**Hybrid AF™ Therapy: The First FDA-Approved Minimally Invasive Device for Patients with Long-Standing Persistent Atrial Fibrillation Is 2x\* More Effective than Endocardial Radiofrequency Ablation Alone**

**Hybrid AF CONVERGE Trial Is the *Only* Superiority Randomized Controlled Trial (RCT) That:**

• Is a prospective multicenter RCT for Hybrid AF Therapy—offering the *highest level of evidence*

• Enrolled the *most challenging to treat long-standing persistent AF patients*

• Shows a *37% difference in AF burden improvement—*vs endocardial RF ablation at 18 months

<INSERT HOSPITAL NAME> is one of the hospitals in the country to offer Hybrid AF Therapy. The FDA-approved Hybrid AF Therapy with the Epi-Sense Device treats patients with long-standing persistent AF, historically, the most challenging patients suffering from atrial fibrillation.

**Atrial Fibrillation Is a Sizeable and Growing Health Problem**

Atrial fibrillation is an abnormal heart rhythm caused by erratic electrical signals in the heart. Normally the heart creates regular electrical signals that are essential for the heart to beat in a steady, rhythmic way, and pump blood to all parts of the body. Sometimes the electrical signals become irregular, and the heart beats abnormally.

Atrial fibrillation is the most commonly diagnosed arrhythmia in the United States. In fact, 1 in 4 adults over 40 will develop AF in their lifetime.1 AF affects over 33 million people worldwide,2 and about 8 million people in the United States.3 Approximately 45% of AF patients have long-standing persistent AF, affecting more than 3.5 million patients in the United States.3

**Importance of Treatment**

Atrial fibrillation is a progressive disease, so it's best if patients are treated before it progresses and causes other health problems.4 Left untreated, AF is associated with:

**5x** increase in stroke risk5

**5x** increase in heart failure development6

Atrial fibrillation also increases risk for:

* Chronic fatigue
* Decreased activity levels
* Diminished quality of life

**The Stages and Symptoms of Atrial Fibrillation**

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Symptoms of paroxysmal atrial fibrillation include:

* Palpitations
* Fluttering feeling in the chest
* Rapid or irregular heartbeat

Symptoms of the two advanced stages of AF include:7,8

* Shortness of breath
* Dizziness
* Weakness
* Fatigue
* Lowered blood pressure
* Pain or pressure in the chest
* Rapid or irregular heartbeat

**Which Patients Are a Good Fit for Ablation Treatments and Hybrid AF Therapy**

Hybrid AF Therapy with the Epi-Sense Device is the only FDA-approved device for minimally invasive ablation therapy to treat long-standing persistent patients (atrial fibrillation that lasts longer than one year).

If you have patients or loved ones who have suffered with AF that lasts longer than one year and is not responding to medication, they may be good candidates for this therapy.

**Hybrid AF Therapy Is 2x More Effective9,\* Than Endocardial RF Treatment Alone**

Compared to endocardial radiofrequency (RF) ablation alone, Hybrid AF Therapy results in:

* **90%** less time in atrial fibrillation for 79% of people in the study9

Patients who had Hybrid AF Therapy also reported feeling better, both physically and emotionally, and report having fewer symptoms than before the procedure.10

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

**The Procedure**

Hybrid AF Therapy combines endocardial RF ablation, which treats the inside the heart, with epicardial ablation, which treats the outside of the heart. In this way Hybrid AF Therapy targets two key areas where AF originates, the pulmonary veins and the posterior (back) wall of the heart. This therapy can provide a lasting solution to long-standing persistent Afib. Eighteen months after treatment patients in the Hybrid AF Therapy arm of the CONVERGE trial are 2x more likely to be free of AF (vs catheter ablation alone) with no additional anti-arrhythmic drugs.9

In the CONVERGE trial, primary safety data show adverse events of:

* 2.9% at 7 days (not pre-specified by protocol, in-line with endocardial studies),
* 7.8% at 30 days (pre-specified CONVERGE protocol),

CONVERGE Safety Events (full cohort): No deaths, atrioesophageal fistulas, or cardiac perforations.

30 Day: Protocol pre-specified definition

* 1 Stroke (slightly slower left facial movement, did not have debilitating effect)
* 1 Phrenic nerve injury (PNI), resolved
* 1 Bleed
* 1 Bleed with late pericardial effusion
* 1 Transient ischemic attack (TIA)
* 4 Cardiac Tamponade

**Our Goal: Optimal Therapies for All Patients**

It is the mission of <INSERT HOSPITAL NAME> to continue to offer new and innovative therapies for patients who had limited options in the past. We look forward to providing Hybrid AF Therapy to patients who are indicated for this treatment.

**EPi-Sense® Coagulation System/EPi-Sense ST™ Coagulation Device**

The EPi-Sense Coagulation System/EPi-Sense ST™ Coagulation Device 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 postprocedure to monitor for signs of delayed onset pericarditis or pericardial effusion.

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.

4. Benussi, S., & de Maat, G.E. (2018). Atrial remodelling and function: implications for atrial fibrillation surgery. *European journal of cardio-thoracic surgery,* 53(i1):i2–i8, https://doi.org/10.1093/ejcts/ezx340

5. Benjamin, E.J., et al. (2019). Heart Disease and Stroke Statistics — 2019 Update: A Report From the American Heart Association. *Circulation,* 139:e56-e528, DOI: 10.1161/CIR.0000000000000659

6. Odutayo, A. et al. (2016). Atrial fibrillation and risks of cardiovascular disease, renal disease, and death: systematic review and meta-analysis. *BMJ,* 354, i4482.

7 Calkins, H. et al. (2018). 2017 HRS/EHRA/ECAS/APHRS/SOLAECE Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation. *Heart rhythm,* 14(10), e275-444.

8. Barbarossa, A., et al. (2014). Silent atrial fibrillation: a critical review. *Journal of atrial fibrillation,* 7(3): 1138, http://www.jafib.com/PMC/XML/Inprogress/1138/1138pdf\_federico\_guerra.pdf

9. DeLurgio, D.B., et al. (2021). *Hybrid epicardial-endocardial RF ablation vs. endocardial catheter ablation for long-standing persistent atrial fibrillation treatment: Results from CONVERGE randomized controlled trial.* International AF Symposium.

10. AtriCure. (2020). *PMA P200002 FDA Summary of Safety and Effectiveness Data: Epi-Sense® Guided Coagulation System.*

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