AtriCure Receives Clearance for Expanded Labeling Claims for AtriClip Devices

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Clinical evidence demonstrates that AtriClip® devices exclude and electrically isolate the left atrial appendage

MASON, Ohio--(BUSINESS WIRE)--Aug. 27, 2019-- AtriCure, Inc. (Nasdaq: ATRC), a leading innovator in surgical treatment for atrial fibrillation (Afib) and left atrial appendage (LAA) management, today announced that it has received U.S. Food and Drug Administration (FDA) 510(k) clearance of additional labeling claims for AtriClip® LAA management devices, including changing the indication from occlusion of the LAA to exclusion, and also adding electrical isolation as a labeling claim. Exclusion shuts off and/or eliminates the appendage from the left atrium, whereas occlusion plugs the opening to prevent flow into the LAA. The electrical isolation claim was granted after testing demonstrated that when excluding the LAA using an AtriClip device, the appendage can no longer conduct electrical activity.

AtriClip devices are the most widely implanted left atrial appendage management devices on the market, having been used in more than 190,000 procedures worldwide. Over the past several years, new iterations of the AtriClip device have been developed and brought to market. These include enhancements to make the devices less invasive, amenable to a wider range of patient anatomies, and adaptable to varying operator preferences and techniques. These new labeling claims reflect that AtriClip devices exclude the appendage resulting in eliminating it as a source of electrical activity through the process of ischemic necrosis. The safety and effectiveness of AtriClip devices in rhythm control management of an atrial arrhythmia, either alone or in combination with ablative treatment, has not been established.

“We continue to demonstrate our leadership in the LAA management space by expanding our labeling claims for AtriClip devices,” said Michael Carrel, President and Chief Executive Officer of AtriCure. “The ability to simultaneously exclude and electrically isolate the LAA using an AtriClip device builds on our growing portfolio of devices. Over the past several years, we have incrementally expanded our labeling to reflect the growing clinical use for AtriClip devices. We anticipate additional labeling expansion in the future as the number of users of AtriClip devices grow.”

“Historically, the surgical amputation of the left atrial appendage in a cut-and-sew fashion was considered to be the gold standard for LAA management," said S. Patrick Whalen, MD, from Wake Forest Baptist Health. "The AtriClip device mimics the gold standard by eliminating the LAA by epicardial, mechanical closure. The subsequent ischemic necrosis process ceases all electrical activity in the LAA perioperatively and the appendage is ultimately resorbed.”

"Our research has defined a clear benefit of the electrical isolation of the LAA," said Dhanunjaya Lakkireddy, MD, from Kansas City Heart Rhythm Institute (KCHRI). "The AtriClip device excludes the left atrial appendage in a manner that could result in its electrical isolation.”

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 receive FDA approval for the treatment of persistent Afib. AtriCure’s AtriClip ® Left Atrial Appendage Exclusion System products are the most widely sold left atrial appendage management devices worldwide. For more information, visit AtriCure.com or follow us on Twitter @AtriCure.

Forward-Looking Statements

This press release contains “forward-looking statements”– that is, statements related to future events that by their nature address matters that are uncertain. For details on the uncertainties that may cause our actual results to be materially different than those expressed in our forward-looking statements, visit http://www.atricure.com/fls as well as our Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q which contain risk factors. We do not undertake to update our forward-looking statements. This document also includes forward-looking projected financial information that is based on current estimates and forecasts. Actual results could differ materially.

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