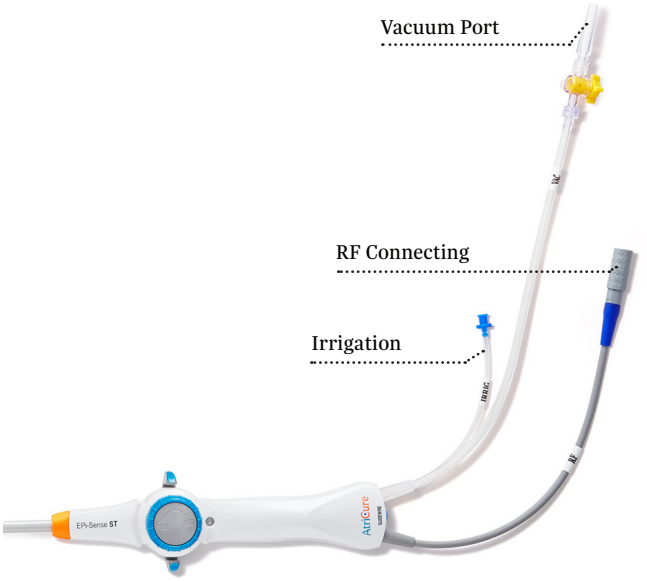
Hybrid AF™ Therapy
EPi-Sense ST™ Coagulation Device

The Latest Innovation in Deflection and Control for Epicardial Atrial Fibrillation Ablation for the Treatment of Advanced Afib Patients

AtriCure

Features

- Deflection of distal tip +/- 30° degrees
- Locking mechanism
- Torqueability (1:1 rotation)
- LED indicator light
- 3 cm device electrode length
- 2 distal and proximal sensing electrode pairs
- Irrigation/perfusion lumen
- Integrated suction



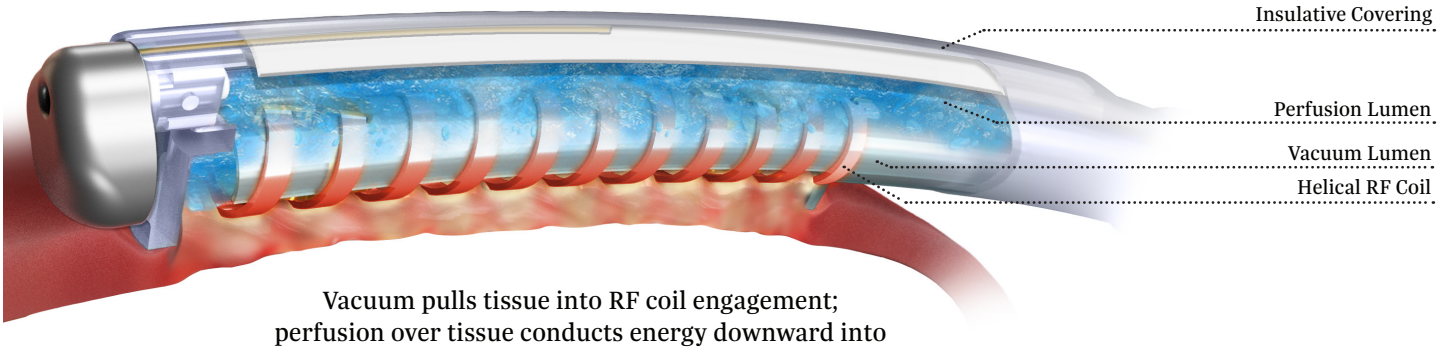
Benefits

- Steering lever allows the distal tip to deflect, allowing the operator to adjust the location of ablation coil
- Steering and braided catheter design provide control to position placement of the EPi-Sense ST
- Intuitive handle design and braided shaft allows for fine rotational and controlled positioning of the ablation coil
- LED on handle alerts user when device distal end exceeds temperature threshold

How EPi-Sense ST Works

Consistent Tissue Contact = Consistent Energy Transmission = Complete Lesions

Saline cooling solution cools the backside of the EPi-Sense ST device



Vacuum pulls tissue into RF coil engagement; perfusion over tissue conducts energy downward into tissue while circulating blood absorbs excess heat.

EPi-Sense ST™ Guided Coagulation System

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

EPi-Sense ST™ System Summary of Safety and Effectiveness data: PMA P200002. Data based on the post-hoc analysis of long-standing persistent AF sub-groups (N=65).

ATRICURE, INC.
7555 Innovation Way
Mason, OH 45040 USA
+1 (513) 755-4100
+1 (888) 347-6403
CustomerService@AtriCure.com
www.AtriCure.com

PM-US-2247A-0824-G

EPi-Sense ST Ablation Device	
Device	**Product Code**
3 cm EPi-Sense ST Device	EPIST-30
3 cm EPi-Sense ST Device (No Cannula)	EPIST-PK

AtriCure