

## Ventriculoamniotic Shunt for Fetal Aqueductal Stenosis (VASFAS)

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Fetal obstructive hydrocephalus causes permanent brain damage due to increased intracerebral pressure. Because of obstruction of the flow of cerebrospinal fluid, CSF accumulates within the cerebral ventricles, causing increased intracerebral pressure, which leads to decreased blood flow, as well as damage from stretch of neurons. In-utero relief of increased intracerebral pressure may result in normal brain development, thereby preventing lifelong disability. Our objective is to design and test a ventriculo-amniotic shunt that will be used to treat fetal pressure hydrocephalus. Pressure hydrocephalus complicates approximately 3 per 100,000 births. Shunting is currently not a management option. Our shunt represents a treatment breakthrough. Current management involves serial ultrasounds through gestation and preterm delivery by classical cesarean section, followed by post-natal shunting. The majority of survivors have long-term neurologic disability.

### Technology Description

The ventriculo-amniotic shunt is designed to meet specific performance requirements for in-utero drainage of CSF. It must have a low profile to allow for percutaneous, ultrasound-guided placement. It must be atraumatic to brain and intrauterine tissues. It must have an anchoring system to prevent dislodgement. It must be engineered against clogging. Finally, it must have a one-way valve to prevent inflow of amniotic fluid into the cerebral ventricles. The design has been tested in an in vitro model and is undergoing refinement in a large animal model (fetal sheep).

### Advantages

- In-utero treatment of obstructive hydrocephalus, thereby preventing ongoing brain damage
- May allow for in-utero healing of damaged brain tissue
- Percutaneous, ultrasound-guided insertion for minimal maternal risk
- Atraumatic design; constructed of FDA-approved materials
- Anchoring system to prevent dislodgement or migration
- Nitinol wire cages on either end to prevent clogging
- One-way valve to prevent inflow of amniotic fluid into the cerebral ventricles

### Applications

- In-utero treatment of fetal obstructive hydrocephalus from isolated aqueductal stenosis
- In-utero treatment of obstructive hydrocephalus from other causes (hemorrhage, infection)
- In-utero treatment of lower urinary tract obstruction (LUTO)
- In-utero treatment of pressure hydrothorax.



Ventriculo-amniotic shunt (VASFAS) in comparison to a dime.

### Stage of Development

In vitro design testing completed. In vivo safety and feasibility testing using hydrocephalic fetal sheep underway.

### IP Status

US non-provisional patent application 15/765,723, Priority Date 10/13/2016