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

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

EU. Indications: *The EPi-Sense® Guided Coagulation System with VisiTrax® is intended for the coagulation of cardiac tissue using radiofrequency (RF) energy during cardiac surgery for the treatment of arrhythmias including Atrial Fibrillation (AF) or Atrial Flutter (AFL).*

Contraindications: *Patients with presence of left atrial thrombus, a systemic infection, active endocarditis, or another infection local to the surgical site at the time of surgery. Patients with Barrett's Esophagus.*