S4 Medical Receives De Novo Approval by the FDA for Esophageal Deviation Device used in Atrial Fibrillation Ablation

CHAGRIN FALLS, OHIO, USA, September 11, 2023 /EINPresswire.com/ -- S4 Medical Receives De Novo Approval by the FDA for Esophageal Deviation Device used in Atrial Fibrillation Ablation Procedures

S4 Medical Corporation, an Ohio-based company committed to improving safety in atrial ablation procedures, announced today that it has received de novo approval by the U.S. Food and Drug Administration (FDA) for its esolution® esophageal deviation device. The landmark approval was based on data from the EASY AF (Esophagus Deviation During Radiofrequency Ablation of Atrial Fibrillation) study which enrolled 120 total patients at 12 centers and demonstrated an 84% reduction in esophageal injury. The study also showed an 18% reduction in radiofrequency time, and no device-related complications.

Thermal injury to the esophagus is a known and serious complication associated with atrial fibrillation (AF) ablation procedures. The most serious complication is atrioesophageal fistula which results from thermal injury to the esophagus and is associated with high mortality. The approval of the esolution device represents the first FDA-approved strategy to mitigate this risk.

Current ablation technologies are effective and represent a proven treatment option for atrial fibrillation, but every procedure runs the risk of esophageal injury. “This is an important day for patients with AF and their care providers,” says William Fuller, co-founder and Chief Executive Officer. “Protecting the esophagus is long overdue.”

Last year the company completed its multi-center, randomized, blinded, prospective IDE study, which was stopped early by recommendation of the Data Safety and Monitoring Board due to confirmation of the esolution device demonstrating significant reduction of esophageal injury. “No multi-center study has even been conducted in the U.S. specifically looking at endoscopic findings between control and treatment groups in atrial fibrillation,” says co-founder and Chief Medical Officer Emile Daoud, MD, of The Ohio State University. “The data speaks for itself, and we look forward to using the esolution in every AF ablation procedure.”

Jose Osorio, MD, Director of Cardiac Electrophysiology at HCA Florida Miami and founder of Heart Rhythm and Clinical Research Solutions, was a Principal Investigator in the EASY AF Study. “I have seen a lot of innovation in electrophysiology,” he says, “and S4 delivered on something that solves a real problem, fits into the workflow, and works within the economics of AF ablation. I was pleased to be a part of this study and look forward to using the esolution device.”

Comments from other EASY AF study investigators include Rohit Mehta, MD, with Atrium Health Sanger Heart & Vascular Institute in Charlotte, North Carolina: "Our experience with the device during the clinical trial was very positive and the trial results reinforce the safety and likely downstream efficacy we will see with use. I am pleased there will soon be a commercially available device to help reduce esophageal complications.”

Amin Al-Ahmad, MD, with Texas Cardiac Arrhythmia in Austin, Texas, says “the study showed very compelling data in reducing thermal injury – we also believe that there could be an increase in success rates because of the ability to perform more complete ablations without worry of esophageal complications.”

About S4 Medical Corp

S4 Medical Corp is a medical device company focused on innovative solutions for cardiac procedures. The company’s initial product is a simple solution intended at reducing complications to the esophagus during catheter ablation procedures for atrial fibrillation. S4’s team is motivated by making medical procedures safer and more effective. For more information please visit S4medical.com.

William Fuller
S4 Medical
email us here
Visit us on social media:
Twitter
LinkedIn