[PHYSICIAN’S LETTERHEAD]

[MD NAME]

[CENTER] [ADDRESS] [CITY STATE ZIP]

[DATE]

Dear Dr. [NAME]:

I’d like to make you aware of [HOSPITAL NAME] now routinely performing a therapy for atrial fibrillation (AF) patients called Hybrid AF™ Therapy.

In your practice, you see patients who suffer from AF. Some of them are affected from non-paroxysmal forms of AF, with AF episodes lasting over 7 days (persistent AF) or even over 1 year (long-standing persistent AF). Until now, effective treatment has been extremely limited for this category of AF patients. We now offer this therapy in our practice, and I would like to share some data about the Hybrid AF Convergent procedure.

Atrial fibrillation is the most commonly diagnosed arrhythmia in Europe, with 1 in 4 adults over 40 developing AF in their lifetime. AF affects over 33 million people worldwide, and about 10 million people in Europe Approximately 50% of AF patients have non-paroxysmal forms of AF.

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.

Available data (CONVERGE trial) demonstrate that Hybrid AF therapy is more effective than conventional endocardial radiofrequency RF ablation to treat non-paroxysmal forms of AF. In particular, Hybrid AF Therapy was found to be

* 39% more effective at stopping AF at 1 year
* 2.3x more effective at stopping long-standing persistent AF at 18 months
* Long-standing persistent patients were **> 2x** as likely to be off antiarrhythmics at 18 months
* Majority (79%) of patients experienced a **≥ 90%** reduction in AF burden

Patients enrolled in the CONVERGE study:

* had over 4 years in AF since first diagnosis
* 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, resolved

Incorporating both endocardial RF and epicardial therapies, the Hybrid AF 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 persistent and 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 persistent and 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**

**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).

**EPi-Sense ST™ Coagulation Device**

**EU Indications:** The EPi-Sense ST™ Coagulation Device is indicated for the epicardial treatment of arrhythmias including atrial fibrillation (AF) when augmented with an endocardial ablation, with the aim to restore normal sinus rhythm, reduce AF symptoms, and improve quality of life.

Please review the Instructions for Use for a complete listing of contraindications, warnings, precautions and potential adverse events prior to using these devices.

**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.

Sincerely,

[PHYSICIAN NAME]

[TITLE]

[INSTITUTION]