

Medtronic

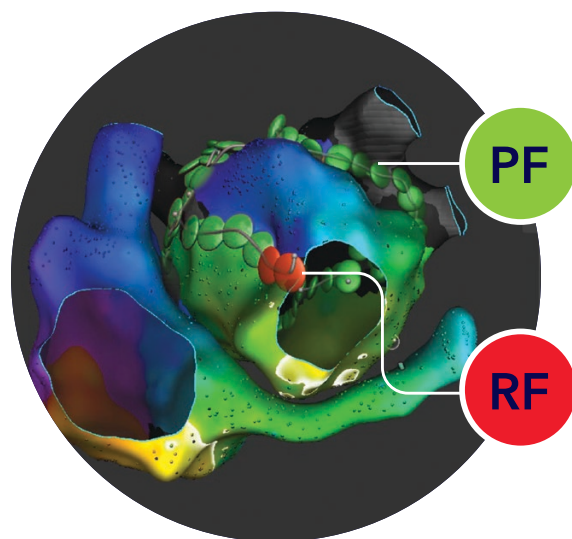
Sphere-9™ catheter

Map. Ablate. Validate.

Indicated for atrial and ventricular ablation

Map

Close-Unipolar™ mapping combines the benefits of bipolar and unipolar electrograms while minimizing the challenges of each¹ using **nine mini surface electrodes and one central reference electrode**.



Validate

Transition from ablation to validation using a **single transeptal access and zero exchange workflow**³ with **8 Fr bidirectional catheter** design.

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



11
minutes²

5,000
points²

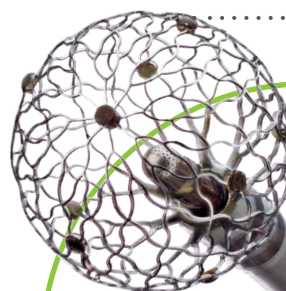
Ablate

Safe,³ effective,³ and durable⁴
PF and RF lesions

The compressible, 9 mm, wide-area focal lattice creates larger lesions in less time with fewer applications.^{5,6}

10× Larger surface area compared to standard irrigated ablation catheters⁶

97% Per-vein durability at three months (PULSE3 waveform)⁴



SPHERE Per-AF IDE³

First and only randomized 1:1 persistent AF clinical trial

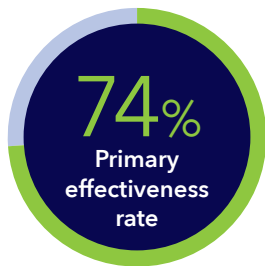
Sphere-9 catheter

with Affera™ mapping and ablation system | n = 212

THERMOCOOL SMARTTOUCH™* SF (STSF)

with CARTO™* mapping system | n = 208

Approaching superior effectiveness†



Proven safety‡



Superior procedural efficiency over STSF



† 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 three hospitalizations within one week postprocedure 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, Mansour M, Nair DG, et al. Dual-energy lattice-tip ablation system for persistent atrial fibrillation: a randomized trial. *Nat Med.* August 2024.
4. Reddy VY, Peichl P, Anter E, et al. A Focal Ablation Catheter Toggling Between Radiofrequency and Pulsed Field Energy to Treat Atrial Fibrillation. *JACC Clin Electrophysiol.* August 2023;9(8 Pt 3):1786-1801.
5. 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.
6. 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.
7. Kiehl EL, Mountantonakis SE, Mansour MC, et al. Operator learning curve with a novel dual-energy lattice-tip ablation system. *Heart Rhythm.* January 2026;23(1):89-96.

This material should not be considered the exclusive source of information, it does not replace or supersede information contained in the device manual(s).

Please note that the intended use of a product may vary depending on geographical approvals.

See the device manual(s) for detailed information regarding the intended use, the (implant) procedure, indications, contraindications, warnings, precautions, and potential adverse events.

For a MRI compatible device(s), consult the MRI information in the device manual(s) before performing a MRI.

If a device is eligible for eIFU usage, instructions for use can be found at Medtronic's website manuals.medtronic.com.

Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

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