



Stereotaxis Submits EMAGIN Catheter for Regulatory Clearance as it Pioneers Robotics for Endovascular Surgery

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ST. LOUIS, March 03, 2025 (GLOBE NEWSWIRE) -- Stereotaxis (NYSE: STXS), a pioneer and global leader in surgical robotics for minimally invasive endovascular intervention, today announced FDA regulatory submission for the first robotically navigated catheter designed to expand usage of Robotic Magnetic Navigation into the broader endovascular field.

EMAGIN™ 5F is the first in a family of robotically navigated endovascular devices being developed by Stereotaxis. The EMAGIN brand – short for Endovascular Magnetic Intervention – will encompass a comprehensive portfolio of robotic catheters and wires. EMAGIN 5F is a catheter guide with a 5-French diameter used to navigate tortuous venous and arterial vasculature. Robotic navigation of the catheter directly from the distal tip, using precise magnetic fields, is designed to enable efficient and safe navigation to otherwise difficult-to-reach vascular anatomy. It expands the established benefits of Robotic Magnetic Navigation into multiple new clinical applications including minimally-invasive procedures used to treat stroke, cancer, and cardiovascular disease.

"Robotic Magnetic Navigation offers significant promise to address clinical challenges we face in the neurointerventional field by enabling safe and rapid navigation through tortuous vasculature," said Prof. Timo Krings, Chair of the Division of Neurointerventional Radiology at Beth Israel Lahey Health in Boston and Professor of Radiology at UMass TH Chan School of Medicine. "I'm excited by the opportunity to help pioneer this technology, evaluate and demonstrate its clinical value, and explore entirely new applications that may become possible. Our field is uniquely poised to benefit from robotics and we look forward to advancing the technology and clinical science over the coming years."

"The evolution of robotics in interventional cardiology is inevitable and will be of significant benefit to patients, physicians, and healthcare systems," said Dr. Kalpa De Silva, Interventional Cardiologist at St Thomas' Hospital, Guy's and St Thomas' NHS Foundation Trust in London. "I see significant promise in the use of the robotically-steered EMAGIN catheter to enhance the safety, precision, and efficiency of various challenging procedures including renal denervation and complex percutaneous coronary interventions. I look forward to helping pioneer this technology."

Stereotaxis submitted a 510(k) application for EMAGIN 5F with the FDA and expects to submit the catheter for European CE Mark clearance this month. EMAGIN 5F was designed and is manufactured by Stereotaxis' fully-owned subsidiary Access Point Technologies in Minnesota. Stereotaxis expects to launch EMAGIN 5F following anticipated approvals in the second half of this year, with a focus on demonstrating clinical value for Robotic Magnetic Navigation in multiple new endovascular applications.

"Robotic Magnetic Navigation is a platform technology that can offer significant clinical value across endovascular medicine," said David Fischel, Stereotaxis Chairman and CEO. "We are thrilled to announce this milestone as we embark on the journey to make Stereotaxis a multi-specialty robotics leader advancing clinical care in interventional cardiology, radiology and neurology."

About Stereotaxis

Stereotaxis (NYSE: STXS) is a pioneer and global leader in innovative surgical robotics for minimally invasive endovascular intervention. Its mission is the discovery, development and delivery of robotic systems, instruments, and information solutions for the interventional laboratory. These innovations help physicians provide unsurpassed patient care with robotic precision and safety, expand access to minimally invasive therapy, and enhance the productivity, connectivity, and intelligence in the operating room. Stereotaxis technology has been used to treat over 150,000 patients across the United States, Europe, Asia, and elsewhere. For more information, please visit www.stereotaxis.com

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