ensoETM®

For controlling patient temperature and reducing the likelihood of ablation-related esophageal injury resulting from radiofrequency cardiac ablation procedures

Instructions for Use

Caution: Read all instructions prior to use.

- For single use only. Reuse may expose patients to infection risk.
- Provided non-sterile.
- Do not use if packaging is compromised.
- This product does not contain dry natural rubber.

REF ECD02-A

Description

The ensoETM is a non-sterile multi-lumen silicone tube placed in the esophagus for the primary purpose of either (1) cooling or warming a patient or (2) cooling the esophagus to reduce the likelihood of ablation-related esophageal injury resulting from radiofrequency cardiac ablation procedures. A secondary purpose of the ensoETM is to allow gastric decompression and suctioning. Control of patient temperature and cooling the esophagus are achieved by connecting the ensoETM to an external heat exchanger. Two lumens connect to the external heat exchanger, while a third central lumen provides stomach access for connection to a fluid collection device with low intermittent suction for gastric decompression (Figure 1). The ensoETM is made of standard medical-grade silicone. It is a single-use, disposable, non-implantable device with an intended duration of use of 72 hours or less.

NOTE: This ensoETM (ECD02-A) is designed to be used with the Gentherm/Cincinnati Sub-Zero Blanketrol II (model #: 222S) or Blanketrol III (model #: 233) Hyper-Hypothermia System with the following operating specifications:

- Dead Head Pressure: Maximum 11 psi (76 kPa)
- Flow: Minimum 0.6 gpm (136 L/hr)
- Water Temperature Control Range: 4°C - 42°C

Intended Use / Indications for Use

The ensoETM is a thermal regulating device, intended to:

- connect to a Gentherm/Cincinnati Sub-Zero Blanketrol II or Blanketrol III Hyper-Hypothermia System to control patient temperature,
- connect to a Gentherm/Cincinnati Sub-Zero Blanketrol II or Blanketrol III Hyper-Hypothermia System to reduce the likelihood of ablation-related esophageal injury resulting from radiofrequency cardiac ablation procedures, and
- provide gastric decompression and suctioning.

Warnings and Precautions

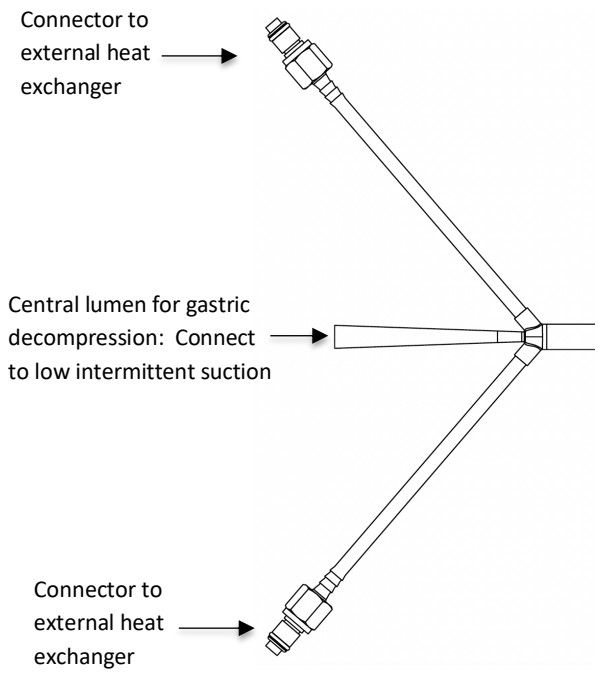
- The ensoETM may cause or exacerbate esophageal tissue damage in patients with known esophageal deformity or evidence of esophageal trauma, or in patients known to have ingested acidic or caustic poisons within the prior 24 hours.
- The safety and effectiveness of the ensoETM have not been evaluated in patients with less than 40 kg of body mass.
- The ensoETM should only be used by healthcare professionals with training in the use of orogastric tubes and the use of the external heat exchanger.
- The ensoETM is intended for esophageal placement. Inserting the ensoETM in the trachea, bronchi or lungs can result in serious patient harm.
- The suction collection system for the gastric tube that is connected to the ensoETM should be monitored throughout treatment of the patient. If the accumulation of liquid is greater than expected, treatment should be stopped and the ensoETM should be removed and examined for the presence of leaks.
- Always follow the Instructions for Use for the external heat exchanger and monitor it for alerts. If a low water alert or an occlusion alert occurs and the cause of this decreased amount of water or obstruction of water flow is not found, treatment should be stopped and the ensoETM should be removed and examined for failure.
- The coolant (water) ports on the ensoETM (Figure 1) must be connected only to the external heat exchanger. The central lumen must be connected only to a suction canister with low intermittent suction (Figure 1). Attachment of the ensoETM to unapproved or unintended connections can result in serious patient harm.

