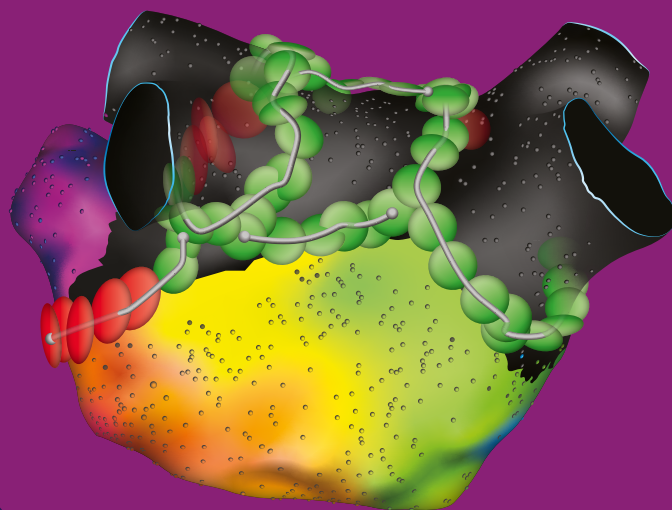


Medtronic



Success Simplified

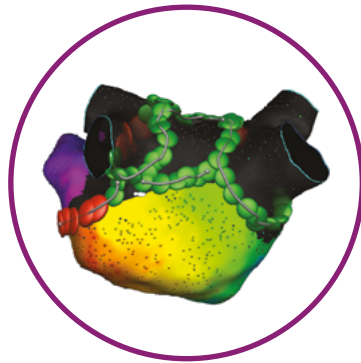
Affera[™] mapping and ablation system

Intuitive mapping. Refined insights. Streamlined workflows.

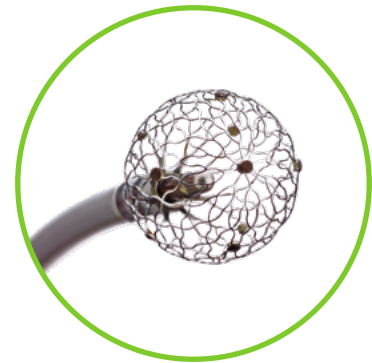
Affera mapping and ablation system

Experience a new paradigm in EP

The Affera mapping and ablation system is a fully integrated solution offering more predictable and flexible procedures¹ while empowering physicians to accurately map and safely² ablate **using an all-in-one, HD mapping and dual energy (PF and RF) catheter** through a single transeptal access **with a zero exchange workflow.**¹



Affera™ Prism-2
mapping software



Sphere-9™
catheter



HexaGen™ RF generator

Temperature-controlled RF energy delivery

HexaPulse™ PF generator

Unipolar, biphasic PF energy delivery

HexaMap™ catheter interface unit (CIU)

Magnetic and impedance navigation and map acquisition with intracardiac electrogram and electrocardiogram display, recording, and pacing

HexaFlow™ irrigation pump

Responsive, automated irrigation and bubble detection

Affera Prism-2 mapping software

Intuitive mapping

Efficient, high-fidelity mapping

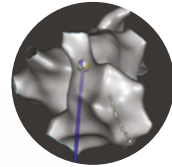
Quickly generate high-fidelity, realistic anatomy to enable identification of ablation targets.

Synergy navigation

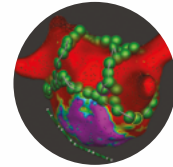
Hybrid impedance and magnetic mapping modalities for visualization of sensor-based and non-sensor-based catheters.

Vein Mode

Designed to delineate complex regions of the heart, which may reduce the use of fluoroscopy.^{1,3}

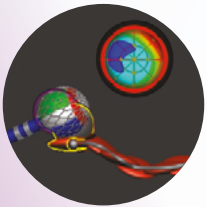


CS catheter visualization



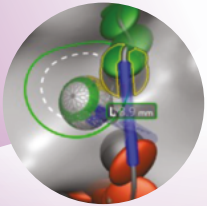
Zero-fluoro procedure post-map

Refined insights



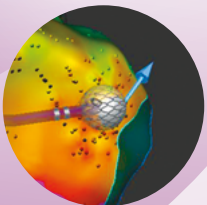
Automatic tags

Instant insights about tip location, orientation, and lesion creation



AfferaConnect™ line

Visually confirm ablation groups and lesion set contiguity

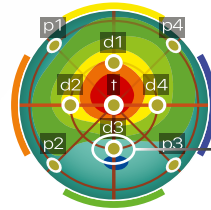


Propagation arrow

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

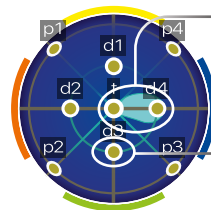
Sensor globe

Real-time mapping and ablation guide with tissue temperature display during RF and PF delivery



Real-time local impedance

Real-time local impedance providing tissue proximity feedback



PF Signature™ software

Visualize physiologic response of PF energy delivery to the tissue

Streamlined workflows

Integrated stimulator

Validate lesion sets using exclusive pacing modes and expedite differential pacing workflows

Low- or zero-fluoro workflows

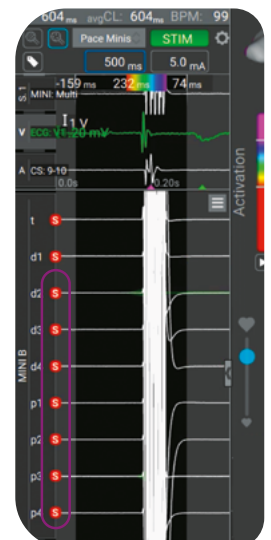
Minimize fluoroscopy time with synergy navigation

Seamless dual-energy modality transition

Easily and quickly transition between energy sources to deliver safe¹, durable² lesions

Efficient lab setup

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



Sphere-9 catheter

Map. Ablate. Validate.

