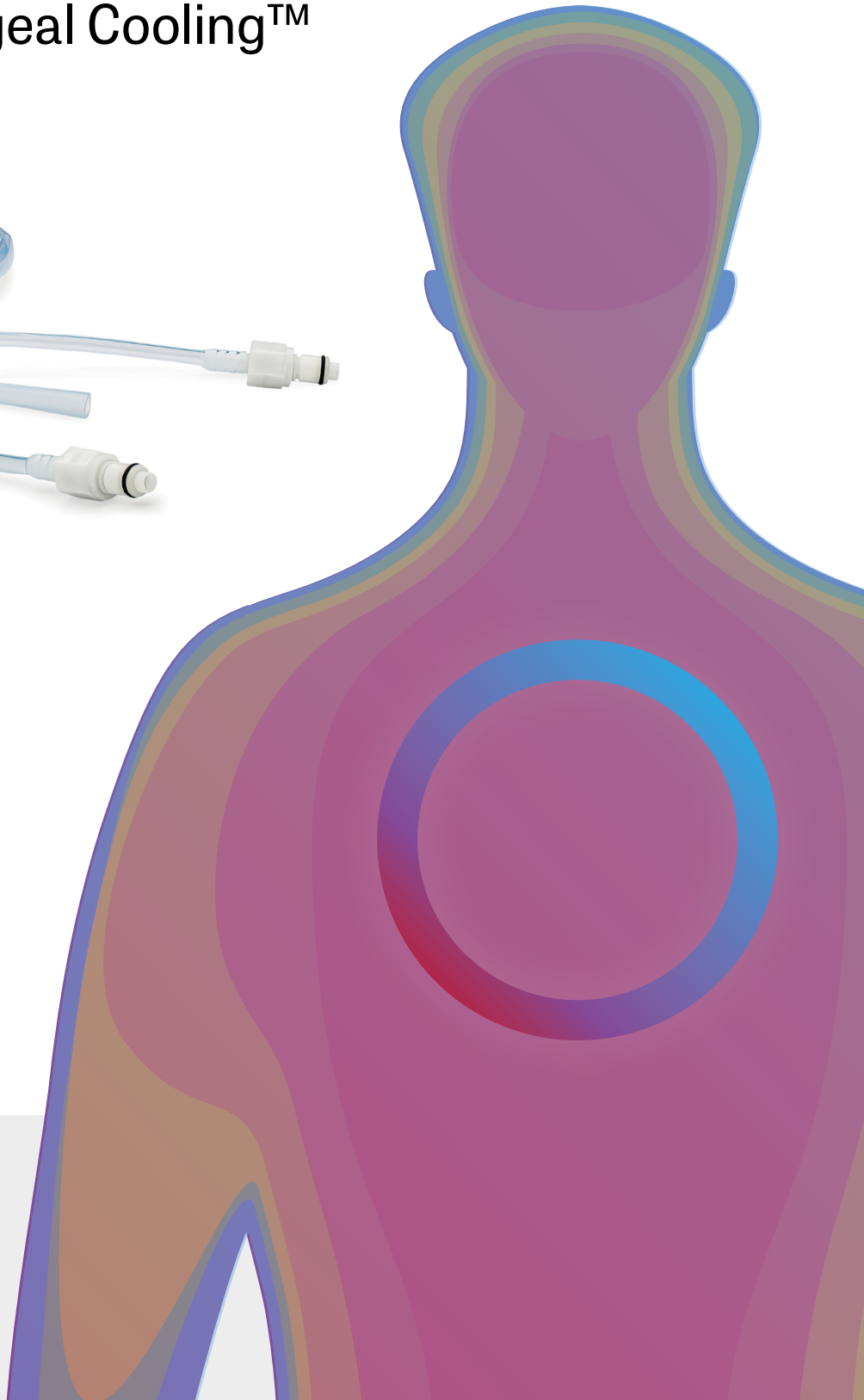
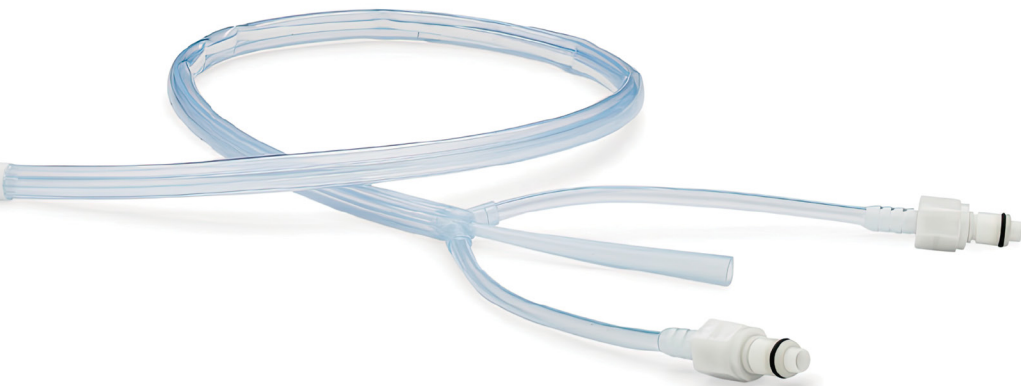