- The presence of the ensoETM may interfere with other devices in the esophagus or mouth. Dual placement of other devices in the esophagus with the ensoETM is an unintended use and may result in patient harm. Do not use an esophageal temperature probe, oral thermometer, esophageal Doppler stethoscope, or enteral feeding tube with the ensoETM in place.
- In patients with intact dentition, a bite block may be required to prevent damage to the ensoETM.
- Periodically reposition the ensoETM in accordance with hospital protocol. Prolonged excessive pressure may cause dermal injury, tissue ischemia, or necrosis.
- Large patients with a body mass greater than 120 kg may exhibit slower responses to intended temperature changes. Small patients with a body mass less than 60 kg may exhibit faster cooling than anticipated, and may exhibit slower rewarming than anticipated. Environmental conditions, such as the temperature of the room, may also affect patient temperature. Removing or adding blankets or sheets may be necessary if the desired cooling or warming rate is not being achieved.
- Avoid pinching or kinking the ensoETM during placement or use, because this may cause the flow of coolant to become occluded.
- When using the ensoETM to reduce the likelihood of ablation-related esophageal injury resulting from radiofrequency cardiac ablation procedures, follow the radiofrequency ablation catheter manufacturers' instructions for use.

Placement of the ensoETM

1. The external heat exchanger must be in proper operating condition and must have received all the required maintenance. Failure to ensure that the heat exchanger is in proper condition may result in suboptimal performance. Ensure that no contaminants are present in the heat exchanger water.
2. Measure the patient for ensoETM placement carefully before use. Insertion of an excessive length of the ensoETM into the stomach may lead to coiling, kinking, knotting, or breakage of the ensoETM. To measure the patient for ensoETM placement, extend the ensoETM from the patient's lips to the earlobe and then from the earlobe to the tip of the xiphoid process (xiphisternum). Mark the location on the ensoETM.
3. Follow the Instructions for Use for the external heat exchanger for all device operations, including connections to electric wall power, patient probes, and tube set connections. Connect the ensoETM (Figure 1) to the external heat exchanger in place of a blanket or pad, using a Gentherm/Cincinnati Sub-Zero connector hose (CSZ P/N 286) with the connectors as shown in Figure 1. Turn on the external heat exchanger.
4. When using the ensoETM to control patient temperature, ensure the patient has two (2) temperature probes with separate monitors in use (for example, a Foley catheter temperature probe and a rectal temperature probe). One of the temperature probes must be connected to the external heat exchanger, as directed in the external heat exchanger's Instructions for Use. Ensure that both temperature monitors are functioning correctly and that the temperature probes are not damaged, expired, or compromised in any other way.

