AtriCure's AtriClip System Surpasses 100,000 Units Sold Worldwide

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AtriClip is the most widely used device globally for left atrial appendage management

MASON, Ohio--(BUSINESS WIRE)--Apr. 25, 2017-- AtriCure, Inc. (Nasdaq: ATRC), a leading innovator in surgical treatments for atrial fibrillation (Afib) and left atrial appendage management, today announced it has sold more than 100,000 AtriClip® Left Atrial Appendage Exclusion System devices worldwide, which makes it the most widely used of all devices for excluding the left atrial appendage (LAA).

“The AtriClip franchise is one of the fastest growing parts of our business and is a meaningful driver of our broadening presence in the Afib market, which is vastly underserved and underpenetrated,” said Mike Carrel, President and Chief Executive Officer of AtriCure. “This milestone represents an incredible amount of hard work on the part of our employees and our customers as we pursue our mission to decrease the global Afib epidemic and heal the lives of those affected.”

The LAA is a muscular pouch attached to the heart’s left atrium. In patients with Afib and other cardiac arrhythmias, blood can pool and form clots in the appendage, which may then leave the heart and cause strokes. One study concluded that more than 90 percent of detected blood clots in patients with atrial fibrillation are formed in the LAA.[1]

Patients who suffer from Afib have a 500 percent greater risk of stroke, compared with the general population.[2] Afib-related strokes are associated with higher morbidity and mortality than non-Afib related strokes.[3] Prior to the invention of the AtriClip system, cardiac surgeons typically addressed the LAA during open heart surgery by cutting it off or closing off the opening of LAA to the atrium. This approach required extra time on the heart-lung machine and posed a risk of hemorrhaging and or reopening over time.

“Since the launch of the AtriClip system in 2010, we have continued to add capabilities and new technology to the platform,” continued Carrel. “These innovations, most recently with the AtriClip PRO2™ device which was launched in 2016, have served to fuel continued adoption in both open and minimally-invasive cardiac surgery. Moving forward, we are excited about our robust pipeline of products coming to market.”

The AtriClip System is cleared by the Food and Drug Administration with an indication for occlusion of the left atrial appendage, under direct visualization, in conjunction with other open cardiac surgical procedures. The clearance resulted in part from the successful EXCLUDE trial (NCT00779857), which showed the LAA was closed successfully with the AtriClip device in 98.4 percent of patients, with no device-related mortality.[4]

In February of 2016, AtriCure enrolled the first patient in the ATLAS (AtriClip® Left Atrial Appendage Exclusion Concomitant to Structural Heart Procedures) clinical study. This observational study can enroll up to 2,000 patients without a documented pre-operative history of Afib but who present with significant risk factors for developing post-operative AF (POAF) and also have significant risk factors for bleeding on commonly prescribed medication to decrease the risk of Afib-related stroke.

This randomized prospective study (AtriClip vs. no AtriClip) will evaluate resource utilization, including hospital length of stay, emergency room and/or hospital re-admissions, and costs associated with specific adverse events that may be related to atrial fibrillation through 365 days post index procedure.

About AtriCure, Inc.

AtriCure, Inc. provides innovative technologies for the treatment of Afib and related conditions. Afib affects more than 33 million people worldwide. Electrophysiologists and cardiothoracic surgeons around the globe use AtriCure technologies for the treatment of Afib and reduction of Afib related complications. AtriCure’s Isolator® Synergy™ Ablation System is the first and only medical device to receiveFDA approval for the treatment of persistent Afib. AtriCure’s AtriClip Left Atrial Appendage Exclusion System products are the most widely sold LAA management devices worldwide, with more than 100,000 implanted to date. For more information, visit AtriCure.com or follow us on Twitter @AtriCure.

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[1] Jeff S. Healey, MD, Eugene Crystal, MD, Andrew Lamy, et al. “Left Atrial Appendage Occlusion Study (LAAOS): Results of a randomized controlled pilot study of left atrial appendage occlusion during coronary bypass surgery in patients at risk for stroke.” American Heart Journal. 2005 Aug; 150:288-93.

[2] Benjamin EJ, Chen PS, Bild DE, et al. Prevention of atrial fibrillation: report from a national heart, lung, and blood institute workshop. *Circulation*. 2009 Feb 3; 119(4):606-18.

[3] Marini C, De Santis F, Sacco S, et al. “Contribution of atrial fibrillation to incidence and outcome of ischemic stroke: results from a population-based study.” Stroke. 2005 Jun; 36 (6):1115-9.

[4] Data on file at AtriCure. IDE G080095, EXCLUDE study.

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