

## **Serenity Medical Receives U.S. FDA Breakthrough Device Designation for The Serenity Shepherd Stent™ System to Treat Pulsatile Tinnitus**

*Second FDA Regulatory Milestone for Serenity's Novel Platform, Following the Recent HDE Approval of the River Stent™ – First Venous Stent for Severe, Refractory Idiopathic Intracranial Hypertension (IIH)*

Harrison, NY, June 30, 2026 (Globe Newswire) – [Serenity Medical](#), a [NeuroTechnology Investors \(NTI\)](#) portfolio company and pioneer in venous sinus stenosis treatment, today announced the Company received U.S. Food and Drug Administration (FDA) Breakthrough Device Designation for its Serenity Shepherd Stent™ System for the treatment of severe pulsatile tinnitus. The stent system is designed to navigate the tight curves and complex anatomy of the cerebral sinuses and to treat venous sinus stenosis.

Pulsatile tinnitus is a debilitating disease characterized by a continuous sound that is pulse synchronous, i.e., it follows the rhythm of the heartbeat and cannot be silenced. This condition carries major repercussions, leading to chronic depression, severe quality of life impairment, and elevated suicide risk.<sup>1</sup>

“Breakthrough Device Designation for the Serenity Shepherd Stent System validates what we've built at Serenity — a platform capable of delivering consecutive FDA milestones in venous sinus stenosis,” said Y. Pierre Gobin, MD, Founder of Serenity Medical and an internationally recognized neurointerventional expert practicing at Weill-Cornell Medicine in New York, NY. “Following the River Stent's HDE approval for Idiopathic IIH earlier this year, this designation accelerates our path through clinical development for pulsatile tinnitus and signals the breadth of what this technology can address, ultimately reaching patients desperately needing solutions.”

Martin Dieck, Chairman of Serenity Medical, Managing Director of NTI, and Chairman for Radical Catheter Technologies, states, “Serenity has achieved two consecutive FDA milestones across two high-burden indications, which is exactly the kind of platform that moves a market. Radical's commercial infrastructure is designed for this opportunity: specialized neurovascular relationships, deep clinical education capabilities, and the hands-on procedural support that drives durable adoption. We are positioned to move fast.”

### **FDA Breakthrough Device Designation**

The FDA has granted the Breakthrough Device Designation to the Serenity Shepherd Stent System for the treatment of stenotic (narrowed) venous sinuses in patients with severe pulsatile tinnitus.

Breakthrough Device Designation is intended for technologies that have the potential to provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The designation provides an expedited pathway for FDA review, including prioritized regulatory engagement, to help advance the development and availability of safe and effective innovative devices for patients in the U.S.

### **About Serenity Medical**

[Serenity Medical](#) is a pioneering neurovascular device company dedicated to the treatment of venous diseases. Its flagship River Stent™ System, 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 to minimize venous thrombotic risk. Along with the Serenity Shepherd Stent System,

the Company is expanding its portfolio of complementary technologies to optimize venous sinus stenosis procedures.

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.<sup>ii</sup> Improvements were observed in opening CSF pressure, headaches, papilledema, pulsatile tinnitus, visual symptoms, and Quality of Life scores.

#### **About the Radical Commercial Team**

The Radical Catheter Technologies commercial team is a specialized neurovascular group built to move breakthrough technologies from regulatory approval to large-scale clinical adoption. Through KOL engagement, physician education, and hands-on clinical support, Radical drives safe, rapid market penetration. Integrated with NeuroTechnology Investors' expanding neurovascular and neurosurgical portfolio, including Borvo Medical and Serenity Medical, Radical provides a unified commercial platform purpose-built for highly unmet-need indications.

#### **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.

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<sup>i</sup> Jin K, Chmiel B, Kim KM, Mehta T. Narrative Review: Suicide Risk in Headache, Pulsatile Tinnitus, And Cognitive Decline. *Psychology and Mental Health Care*. 2025.

<sup>ii</sup> 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](https://doi.org/10.1136/jnis-2024-022540).