AtriCure, Inc. Logo

AtriCure Enrolls First Patient in Randomized Multi-Center Trial Evaluating Post-Operative Afib

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This study will evaluate the effects of excluding the LAA in cardiac surgery patients at high risk of developing post-operative Afib

WEST CHESTER, Ohio--(BUSINESS WIRE)--Feb. 17, 2016-- AtriCure, Inc. (Nasdaq: ATRC), a leading innovator in treatments for atrial fibrillation (Afib) and left atrial appendage management, announced today that the first patient was enrolled and treated at PinnacleHealth Hospitals in Harrisburg, Pennsylvania in the ATLAS (AtriClip® Left Atrial Appendage Exclusion Concomitant to Structural Heart Procedures) clinical study. This observational study explores the use of the AtriClip device to decrease complications associated with post-operative Afib (POAF) by targeting specific cardiac surgery patient populations at the highest risk of developing POAF.

Postoperative Afib occurs in up to 30% of patients undergoing cardiac surgery.(1) Research has shown that specific risk factors predict patients at greatest risk.(2) POAF is associated with increased complications, increased reoperations and longer hospital length of stay.(3) The ATLAS study will compare the clinical impact of patients at highest risk of developing POAF to two randomized treatment arms: surgical left atrial appendage (LAA) exclusion (using AtriClip LAA Exclusion Systems) and patients with POAF and no surgical LAA exclusion. In addition, the study will evaluate healthcare resource utilization between the two groups.

“This is a very important study that will help us evaluate how left atrial appendage management can improve care for cardiac surgery patients,” said Michael Carrel, President and Chief Executive Officer of AtriCure. “Studies have shown that the incidence of POAF in patients undergoing cardiac surgery remains high in spite of numerous attempts to drive this complication of surgery down. This study will help us determine if a better care path exists for these at-risk patients with the ultimate goal of improving patient care and decreasing healthcare costs.(1)”

This observational study will evaluate the thromboembolic and hemorrhagic events of subjects diagnosed with POAF (AtriClip vs. no AtriClip) through 365 days post index procedure. The study will enroll up to 2,000 patients at 20 sites who are scheduled for cardiac surgery with specific risk factors for developing new onset POAF as well as significant risk factors for bleeding on commonly prescribed medications to decrease the risk of Afib-related stroke.

“Clinical equipoise exists between effective LAA exclusion at the time of cardiac surgery vs prophylactic anti-coagulation of POAF in patients at elevated risk of major bleeding.” said Dr. Basel Ramlawi, Chairman Heart and Vascular Center, Valley Health System/Winchester Medical Center. “The ATLAS trial has the potential to directly impact clinical practice for hundreds of thousands of cardiac surgical patients by answering this question.”

"It is an honor and privilege for our team at Pinnacle to be part of this highly important trial and enroll the first patient,” said Mubashir Mumtaz, MD FACS FACC, Chief of Cardiovascular and Thoracic Surgery at PinnacleHealth Hospitals, who performed the first procedure in the study. “It demonstrates our partnership and commitment in understanding the importance of left atrial appendage management in cardiac surgery patients.”

About AtriCure

AtriCure, Inc. is a medical device company providing innovative atrial fibrillation (Afib) solutions designed to produce superior outcomes that reduce the economic and social burden of atrial fibrillation. AtriCure’s Synergy™ Ablation System is the first and only surgical device approved for the treatment of persistent and longstanding persistent forms of Afib in patients undergoing certain open concomitant procedures. AtriCure’s AtriClip™ left atrial appendage management (LAAM) exclusion device is the most widely sold device worldwide that’s indicated for the occlusion of the left atrial appendage. The company believes cardiothoracic surgeons are adopting its ablation and LAAM devices for the treatment of Afib and reduction of Afib related complications such as stroke. AtriCure recently acquired nContact, a leader in minimally invasive technology for epicardial ablation. nContact’s mission is to transform the underserved arrhythmia population through a multidisciplinary epicardial-endocardial ablation approach. Afib affects more than 33 million people worldwide. For more information visit AtriCure.com or follow us on Twitter @AtriCure.

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2. Steinberg, BA, et. al, Management of POAF and Subsequent Outcomes in Contemporary Patients Undergoing Cardiac Surgery: Insights from the CAPS-Care STS AF Registry. Clinical Cardiology, 2014 January; 37(1), doi:10.1002/clc.22230.
3. Chua, SK, et al, Clinical Utility of CHADS2 and CHA2DS2-VASc scoring systems for predicting postoperative atrial fibrillation after cardiac surgery. The Journal of Thoracic and Cardiovascular Surgery, 2013:146:919-26.

Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements that address activities, events or developments that AtriCure expects, believes or anticipates will or may occur in the future, such as earnings estimates (including projections and guidance), other predictions of financial performance, launches by AtriCure of new products and market acceptance of AtriCure’s products. Forward-looking statements are based on AtriCure’s experience and perception of current conditions, trends, expected future developments and other factors it believes are appropriate under the circumstances and are subject to numerous risks and uncertainties, many of which are beyond AtriCure’s control. These risks and uncertainties include the rate and degree of market acceptance of AtriCure’s products, AtriCure’s ability to develop and market new and enhanced products, AtriCure’s ability to retain and attract key employees, the timing of and ability to obtain and maintain regulatory clearances and approvals for its products, the timing of and ability to obtain reimbursement of procedures utilizing AtriCure’s products, AtriCure’s ability to continue to be in compliance with applicable U.S. federal and state and foreign government laws and regulations, AtriCure’s ability to consummate acquisitions or, if consummated, to successfully integrate acquired businesses into AtriCure’s operations, AtriCure’s ability to recognize the benefits of acquisitions, including potential synergies and cost savings, failure of an acquisition or acquired company to achieve its plans and objectives generally, risk that proposed or consummated acquisitions may disrupt operations or pose

difficulties in employee retention or otherwise affect financial or operating results, competition from existing and new products and procedures, including the development of drug or catheter-based technologies, or AtriCure's ability to effectively react to other risks and uncertainties described from time to time in AtriCure's SEC filings, such as fluctuation of quarterly financial results, fluctuations in exchange rates for future sales denominated in foreign currency, which represent a majority of AtriCure's sales outside of the United States, reliance on third party manufacturers and suppliers, litigation or other proceedings, government regulation and stock price volatility. AtriCure does not guarantee any forward-looking statement, and actual results may differ materially from those projected. AtriCure undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. A further list and description of risks, uncertainties and other matters can be found in our Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q.

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