

For immediate release
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<Hospital Heart Program NAME> Now provides an FDA Approved Treatment for Patients Suffering from Advanced Atrial Fibrillation

This is the only FDA approval of its kind—minimally invasive ablation therapy—for more than 3.5 million patients in the United States with long-standing persistent atrial fibrillation (AF).

It significantly expands AF treatment options for patients suffering from advanced atrial fibrillation.

With this therapy, the superiority trial showed a 35% difference in effectiveness at 18 months compared to endocardial RF ablation alone.

The U.S. Food and Drug Administration (FDA) has approved the EPI-Sense® System to treat patients diagnosed with long-standing persistent atrial fibrillation (AF). We at <HOSPITAL NAME> are pleased to announce that we offer this therapy to treat advanced atrial fibrillation, who until now had very few treatment options.

One in 4 adults over age 40 will develop atrial fibrillation in their lifetime.¹ AF affects about 33 million people worldwide,² and about 8 million people in the U.S.³ It also increases a person's risk of stroke and heart failure, and it is linked with increased risk of mortality.

Approximately 45% of patients with atrial fibrillation have long-standing persistent AF, affecting more than 3.5 million patients in the United States.³ “Given that these patients have no other comparable treatment options today, our electrophysiology practice will now offer the Hybrid AF Convergent procedure,” said <HOSPITAL MD, TITLE>.

The minimally invasive Hybrid AF™ Convergent procedure involves epicardial (outside of the heart) ablation plus endocardial (inside of the heart) radiofrequency (RF) ablation—thereby treating 2 key trigger areas where AF can begin. The CONVERGE IDE clinical trial demonstrated superiority in the Hybrid AF Convergent arm compared to endocardial RF catheter ablation, showing a 35% difference at 18 months in long-standing persistent AF patients. There was also a 37% improvement in AF burden (at 18 months) in favor of the Hybrid AF Convergent procedure.

The Hybrid AF Convergent procedure is the only proven minimally invasive ablation therapy to treat patients who have been in AF for more than one year.

18-Month Data Reveal Durability

Both 12-month (Table 1) and 18-month (Table 2) data from the CONVERGE IDE trial show that the Hybrid AF Convergent procedure provides durable, long-lasting efficacy. In the Hybrid AF Convergent arm, 61% of patients were free from all arrhythmias at 18 months, versus 26% of the patients treated with endocardial RF catheter ablation alone. Moreover, 68% of patients in the Hybrid AF Convergent arm were free from AF, versus 30% in the catheter ablation arm.

“These 18-month results are incredible and demonstrate the durability of the procedure,” said principal investigator David DeLurgio, MD. “This is a key finding from the trial and shows that patients who undergo a Hybrid AF Convergent procedure should expect continued freedom from atrial fibrillation.”

Parameter	Hybrid AF Convergent Ablation Arm (N=38)	Endocardial RF Catheter Ablation Arm (N=27)	Difference (Convergent – Control)
Freedom from AF/AFL/AT from 3-month blanking period through 12 months* <i>n%, (95% Confidence Interval)</i>	65.8% (50.7%, 80.9%)	37.0% (18.8%, 55.3%)	28.8% in favor of Convergent
≥90% burden reduction at 12 months* <i>n%, (95% Confidence Interval)</i>	78.9% (66.0%, 91.9%)	46.2% (27.0%, 65.3%)	32.7% in favor of Convergent
Freedom from AF through 12 months * <i>n%, (95% Confidence Interval)</i>	71.1% (56.6%, 85.5%)	37.0% (18.8%, 55.3%)	34.1% in favor of Convergent

Parameter	Hybrid AF Convergent Ablation Arm (N=38)	Endocardial RF Catheter Ablation Arm (N=27)	Difference (Convergent – Control)
Freedom from AF/AFL/AT from 3-month blanking period through 18 months* <i>n%, (95% Confidence Interval)</i>	60.5% (45.0%, 76.1%)	25.9% (9.4%, 42.5%)	34.6% in favor of Convergent
≥90% burden reduction at 18 months* <i>n%, (95% Confidence Interval)</i>	73.0% (58.7%, 87.3%)	36.0% (17.2%, 54.8%)	37.0% in favor of Convergent
Freedom from AF through 18 months * <i>n%, (95% Confidence Interval)</i>	68.4% (53.6%, 83.2%)	29.6% (12.4%, 46.9%)	38.8% in favor of Convergent

