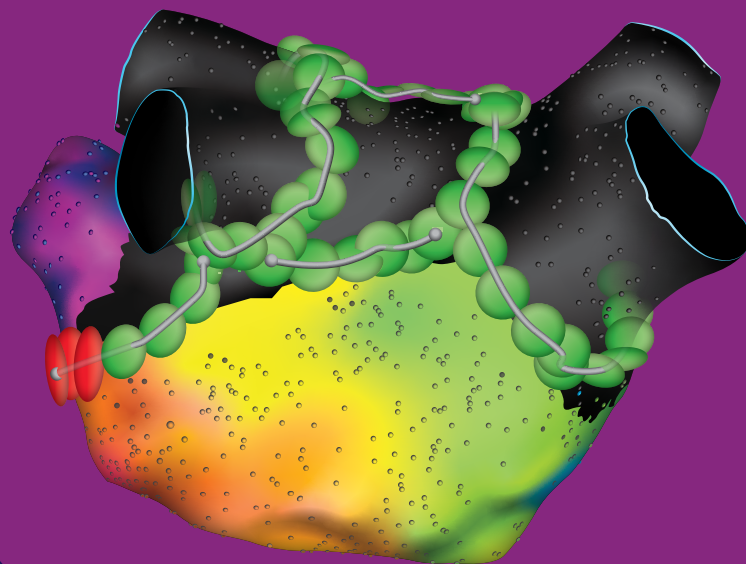


Medtronic



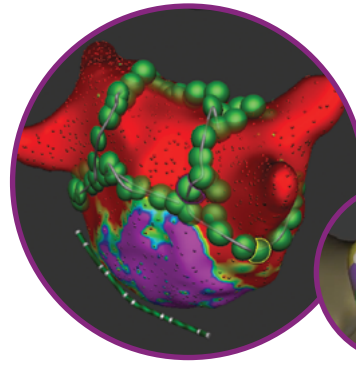
Success Simplified

AfferaTM mapping and ablation system

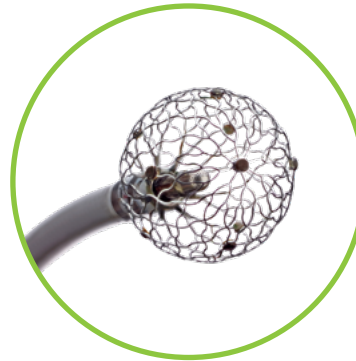
Intuitive. Refined. Streamlined.

Affera mapping and ablation system

Designed to innovatively address electrophysiology needs today and in the future, the Affera mapping and ablation system offers a uniquely intuitive mapping experience, delivering refined clinical insights and enabling streamlined procedural workflows as the sole platform for the all-in-one dual-energy Sphere-9™ catheter and Sphere-360™ pulsed field ablation catheter.



Affera™ Prism-2
mapping software



Sphere-9
catheter



Sphere-360
pulsed field
ablation catheter



- 1 HexaFlow™ irrigation pump**
Responsive, automated irrigation and bubble detection
- 2 HexaGen™ RF generator**
Temperature-controlled RF energy delivery
- 3 HexaPulse™ PF generator**
Unipolar, biphasic PF energy delivery
- 4 HexaMap™ catheter interface unit (CIU)**
Magnetic and impedance navigation and map acquisition with intracardiac electrogram and electrocardiogram display, recording, and pacing

Affera Prism-2 mapping software

Intuitive mapping

Automatic and continuous data collection

Display any point regardless of the map filters used during collection

Synergy navigation

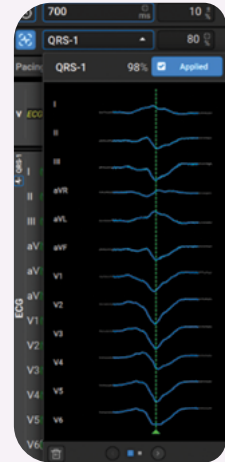
Utilize hybrid impedance and magnetic mapping modalities for visualization of sensor-based and non-sensor-based catheters

