ambient

pressure as opposed to differential pressure. This will remove many complications patients suffer when standing up or changing elevations (such as in air travel).

b. **Safety:** The device poses two main safety concerns if it is improperly designed: over draining and under draining of cerebrospinal fluid from the skull. Over drainage can cause a significant drop in intracranial pressure, and in extreme cases, leading to the collapse of the ventricles in the brain due to insufficient support. In the reverse scenario, under drainage increases intracranial pressure, increased size of the ventricles push the brain out, damaging the tissues [1]. Almost all of the ways that the device would fail, would cause one of these two scenarios to occur if untreated.

c. **Accuracy and Reliability:** Current devices have a failure rate of about 40%, so the proposed design needs to be more reliable than the standard for shunt valves. This lowered failure rate must be retained throughout the entire life of the product, corresponding with the patient's lifespan. The shunt should not need to be removed. Shunts will also need to be flexible in design, so that they may be customized for each patient's unique physiology.

d. **Life in Service:** Each shunt should be designed so that it may last the lifetime of the patient. In order to have the required longevity, the device needs to be designed to include ambient pressure as opposed to differential pressure. Differential pressure based shunts tend to cause complications with common actions, such as standing up too quickly or riding on airplanes.

e. **Shelf Life:** The device will be made out of polymers or biocompatible metals, so the storage life will be limited by the methods of sterilization. If the device can be re-sterilized before implantation, the shelf life should be indefinite.

f. **Operating Environment:** The device will function in standard human physiological conditions and fail to instigate an immune response. Such physiological conditions include a pH of 7.4 and temperature of approximately 37 degrees Celsius. The device will need to withstand pressure on all faces from the forces CSF will be exerting on the device's internal walls. Additionally, the final product must be resistant to failure as a result of tissue ingrowths. The device should prevent backflow through the valve and provide resistance to rapid opening and closing resulting from sudden pressure fluctuations such as heartbeats and changes due to standing or altitude.

g. **Ergonomics:** A common problem with competing shunt valves is the disconnection of tubing and migration of the valve from the original implantation site. To avoid this issue, the device must be completely immobilized within tissue. Further, the device must also not allow for tissue ingrowth to occur to an extent that function is lost. Since the device is idealized to remain in the patient for the remainder of his/her life, the device must be composed of materials resistant to biodegradation. Though infection is highly unlikely to occur with commonly used biomaterials, special caution may need to be taken with the implantation occurring in close proximity to the skull and brain.

   With regard to device function, multiple factors must be considered with respect to ergonomics. The valve must be able to withstand the hydrostatic pressure of the CSF it contains, pressures from surrounding tissues, and other biological material on the outer walls. Fracture is the most common source of failure in hydrocephalus shunt valves and a tough material is required to avoid this pitfall. The device will also need to operate with the pressure ranges from CSF in the human brain. The entire function of the shunt valve will be anticipated to rely on CSF reaching a certain pressure threshold, at which time the valve opens and pressure is relieved.

h. **Size:** The design is estimated to be comparable to a half dollar, circular with a diameter of approximately 32 mm. The thickness is speculative, but is likely to be less than 20 mm. The principal concern for reducing the size is the patient's comfort.

i. **Weight:** The weight will likely be under 10g. The principal concern for reducing the weight is for the patient's comfort.

j. **Materials:** All materials used should be biocompatible (i.e. not degrade or cause immune reactions in the body). Furthermore, the materials used should be able to withstand repetitive loading and unloading without changes to their physical properties or breaking. Finally, magnetic metals need to be avoided since hydrocephalus is a condition that often requires MRIs.

k. **Aesthetics, Appearance, and Finish:** Finish of material should be smooth to reduce patient discomfort and to allow for optimal flow of fluid through the device. Outward superficial aesthetics are not a concern as the device is an implant, however, the valve ought to be visibly labeled for implantation ease.

2. Production Characteristics

a. **Quantity:** Only one working prototype needs to be produced for demonstrative purposes.

b. **Target Product Cost:** The Cost should be around the $100 budget proposed by the client.

3. Miscellaneous

a. **Standards and Specifications:** The FDA has set forth requirements for Neurological devices under 21 CFR § 882.5550. Hydrocephalus Shunts are considered to be a Class II medical device (21 CFR § 860.3(c)), needing to demonstrate effectiveness and safety (21 CFR § 860.7). The FDA recognizes ISO 7192 (2006) and ASTM F647 (2014) relating to Hydrocephalus Shunts.

b. **Customer:** Customers will be considered to be the implanting surgeons and the patients who use the valve. The valve should not be noisy for the patient (no repetitive clicking for example). The device should also be as small as possible to complete its function so that the patient can live a relatively normal life after implantation.

c. **Patient-related concerns:** As mentioned in the 'operating environment' section, there is serious risk of shunt valve failure in patients with hydrocephalus. Research studies have shown upwards to 81% of shunt valve implants fail within their twelve years of implantation. Additionally, failure of the first implant increases risk of failure in subsequent implants [2]. Patients receiving these valve implants must understand these associated risks of failure when being provided treatment options.

   Another important concern for patients is that no valve mechanisms proposed to date have shown to be a unanimous best option for all. Devices containing anti-siphoning mechanisms to prevent backflow and overdrainage are highly suggest for tall, slender individuals whereas these devices can result in underdrainage in obese individuals. Thus, there is no universal shunt valve design and patients should perform individual research and consult their health professional when considering implants.

d. **Competition**: The first designs for shunt valves appear to come from the 1960s in which one-way spring valves were used in an attempt to provide a novel drainage system to move collecting CSF in the brain into an absorbable area such as the abdomen [3]. Current hydrocephalus shunt valves operate using a variety of components. Some devices consist of fixed differential pressures valves that will open and close at predetermined values while others can be programmed from outside the body to different limits. In order to prevent a siphon effect, anti-siphoning devices such as the ball and cone mechanisms are often used. There are also new patent designs in which the valve operates purely

mechanically with no need for electronics [4]. It appears these new biomaterial-inspired designs could overcome many of the shortcomings of current programmed shunt valves. The common theme amongst all researched shunt valves shows a device in which an upper and lower pressure limit is set, similar to a filter mechanism. When the upper threshold is reached in terms of differential pressure, the device opens and CSF is moved through the outflow pipe. When pressure falls back below the lower limit the valve closes and overdrainage is avoided.

References

[1] "Complications Of Shunt Systems | Hydrocephalus Association". *Hydroassoc.org*. N.p., 2017. Web. 2 Feb. 2017.

[2] Sainte-Rose C, Piatt J, H, Renier D, Pierre-Kahn A, Hirsch J, F, Hoffman H, J, Humphreys R, P, Hendrick E, B, Mechanical Complications in Shunts. Pediatr Neurosurg 1991/1992;17:2-9. 21 Jan. 2017.

[3] Salomon, Hakim. Hydrocephalus Shunt with Spring Biased One-way Valves. Salomon Hakim, assignee. Patent US3288142 A. 29 Nov. 1966.

[4] Watson A, David. Shunt Valve for Controlling Siphoning Effect. David Watson, assignee. Patent US9526879 B2. 27 Dec. 2016.