Figure 1. Connections to ensoETM



5. When using the ensoETM to reduce the likelihood of ablation-related esophageal injury resulting from radiofrequency cardiac ablation, ensure the patient has one (1) temperature probe in use (for example, a Foley catheter temperature probe, a rectal temperature probe, or an axillary temperature probe). Ensure the temperature monitor is functioning correctly and that the temperature probe is not damaged, expired, or compromised in any other way.
6. Select the control mode and target patient/water temperature on the external heat exchanger. Ensure that water is flowing through the ensoETM, and that no leaks are present. Failure to initiate water flow prior to insertion may hinder placement of the ensoETM. For easier placement it is recommended to set the target water temperature to room temperature or lower while inserting the device.
7. Lubricate the ensoETM generously with water soluble lubricant prior to insertion. Do NOT use petroleum-based products, because these may be harmful to the respiratory tract.
8. Insert the ensoETM using gentle pressure posteriorly and downwards through the mouth, past the oropharynx and into the esophagus. Gently assist the passage of the ensoETM with light pressure until the required length of tube has been inserted.

9. Do not use force during insertion of the ensoETM, because this may cause bleeding and/or damage to the oropharynx or other structures. If resistance is encountered during insertion of the ensoETM, immediately stop the procedure.
10. Confirm placement of the ensoETM by the following:
    a. inject 5 to 20 mL of air (with a 50 or 60 mL syringe) through the central lumen while auscultating over the stomach for a "swoosh" or a "burp" indicating gastric placement,
    b. aspirate gastric contents with a syringe (using a 50 or 60 mL syringe) through the central lumen, or
    c. confirm the location and placement of the ensoETM with an x-ray or intracardiac echocardiography.
11. Secure the ensoETM with a securement device or tape in accordance with hospital protocol. Do not secure the ensoETM to the endotracheal tube because it may displace the endotracheal tube. Ensure the ensoETM and tube set connections are not in contact with the patient's skin. Direct contact between the ensoETM and exposed skin may cause shivering.
12. When using the ensoETM to reduce the likelihood of ablation-related esophageal injury resulting from radiofrequency cardiac ablation, set the target water temperature on the external heat exchanger to 4°C at least 15 minutes prior to ablating the posterior wall of the left atrium to ensure maximum protection. Target a Tag Index (also known as Ablation Index), provided by the Biosense Webster CARTO 3 EP Navigation System with VISITAG SURPOINT Module, of 350 to 400, or a Lesion Size Index (LSI) provided by the EnSite Precision™ cardiac mapping system, of between 4.5 to 5, when ablating the posterior wall of the left atrium.
13. For stomach decompression, connect the central lumen of the ensoETM (Figure 1) to low-intermittent suction using standard suction tubing (not supplied) and adaptor (not supplied). Always use the lowest suction setting that will effectively decompress the stomach.
14. The central lumen of the ensoETM is not intended for enteral feeding or for administration of oral medication. If the central lumen of the ensoETM becomes blocked or clogged, standard approaches for clearing blocked gastric tubes are recommended. For example, disconnect the ensoETM from wall suction and use a saline flush. If the standard approaches are unsuccessful, it may be necessary to remove and then replace the ensoETM.
15. When using the ensoETM to control patient temperature, monitor patient temperature using both monitors during use. Ensure that the temperature monitors are reporting temperatures that are in agreement; if the discrepancy between the two monitors is greater than 0.5°C, discontinue treatment and investigate the cause of the discrepancy. Replace the temperature probes or secondary monitor if necessary. Ensure both temperature probes remain in place without accidental dislodgement during the entire course of patient treatment. Monitor circulating coolant temperature and ensure that it does not fall below 4°C or exceed 42°C.
16. When using the ensoETM to reduce the likelihood of ablation-related esophageal injury resulting from radiofrequency cardiac ablation, monitor patient temperature and ensure it does not decrease below an acceptable level. Adding blankets or sheets or actively warming the patient may be necessary if patient temperature decreases below an acceptable level. Monitor circulating water temperature and ensure that it does not fall below 4°C.

Note: After this product has been used it may be a potential biohazard. Handle and dispose of the device in a biohazard waste container in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

Note: Report any serious incident that has occurred in relation to this device to Attune Medical and the applicable regulatory authority for the location in which the user and/or patient is established.

Caution: Federal law (U.S.) restricts this device to sale by or on the order of a physician.

U.S. Patents # 8,231,664, # 8,444,684, # 8,523,929 and # 9,326,890. International Patent # EP2401023B1. European Registered Community Design (No. 002243055-0001). Additional U.S. and International patents pending.

