

Experience a
new paradigm
in electrophysiology

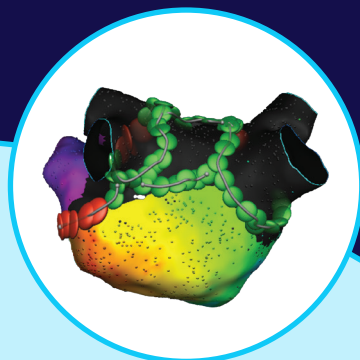
Affera™ Integrated Mapping System
and Affera™ ablation system

Medtronic Engineering the
extraordinary

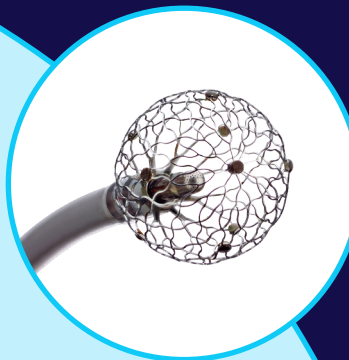
Affera™ Mapping and Ablation System

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) 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 navigation and map acquisition with intracardiac electrogram display, recording, and pacing

HexaFlow™ irrigation pump

Responsive (controlled by the system automated) irrigation and bubble detection

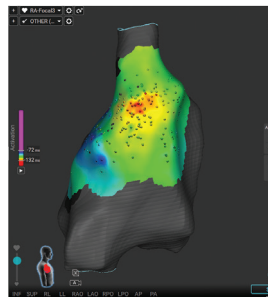
Affera™ Prism-2 Mapping Software

automate | inform | optimize

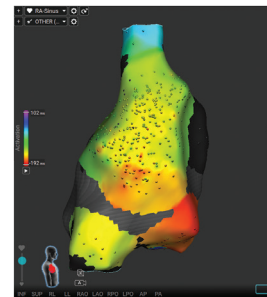
Automate

Automatic and continuous collection

Collect everything; display the rhythm you want to see.

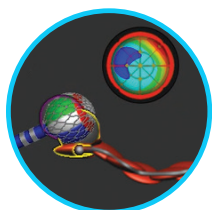


Left: AT at 400 ms



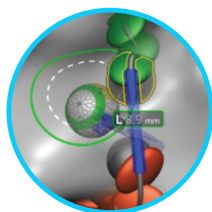
Right: AT at 300 ms

Inform



Automatic tags

Instant insights about tip location, orientation, and lesion creation.

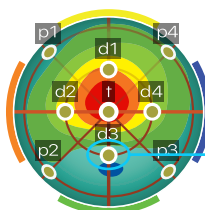


AfferaConnect™ line

Visually confirm ablation groups and lesion set contiguity.

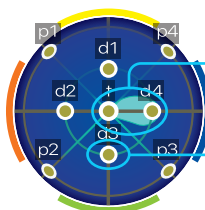
Sensor globe

Real-time mapping and ablation guide. Tissue temperature display during RF and PF delivery.



Real-time local impedance

Providing tissue proximity feedback before, and after ablation.

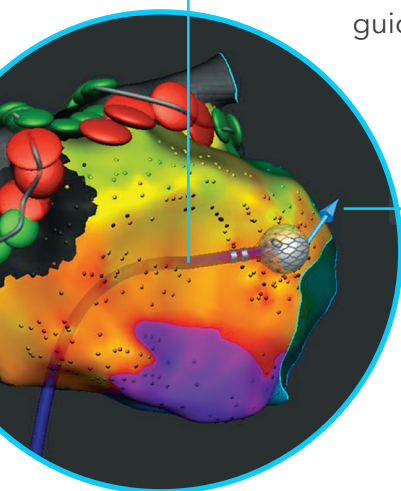


PF Signature™ software

Visual physiologic response of PF energy delivery to the tissue.

Full shaft visualization

Enhancing catheter guidance and alignment.



