Medtronic

Sphere-9™ Catheter

All in one: map | ablate | validate

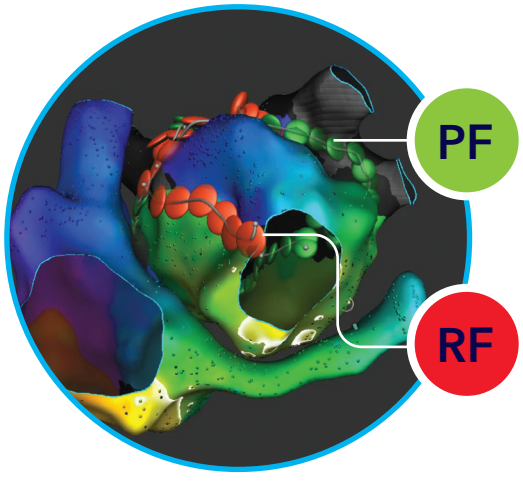
Map

Close-Unipolar™ mapping combines the benefits of bipolar and unipolar electrogram acquisition[1] using nine mini surface electrodes and one central reference electrode.

Mapping controls at your fingertips

11 minutes[2]

5,000 points[2]



Ablate

Compressible, 9 mm ablation electrode lattice tip creates lesions in less time using fewer wide area focal lesions.[3,4]

Safe,[5] effective,[5] and durable[2] lesions with **dual energy ablation: PF and RF.**

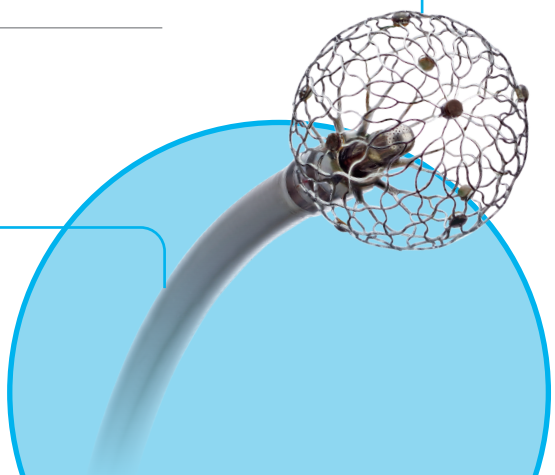
10x Larger **surface area** compared to standard irrigated ablation catheters[3,6]

97% Per-vein **durability** at 3 months (Pulse3 waveform)[2]

Validate

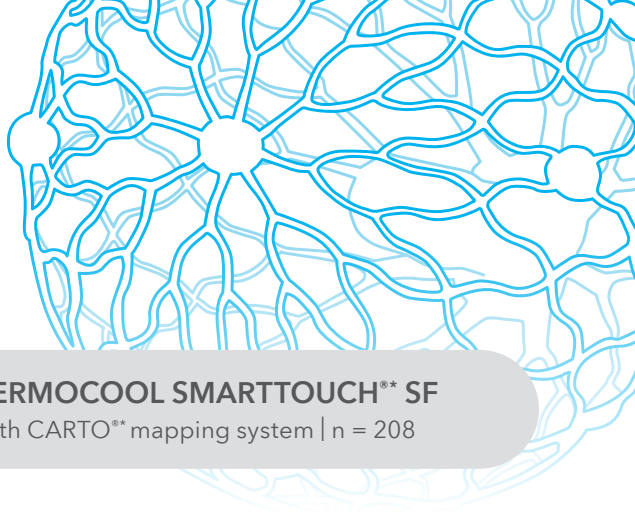
Transition from ablation to validation using a **single transeptal access and zero exchange workflow**[5] with 8 Fr, bidirectional catheter design.

Confirm electrical conduction block with ease using **exclusive pace modes** specifically designed for the Sphere-9 catheter.



SPHERE Per-AF IDE[5]

First and only randomized 1:1 persistent AF clinical trial



Sphere-9 catheter
with Affera mapping and ablation system | n = 212

THERMOCOOL SMARTTOUCH®* SF
with CARTO®* mapping system | n = 208

Approaching superior effectiveness†

74%
Primary effectiveness rate

80%
Effectiveness > 10 cases[7]

The highest **effectiveness** of any IDE treating a persistent population

Proven safety‡

1.4%
Primary safety event rate

Superior procedural efficiency over STSF

25+
minutes saved

† Primary effectiveness endpoint definition: The primary effectiveness endpoint was acute procedure failure, repeat ablation at any time, or after three months: recurrence of AF/AFL/AT, cardioversion, or new/reinitiated/increased AAD usage.
‡ Total of 13 adverse events measured, resulted in 3 hospitalizations within 1-week post- procedure for COPD exacerbation, pulmonary edema, and hemoptysis. For a full list of safety events, review the SPHERE Per-AF manuscript.