An electronic version of this instructions for use is available at: www.attune-medical.com/ifu/ecd02-a.

Clinical Information

Data from preliminary randomized controlled trials (RCTs) and cross-sectional study data from reported clinical use of the ensoETM during electrophysiology procedures have been compiled and published.

Clinical Trial Data

Three randomized controlled trials (RCTs) have been conducted at three different sites to evaluate esophageal cooling in radiofrequency (RF) cardiac ablation. The sites, ClinicalTrials.gov reference numbers, and the number of subjects are presented below.

1. Riverside Medical Center (Riverside, NCT03481023) - 6 patients
2. University of Pennsylvania (Penn, NCT03691571) - 44 patients
3. St. George's University Hospitals (St. George's, NCT03819946) - 120 patients

All three studies evaluated the esophagus with endoscopy post-ablation. Table 1 describes the scoring methodology for each of the sites and the common score that was used to combine the results for overall analysis.

Table 1: The esophageal injury grading scheme that was used in each of the randomized controlled studies (RCT) and the combined scoring scheme used for the combined analysis

Original Study Definitions			Injury Severity (Common Outcome Labels)
Riverside	**Penn**	**St George's**	
Grade 0: Normal examination	**Grade 0**: Normal mucosa	**Grade 0**: Normal mucosa	**Grade 0**: No injury
Grade 1: Edema and hyperemia of the mucosa	**Grade 1**: Erythema	**Grade 1**: Erythema **Grade 2**: Linear erosion <5mm **Grade 3**: Linear erosion(s) >5mm	**Grade 1**: Mild injury
Grade 2a: Superficial ulceration, erosions, friability, blisters, exudates, hemorrhages, whitish membranes	**Grade 2**: Superficial ulceration	**Grade 4a**: Superficial ulceration (clean) **Grade 4b**: Superficial ulceration (visible clot)	**Grade 2**: Moderate injury
Grade 2b: Grade 2a plus deep discrete or circumferential ulcerations **Grade 3a**: Small scattered areas of multiple ulceration and areas of necrosis with brown-black or greyish discoloration **Grade 3b**: Extensive necrosis	**Grade 3**: Deep ulceration **Grade 4**: Fistula/perforation	**Grade 5a**: Deep ulceration (clean) **Grade 5b**: Deep ulceration (visible clot) **Grade 6**: Perforation	**Grade 3**: Severe injury

The Riverside study included six patients (three control group patients; three device group patients). In the three control patients, one had no evidence of esophageal mucosal damage (Zargar grade 0), one had diffuse sloughing of the esophageal mucosa and multiple ulcerations (Zargar grade 2a), and one had a superficial ulcer with a large clot (Zargar grade 2a). In the three patients treated with the cooling device, one had no evidence of esophageal mucosal damage (Zargar grade 0), one had esophageal erythema (Zargar grade 1), and one had a solitary Zargar grade 2a lesion.[1]

The Penn study included 44 patients receiving endoscopy (22 control group, 22 device group). Adjunctive posterior wall isolation was performed more frequently in the device group (11/22, 50% vs. 4/22, 18%). Endoscopic examination was performed with 48 hours of the ablation procedure. In the control group, evidence of esophageal injury was detected in 5/22 (23%) patients, with mild or moderate injury in 2/5 patients (40%) and severe thermal injury in 3/5 patients (60%). In the device group, evidence of esophageal injury was detected in 8/22 (36%) patients, with mild or moderate injury in 7/8 (87%) patients and severe thermal injury in 1/8 (12%) patients. There were no acute perforations or atrioesophageal fistulas (AEF) identified during follow-up.[2]

Table 2: Baseline characteristics for the three randomized controlled studies.