KEEPING IT COOL

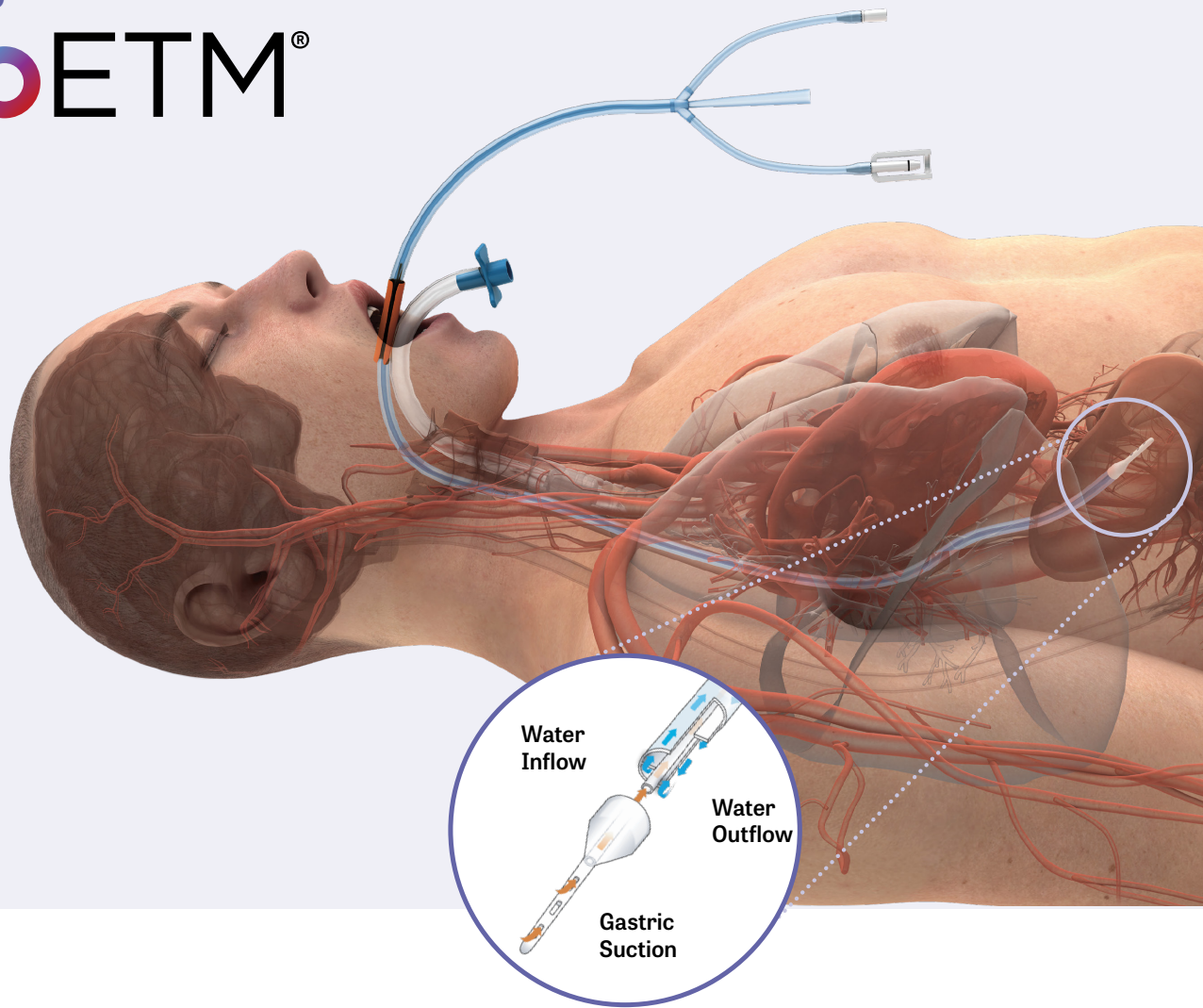
with **enso**ETM[®]

