AtriCure Completes Enrollment in LeAAPS Clinical Trial for Stroke Prevention

July 15, 2025

Largest cardiac surgery device trial ever with 6,500 patients enrolled, this landmark trial evaluates the stroke reduction benefit with AtriClip devices for the over one million cardiac surgery patients globally without a preoperative Afib diagnosis

MASON, Ohio--(BUSINESS WIRE)--Jul. 15, 2025-- AtriCure, Inc. (Nasdaq: ATRC), a leading innovator in surgical treatments for atrial fibrillation (Afib), left atrial appendage (LAA) management, and post-operative pain management, today announced the completion of enrollment in the left atrial appendage exclusion for prophylactic stroke reduction (LeAAPS) clinical trial (NCT05478304). Initiated in January 2023, LeAAPS enrolled 6,500 patients across 137 centers globally.

LeAAPS is a prospective, randomized, blinded, superiority, investigational device exemption (IDE) trial evaluating the AtriClip® LAA Exclusion System for the prevention of ischemic stroke and systemic arterial embolism in cardiac surgery patients without a history of Afib—a large and often underserved population at elevated risk for these events. It is estimated that well over one million cardiac surgery procedures occur annually and more than 70% of these patients have no history of Afib before surgery.

“The LeAAPS trial is a bold clinical evidence initiative that demonstrates AtriCure’s unwavering commitment to improving care for cardiac surgery patients,” said Michael Carrel, President and CEO of AtriCure. “The rapid pace of trial enrollment is a testament to the exceptional team of clinical trial investigators and broader clinician interest in changing the standard of care in cardiac surgery. LeAAPS presents an incredible opportunity to drive improved long-term outcomes for patients while significantly expanding our market leadership through the increased use of our AtriClip devices.”

Results of AtriCure’s LeAAPS trial are expected to inform clinical practice and treatment guidelines for stroke prevention, using AtriClip platform technology, in patients undergoing planned cardiac surgery. The trial will continue with five years of follow-up to assess long-term outcomes. LeAAPS is being conducted in collaboration with the Population Health Research Institute (PHRI), affiliated with McMaster University in Hamilton, Ontario. PHRI brings extensive experience in designing and executing large-scale international clinical trials.

“For decades, the medical community has sought to better understand the role of the LAA in stroke following cardiac surgery,” said Dr. Richard Whitlock, Cardiothoracic Surgeon at McMaster University and Global Principal Investigator for the trial. “LeAAPS aims to deliver definitive evidence to guide optimal care for high-risk patients without Afib who may benefit from LAA exclusion.”

AtriCure first entered the LAA management market with FDA 510(k) clearance of the AtriClip System in 2010. Today, AtriClip devices are the most widely used LAA management device worldwide. The company plans to use LeAAPS data to support an expanded indication for stroke prevention in patients at elevated risk of ischemic stroke.

For more information about the LeAAPS trial, please visit: clinicaltrials.gov/study/NCT05478304.

About AtriCure

AtriCure, Inc. provides innovative technologies for the treatment of Afib and related conditions. Afib affects more than 59 million people worldwide. Electrophysiologists, cardiothoracic and thoracic surgeons around the globe use AtriCure technologies for the treatment of Afib, reduction of Afib related complications, and post-operative pain management. AtriCure’s Isolator ® Synergy™ Ablation System is the first medical device to receive FDA approval for the treatment of persistent and long-standing persistent Afib. AtriCure’s AtriClip ® Left Atrial Appendage Exclusion System products are the most widely sold LAA management devices worldwide. AtriCure’s Hybrid AF™ Therapy is a minimally invasive procedure that provides a lasting solution for long-standing persistent Afib patients. AtriCure’s cryoICE cryoSPHERE ® probes are cleared for temporary ablation of peripheral nerves to block pain, providing pain relief in cardiac and thoracic procedures. For more information, visit AtriCure.com or follow us on X @AtriCure.

Forward-Looking Statements

Certain statements in this press release are forward-looking in nature and are subject to risks, uncertainties and assumptions about us. Actual results may differ materially from those projected by any forward-looking statements. These risks and uncertainties include, but are not limited to, the following: our estimate of the market for our products; the rate and degree of market acceptance of our products; negative clinical data, including data that does not demonstrate sufficient safety and efficacy with respect to our products; the timing of and ability to obtain and maintain regulatory clearances and approvals for our products; our ability to comply with extensive FDA regulations; the timing of and ability to obtain third party payor reimbursement of procedures utilizing our products; the impact of tariffs or other restrictive trade measures; and litigation, administrative or other proceedings. These risks and uncertainties, as well as others, are discussed in greater detail in our filings with the Securities and Exchange Commission ("SEC"), including our Annual Report on Form 10-K for the year ended December 31, 2024 filed with the SEC on February 14, 2025, and our quarterly reports on Form 10-Q. There may be additional risks of which we are not presently aware or that we currently believe are immaterial which could have an adverse impact on our business. Any forward-looking statements are based on our current expectations, estimates and assumptions regarding future events and are applicable only as of the dates of such statements. We make no commitment to revise or update any forward-looking statements in order to reflect events or circumstances that may change.

View source version on businesswire.com: https://www.businesswire.com/news/home/20250715465717/en/

Angie Wirick
Investor Relations
Chief Financial Officer
(513) 755-5334

awirick@atricure.com

Valerie Storch-Willhaus
Media Relations
Vice President, Corporate Marketing & Communications
(612) 605-3311
vstorch-willhaus@atricure.com

Source: AtriCure, Inc.