AtriCure Announces the First Patient Treated in the BoxX-NoAF Clinical Trial

October 28, 2025

Trial will evaluate the safety and effectiveness of the AtriCure Isolator® Synergy™ EnCompass® clamp and AtriClip® Left Atrial Appendage Exclusion System to reduce the occurrence of new-onset atrial fibrillation in cardiac surgery patients

MASON, Ohio--(BUSINESS WIRE)--Oct. 28, 2025-- AtriCure, Inc. (Nasdaq: ATRC), a leading innovator in surgical treatments and therapies for atrial fibrillation (Afib), left atrial appendage (LAA) management and post-operative pain management, today announced that the first patient was enrolled and treated in the **Box** Lesion Creation with Left Atrial Appendage E**x**clusion to Reduce the Occurrence of **N**ew-**o**nset **A**trial **F**ibrillation (**BoxX-NoAF**) clinical trial (NCT06989775). The first patient was treated by Dr. Anthony Rongione, Cardiothoracic Surgeon at Orlando Health Heart and Vascular Institute in Orlando, Florida.

New onset or post-operative Afib (POAF) is the most common complication following cardiac surgery, occurring in as many as 50% of patients[1,2] presenting immediately or in the months following surgery. These arrhythmias are associated with increased mortality, morbidity, cerebrovascular accidents, Afib recurrence, hospital length of stay, and total hospital costs. BoxX-NoAF is a prospective, multicenter, randomized, FDA-approved investigational device exemption (IDE) clinical trial of up to 960 subjects at up to 75 sites worldwide. This seminal trial will ultimately define clinical practice and treatment guidelines for reducing the occurrence of POAF and longer-term clinical Afib in elevated risk cardiac surgery patients.

“The BoxX-NoAF trial, together with our LeAAPS trial that completed enrollment in July 2025, reflects AtriCure’s vision to advance standards of care by expanding the benefits of surgical ablation and LAA exclusion to a broader population of cardiac surgery patients,” said Michael Carrel, President and Chief Executive Officer. “We expect results of these trials to demonstrate that use of AtriCure devices can safely and effectively improve outcomes for cardiac surgery patients worldwide by reducing the prevalence of new-onset Afib, stroke, and systemic embolization. These studies reinforce our commitment to pioneering clinical science to expand our addressable markets.”

“POAF remains one of the most challenging complications for patients who have undergone cardiac surgery, undermining patient recovery and consuming significant hospital resources,” said Edward G. Soltesz, MD, MPH, Cleveland Clinic cardiovascular and thoracic surgeon. “We believe the BoxX procedure, combining a box lesion and LAA exclusion, could meaningfully lower the occurrence of new-onset Afib and significantly improve the quality of care for these patients.”

The BoxX-NoAF trial is the first randomized controlled trial designed to demonstrate superiority of concomitant surgical ablation with LAA management for reducing the occurrence of new-onset Afib POAF compared to no treatment. If successful, trial results would position AtriCure to pursue expanded labeling for the EnCompass clamp and AtriClip systems when used together in a BoxX procedure, and the only FDA-approved devices for the prevention of post-operative and longer-term clinical Afib. For more information about the BoxX-NoAF trial, please visit: clinicaltrials.gov/study/NCT06989775.

1.Raiten et al, Atrial Fibrillation After Cardiac Surgery: Clinical update on the Mechanisms and Prophylactic Strategies, *Journal of Cardiovascular and Thoracic Anesthesia, Vo 26. No 3, (June) 2015, pp 808-816.*

2.Lomivorotov et al, New-onset Atrial Fibrillation After Cardiac Surgery: Pathophysiology, Prophylaxis, and Treatment, *Journal of Cardiovascular and Thoracic Anesthesia, Vo 30. No 1, (February) 2016, pp 208-216.*

About AtriCure

AtriCure, Inc. provides innovative technologies for the treatment of Afib and related conditions. Afib affects more than 59 million people worldwide. 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® and cryoXT® probes are cleared for temporary ablation of peripheral nerves to block pain, providing pain relief in cardiac, thoracic and amputation 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.

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