	Riverside		Penn		St. George's	
	Control (n=3)	**ensoETM (n=3)**	**Control (n=22)**	**ensoETM (n=22)**	**Control (n=60)**	**ensoETM (n=60)**
Age (avg) (years)	55–71 (61.3)	58–70 (64.7)	63.6 ± 9.3	62.8 ± 9.6	65 ± 9	65 ± 10
Sex male, n (%)	2 (67)	3 (100)	16 (73)	14 (64)	37 (61.7)	36 (60)
BMI	NR	NR	31.0 ± 5.1	30.5 ± 7.3	29.8 ± 6.98	28.5 ± 5.3
Obesity (n)	1	2	NR	NR	NR	NR
Paroxysmal AF, n (%)	3 (100)	3 (100)	14 (64)	11 (50)	30 (50)	27 (45)
Left atrial size (avg) (cm)	3.8–4.2(3.9)	4.1–5.7 (4.7)	NR	NR	4.2 ± 0.6	4.1 ± 0.9
LVEF (%)	NR	NR	55.8 ± 9.4	54.7 ± 11.4	52 ± 8	55 ± 9
EF <50% (avg)	0 (0)	2 (67)	NR	NR	NR	NR
CHA2DS2-VASc score	NR	NR	2.2 ± 1.6	2.2 ± 1.4	NR	NR
Hypertension, n (%)	2 (67)	3 (100)	13 (59)	12 (55)	NR	NR
CAD, n (%)	1 (33)	1 (33)	4 (18)	1 (5)	NR	NR
Diabetes mellitus, n (%)	1 (33)	0 (0)	2 (9)	1 (5)	4 (7)	10 (17)
Prior Stroke, n (%)	0 (0)	1 (33)	2 (9)	3 (14)	3 (5)	1 (2)

In the St. George's study, endoscopic examination was performed within seven days of the ablation procedure and, of the 188 patients enrolled in the study, 120 underwent endoscopy (the remaining 66 withdrew consent for the endoscopy but were not lost to follow up). Esophageal injury was significantly more common in the control group than in the device group (12/60 vs. 2/60; p=0.008). There was no difference between groups in the duration of RF or in the force applied (p-value range=0.2 to 0.9). Procedure duration and fluoroscopy duration were similar (p=0.97, p=0.91, respectively).[3]

Differences in patient demographics and clinical protocols adds some uncertainty to the representativeness of the pooled results. These patient demographics are shown in Table 2.

Results of endoscopy in the pooled data showed a nonsignificant difference between the odds of esophageal injury (odds ratio = 0.55, 95% CI = (0.22, 1.35), p = 0.22), presented in Table 3.

In total, 4 serious adverse events and 95 other adverse events occurred in the combined control groups, while 3 serious adverse events and 101 other adverse events occurred in the combined device groups. A summary of all adverse events by site and by group is presented in Table 4.

Table 3: Combined esophageal lesion rates for pooled RCT data using the combined scoring scheme found in Table 1.

		Combined	
		Control	ensoETM
# of Patients Completed		83	83
Severity of Esophageal Injury	No Injury	65 (78%)	72 (87%)
	Mild	7 (8%)	5 (6%)
	Moderate	7 (8%)	5 (6%)
	Severe	4 (5%)	1 (1%)

Table 4: Adverse event rates for the three randomized controlled studies.

