**For immediate release**

[Month] [Day], 2023

 **< Dr. NAME> performed the first Hybrid AF™ Ablation procedure with the new EPi-Sense ST™ device for the Treatment of Patients Suffering from Advanced Atrial Fibrillation at <Hospital/Heart Program Name>**

*The new EPi-Sense ST™ Coagulation Device is the latest innovation available to treat the 3.5 million patients suffering from advanced atrial fibrillation1*

The U.S. Food and Drug Administration (FDA) has approved the new EPi-Sense ST™ System to treat patients diagnosed with long-standing persistent atrial fibrillation (Afib).

We at <HOSPITAL NAME> are pleased to announce that we now offer this latest innovation to our advanced atrial fibrillation patients as part of our Hybrid AF Therapy treatment. Hybrid AF Therapy with the EPi-Sense family of products is the only approved treatment for the 3.5 million patients with advanced atrial fibrillation.

Hybrid AF™ Therapy is the only minimally invasive therapy that involves epicardial (outside of the heart) ablation plus endocardial (inside of the heart) radiofrequency (RF) ablation—treating 2 key areas where Afib can begin.

The CONVERGE IDE clinical trial demonstrated superiority in the Hybrid AF arm compared to endocardial RF catheter ablation alone in advanced atrial fibrillation patients at 18 months\*:

* 39% improvement in freedom from Afib
* 37% improvement in AF burden

One in 4 adults over age 40 will develop atrial fibrillation in their lifetime.2 AF affects about 37 million people worldwide,3 and about 8 million people in the U.S.4 It also increases a person's risk of stroke and heart failure, and it is linked with increased risk of mortality.

EPi-Sense ST™ is the first device in the EPi-Sense family to offer a new deflectable tip and braided catheter design to provide control to position placement of the EPi-Sense ST™ in targeted lesion locations.

Approximately 45% of patients with atrial fibrillation have long-standing persistent AF, affecting more than 3.5 million patients in the United States. “Given that these patients have no other comparable treatment options today, our practice will now offer the Hybrid AF Convergent procedure, utilizing the EPi-Sense ST™ device” said <HOSPITAL MD, TITLE>.

CONTACTS:

**Indications:** 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. **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/EPi-Sense ST device are well informed, the benefits, potential risks and procedural outcomes associated with the EPi-Sense/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/EPi-Sense ST 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**

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

**Sources**

1. Medical management estimate: Colillia, et al. Estimate of Current and Future Incidence and Prevalence of Atrial Fibrillation in the U.S. Adult population. AM Journal of Cardiology 2013, 112: 1142-1147
2. Lifetime risk for development of atrial fibrillation. Circulation, 110 (2004): 1042-1046. doi: 10.1161/01.CIR.0000140263.20897.42
3. European Heart Journal – Quality of Care and Clinical Outcomes (2021) 7, 574-582 doi: 10.1093/ehjqcco/qcaa061
4. The American Journal of Cardiology (2013), 112: 1142-1147