Proactive Esophageal Cooling™



Introducing

ensoETM[®]



Offering local temperature control to significantly reduce thermal injury to the esophagus during left atrial ablation procedures, ensoETM[®]:

- ✓ Is a closed loop system
- ✓ Uses water to cool the esophagus
- ✓ Is placed similarly to an OG tube by anesthesiologists, CRNAs, and nurses
- ✓ Provides a central lumen for gastric suction and decompression, maintaining functionality of a typical NG or OG tube

A Rise in Procedures; A Rise in Risk

Nearly three million people in the U.S. have atrial fibrillation (AFib).¹ That number continues to rise as the population ages. A common treatment for AFib is radiofrequency ablation, which can result in esophageal injury leading to potentially devastating complications, including death.²

A device that reduces the likelihood of ablation-related esophageal injury resulting from cardiac ablation procedures is now available.

How ensoETM® Works

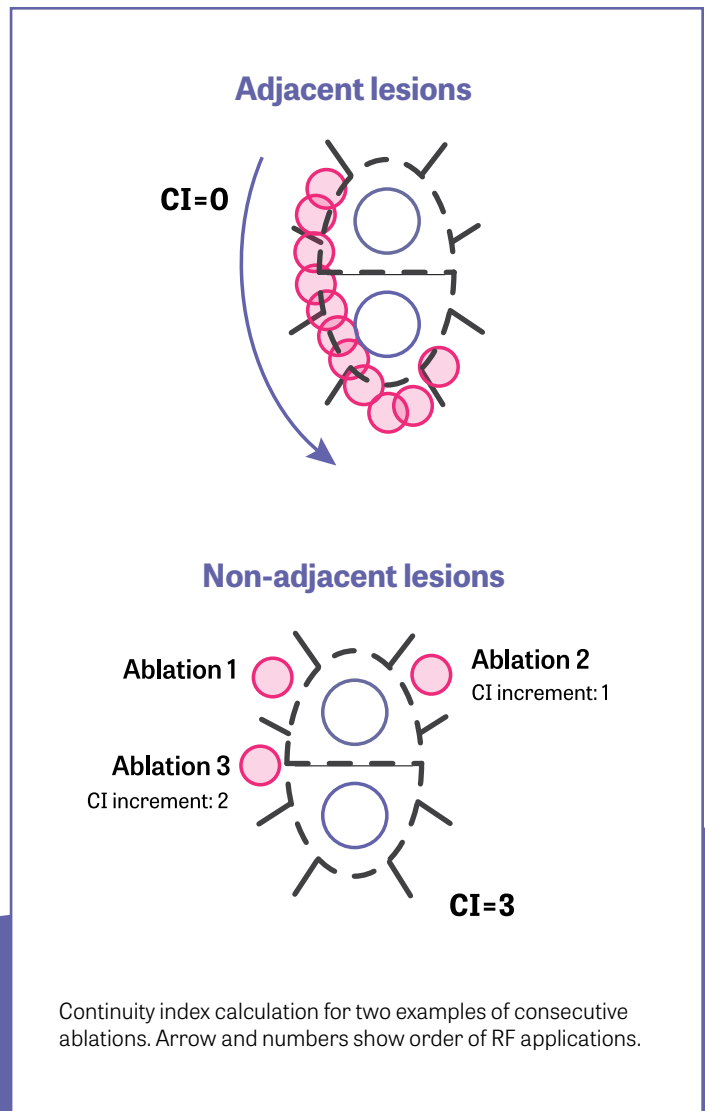
The cooling action of Attune Medical's ensoETM system helps dissipate heat and inhibit the body's inflammatory response caused by thermal injury during cardiac ablation.

