

Safety and Efficacy of Convergent Hybrid Procedure Using Cryo as Endocardial Energy Source for the Treatment of Atrial Fibrillation

This study showed that using endocardial cryotherapy in Hybrid AF Convergent procedures achieved marked reductions in AF burden, even in long-standing persistent AF (LSPAF). Most Hybrid AF Convergent studies use radiofrequency as the endocardial and epicardial energy. This study reports the safety and efficacy of the Hybrid AF Convergent procedure using endocardial cryotherapy.

Method: Retrospective analysis of 226 TRAC-AF Registry patients (2011-2018) who underwent epicardial RF ablation and endocardial cryotherapy.

Parameter	All patients (mean 15.4 ± 6.5 months)	Persistent AF (mean 14.7 ± 6.1 months)	LSPAF (mean 16.8 ± 6.3 months)
Free of AF/AFL/AT: on or off previously failed AADs	75%	85%	70%
Free of AF/AFL/AT: off amiodarone	70%	84%	64%
Free of AF/AFL/AT: off AADs	53%		
AF Burden Reduction (3-12 months)	98.9%	99.3%	98.5%
AF Burden Reduction (12-24 months)	91.5%	89.3%	92.5%

AF: atrial fibrillation; AFL: atrial flutter; AT: atrial tachycardia; AADs: anti-arrhythmic drugs

Results indicate Hybrid AF Convergent using cryo energy provides a promising solution for treatment of persistent AF and LSPAF, evidenced by relatively low AF recurrence rates and marked AF burden reduction after treatment—even in LSPAF patients.

Reference: Makati, K. J. et al. (2020). Safety and efficacy of Convergent Hybrid procedure using cryo as endocardial energy source for the treatment of atrial fibrillation. *Circulation: Arrhythmia and Electrophysiology*, 13:e008556.

EPI-Sense® Guided Coagulation System

EU 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 (AFIB) or Atrial Flutter (AFL).

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.

Reported adverse events associated with epicardial ablation procedure may include, but are not limited to, the following: pericardial effusion, excessive bleeding, Pericarditis, 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://europe.atricure.com/healthcare-professionals/product-labeling>

This material is intended to provide objective information about the use of AtriCure's Technology, including where and how the device can be used within the continuum of care. The enclosed publication includes information regarding patients with persistent or long-standing persistent atrial fibrillation treated with the EPI-sense technology in a hybrid procedure. This material is being provided to demonstrate use of the EPI-Sense system in the treatment of long-standing atrial fibrillation and its clinical outcomes. This publication was chosen for this purpose because the study summarized herein utilized a trial design similar to that used in the CONVERGE IDE study which supported FDA approval of the EPI-Sense System for the indication stated above.

Prescription Use Only.

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