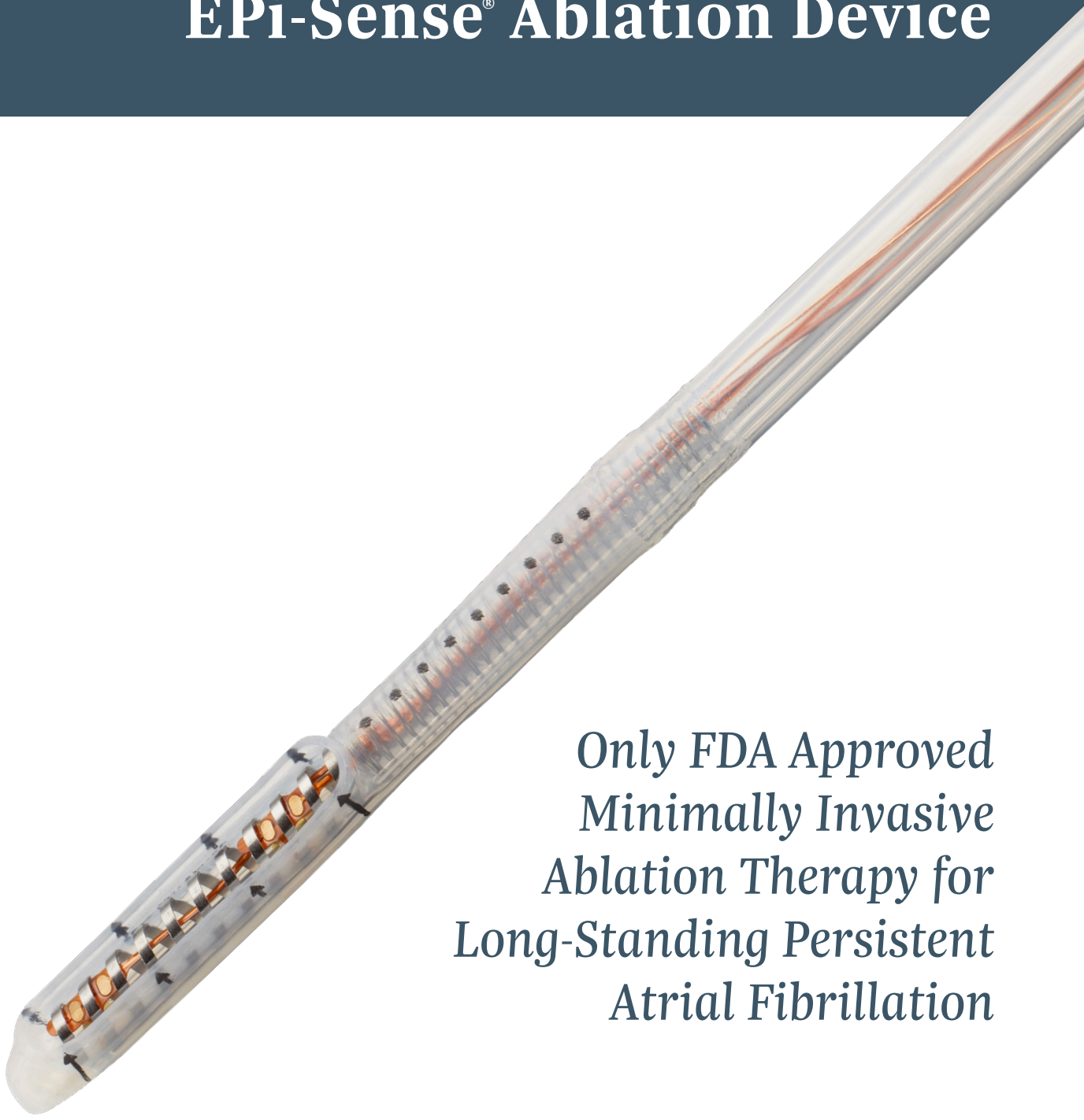
Hybrid AF™ Therapy
EPi-Sense® Ablation Device



Only FDA Approved Minimally Invasive Ablation Therapy for Long-Standing Persistent Atrial Fibrillation

AtriCure

EPi-Sense Ablation Device

EPi-Sense RF Technology combined with Hybrid AF Therapy, is the only ablation system proven safe and effective for the treatment of long-standing persistent atrial fibrillation.

GREATER EFFICACY
35% greater efficacy than endocardial catheter ablation alone at 18 months

AFIB BURDEN IMPROVEMENT
73% of patients with greater than 90% burden reduction at 18 months

SUSTAINABLE LONG-TERM AFIB FREEDOM
69% of patients freedom from afib through 18 months

Features

- 3 cm device electrode length
- 2 distal and proximal sensing electrode pairs
- Irrigation/perfusion lumen
- Integrated suction

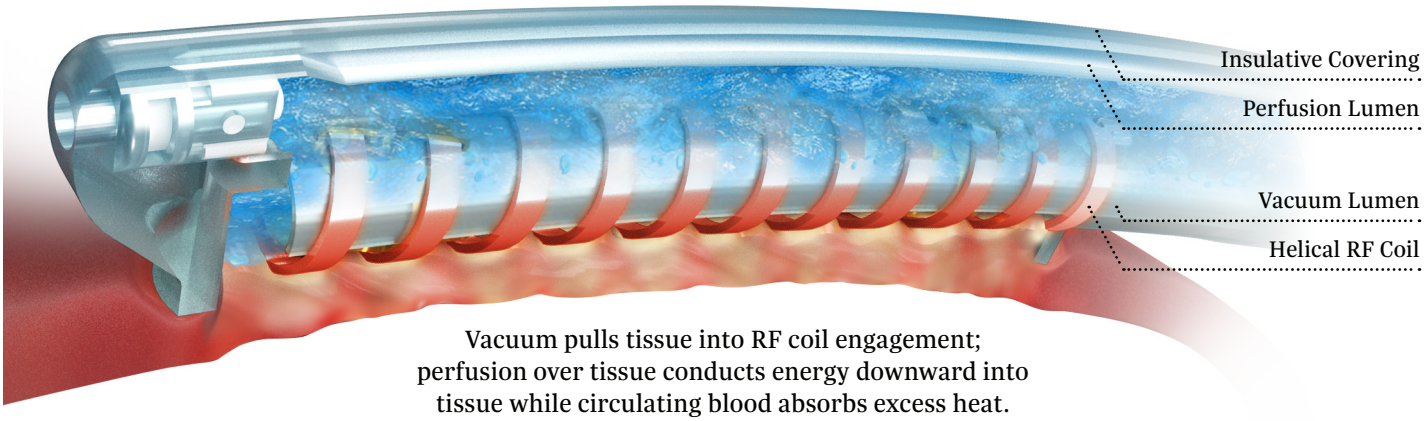
Benefits

- Enables the physician to view epicardial electrograms before, during, and after ablation
- Provides additional information regarding lesion creation and completeness
- EPi-Sense provides comprehensive long linear lesions

How EPi-Sense Works

Consistent Tissue Contact = Consistent Energy Transmission = Complete Lesions

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



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

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.***

EPi-Sense® 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).

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EPi-Sense Ablation Device	
Device	**Product Code**
3 cm EPi-Sense Guided 6130 Device	CDP-4330-1
3 cm EPi-Sense Guided 6130 Device, pack of 3	CDP-4330

PM-US-0053B-1022-G

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