Cooling the esophagus limits the effects of thermal latency that contribute to greater thermal damage.³

Prevent Overheating, Improve Workflow

In addition, with ensoETM, there's no need to skip over segments of the left atrium due to local overheating. Skipping regions reduces the effectiveness of ablation due to edema buildup hindering transmural lesion formation. With cooling, overheating is prevented, allowing uninterrupted point-to-point lesion placement, which provides a consistently low continuity index (typically near 0).

Gaining Momentum



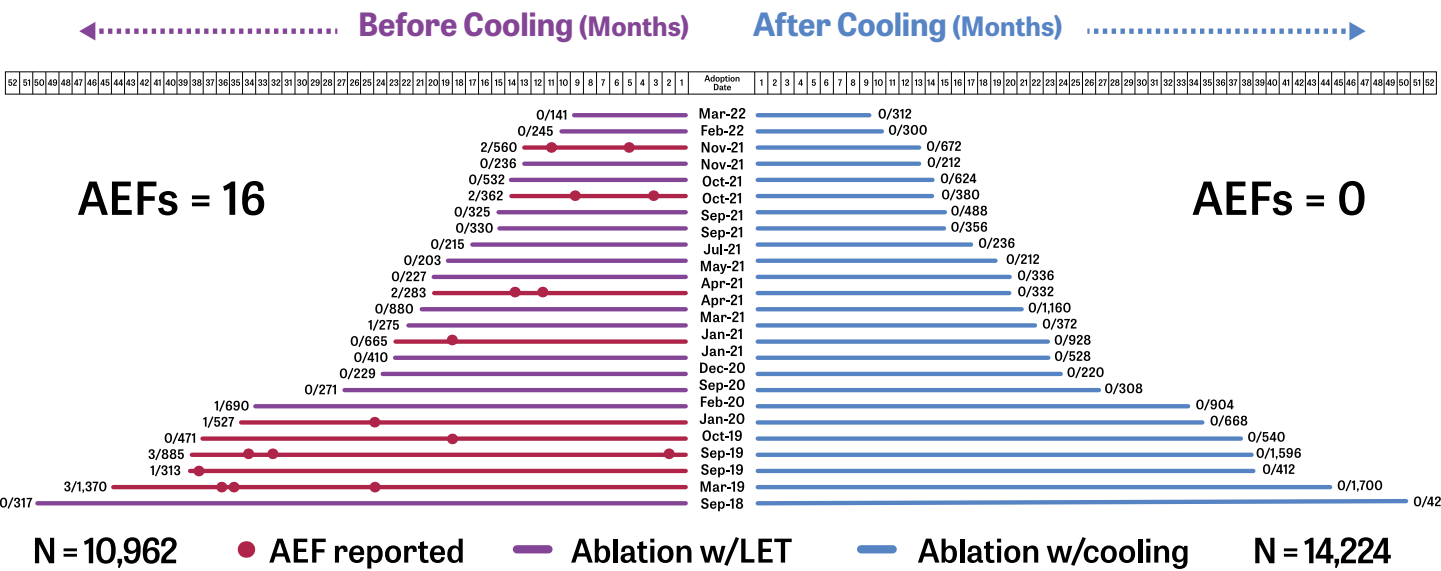
To date, the ensoETM has achieved over **44,000 uses** in EP labs.

There are over **160 active sites** utilizing ensoETM in the United States.

Clinically Proven^{4,5}

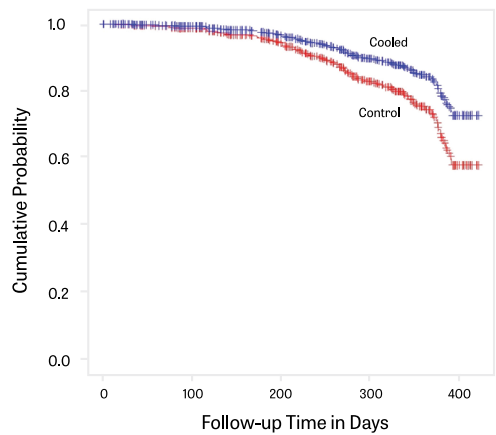
A total of 25,186 patients across 25 hospital systems were studied; 14,224 received COOLING, and 10,962 received luminal esophageal temperature (LET) MONITORING. Among those receiving temperature monitoring, 16 atrioesophageal fistulas (AEF) occurred, one of the most serious complications of atrial ablation.

In 14,224 patients treated with esophageal cooling, no AEFs occurred.

