

Medtronic

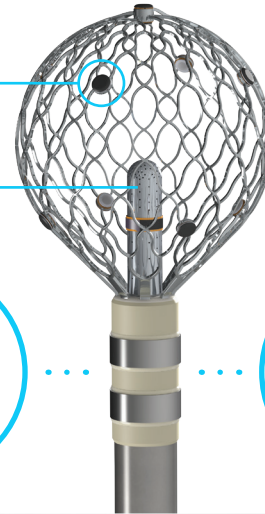
Sphere-9™ Catheter

All in one: map | ablate | validate

Map

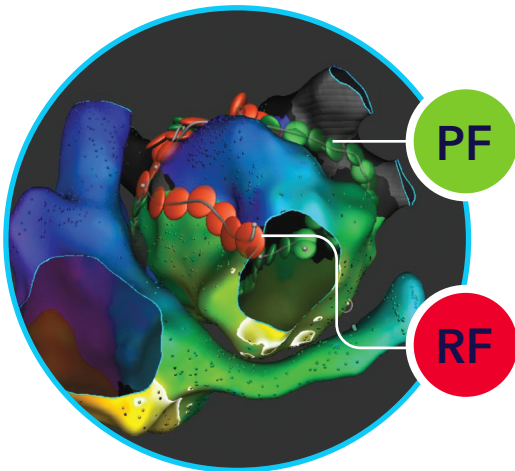
Close-Unipolar™ mapping combines the benefits of bipolar and unipolar electrogram acquisition¹ using **nine mini surface electrodes** and **one central reference electrode**.

Mapping controls at your fingertips



11
minutes²

5,000
points²



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 durable² lesions with **dual energy ablation: PF and RF**.

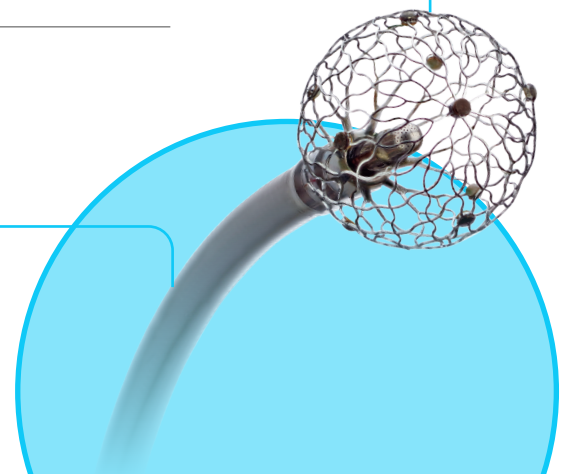
10x Larger **surface area** compared to standard irrigated ablation catheters^{3,6}

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 IDE⁵

First randomized 1:1
persistent AF clinical trial⁸

Sphere-9 catheter

with Affera mapping and ablation system | n = 212

THERMOCOOL SMARTTOUCH[®] SF[§]

with CARTO[®] mapping system | n = 208⁸

Approaching superior
effectiveness[†]

74%

Primary
effectiveness rate⁸

80%

Effectiveness
> 10 cases^{7,8}

Proven safety[‡]

1.4%

Primary safety
event rate⁸

Superior procedural
efficiency over STSF

25⁺

minutes saved⁸

The highest **effectiveness** of any IDE treating a persistent population⁸

† 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.

§ Licensed as ThermoCool SmartTouch SF Bi-Directional Navigation Catheter.

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, Neuzil 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.
8. Medtronic data on file.

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For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use.

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