AtriCure's Synergy Ablation System Receives FDA Approval for the Treatment of Atrial Fibrillation

WEST CHESTER, Ohio--(BUSINESS WIRE [1])--AtriCure, Inc., a medical device company and a leader in cardiac surgical ablation systems and systems for the exclusion of the left atrial appendage, today announced that the U.S. Food and Drug Administration (FDA) has approved AtriCures Synergy Ablation System for the treatment of atrial fibrillation (AF). Specifically, the Synergy Ablation System has been approved for the treatment of patients with persistent and long-standing persistent AF during open-heart concomitant coronary artery bypass grafting and/or valve replacement or repair procedures. This is the first time a surgical ablation system has been approved for the treatment of AF and the first time any system, catheter or surgical, has been approved in the United States for the treatment of patients with persistent and long-standing persistent AF.

"This marks the achievement of a major milestone for AtriCure, the field of cardiac surgery, and the treatment of AF. The approval confirms the effectiveness of the Synergy Ablation System and recognizes the increasing need for the surgical treatment of AF," said David J. Drachman, President and Chief Executive Officer. "We look forward to educating physicians and patients on our surgical alternative for the treatment of AF, which we believe will raise awareness for a large number of AF patients that are currently being undertreated. Importantly, we would like to thank all of our partners who worked with us to achieve this approval, particularly the FDA, physicians and their patients who participated in the ABLATE trial. Additionally, I would like to recognize the efforts of the AtriCure team, who have worked tirelessly toward the successful achievement of this seminal milestone."

The Synergy Ablation System includes AtriCures Isolator Synergy clamps, a radiofrequency generator and related switchbox. It was previously cleared in the United States for cardiac tissue ablation during concomitant open-heart surgical procedures.

The FDAs approval includes the implementation of a 350-patient post-approval study, of which 46 patients have been enrolled through the ABLATE AF study. Additionally, the FDA approval includes a physician training program.

About AtriCure, Inc.
AtriCure, Inc. is a medical device company and a leader in developing, manufacturing and selling innovative cardiac surgical ablation systems designed to create precise lesions, or scars, in cardiac, or heart, tissue for the treatment of Atrial Fibrillation, or AF, and systems for the exclusion of the left atrial appendage. The Company believes cardiothoracic surgeons are adopting its ablation products for the treatment of AF, during concomitant open-heart surgical procedures and sole-therapy minimally invasive procedures. AF affects more than 5.5 million people

worldwide and predisposes them to a five-fold increased risk of stroke. AtriCures Synergy Ablation system is cleared for the treatment of patients with persistent and long-standing persistent AF during open-heart concomitant coronary artery bypass grafting and/or valve replacement or repair procedures. AtriCures other products are not approved in the United States for the treatment of other forms of AF or for other uses for the treatment of AF. Additionally, the FDA has not cleared or approved AtriCures products for a reduction in the risk of stroke.

Posted by Sean Fenske, Editor-in-Chief, MDT

Source URL (retrieved on *09/16/2014 - 7:38pm*):
http://www.mdtmag.com/news/2011/12/atricures-synergy-ablation-system-receives-fda-approval-treatment-atrial-fibrillation

Links:
[1] http://www.businesswire.com/