Source: *Serenity Medical*

March 31, 2026 11:02 ET

Serenity Medical Receives U.S. FDA HDE Approval of the River™ Stent - the First Venous Stent Approved for Severe, Refractory Idiopathic Intracranial Hypertension (IIH)

Landmark regulatory milestone makes the River stent available for adults with severe IIH – a debilitating, historically undertreated condition – who have failed medical therapy

Serenity Medical partners with Radical Technologies' specialized neurovascular team to commercialize the stent in leading centers nationwide to accelerate access for indicated patients

HARRISON, N.Y., March 31, 2026 (GLOBE NEWSWIRE) -- Serenity Medical, a NeuroTechnology Investors (NTI) portfolio company and pioneer in venous sinus stenosis treatment, today announced U.S. Food and Drug Administration (FDA) Humanitarian Device Exemption (HDE) approval for its novel River™ stent – the first FDA-approved cerebral venous stent. The River stent is specifically developed for the treatment of severe idiopathic intracranial hypertension (IIH) in adult patients who have failed medical therapy. The approval is a landmark clinical milestone: for the first time, clinicians now have a purpose-built, FDA-approved tool to help address a condition that has long challenged the neurovascular community and suffering patients.

IIH is a serious neurological condition caused by elevated intracranial pressure, leading to debilitating chronic headaches, vision loss, and cognitive impairment. The condition disproportionately affects women aged 20–50 with obesity, a demographic growing in prevalence. For certain patients with severe IIH symptoms, it has been a struggle to find appropriate surgical therapies that are FDA-approved and indicated to safely relieve their symptoms.

"Delivering the first venous stent approved for severe, refractory IIH is incredibly meaningful to our dedicated team and to people living with IIH who have had limited options for relief until now," said Y. Pierre Gobin, MD, Founder of Serenity Medical and an internationally recognized neurointerventional expert practicing at Weill-Cornell Medicine in New York, NY. "Our company was founded with the goal of addressing a problem that has long perplexed the medical community and caused debilitating symptoms in the women suffering with it. Reaching this moment reflects years of persistence, partnership with investigators, and a shared commitment to bring new possibilities to this underserved patient community."

The FDA review and approval of the River stent is based on the findings of **The River Study: the first multicenter trial of a novel venous stent for the treatment of Idiopathic Intracranial Hypertension (IIH)**, published in the *Journal of Neurointerventional Surgery* (*JNIS*) in February 2025. The study was a prospective, open-label, multi-center, single-arm trial that enrolled 39 subjects at five U.S. centers and aimed to demonstrate the safety and probable benefit of the River stent in patients who are refractory or intolerant to medications. The River Study's one-year results met the primary safety endpoint with an observed major adverse event rate of 5.4%.[i] Improvements were observed in opening CSF pressure, headaches, papilledema, pulsatile tinnitus, visual symptoms, and Quality of Life scores.

"The River Study was groundbreaking as the first-of-its-kind study to evaluate a stent specifically designed for intracranial venous sinuses," said Adnan Siddiqui, MD, PhD, FAANS, FACS, FAHA, vice chairman and professor of neurosurgery, Jacobs School of Medicine & Biomedical Sciences, and senior author on the paper. "There is no other stent that is optimized or approved for this indication. The FDA's review and acceptance of these data will now enable access to this important tool to the broader medical community to treat these patients."

Serenity Medical has formed a strategic partnership with Radical Catheter Technologies to commercialize the River stent. Martin Dieck, Chairman of Serenity Medical and Managing Director of NTI, also serves as Chairman for Radical Catheter Technologies. Dieck said, “Radical has built a world-class commercialization team with a proven track record of launching breakthrough neurovascular technologies through strategic physician engagement, rigorous clinical education, and hands-on procedural support.” The team is now expanding its collaborative reach across the NTI portfolio and beyond to serve as a commercialization partner — uniting its industry-leading neurovascular access and delivery catheters with other innovative neuro solutions to accelerate market adoption and broaden patient access to transformative care.

Humanitarian Device Exemption

The FDA has approved the humanitarian use of the River™ stent for adult patients with IIH with significant stenosis who are resistant or intolerant to medications. It is reserved for patients with severe headaches who have failed to respond to 6 months of medical therapy, including attempts at weight loss, or for patients who have had visual symptoms or visual signs that are vision-threatening despite medical therapy.

About Serenity Medical

Serenity Medical is a pioneering neurovascular device company dedicated to the treatment of venous sinus stenosis. Its flagship River™ stent – now FDA HDE-approved for severe, refractory IIH – is a purpose-engineered venous stent uniquely designed for the anatomy of the stenotic sinuses, featuring variable radial force and diameter, flexible construction, and reduced metal surface area designed to minimize venous thrombotic risk. Serenity Medical is expanding its portfolio of complementary technologies to optimize venous sinus stenosis procedures.

About the Radical Technologies Commercialization Team

Radical Technologies fields a specialized neurovascular team with deep expertise in bringing breakthrough medical technologies to market. Through hospital and KOL engagement, physician education, and ongoing clinical support, Radical ensures safe and efficacious adoption on a large scale. By integrating its industry-leading neurovascular access and delivery catheters with NeuroTechnology Investors’ expanding portfolio of innovative neurovascular and neurosurgical solutions, Radical Technologies is building a unified commercial infrastructure to address significant unmet clinical needs and expand patient access to transformative care.

About NeuroTechnology Investors (NTI)

NeuroTechnology Investors (NTI) is a leading investment group dedicated to advancing breakthrough neurological technologies in the medical device sector, with a diverse portfolio that includes Synchron, Radical Technologies, Borvo Medical, and Serenity Medical. Established in 2016 and headquartered in Mountain View, California, NTI investors bring extensive clinical expertise to accelerate portfolio company development and improve patient access to transformative clinical solutions.

Media Contact:
Tara DiMilia
TellMed Strategies
tara.dimilia@tmstrat.com
908-884-7024

[i] Patsalides A, Fargen KM, Davies JM, et al. The River study: the first prospective multicenter trial of a novel venous sinus stent for the treatment of idiopathic intracranial hypertension. *J Neurointerv Surg*. 2025;18(1):11-19. Published 2025 Dec 17. doi:10.1136/jnis-2024-022540