**Hybrid AF™ Therapy: There is now a minimally invasive treatment for patients with advanced Atrial Fibrillation**

<INSERT HOSPITAL NAME> is proud to offer Hybrid AF Therapy, a minimally invasive therapy for the treatment of patients with advanced atrial fibrillation (Afib), historically, the most challenging patients suffering from atrial fibrillation. The Hybrid AF Therapy incorporates both epicardial ablation (outside of the heart) and endocardial ablation (inside the heart) procedures, compared to endocardial catheter ablation alone.1 In this way, Hybrid AF Therapy targets the trigger areas in the heart where Afib originates.

**Atrial Fibrillation Is A Growing Health Concern**

A healthy heart creates regular electrical signals that are essential for the heart to beat in a steady, rhythmic way, allowing the heart to supply the body with blood. Afib is an abnormal heart rhythm caused by erratic electrical signals in the heart.

Afib is the most commonly diagnosed arrhythmia in the United States. In fact, 1 in 4 adults over 40 will develop Afib in their lifetime.2 Afib affects over 59 million people worldwide,3 and about 10 million people in the United States.4 Approximately 45% of Afib patients have advanced Afib, affecting more than 4 million patients in the United States.4

**Importance of Treatment**

Afib is a progressive disease, the longer it remains untreated, the higher the risk for progressive disease, leading to other potential health concerns.5 Left untreated, Afib is associated with:

* **5x** increase in stroke risk5
* **5x** increase in heart failure development6
* **3x** increase in dementia7

Atrial fibrillation also increases risk for:

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

**The Stages and Symptoms of Atrial Fibrillation**

 **Early Stage Afib Advanced Stage Afib**

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Symptoms of paroxysmal Afib include:

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

Symptoms of the two advanced stages of Afib include:8,9

* 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-SenseTM Device is the only FDA-approved device for minimally invasive ablation therapy to treat patients with advanced Afib (Afib that lasts longer than one year).

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

**Hybrid AF Therapy Is 2x More Effective10,\* 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 Converge RTC study10

\*Data based on post-hoc analysis of advanced Afib sub-groups (N=65)

**Additionally, Results from More than 1,100 Patients with Advanced Afib Who Underwent Hybrid AF Therapy:**

* Up to 88% of patients treated with Hybrid AF Therapy were free from Afib1,10,11-23
* Up to 94% of patients had reduced Afib burden after being treated with Hybrid AF Therapy11,15,22,23
* Patients reported > 2x improvement in quality of life24,25
* Patients reported > 3x improvement in Afib symptoms24
* Patients in these studies included: enlarged left atria, Afib for greater than 1 year, failed medical management

**The Procedure**

Hybrid AF Therapy combines endocardial RF ablation, which treats the inside the heart, and epicardial ablation, which treats the outside of the heart. In this way Hybrid AF Therapy targets two key areas where Afib originates, the pulmonary veins and the posterior (back) wall of the heart. This therapy can provide a lasting solution for patients with advanced Afib. Eighteen months after treatment, patients in the Hybrid AF Therapy arm of the CONVERGE trial are 2x more likely to be free of Afib (vs catheter ablation alone) with no additional anti-arrhythmic drugs.10

**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.

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