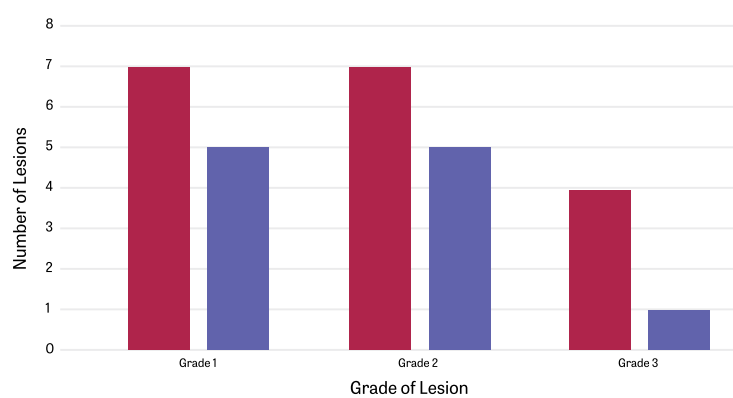


Published data from over 500 patients show ensoETM[®] use is associated with a **14% absolute increase in freedom from arrhythmia** compared to LET monitoring, providing a significant long-term efficacy improvement.

Freedom from Atrial Arrhythmia (Unweighted)



Esophageal Lesion Rates in RCTs

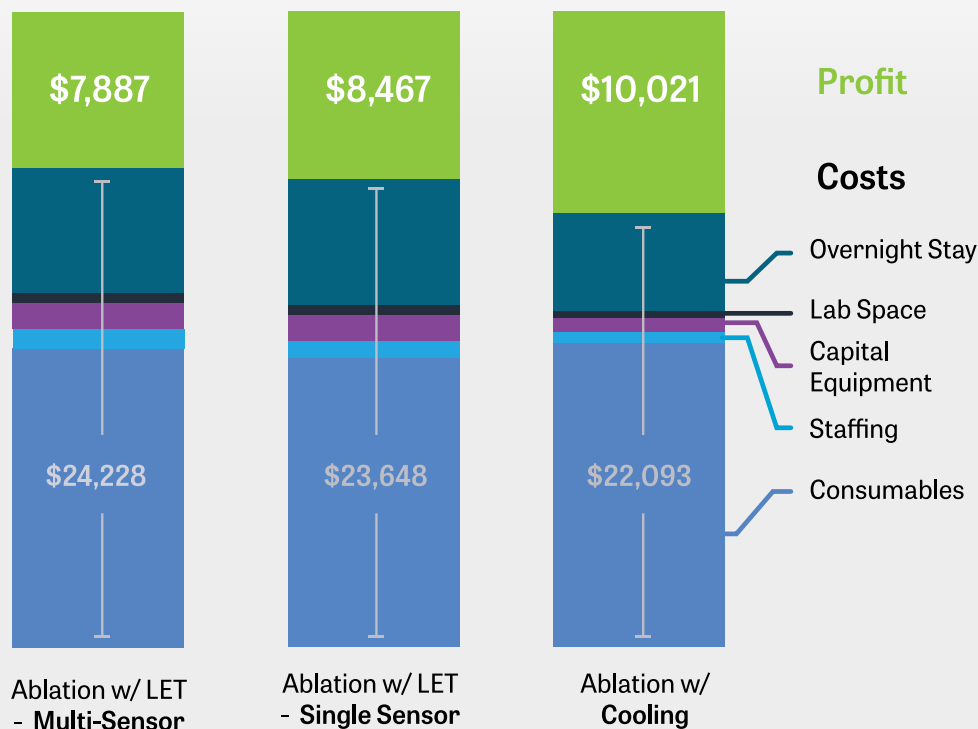


Results of endoscopy in pooled RCT data from 170 patients showing the odds of esophageal injury with ensoETM (odds ratio = 0.55)

Additional Benefits

- Procedure time reduction of 29.1% to 34.7%^{6,7}
- Reduction of post-ablation chest pain by 45%¹⁰
- Reduction or complete elimination of fluoroscopy requirements^{8,9}
- Increase in same-day discharge by 18%¹¹

Profit Comparison Based on Average DRG Payment*



Cost Analysis¹¹

A formal economic analysis found a net **cost savings of \$2,135 per patient**, inclusive of ensoETM[®] device cost, as a result of savings from improved procedure throughput and same-day discharge rate.