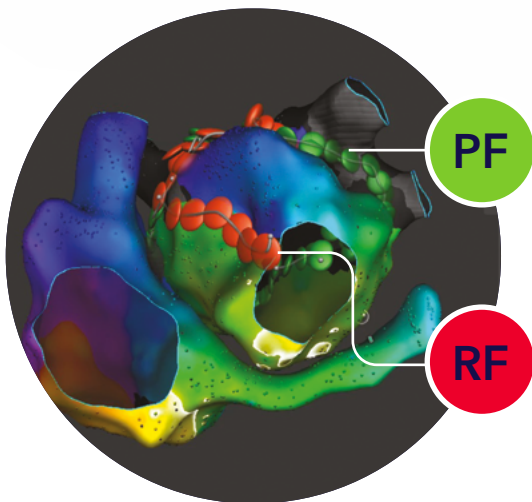
Map

Close-Unipolar™ mapping combines the benefits of bipolar and unipolar electrogram acquisition⁴ using **nine mini surface electrodes** and **one central reference electrode**.



11
minutes²

5,000
points²



Ablate

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

Safe,¹ effective,¹ and durable²
PF and RF lesions

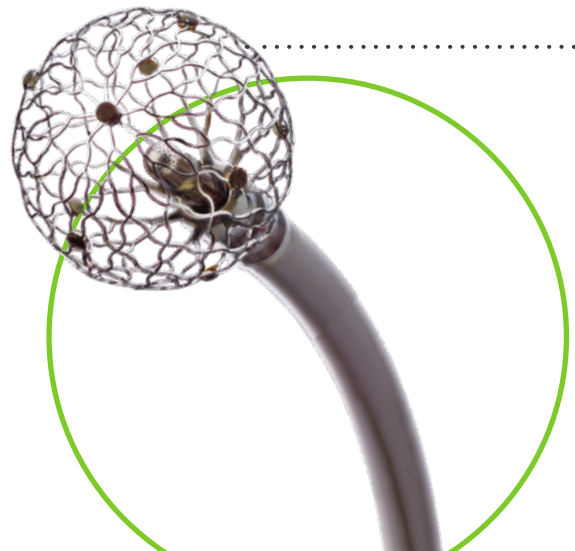
10x Larger surface area compared to standard irrigated ablation catheters^{5,7}

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

Validate

Transition from ablation to validation using a **single transeptal access and zero exchange workflow¹** 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 IDE¹

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[†]



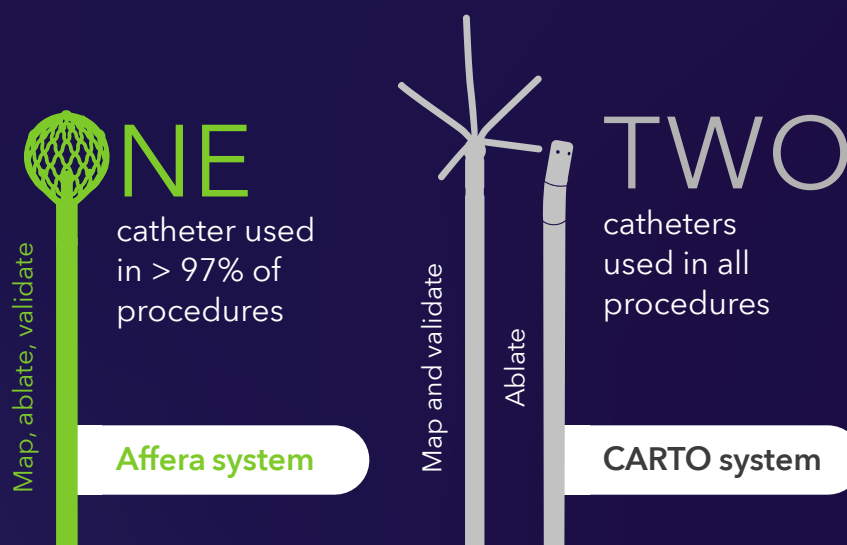
Proven safety[‡]



Primary safety event rate

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

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



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 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. 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. M060056C001, Affera Prism-2 Mapping Software Manual. July 22, 2025.
4. 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.
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. 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.
8. Nair D. Operator Learning Curve with a Novel Dual-Energy Lattice-Tip Ablation System. Presented at: APHRS 2024; September 28, 2024; Sydney, Australia.

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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