# Cerebral Edema Management in Traumatic Brain Injury: The Twin Star Approach

## Cerebral Edema: A Compelling Problem

Traumatic Brain Injury (TBI) is the leading cause of disability and death among the civilian population under 45 years of age in the US. Military combat casualties frequently present with TBI from projectile, blunt force or blast injury, and are creating a sobering number of military personnel with TBI and accompanying death and disability. Much of this injury in TBI is the result of intracranial pressure from cerebral edema. Better management of intracranial pressure has helped reduce the mortality rate from severe TBI, but secondary insults from cerebral edema may be responsible for one-third of TBI deaths. Innovative approaches to this problem have been lacking. Hemicraniectomy represents the most aggressive intervention as standard practice in some institutions for severe TBI patients. Given the morbidity of this procedure, less invasive therapies, such as the Twin Star approach, are likely to be favored as effectiveness is demonstrated.

## The Twin Star Approach

Twin Star's system has been designed to reduce cerebral edema based on vaporization and removal of free water from the cerebrospinal fluid (CSF) within the ventricles of the brain, using the Company's proprietary microporous catheter technology. The therapy has been coined Reductive Ventricular OsmoTherapy (RVOT). The primary therapeutic mechanism is that free water removal causes an increase in osmolarity of the CSF, favoring movement of tissue bound water to the ventricles, where the water can be removed and minimize cerebral edema. Microporous catheters are placed directly into the cerebral ventricles and designed to provide CSF drainage and intracranial pressure monitoring, just like the placement of contemporary ventriculostomy catheters.

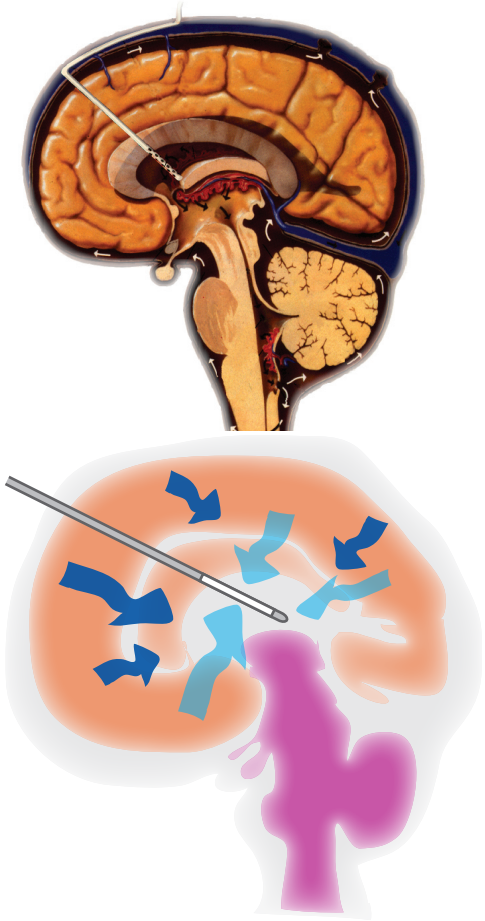
## Potential for Improved Outcomes

Removing water from within the cerebral ventricles to decrease tissue edema is a compelling concept. A controlled study in swine with cortical contusion was performed to evaluate this concept. Controls were treated with conventional CSF drainage. With RVOT treatment, CSF osmolality in injured brain tissue increased versus a decrease with control treatment. RVOT treatment yielded a reduction in intracellular edema relative to control treatment as evidenced by apparent diffusion coefficient (ADC) maps generated from magnetic resonance (MR) scans. Analyzed variables consistently indicated that microporous catheter water removal produced either significant improvement, or a favorable trend versus controls. Results support the central hypothesis that RVOT reduces cellular swelling and improves cerebral function.

*(over)*

## RVOT - Reduction of cerebral edema

*Severe cerebral edema frequently is treated through a Hemicraniectomy; a complete open resection of a portion of the skull to reduce pressure.*



*RVOT is designed to pull edema fluid from the tissue into the ventricles by osmotic and hydrostatic gradients. Water diffusion into the ventricles dilutes the CSF components, ideally preventing a measurable increase in CSF osmolarity. Increased mobile, free water in ventricular fluid is removed while maintaining ventricular volume*

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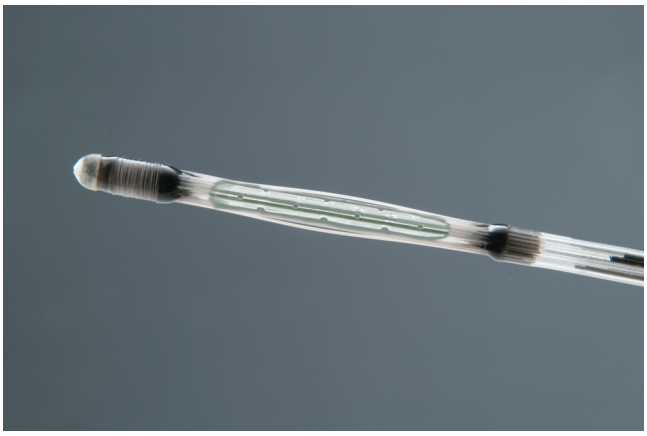
## Technology Development History and Plans

Bench and animal studies evaluating RVOT have been performed with NIH SBIR Phase I and II grants. The next step is to finalize catheter design for human studies, and demonstrate the clinical utility of RVOT as an adjunctive therapy in combination with the current standard of care for TBI patients. NIH and DoD government funding is being sought to undertake human studies. A commercialization partner will be retained to launch RVOT for widespread clinical adoption.



*RVOT Microporous Catheters can be placed in standard fashion for cerebral ventricular access. The Microporous Catheter design allows vaporized water collection through the surface of the outer microporous catheter bundles, and CSF collection or pressure monitoring through the central lumen of the microporous catheter.*

*A fluid management console is used with the microporous catheter, which includes pressure monitoring capability.*

Caution: Investigational device. Limited by U.S. Federal law to investigational use.

Patents issued and pending.

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