**Hybrid AF™ Therapy: The First FDA-Approved Therapy for Long-Standing Persistent Atrial Fibrillation Patients 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 first hospitals in the country to offer Hybrid AF Therapy, treating patients with long-standing persistent atrial fibrillation (AF, or Afib). Historically, this category of AF patients has been more challenging to treat.

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

Atrial fibrillation is an abnormal heart rhythm caused by erratic electrical signals in the heart. A heart normally 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. But 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**



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 is the only FDA-approved 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 having fewer symptoms than before.10

**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 RF 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.

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

**EPi-Sense® Guided Coagulation System**

**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 (AFIB) 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.

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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.

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PM-EU-1682A-0622-G