Stereotaxis Receives U.S. FDA Clearance for MAGiC Sweep Catheter

July 28, 2025

ST. LOUIS, July 28, 2025 (GLOBE NEWSWIRE) -- Stereotaxis (NYSE: STXS), a pioneer and global leader in surgical robotics for minimally invasive endovascular intervention, today announced that it has received U.S. Food and Drug Administration (FDA) 510(k) clearance for its groundbreaking MAGiC Sweep™ catheter. MAGiC Sweep is the world's first robotically navigated high-density electrophysiology (EP) mapping catheter, representing a significant advancement in the technology available to diagnose and treat complex arrhythmia patients.

High density mapping has transformed the EP field, enhancing cardiac ablation procedures by enabling more efficient, detailed and precise identification of arrhythmia origin. The combination of high-density mapping with robotics is designed to offer multiple improvements:

- Efficient High-Density Mapping: Equipped with 20 electrodes, MAGiC Sweep facilitates rapid and detailed electroanatomical mapping of the heart chambers.
- Extended Reach & Precision: Seamless integration with Stereotaxis' Robotic Systems enables precise navigation of the catheter to otherwise difficult to reach areas of the heart.
- Atraumatic Design: The catheter's design prioritizes patient safety with an atraumatic shaft.
- Anatomical Accuracy: The catheter supports more anatomically accurate maps by avoiding the distension caused by rigid catheters.
- Efficient Workflow: MAGiC Sweep enables improved robotic procedural workflow, particularly as Stereotaxis advances algorithms that support automated mapping with MAGiC Sweep.

"The development of the first ever robotically navigated high-density mapping catheter is a major milestone for the EP field," said Dr. Roderick Tung, Chief of Cardiology and Director of Cardiovascular Clinical Research at The University of Arizona College of Medicine - Phoenix. "Mapping with multi-electrode catheters has taught us so much in both mechanism and therapy for both atrial and ventricular arrhythmias. Remaining limited to only point-by-point mapping has held back the adoption of robotic navigation, as we have become accustomed to seeing human arrhythmias in exquisitely high resolution. We look forward to the positive impact we expect MAGiC Sweep to have on our patients and new possibilities in the field."

"The ability to combine high-density mapping with robotics is an exciting long-awaited milestone for the community of robotic electrophysiologists and the broader EP field," said Dr. Daniel Cooper, Professor of Medicine and Director of Electrophysiology Lab at Washington University. "By helping us efficiently create more accurate and detailed maps of complex arrhythmia, robotic high-density mapping with MAGiC Sweep supports our efforts to provide the most effective and safe ablation procedures for our patients."

"FDA clearance of MAGiC Sweep marks a pivotal moment for Stereotaxis as we advance a broad portfolio of differentiated robotically-navigated catheters. MAGiC Sweep is Stereotaxis' first FDA clearance for an interventional catheter in nearly 20 years, but is only the first of multiple robotically-steered interventional devices being advanced as part of our comprehensive innovation strategy," said David Fischel, Stereotaxis Chairman and CEO. "This catheter reflects our commitment to significant innovations that advance robotics in electrophysiology and across endovascular interventions."

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*

This press release includes statements that may constitute "forward-looking" statements, usually containing the words "believe", "estimate", "project", "expect" or similar expressions. Forward-looking statements inherently involve risks and uncertainties that could cause actual results to differ materially. Factors that would cause or contribute to such differences include, but are not limited to, the Company's ability to manage expenses at sustainable levels, acceptance of the Company's products in the marketplace, the effect of global economic conditions on the ability and willingness of customers to purchase its technology, competitive factors, changes resulting from healthcare policy, dependence upon third-party vendors, timing of regulatory approvals, the impact of pandemics or other disasters, statements relating to our recent acquisition of APT, including any benefits expected from the acquisition, and other risks discussed in the Company's periodic and other filings with the Securities and Exchange Commission. By making these forward-looking statements, the Company undertakes no obligation to update these statements for revisions or changes after the date of this release. There can be no assurance that the Company will recognize revenue related to its purchase orders and other commitments because some of these purchase orders and other commitments are subject to contingencies that are outside of the Company's control and may be revised, modified, delayed, or canceled.

Stereotaxis Contacts:
David L. Fischel
Chairman and Chief Executive Officer

Kimberly Peery
Chief Financial Officer

314-678-6100
Investors@Stereotaxis.com

Source: Stereotaxis, Inc.