Regulatory Clearance

ensoETM first received de novo marketing authorization in 2015 (DEN140018) with subsequent 510(k) clearances for compatibility with heat exchangers: Altrix[®], Medi-Therm[®] III, and Blanketrol[®] II/III. In September 2023, FDA granted de novo marketing authorization for ensoETM (DEN230021) to reduce the likelihood of ablation-related esophageal injury resulting from radiofrequency cardiac ablation procedures.

*Includes same-day discharge. Adjusted to 2022 dollars using the medical component of the consumer price index (CPI).

ensoETM[®] Product Specs

	ECD01	ECD02
Eternal Heat Exchanger	Stryker Altrix [®] Temperature Management System; Gaymar/Stryker Medi-Therm [®] III	Cincinnati Sub-Zero/Gentherm; Blanketrol [®] II or III
Heat Exchange Connector	Gaymar/Stryker Clik-Tite	Colder Products Company PLCD22004
FDA Marketing Authorization	DEN230021	DEN230021

Intended Duration of Use	72 hours (in the US)
Material	Medical-grade silicone
Water Volume	~55 mL (1.9 fl oz)
Outside Diameter	12.0 mm (0.47 in, 36 Fr)
Inside Diameter of Gastric Lumen	2.6 mm (0.10 in)
Length	758 mm (29.8 in)



Altrix[®]



Medi-Therm[®] III



Blanketrol[®] II or III

Adopters of Attune's ensoETM[®] will be provided the opportunity to use a bundled disposable purchase option to acquire Gentherm's Blanketrol III directly from Attune. Attune will also offer customers an evaluation program for the Blanketrol III.

Just a Phone Call Away

Attune Medical[®] provides a 24/7 clinical support line (888-534-4873), as well as clinical experts in the field. Our staff work with your organization to develop protocols and perform on-site training. An education portal exists with on-demand resources and annual competency assessment tools.

If you're interested in learning more, please visit our website at www.attune-medical.com or contact one of our representatives at (888) 534-4873.



References: 1. Lip GY, Kakar P, Watson T. Atrial fibrillation—the growing epidemic. *Heart*. 2007 May;93(5):542-3. 2. Cooper J, Joseph C, Zagrodzky J, et al. Active esophageal cooling during radiofrequency ablation of the left atrium: data review and update. *Expert Rev Med Devices*. 2022;19(12):949-957. 3. Mercado Montoya M, Gomez Bustamante T, Berjano E, et al. Proactive esophageal cooling protects against thermal insults during high-power short-duration radiofrequency cardiac ablation. *Int J Hyperthermia*. 2022;39(1):1202-1212. 4. Sanchez J, Woods C, Zagrodzky J, et al. Atrioesophageal Fistula Rates Before and After Adoption of Active Esophageal Cooling During Atrial Fibrillation Ablation. *JACC Clin Electrophysiol*. 2023 Sep 12. 5. Joseph C, Nazari J, Zagrodzky J, et al. Improved 1-year outcomes after active cooling during left atrial radiofrequency ablation. *J Interv Card Electrophysiol*. 2023;66(7):1621-1629. 6. Joseph C, Cooper J, Zagrodzky J, et al. Impact of active esophageal cooling on catheter ablation procedure times across five healthcare systems. *European Heart Journal* 2023, 44(Supplement_2). 7. Joseph C, Sherman J, Ro A, et al. Procedural time reduction associated with active esophageal cooling during pulmonary vein isolation. *J Interv Card Electrophysiol* 2022, 65(3):617-623. 8. Zagrodzky J, Bailey S, Shah S, et al. Impact of Active Esophageal Cooling on Fluoroscopy Usage During Left Atrial Ablation. *J Innov Card Rhythm Manag*. 2021;12(11):4749-4755. 9. Joseph C, Woods C, et al. Economic Analysis of Active Esophageal Cooling in Zero-Fluoroscopy Settings Without Intracardiac Echocardiography. *EP Lab Digest*, online 2023. 10. Zagrodzky W, Small A, Joseph C, et al. Reduced Post-Ablation Chest Pain with Active Esophageal Cooling. *Authorea*. November 10, 2023. 11. Joseph C, Cooper J, Sikka R, et al. Improved hospital discharge and cost savings with esophageal cooling during left atrial ablation. *J Med Econ*. 2023;26(1):158-167.