Fast remap and cloning

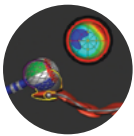
Seamlessly remap or clone an existing map for intraprocedural efficiencies

Beat Matching

Filter maps to electrogram data matching the ECG morphology of a beat of interest

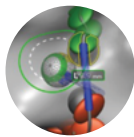


Refined insights



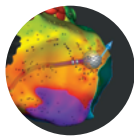
Automatic tags

Leverage instant analysis from lesion tags about lesion location, orientation, and quality, and from Pace Tags about paced morphology response



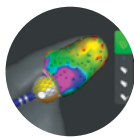
AfferaConnect™ line

Visually confirm ablation groups and lesion set contiguity



Propagation arrow

Assess wavefront directionality for every beat before, during, and after ablation

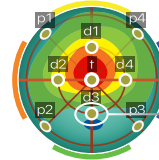


Vein mode

Enhance the precision of anatomical models and complex regions while minimizing the reliance on fluoroscopy^{1,2}

Sensor globe

Consult real-time mapping and ablation guide for local impedance feedback and tissue temperature display during RF and PF delivery



AfferaTouch™ feature

Real-time local impedance providing tissue proximity feedback



PF Signature™ feature

Visualize physiologic response of PF energy delivery to the tissue

Streamlined workflows

Integrated stimulator

Expedite pacing workflows with custom pacing modes and Pace Tagging pacing analysis

Low- or zero-fluoro workflows

Further or entirely reduce fluoroscopy time with synergy navigation

Seamless dual-energy modality transition

Easily and quickly transition between energy sources to deliver safe,¹ durable² lesions

Efficient lab setup

Simplify lab and procedure preparation with direct 12-lead signal acquisition



Some features are only supported with the Sphere-9 catheter.

Sphere-9 catheter

Map. Ablate. Validate.

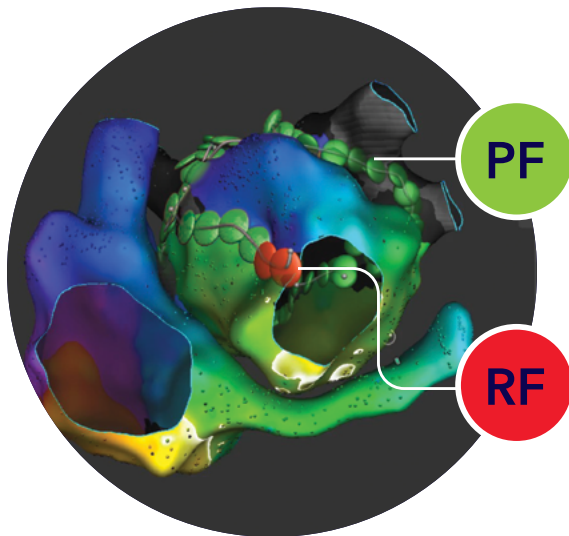
Map

Close-Unipolar™ mapping combines the benefits of bipolar and unipolar electrograms while minimizing the challenges of each³ using **nine mini surface electrodes** and **one central reference electrode**.



11
minutes²

5,000
points²



Ablate

Safe,¹ effective,¹ and durable⁴
PF and RF lesions

Indicated for persistent AFib and typical flutter using RF energy, **the compressible, 9 mm wide-area focal lattice** creates larger lesions in less time with fewer applications.^{5,6}

10x Larger surface area compared to standard irrigated ablation catheters⁶

97% Per-vein durability at three months (PULSE3 waveform)²

Validate

Transition from ablation to validation using a **single transseptal access and zero exchange workflow**¹ with **8 Fr bidirectional catheter** design.

