

[PHYSICIAN'S LETTERHEAD]
[MD NAME]
[CENTER] [ADDRESS] [CITY STATE ZIP]
[DATE]

Dear Dr. [NAME]:

There is now an FDA approved minimally invasive therapy for patients with advanced atrial fibrillation (AF). Hybrid AF™ Therapy is now approved to treat patients with **long-standing persistent AF**, those who are in AF for 12 months or longer.

Atrial fibrillation is the most commonly diagnosed arrhythmia in the U.S., with 1 in 4 adults over 40 developing AF in their lifetime. AF affects over 33 million people worldwide, and about 8 million people in the United States. Approximately 45% of patients with AF have long-standing persistent AF, affecting more than 3.5 million patients in the United States.

If AF is not properly treated, it leads to a higher risk of chronic fatigue, decreased activity level, diminished quality of life, and sudden death. Moreover, AF imparts a 5x higher risk of both stroke and heart failure. Because AF is a steadily progressive condition, patients should receive optimal treatment before their arrhythmia worsens.

In your practice, you see patients who suffer from atrial fibrillation. We now offer *Hybrid AF™ Therapy* in our practice, and I would like to share some data about the procedure. Until now, effective treatment has been extremely limited for patients with long standing persistent AF.

*New 18-month data showed that in the Hybrid AF Convergent arm (compared to the endocardial radiofrequency RF ablation arm):

- Therapy was **2.3x** more effective
- Patients were **> 2x** as likely to be off antiarrhythmics

Additionally, the FDA-approved therapy showed a **≥ 90%** reduction in burden for most patients (79%) at 1 year.

Patients enrolled in the Hybrid AF CONVERGE study:

- had AF that lasted more than 1 year
- were refractory or intolerant to one antiarrhythmic drug
- had left atrial size < 6.0 cm
- were between ages > 18 and < 80 years

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

Incorporating both endocardial RF and epicardial therapies, the Hybrid AF Convergent procedure targets two key areas where AF originates and creates transmural lesions that stop the onset of AF. This therapy may provide a long-term solution for appropriately selected patients with long-standing persistent AF. See the indications below.

I hope that as you evaluate patients in your daily practice, you consider referring patients who may be candidates for this procedure.

Your patients with long-standing persistent AF may exhibit these symptoms: dyspnea • dizziness • hypotension • weakness • fatigue • angina • tachyarrhythmias or palpitations.

If you have any questions, want more information about the procedure, or would like to discuss a specific case, please contact me directly at <[PHONE/EMAIL](#)>. I look forward to working with you to offer an option to patients who are seeking treatment for their long-standing persistent AF.

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

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.**

Sincerely,
[PHYSICIAN NAME]
[TITLE]
[INSTITUTION]