

# S4 Medical Corp Launches Atrial Fibrillation Esophageal Protection Device Following FDA Clearance

CHAGRIN FALLS, OH, UNITED STATES, February 10, 2025 /EINPresswire.com/ -- [S4 Medical](#) Corp, an Ohio based company committed to making atrial fibrillation (AF) ablation procedures safer, which recently received 510(k) approval by the U.S. Food and Drug Administration for its redesigned [esolution](#)® esophageal deviation device, has begun its commercial launch starting in the United States. S4 has the first and only FDA approved device to prevent ablation-related esophageal injury using any catheter ablation modality.



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*William Fuller*

The commercial launch follows years of meeting regulatory and clinical milestones. S4's patented esolution esophageal protection device attained strong clinical data in its multicenter, international, randomized-controlled IDE Trial (The EASY AF Study | NCT04659213), demonstrating a capability to significantly reduce thermal injury risk in AF ablation patients. A key differentiator to other devices is that the esolution showed a reduction in all thermal injury, not just the risk of esophageal fistula. The company received an FDA De Novo grant in September 2023, but then optimized the device for manufacturability, improved workflow, and enhanced usability, which concluded in

attainment of FDA 510(k) clearance in November 2024.

Cofounder and CEO, William Fuller, says “There is a very strong use case for esophageal protection. If you're using RF or cryo, add the esolution and it will be every bit as fast as PFA, it is for sure as safe, and costs about one-third as much to the hospital.” Although the company is early stage, this provides some advantages, Fuller adds “not only do we have the best product, but S4 is one hundred percent focused on commercialization of the esolution and delivering outstanding support to our customers.”

Currently, the esolution device is the only device approved for use for reducing ablation-related

thermal injury to the esophagus with any percutaneous ablation technology.

The esolution device conveys impressive clinical data, reduces procedure time, and unlike other devices can claim complete prevention of an esophageal fistula. Accordingly, the company's launch will focus on converting all radiofrequency and cryoablation procedures to include the esolution device.

As part of its commercial expansion efforts, S4 recently signed on MedVida LLC and veteran clinical sales director, Greg Hunter, who has 30 years of experience in electrophysiology sales. "There is no doubt, esolution will be a welcome addition to any EP lab given the therapeutic benefit of the device. Our challenge will be to crash through the noise of inferior options, get through the VAC committees, get into the procedures, and support our physicians." The company is currently contracting with other distributors as well as ramping up its direct sales force.

Esophageal protection has recently garnered growing levels of attention from the AF Ablation market, largely due to the introduction of a new ablation modality known as Pulsed-Field Ablation (PFA). This technology claims to deliver improved esophageal safety, but it is non-superior in AF ablation outcomes, introduces new complications that are actively being reported, and comes at considerably higher costs to other modalities. Nevertheless, the AF ablation market conveys rich opportunity for the esolution device.

Physician interest has been highly positive. Gery Tomassoni, MD of Baptist Health says, "esolution is the only esophageal protection device with multicenter randomized controlled trial data that is indicated for any ablation modality. This is a great addition to our lab for patient safety and procedure workflow."

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 AF. S4's team is motivated by making medical procedures safer and more effective.

Ron Farnham

S4 Medical

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