ENGINEERING STROKE SOLUTIONS

PRESS RELEASE

Acandis Receives Regulatory Approval to Launch International RESOLVE Clinical Investigation Evaluating the SiREX® Stent for Pulsatile Tinnitus Caused by Venous Sinus Stenosis

Pforzheim, Germany – [July 28, 2025]
Acandis GmbH, a leading Germany-based medical technology company specializing in neurovascular interventions, today announced that it has received approval from the French national competent authority (ANSM) and the responsible ethics committee to initiate the **RESOLVE clinical investigation**. The pivotal, multicenter, international clinical investigation will evaluate the SiREX® Stent for the treatment of pulsatile tinnitus caused by symptomatic lateral venous sinus stenosis. The first study initiation is scheduled to take place in early August.

The **RESOLVE study** (ClinicalTrials.gov Identifier: NCT06726928) is designed to assess the safety, efficacy, and clinical benefit of the SiREX® Stent, a novel braided and fully radiopaque implant engineered specifically for the unique anatomical and clinical challenges of venous sinus stenting. A total of **78 patients** will be enrolled across **five leading European centers**, with the study coordinated by **Prof. Dr. Emmanuel Houdart**, interventional neuroradiologist at **Hôpital Lariboisière** in Paris, France and leading expert in the field of venous sinus stenting.

Pulsatile tinnitus—an often debilitating condition characterized by a sound synchronized with the heartbeat—is frequently caused by stenosis of the lateral venous sinus. While clinicians such as Prof. Houdart have successfully treated this condition for years using available stents originally developed for arterial use, the SiREX® Stent represents an important next step by offering a solution specifically tailored for venous applications. Its advanced features aim to make treatment more accessible, safer and reliable for a broader patient population.

“The possibility to treat pulsatile tinnitus via stenting has already changed lives,” said Prof. Houdart. “What sets the SiREX® Stent apart is that it is purpose-built for this indication. It combines technical specifications such as flexibility, full radiopacity and a dedicated small delivery system to make the procedure safer and more consistent.”

The RESOLVE study's **primary objective** is to demonstrate both performance and safety of the device. The **primary clinical endpoints** include the disappearance of pulsatile tinnitus at 90 days and confirmation of stent patency via venous cerebral angio-CT. Safety will be measured by the rate of device- and procedure-related complications, as well as device-related serious adverse events at 90 days, 12 months, and 24 months.

“Launching the RESOLVE study marks a major milestone for Acandis in addressing unmet clinical needs,” said **Dr. Andreas Schüßler**, Founder and CEO of Acandis GmbH. “The SiREX® Stent reflects our commitment to innovation in neurovascular care—designed from the ground up to treat patients with lateral sinus stenosis more effectively and safely.”

Enrollment is expected to conclude within 24 months, with follow-ups continuing for an additional two years. Results from RESOLVE are intended to support CE certification of the SiREX® Stent and expand its clinical use across Europe and beyond.

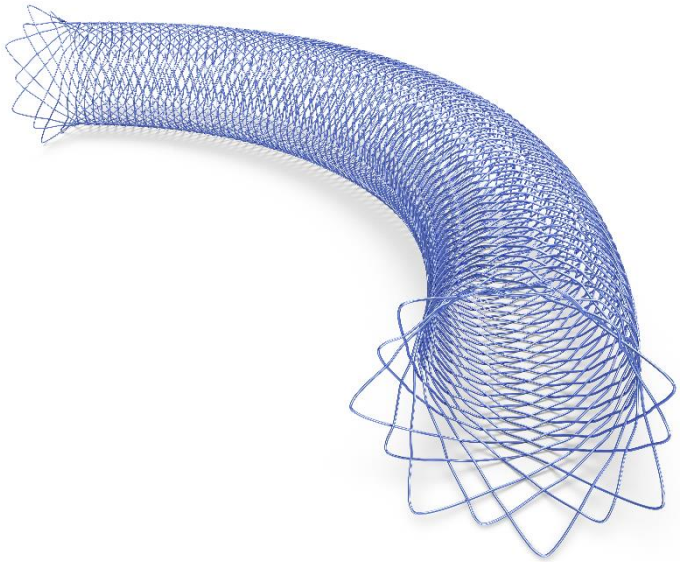

Fig. 1: The SiREX® Stent – specifically developed for the treatment of lateral venous sinus stenosis.

About Acandis GmbH

Acandis GmbH, headquartered in Pforzheim, Germany, develops and manufactures medical devices for the treatment of neurovascular diseases. The company focuses on advancing minimally invasive technologies that improve outcomes for patients suffering from complex cerebrovascular conditions.

Media Contact

Acandis GmbH
Theodor-Fahrner-Straße 6
75177 Pforzheim, Germany
Phone: +49 7231 155 00 0
Email: info@acandis.com
Web: www.acandis.com