Hybrid AF™ CONVERGE Trial

Only Prospective, Multicenter Superiority RCT

The Highest Level of Evidence

The CONVERGE Study with the EPi-Sense® System is the only FDA approved minimally invasive ablation therapy of its kind to treat patients diagnosed with long-standing persistent atrial fibrillation (afib).

- Afib affects over 33 million people worldwide[1] and about 8 million people in the United States[2]
- Approximately 45% of those people have long-standing persistent afib
- More than 3.5 million patients in the United States have long-standing persistent afib
- Afib increases a person's risk of stroke and heart failure, and it is linked with increased risk of mortality[1]

The Hybrid AF Convergent procedure is the only proven therapy to treat patients who have been in afib for more than one year. Until now, patients with long-standing persistent atrial fibrillation had very few treatment options.

Parameter	Hybrid AF Convergent Ablation Arm (N=38)	Endocardial RF Catheter Ablation Arm (N=27)	Difference (Convergent – Control)
Freedom from Afib/AFL/AT from 3-month blanking period through 18 months*	60.5%	25.9%	34.6% in favor of Convergent
≥90% burden reduction at 18 months*	73.0%	36.0%	37.0% in favor of Convergent
Freedom from Afib through 18 months*	68.4%	29.6%	38.8% in favor of Convergent

*Without new/ increased dosage of previously failed class I/III AADs
AADs: anti-arrhythmic drugs; Afib: atrial fibrillation; AFL: atrial flutter; AT: atrial tachycardia

**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.*

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

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

The CONVERGE IDE trial is a landmark 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 afib.

The trial enrolled 153 patients, 88 persistent and 65 long-standing persistent, 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 Convergent therapy or endocardial RF catheter ablation alone.

The procedure combines a minimally invasive, closed chest epicardial ablation performed by a surgeon with endocardial RF catheter ablation performed by an electrophysiologist.

AtriCure

Hybrid AF CONVERGE Trial

CONVERGE Primary Safety Data

- 7 days (not pre-specified by protocol): 2.9%
- 30 days (CONVERGE Protocol): 7.8%

Safety Events

- No deaths*
- No cardiac perforation*
- No AE fistula*
- 4 Cardiac Tamponade
- 1 stroke (slightly slower left facial movement, did not have debilitating affect)
- 1 phrenic nerve injury (PNI), resolved
- 1 bleed
- 1 bleed with late pericardial effusion
- 1 transient ischemic attach (TIA)

**Reported in either study arm*

Treating Afib Is Always Very Important Because

It's a progressive disease.

Atrial fibrillation puts a person at 5x higher risk of stroke[3] and 5x greater risk of heart failure.[4] It is also associated with being less active and a diminished quality of life.[5]

What Patients Should Know

The symptoms for early stage and advanced stage afib are different. Symptoms for long-standing persistent afib can include shortness of breath, lightheadedness, fainting, weakness, lack of energy, and chest pain/angina.[5,6]

References:

[1]*Rahman, F., Kwan, G.F., & Benjamin, E.J. (2014). Global epidemiology of atrial fibrillation. Nat Rev Cardiol, 11(11):639-54. https://doi.org/10.1038/nrcardio.2014.118.*

[2]*Colilla, S. et al. (2013). Estimates of current and future incidence and prevalence of atrial fibrillation in the U.S. adult population. Am J Cardiol, 112(8), 1142-7.*

[3]*Benjamin, E.J. et al. (2019). Heart Disease and Stroke Statistics — 2019 Update: A Report From the American Heart Association. Circulation, 139:e56-528, DOI: 10.1161/CIR.0000000000000659.*

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

[5]*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.*

[6]*Barbarossa, A., Guerra, F., & Capucci, A. (2014). Silent atrial fibrillation: a critical review. J Atr Fibrillation, 7(3):1138, http://www.jafib.com/PMC/XML/Inprogress/1138/1138pdf_federico_guerra.pdf.*

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.***