Adverse Event	Riverside		Penn		St. George's		Combined	
	Control	ensoETM	Control	ensoETM	Control	ensoETM	Control	ensoETM
Serious Adverse Events								
All-cause mortality*	0	0	0	0	1	0	1	0
Bradycardia	0	0	0	0	0	1	0	1
Hematuria	0	0	1	0	0	0	1	0
Pericardial effusion	0	0	0	0	1	0	1	0
Prolonged hospital stay due to previous heparin allergy	0	0	0	0	1	0	1	0
Pseudoaneurysm	0	0	0	0	0	2	0	2
Other Adverse Events								
Abdominal bloating	0	0	0	0	6	4	6	4
Abdominal pain	0	0	0	0	5	5	5	5
Acid reflux	0	0	0	0	3	5	3	5
Arrhythmia	0	0	4	3	0	2	4	5
Chest Pain/ Pericarditis	0	0	3	2	7	11	10	13
Difficulty Swallowing	0	0	0	1	0	0	0	1
Early satiety	0	0	0	0	6	7	6	7
Esophageal candida	0	0	0	0	2	5	2	5
Esophagitis	0	0	1	0	4	3	5	3
Gastric polyps	0	0	0	0	3	0	3	0
Gastritis	0	0	0	0	11	10	11	10
Headache	0	0	1	3	0	0	1	3
Hemoptysis	0	0	1	0	0	0	1	0
Hiatus hernia	0	0	0	0	4	6	4	6
Insomnia due to chest discomfort	0	0	0	0	3	5	3	5
Knee Pain	0	0	1	0	0	0	1	0
Leg Edema	0	0	0	1	0	0	0	1
Lip Sore	0	0	1	0	0	0	1	0
Nausea	0	0	0	0	5	4	5	4
Presyncope/ Palpitations	0	0	0	1	13	9	13	10
Sinus Infection	0	0	0	1	0	0	0	1
Sore throat/ Cough/ Phlegm	0	0	8	10	0**	0**	8	10
Vomiting	0	0	0	0	3	3	3	3

* All-cause mortality refers to one patient that was part of the study who was admitted to the hospital for heart failure over 3 months after the ablation procedure. This patient had several comorbidities, including underlying cardiomyopathy. The patient's heart failure worsened, followed by pneumonia and septicemia, leading to death. The patient's death was reviewed and is believed to be an acute episode related to the heart failure and hospital acquired pneumonia. The patient's death is not believed to be related to the ablation procedure.

** St George's did not record reports of sore throat, cough, or phlegm as adverse events. Therefore, these data may be incomplete.

Cross-Sectional Study

A cross-sectional study using retrospective cohorts of patients who underwent a radiofrequency (RF) ablation procedure to treat atrial fibrillation (AF) was conducted.[4] For the primary study endpoint, a retrospective review of data from 25 hospital systems was conducted to quantify the effect of active esophageal cooling by: (1) measuring AEF rates across hospital systems with the highest utilization of active esophageal cooling (utilizing the ensoETM) during RF ablation for AF and (2) comparing AEF rates before and after the adoption of active esophageal cooling. Data were extracted by site investigators to determine the total number of RF ablations performed for the treatment of AF over the study time frame and the number of AEFs that occurred over this time frame.

At each site, the number of reported AEFs after the adoption of active esophageal cooling utilizing the ensoETM was compared to the number of reported AEFs during an equivalent period before the adoption of esophageal cooling.