1. de Bakker JMT. Electrogram recording and analyzing techniques to optimize selection of target sites for ablation of cardiac arrhythmias. *Pacing Clin Electrophysiol*. 2019;42(12):1503–1516.
2. Reddy VY, Anter E, Rackauskas G, et al. Lattice-Tip Focal Ablation Catheter That Toggles Between Radiofrequency and Pulsed Field Energy to Treat Atrial Fibrillation: A First-in-Human Trial. *Circ Arrhythm Electrophysiol*. June 2020;13(6):e008718.
3. Anter E, Neužil P, Rackauskas G, et al. A Lattice-Tip Temperature-Controlled Radiofrequency Ablation Catheter for Wide Thermal Lesions: First-in-Human Experience With Atrial Fibrillation. *JACC Clin Electrophysiol*. May 2020;6(5): 507–519.
4. Barkagan M, Leshem E, Rottmann M, Sroubek J, Shapira-Daniels A, Anter E. Expandable Lattice Electrode Ablation Catheter: A Novel Radiofrequency Platform Allowing High Current at Low Density for Rapid, Titratable, and Durable Lesions. *Circ Arrhythm Electrophysiol*. April 2019;12(4):e007090.
5. Anter E, Mansour M, Nair DG, et al. Dual-energy lattice-tip ablation system for persistent atrial fibrillation: a randomized trial. *Nat Med*. August 2024;30(8):2303–2310.
6. Reddy VY, Peichl P, Anter E, et al. Atrial Fibrillation Using a Focal Lattice-tip Catheter that Toggles Between Pulsed Field and Radiofrequency Energy: Effect on the Esophagus. *Heart Rhythm*. August 2021;18(S8):S73.
7. Nair D. Operator Learning Curve with a Novel Dual-Energy Lattice-Tip Ablation System. Presented at APHRS 2024. Sydney, Australia, September 28, 2024.

Sphere-9™ Catheter Brief Statement
Indications
The Sphere-9 catheter is indicated for use in cardiac electrophysiological mapping (stimulation and electrogram recording) and for treatment of drug refractory, recurrent, symptomatic persistent atrial fibrillation (episode duration less than 1 year) and radiofrequency ablation of cavotricuspid isthmus dependent atrial flutter when used with the Affera mapping system.

Contraindications
Do not use this device under the following circumstances:
- In patients with an active systemic infection.
- In patients who have had cardiac surgery in the preceding eight weeks, as the risk of perforation may increase.
- In patients with intracardiac thrombus or myxoma, as the catheter may precipitate an embolus.
- In coronary vessels with diameter smaller than the expandable ablation electrode, as the catheter may damage the coronary vessels.
- In patients with prosthetic valves, as the catheter may damage the prosthesis.
- Using the transaortic retrograde approach in patients who have had aortic valve replacement.
- Using the transseptal approach in patients with an interatrial baffle or patch, as the opening could persist and result in an iatrogenic atrial shunt.

Warnings and Precautions
Do not reuse, reprocess, or resterilize devices labeled single-use only. The Sphere-9 catheter is designed for use only with compatible devices.

Intravenous heparin must be used to reduce the likelihood of thromboemboli developing during the procedure. Anticoagulation treatment should adhere to consensus guidelines,

Avoid steering the Sphere-9 catheter near other catheters to reduce the possibility of the catheters becoming entangled. Cardiac devices may be damaged by energy delivery. Catheter interactions with implantable leads may result in lead dislodgement or possible thrombus.

Cardiac ablation may induce intentional or unintentional life-threatening cardiac arrhythmias.

Care should be taken when ablating near sensitive structures (i.e. conduction system, coronary arteries) as unintended patient harm may occur. Catheter entrapment within the heart is a possible complication of cardiac ablation procedures that could necessitate surgical intervention.

The Sphere-9 catheter has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment.

Potential Adverse Events or Potential Complications
Atrioesophageal fistula, Cardiac perforation / tamponade, Cardiac or respiratory arrest, Stroke Conduction system injury, Coronary artery spasm / occlusion / stenosis, Damage / dislodgement to ICD or implantable pacemaker, Death, Embolism, Hemoptysis, Infection, Myocardial infarction, Phrenic nerve palsy / paralysis, Pulmonary edema, Pulmonary vein stenosis, Valve damage, Vessel dissection

Refer to the device technical manual for detailed information regarding the procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at www.medtronic.com.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

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