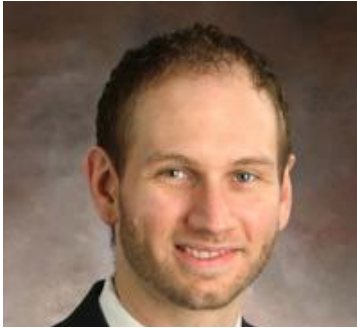


# Case Study: Hybrid Ablation Left Ventricular Function Normalized, Medication Reduced



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## **Patient**

A woman presented to Norton Audubon Hospital with shortness of breath and dizziness and was noted to be in new-onset atrial fibrillation (Afib). She underwent immediate cardioversion but had recurrent Afib and then was placed on Flecainide with a repeat successful cardioversion. Her echocardiogram showed normal left ventricular function.

## **Challenge**

The following day, the patient returned to the hospital with abrupt return of dyspnea and was found to be in acute pulmonary edema. Echocardiogram showed her ejection fraction had dropped to 33%. Her Flecainide was stopped and she was placed on guideline-directed medical therapy for heart failure and given a LifeVest™, an external, wearable defibrillator to protect from sudden cardiac arrest. She also was placed on Amiodarone but unfortunately developed severe side effects warranting cessation. Her Afib became persistent once the amiodarone was stopped.

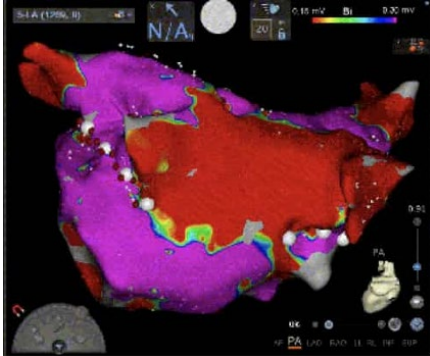
## **Solution**

She was seen in the Norton Heart & Vascular Institute Afib Clinic, and options were discussed with her, which included referral for a hybrid ablation for Afib.

Hybrid ablation for Afib is a two-stage procedure involving ablation along the epicardial and endocardial surfaces of the left atrium. Steven Peterson, M.D., Cardiothoracic Surgeon with Norton Heart & Vascular Institute, completed the first stage, an epicardial ablation along the posterior left atrial wall via a sub-xiphoid approach. The second stage is a standard endocardial catheter ablation performed by a Cardiac Electrophysiologist — in this case, Kent E. Morris, M.D., MBA, electrophysiologist with Norton Heart & Vascular Institute. The patient was in favor of this approach and has successfully completed both stages of the procedure.

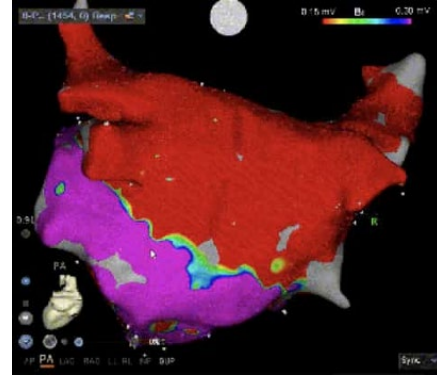
# Hybrid Ablation Left Ventricular Function Normalized, Medication Reduced (continued)

Map 1.



Electrical isolation of the left atrium including the posterior left atrial wall and the pulmonary veins after the first stage. Red indicates silenced electrical signals.

Map 2.



After the second endocardial stage.

## Result

The patient resumed normal sinus rhythm, and her left ventricle function normalized. She no longer requires the use of the LifeVest and has been able to come off of several of her medications. Most important, her quality of life has dramatically improved, and she is back to doing the activities she loves.

The hybrid ablation is a highly effective option for patients with persistent atrial fibrillation that is refractory to other treatment options and highlights the collaborative approach at Norton Heart & Vascular Institute between cardiac electrophysiology and cardiothoracic surgery in order to maximize patient outcomes.

Treatment and results may not be representative of all similar cases.

Note: Clinical results from case studies are not predictive of results in other cases. Results in other cases may vary.

### EPI-Sense Coagulation System/EPI-Sense ST™ Coagulation Device

**U.S. 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 ST 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-xiphoid 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.**