

Reflow Medical, Inc.
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FDA Grants De Novo Clearance for Reflow Medical's Spur® Peripheral Retrievable Stent System

San Clemente, CA – May 29, 2025 – Reflow Medical, Inc., a leading developer of innovative medical devices focused on complex cardiovascular disease, announced that the U.S. Food and Drug Administration (FDA) has granted De Novo clearance for the company's [Spur Peripheral Retrievable Stent System](#), a unique clinical solution for the treatment of de novo or restenotic lesions following predilatation in patients with infrapopliteal arterial disease.

The Spur Stent System is the first and only retrievable stent system that features a self-expanding stent with an integrated dilatation balloon catheter on an over-the-wire system. It is designed for controlled lesion penetration and treatment through a series of radially expandable spikes. Known as Retrievable Scaffold Therapy (RST), the spikes on the Spur Stent penetrate the lesion to increase the acute luminal diameter and modify the lesion morphology to change vessel compliance and reduce vessel recoil effect.

Results of the recently concluded [DEEPER REVEAL](#) clinical trial (NCT05358353) to evaluate the Reflow Medical Spur Stent System for below-the-knee (BTK) treatment of chronic limb-threatening ischemia (CLTI), demonstrated that following predilatation, the Spur Stent System achieved a 99.2% technical success¹ rate and 97.0% freedom from MALE² and POD³ at 30 days.

“Clinical data submitted to the FDA demonstrated the safety and efficacy of the Spur Stent System,” said Mahmood K. Razavi, MD, FSIR, FSVI, who serves as Director of the Clinical Trials and Research Center at St. Joseph Heart and Vascular Center in Orange, California. “This novel device will be a valuable and innovative expansion of our treatment toolbox as a unique device for the treatment of complex BTK disease,” he added.

S. Jay Mathews, MD, MS, FACC, FSCAI, Cath Lab Director at Bradenton Cardiology/Manatee Memorial Hospital in Bradenton, Florida commented, “It’s exciting to see the clinical success of the DEEPER REVEAL trial enabling the De Novo clearance of the Spur Stent System. This first-of-its-kind technology offers a truly novel approach to treating patients with BTK CLTI disease. As an adjunct to standard balloon angioplasty, Spur RST enables us to address this complex disease in a more effective way, achieving these outcomes that go beyond what PTA alone can deliver.”

Both Dr. Mathews and Dr. Razavi were lead Principal Investigators for the study, which was conducted at 49 centers in the U.S. and enrolled 130 patients.

“Extensive research and development, which laid the groundwork for the DEEPER REVEAL trial, enabled the creation and clinical validation of the Spur Stent System, an innovative mechanical endovascular device engineered to enhance lesion penetration and optimize the treatment of BTK peripheral arterial disease,” said Teo Jimenez, Senior Vice President of R&D at Reflow Medical.

According to Reflow Medical CEO and Co-Founder, Isa Rizk, “The FDA's De Novo clearance, following positive clinical trial results in patients with CLTI, enables us to provide physicians with an effective therapeutic option for this growing patient population. We are fully prepared to launch our innovative technology through our dedicated sales force, ensuring it promptly reaches physicians to support patients.”

The FDA decision will be available on their website under DEN240048.

[About Reflow Medical, Inc.](#)

Reflow Medical is a global company that partners with leading physicians to develop innovative technologies addressing unmet clinical needs in the endovascular treatment of complex cardiovascular disease. The company's portfolio includes coronary and peripheral microcatheters, crossing catheters, and a revolutionary system known as Retrievable Scaffold Therapy (RST). Products include the CoraCatheters line, available in the U.S. only; the Wingman™, Spex® and Spex LP, available in the U.S., CE Mark and CE Mark-accepting countries, and selected markets; and the Spur®. Spur received CE Mark approval for the treatment of restenotic lesions in below-the-knee arteries, when used in conjunction with a commercially available drug-coated balloon. Reflow Medical is headquartered in San Clemente, California.

1. Technical success defined as less than 30% residual stenosis by visual estimation,
2. Major adverse limb events, 3. Perioperative death

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