Committed to Afib solutions

US-based AtriCure manufactures and markets cardiac surgical ablation systems designed to treat atrial fibrillation (Afib) and systems for the exclusion of the left atrial appendage. The company brought on Michael Carrel as president and chief executive officer of AtriCure in 2012. Having initially spent considerable time evaluating the strategic and operational aspects of the company, he has now focused AtriCure's efforts on their Synergy Ablation System and the AtriClip® Left Atrial Appendage Exclusion System. Of the latter, the company has sold more than 50,000 devices worldwide.

Prior to his tenure at AtriCure, Mr. Carrel served as the President and Chief Executive Officer of Vital Images, a global leader of advanced imaging software for use in disease screening, clinical diagnosis and therapy decision making and planning – for over 6,000 customers, in 90 countries. The company was publicly-traded, until acquired by Toshiba Medical Systems Corporation in June of 2011. He joined AtriCure in 2012. "My mother is an Afib patient so I felt drawn to the company," he says. "I was looking for some opportunities, and this one came up and got me excited." He praises AtriCure's technology, noting that the company's Synergy Ablation System is the first surgical ablation device in the United States to receive FDA approval to treat atrial fibrillation. He also highlights AtriClip, the company's family of products for exclusion of the left atrial appendage, as well as its sales momentum, growth potential, and physicians training programs in the Maze IV technique for treating Afib.

Mr. Carrel sees raising awareness around Afib as one of his main challenges. Afib is short for atrial fibrillation, which can have various symptoms such as an irregular heartbeat, a rapid heartbeat, or a quivering of the upper chambers of the heart, called the atria. Atrial fibrillation is due to a malfunction in the heart's electrical system, and is the most common form of an irregular heartbeat, or cardiac arrhythmia. The condition can be quite risky and potentially even life threatening. Since the blood doesn't properly move from the atria into the ventricles and then on to the rest of the body, it can starve the body of oxygen-rich blood, leaving patients feeling weak, tired, or even incapacitated. Even more serious is that the blood that remains in the atria can

pool and create blood clots, which may get spawned to the rest of the body, causing a stroke. Stroke is not only the number three killer; it is the number one cause of permanent disability in the western world, and patients that have Afib are five times more likely to have a stroke. Afib can also overwork the heart, and over a long period of time can cause heart failure. Some patients successfully manage their Afib condition with medication but this doesn't always work; according to Mr. Carrel, it only works in 50 percent of those patients. When the drugs don't work or if they take them for a period of time, they become used to them, and they can no longer take them. Depending on whether they also have other structural heart diseases, patients can subsequently go down different surgical routes involving cardiac ablation. AtriCure has cardiac ablation technology for both open heart surgery and minimally invasive procedures.

The company notably offers the AtriCure Synergy Ablation System, which is used to ablate heart tissue. The system includes the Synergy Ablation Clamp, a handheld surgical device that burns or ablates the heart tissue that is grasped between the clamp's jaws during open-heart surgery. The clamp is also connected to a generator that delivers radiofrequency (RF) energy2 to the clamp during ablation. 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 other main product, the 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. 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 haemorrhaging or reopening over time.

More than 50,000 AtriClip® Left Atrial Appendage Exclusion System devices have been sold worldwide. The system is cleared by the FDA for occlusion of the left atrial appendage, under direct visualisation, in conjunction with other open cardiac surgical procedures. The company has built a bulk of clinical evidence around AtriClip for this indication, says Mr. Carrel, and also continues to research new indications. In early 2014, they initiated the Stroke Feasibility Study (NCT01997905) using the AtriClip system in a minimally invasive procedure on a beating heart in seven hospitals across the United States. This study evaluated the safety of the AtriClip system when used for stroke prevention in patients with non-valvular Afib who can't take long-term anticoagulation medications. Complete exclusion of the LAA is confirmed during the procedure using echo graphic imaging. "Cardiac Surgeons are increasingly becoming more comfortable with using our device versus the traditional methods of amputation or simply closing the opening with suture or stapling devices," says Mr. Carrel. "We are excited about our prospects for continued significant growth."

To facilitate continued growth, the company last year started construction of its new landmark headquarters in Mason with additional manufacturing and research space and has also opened an R&D centre in Minneapolis.

AtriCure

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