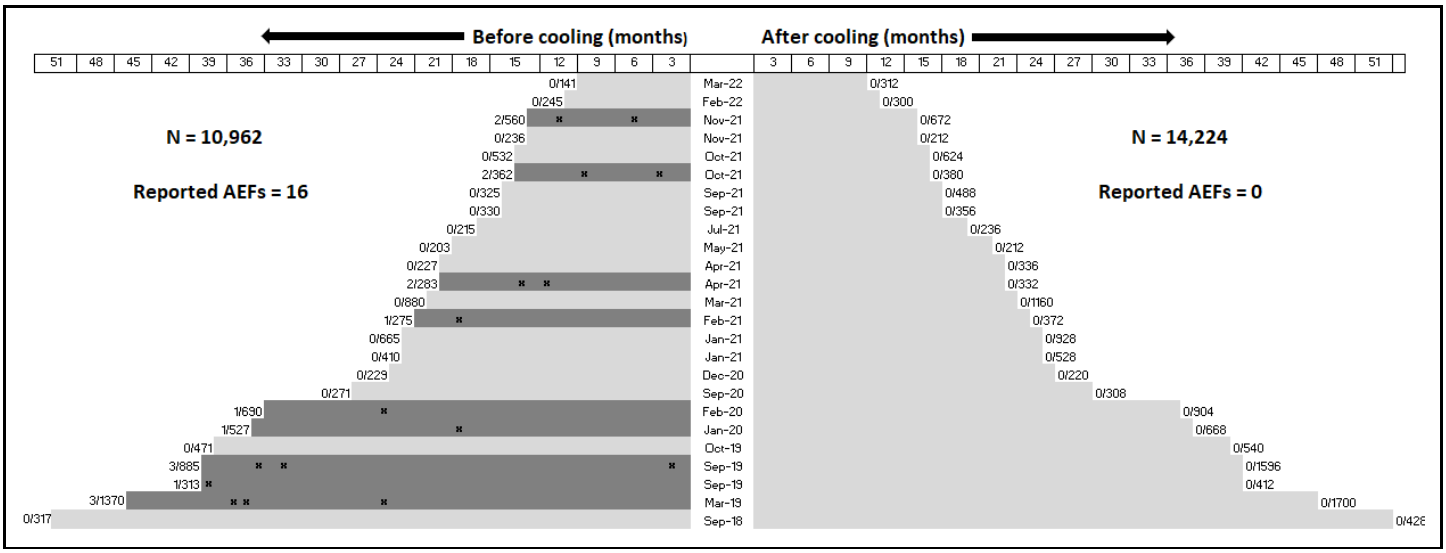


Figure 2: *Graph demonstrating the reported number of RF ablation procedures for atrial fibrillation during equivalent time periods before and after adoption of esophageal cooling utilizing the ensoETM. Reported atrioesophageal fistulas (AEFs) are indicated by a black "x" and centers with reported AEFs are shaded. Please note FDA concerns for these data as described in the limitations in the published manuscript which suggest that the above results may not be fully representative.[4]*

The sample size for the primary analysis was 25,186 patients (10,962 before and 14,224 after adoption of esophageal cooling utilizing the ensoETM). Limitations of the study included (1) assumed, not controlled device usage (2) no follow-up was performed, and (3) no linkage to specific patients.

A second analysis was performed by conducting a retrospective data review on a subset of the primary analysis data from two healthcare systems. All patients who underwent an RF ablation procedure to treat AF performed by any of four electrophysiologists in two healthcare systems over the study time frame (January 2018 to March 2020) were included in this analysis. No patients who underwent RF ablation procedure to treat AF were excluded from this review. The purpose of this study was to determine the recurrence rates of AF and to compare these rates before and after the adoption of active esophageal cooling.

The sample size for the analysis was 513 patients (253 before, and 260 after adoption of esophageal cooling utilizing the ensoETM).[5] At 12 months, 58.2% of the pre-cooling (control) patients were free of arrhythmia, and 72.2% of patients treated with esophageal cooling were free from arrhythmia, for an absolute difference in freedom from arrhythmia of 14% with active esophageal cooling (p=.03).

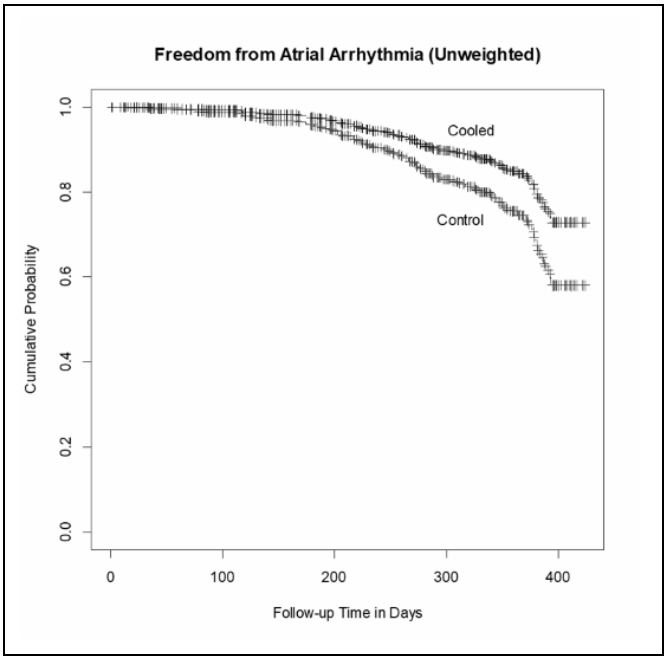


Figure 3: *Graph demonstrating cumulative probability of atrial fibrillation (AF) recurrence in patients before and after adoption of esophageal cooling utilizing the ensoETM.*