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

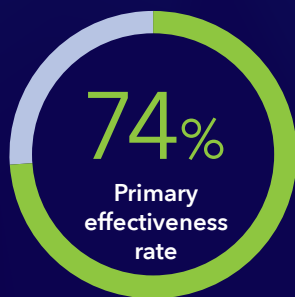


SPHERE Per-AF¹

Randomized persistent AF IDE 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[†]



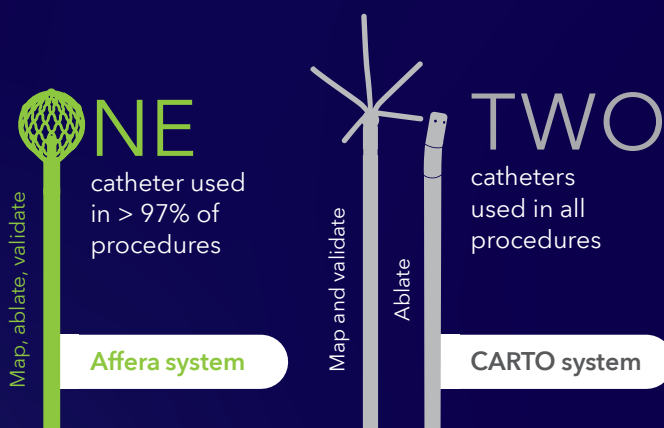
Proven safety[‡]



Primary safety event rate

- 0 PV stenosis
- 0 Phrenic nerve paralysis
- 0 Cardiac tamponade
- 0 Atrio-esophageal fistula

0 primary safety events in zero-fluoro cases⁸



Superior procedural efficiency and predictability⁹ compared to STSF

- 10x decrease in EP lab staff overtime^{§,9}
- 45% increase in days with time for addition of a non-ablation procedure^{§,9}
- 55% increase in days that allowed for third case same-day discharge^{§,9}



[†] 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.

[§] Based on a discrete event simulation of 1,000 lab days using the SPHERE Per-AF trial data. These are not endpoints from the SPHERE Per-AF study but rather hypothetical modeling based on the data generated from the SPHERE Per-AF study. For a full list of safety events, review the SPHERE Per-AF manuscript.

Sphere-360 PFA catheter

Rethink single shot

Full circle ablation

Adapts to anatomy

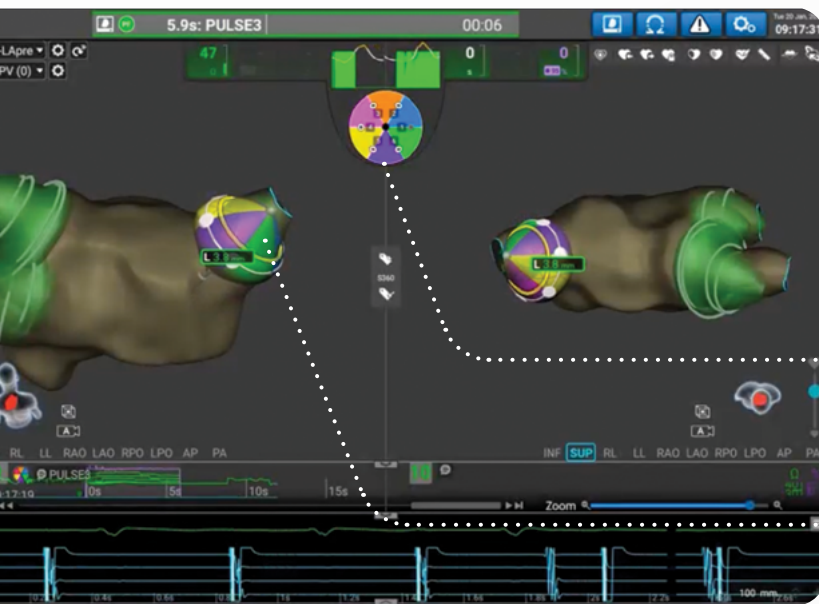
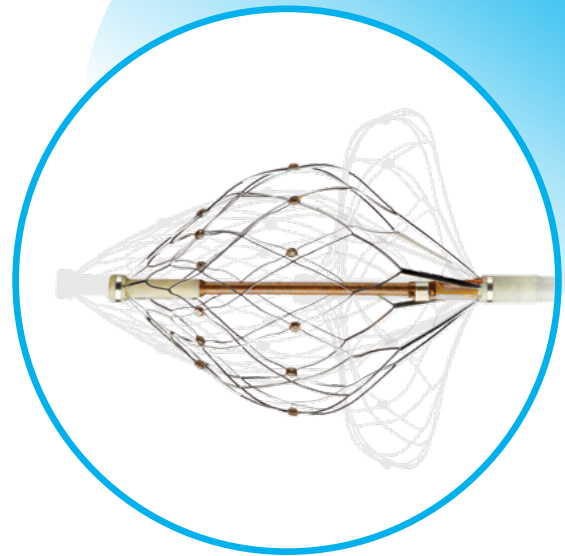
Seamlessly adjusts between a linear and disc shape to treat anatomies of various sizes.