About the CONVERGE IDE Trial

The CONVERGE IDE trial is a prospective, superiority, randomized, controlled pivotal trial to evaluate the success of Hybrid AF Convergent ablation compared to endocardial RF catheter ablation for patients with persistent or long-standing persistent AF. The procedure combines a minimally invasive, closed chest epicardial ablation performed by a surgeon with endocardial RF catheter ablation performed by an electrophysiologist. The trial enrolled 153 patients at 27 locations (25 in the United States and 2 in the United Kingdom). Patients were randomized at a rate of 2:1 and received either Hybrid AF Therapy Convergent or an endocardial RF catheter ablation alone. David DeLurgio, MD, of Emory St. Joseph’s Hospital in Atlanta, Georgia, was the trial’s national principal investigator.

*Data based on the post-hoc analysis of long-standing persistent AF sub-groups (N=65)

EPI-Sense® Guided Coagulation System

U.S. Indications: The EPI-Sense Guided Coagulation System is intended for the treatment of symptomatic long-standing persistent atrial fibrillation (continuous atrial fibrillation greater than 12 months duration) when augmented in a hybrid procedure with an endocardial catheter listed in the instructions for use, in patients (1) who are refractory or intolerant to at least one Class I and/or III antiarrhythmic drug (AAD); and (2) in whom the expected benefit from rhythm control outweighs the potential known risks associated with a hybrid procedure such as delayed post-procedure inflammatory pericardial effusions. **Contraindications** include patients with Barrett's Esophagitis, left atrial thrombus, a systemic infection, active endocarditis, or a localized infection at the surgical site at the time of surgery. **Adverse Events:** Reported adverse events associated with epicardial ablation procedure may include, but are not limited to, the following: pericardial effusion/cardiac tamponade, pericarditis, excessive bleeding, phrenic nerve injury, stroke/TIA/neurologic complication. Please review the Instructions for Use for a complete listing of contraindications, warnings, precautions and potential adverse events located at the following AtriCure web address: <https://www.AtriCure.com/EPI-Sense-Coagulation-Device>. **Warnings:** Physicians should consider post-operative anti-inflammatory medication to decrease the potential for post-operative pericarditis. and/or delayed post-procedure inflammatory pericardial effusions. Physicians should consider post-procedural imaging (i.e. 1-3 weeks post-procedure) for detection of post-procedure inflammatory pericardial effusions. **Precautions:** Precautionary measures should be taken prior to considering treatment of patients: (1) Deemed to be high risk and who may not tolerate a potential delayed post-procedure inflammatory pericardial effusion. (2) Who may not be compliant with needed follow-ups to identify potential safety risks. To ensure patients undergoing treatment with the EPI-Sense device are well informed, the benefits, potential risks and procedural outcomes associated with the EPI-Sense Hybrid Convergent procedure should be discussed with the patient. Physicians should document accordingly in the medical record. Qualified operators are physicians authorized by their institution to perform surgical sub-xyphoid pericardial access. The coagulation devices should be used by physicians trained in the techniques of minimally invasive endoscopic surgical procedures and in the specific approach to be used. Operators should undergo training on the use of EPI-Sense device before performing the procedure. Safety and effectiveness of concomitant left atrial appendage closure was not evaluated in the CONVERGE study. Follow-up should be conducted at approximately 30 days post-procedure to monitor for signs of delayed onset pericarditis or pericardial effusion. **Rx Only.**

Sources

1. Lloyd-Jones, D.M., et al. (2004). Lifetime risk for development of atrial fibrillation. *Circulation*, 110, 1042-1046. doi: 10.1161/01.CIR.0000140263.20897.42.
2. Rahman, F., et al. (2014). Global epidemiology of atrial fibrillation. *Nature reviews cardiology*, 11, 639-654. <https://doi.org/10.1038/nrcardio.2014.118>
3. Colilla, S. et al. (2013). Estimates of current and future incidence and prevalence of atrial fibrillation in the U.S. adult population. *American journal of cardiology*, 112(8), 1142-1147.