References

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4. Sanchez J, Woods C, Zagrodzky J, Nazari J, Singleton MJ, Schricker A, Ruppert A, Brumback B, Jenny B, Athill C *et al*: **Atrioesophageal Fistula Rates Before and After Adoption of Active Esophageal Cooling During Atrial Fibrillation Ablation**. *JACC Clinical electrophysiology* 2023 doi: 10.1016/j.jacep.2023.08.022 PMID: 37737773.
5. Joseph C, Nazari J, Zagrodzky J, Brumback B, Sherman J, Zagrodzky W, Bailey S, Kulstad E, Metzl M: **Improved 1-year outcomes after active cooling during left atrial radiofrequency ablation**. *Journal of Interventional Cardiac Electrophysiology* 2023 doi: 10.1007/s10840-023-01474-3 PMID: 36670327.

MRI Safety Information:

A patient with the ensoETM may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Name/Identification of device	ensoETM (ECD02-A)
Nominal value(s) of Static Magnetic Field [T]	1.5 T or 3 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	12 T/m (1200 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-receive coil
Maximum Whole Body SAR [W/kg]	2.0 W/kg (Normal Operating Mode)
Limits on Scan Duration	2.0 W/kg whole body average SAR for 15 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR Image Artifact	The presence of the ensoETM may produce an image artifact of 103 mm.
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

Symbol Glossary

Symbol	Symbol Title	Explanatory Text	Symbol Reference Number	Standard Title and Designation Number
	Manufacturer	Indicates the medical device manufacturer.	5.1.1	ISO 15223-1:2021, Medical Devices- Symbols to be used with information to be supplied by the manufacturer
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	5.1.6	ISO 15223-1:2021, Medical Devices- Symbols to be used with information to be supplied by the manufacturer
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	5.1.5	ISO 15223-1:2021, Medical Devices- Symbols to be used with information to be supplied by the manufacturer
	Use-by date	Indicates the date after which the medical device is not to be used.	5.1.4	ISO 15223-1:2021, Medical Devices- Symbols to be used with information to be supplied by the manufacturer
	Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use.	5.4.3	ISO 15223-1:2021, Medical Devices- Symbols to be used with information to be supplied by the manufacturer
	Do not reuse	Indicates a medical device that is intended for one single use only.	5.4.2	ISO 15223-1:2021, Medical Devices- Symbols to be used with information to be supplied by the manufacturer
	Do not use if package is damaged and consult instructions for use	Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.	5.2.8	ISO 15223-1:2021, Medical Devices- Symbols to be used with information to be supplied by the manufacturer
	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.	5.2.7	ISO 15223-1:2021, Medical Devices- Symbols to be used with information to be supplied by the manufacturer
	Not made with natural rubber latex	Indicates that natural rubber latex was not used in the construction within the medical device or the packaging of a medical device.	5.4.5 & Annex B.2 Negation Symbol	ISO 15223-1:2021, Medical Devices- Symbols to be used with information to be supplied by the manufacturer
	Medical device	Indicates the item is a medical device.	5.7.7	ISO 15223-1:2021, Medical Devices- Symbols to be used with information to be supplied by the manufacturer
	Prescription only	Caution: Federal (US) law restricts this device to sale by or on the order of a physician.	N/A	21 CFR 801.109, Labeling-Prescription Devices 21 CFR 801.15(c)(1)(i)F, Labeling- Medical devices; prominence of required label statements; use of symbols in labeling
	MR Conditional	Indicates an item with demonstrated safety in the MR environment within defined conditions including conditions for the static magnetic field, the time-varying gradient magnetic fields and the radiofrequency fields.	N/A	ASTM F2503-20, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

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