Conformable lattice

Atraumatic nitinol lattice adjusts to shape of the vein.

Span360™ lesions

Delivers circumferential ablation with no rotation – requiring only four applications per vein.



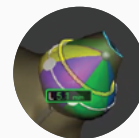
360 integration

Exclusively integrated with the Affera system, the Sphere-360 PFA catheter is an all-in-one system that provides navigation, mapping, and ablation in a single catheter.



AfferaTouch™ feature

Real-time local impedance providing tissue proximity feedback.



Lesion creation

Receive instant insights about catheter orientation and lesion location.



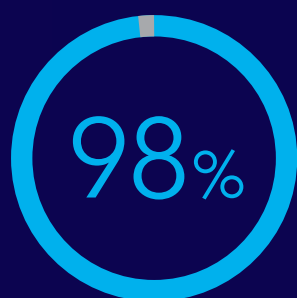
Consistent outcomes

The Sphere-360 catheter delivers predictable workflows and lasting results across centers – with reliability and confidence in your procedures.

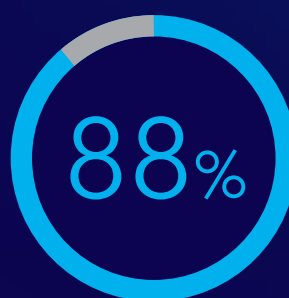
Sphere-360 catheter European study

Single-arm paroxysmal AF trial¹⁰

Lasting results



per PV durability
(75-day remap)[†]



efficacy
(1-year follow-up)[†]

Unmatched safety



No occurrence of coronary spasm, phrenic nerve injury, esophageal events, PV stenosis, TIA, stroke, or acute kidney injury. (N = 100)

Enhanced efficiency[§]



22 min LA dwell time

< 12 min PV transpired time



< 6 min mapping time

< 7 min fluoroscopy time[¶]

[†] Fifty patients treated with the PULSE3 optimized and most recent waveform configuration, 40 of which completed the optional remapping procedure.

[‡] See manuscript for all adverse event incidence.

[§] Total cohort [N = 100].

[¶] Four patients done with 0 fluoro; 26 patients with less than or equal to three minutes of fluoro.

1. 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.
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. de Bakker JM. Electrogram recording and analyzing techniques to optimize selection of target sites for ablation of cardiac arrhythmias. *Pacing Clin Electrophysiol*. December 2019;42(12):1503–1516.
4. M060056C001, Affera Prism-2 Mapping Software Manual. July 22, 2025.
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.
8. Nair DG, Sharma D, Osorio J, et al. Impact of a fully integrated wide-footprint lattice-tip dual-energy mapping and ablation system on fluoroscopy usage (AFS2025-59). *J Cardiovasc Electrophysiol*. March 24, 2025;36(5):1119–1192.
9. Mountantonakis SE, Anter E, Marschke J, et al. Electrophysiology lab efficiency simulation: a comparison between novel dual-energy lattice-tip and conventional contact-force sensing radiofrequency ablation systems. *J Invasive Cardiol*. December 2025;37(12).
10. Reddy VY, Peichl P, Kautzner J, et al. One-year outcomes of a conformable single-shot pulsed-field ablation catheter for the treatment of paroxysmal atrial fibrillation. *Heart Rhythm*. October 2025;22(10):2551–2561.

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