PRESS RELEASE

Acandis GmbH Announces Start of Patient Recruitment for CARESTAR Study in Symptomatic Non-stenotic Carotid Disease (SyNC)

Pforzheim, Germany – 25 February 2026

Acandis GmbH, a leading German-based medical technology company specialising in medical devices for the treatment of neurovascular diseases, today announced the start of patient recruitment for the CARESTAR study following final positive approval from the responsible Ethics Committee. The study is registered on ClinicalTrials.gov (Identifier: NCT07166731).

CARESTAR is a prospective, randomised, multicentre, international post-market clinical follow-up (PMCF) study evaluating the treatment of symptomatic non-stenotic carotid disease (SyNC, < 50% stenosis) using the CARESTO® heal Stent compared to best medical therapy alone.

Addressing an unmet clinical need

CARESTAR (High Coverage **CAR**otid Stenting vs. Medical Management Alone to Prevent **E**mboli**S**m From symptoma**T**ic Non-stenotic c**AR**otid Disease) addresses a pressing clinical challenge: how to reduce the risk of recurrent embolic events in patients with symptomatic carotid lesions that do not meet the criteria for high-grade stenosis but exhibit features of plaque vulnerability.

While current clinical guidelines primarily focus on high-grade carotid stenosis, low-grade (< 50%) SyNC lesions represent a high-risk population for whom evidence-based treatment options remain limited. CARESTAR aims to close this evidence gap by generating randomised clinical data to inform optimal patient management in this group.

A novel therapeutic approach for vulnerable low-grade plaques

CARESTAR investigates whether early endovascular stabilisation of vulnerable carotid plaques using the CARESTO® heal Stent can reduce embolic events and improve long-term neurological outcomes compared with medical therapy alone. The device is designed to provide a minimally invasive treatment option for patients whose risk profile is not adequately addressed by current standards of care.

Study design and primary objectives

CARESTAR is a prospective, randomised, parallel-group, multicentre and international PMCF study with blinded functional assessment of the safety endpoint. The primary objective is to demonstrate the superiority of carotid stenting over best medical therapy alone in patients with symptomatic non-stenotic carotid disease.

Key endpoints include:

- Rate of recurrent ischaemic stroke or retinal artery ischaemia over a follow-up period of 1 to 6 years
- Rate of stroke, death or myocardial infarction at 30 days assessed as safety outcome
- Generation of the first randomised clinical insights into optimised treatment strategies for carotid disease < 50% stenosis

This study is coordinated by an international consortium of leading stroke and neurovascular experts: PD Dr. Hannes Nordmeyer, Prof. Dr. Götz Thomalla, Prof. Dr. Mayank Goyal, and Prof. Dr. Marcel Dihné. According to the coordinating investigators, there is a clear need for robust clinical evidence to guide treatment decisions in symptomatic non-stenotic carotid disease, which CARESTAR is designed to address.

A milestone for Acandis®

“With the initiation of patient recruitment for CARESTAR, Acandis® reinforces its commitment to driving innovation and addressing unmet clinical needs in neurovascular care,” said Dr. Andreas Schüßler, Founder and CEO of Acandis GmbH. “This study represents an important step in evaluating the potential of the CARESTO® heal Stent in an underserved and clinically challenging patient population with the goal of reducing the risk of recurrent stroke in patients with vulnerable plaques.”

Patient recruitment is expected to begin across multiple centres over the coming months. Acandis® will provide further updates as recruitment progresses.

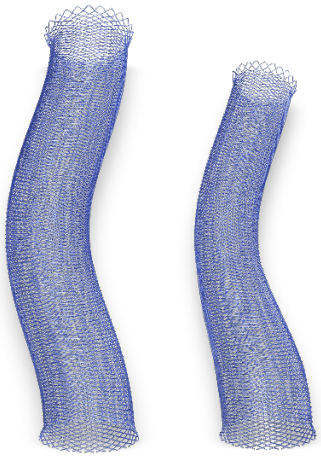

Fig. 1: CARESTO® heal Stent
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About Acandis GmbH

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.

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