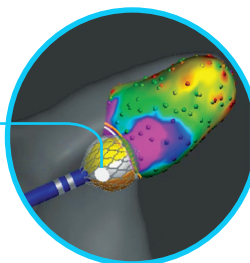
Propagation arrow

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

Optimize

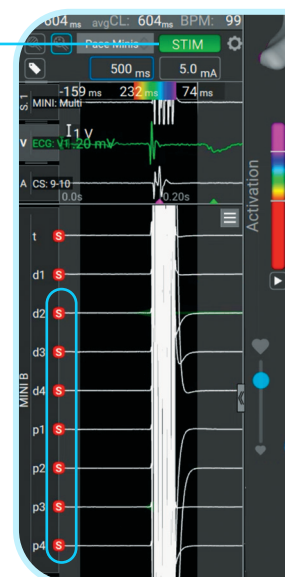
Vein mode

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



Integrated stimulator

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



Sphere-9™ Catheter

All in one: map | ablate | validate

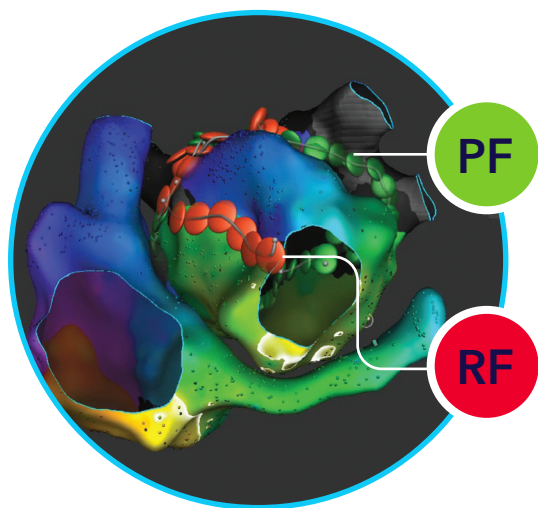
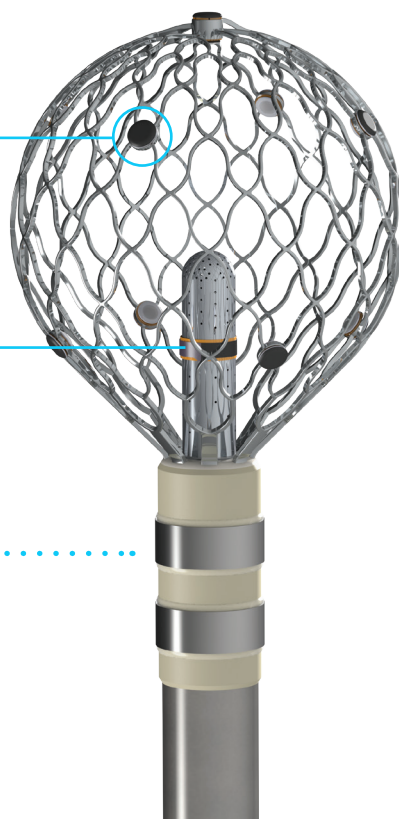
Map

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

Mapping controls at your fingertips



Ablate

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

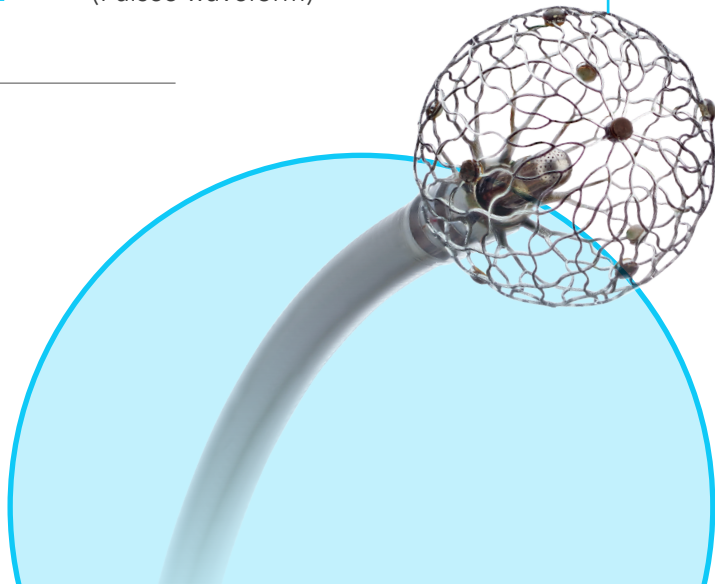
10x Larger surface area compared to standard irrigated ablation catheters^{5,7}

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

Validate

Transition from ablation to validation using a **single transeptal access and zero exchange 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-AF IDE[†]

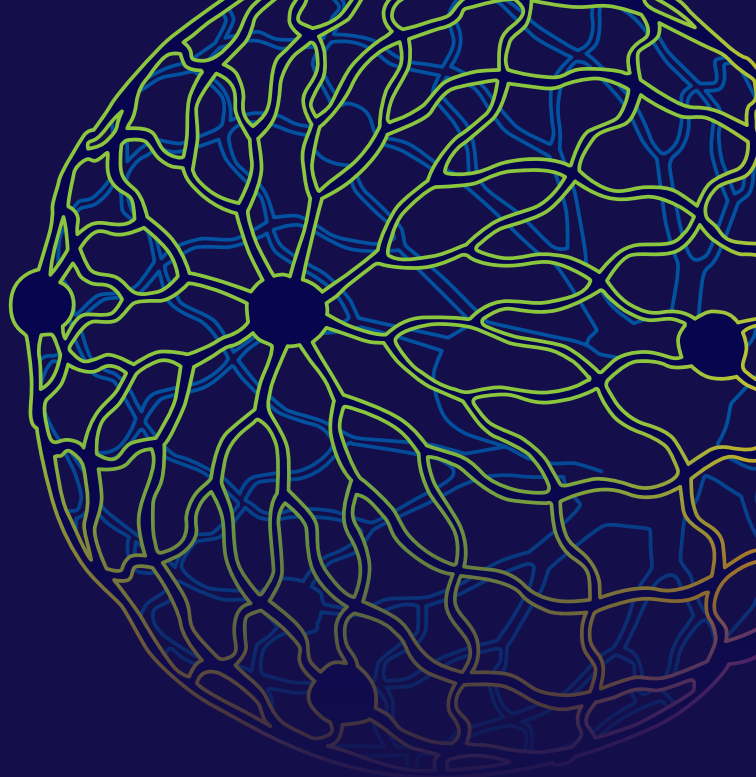
First and only randomized 1:1
persistent AF clinical trial

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 cases⁸

Proven safety[‡]

1.4%

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 population⁹

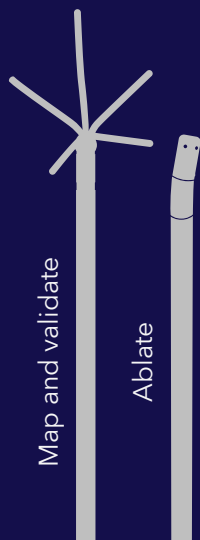


ONE

catheter used
in > 97% of
procedures

Map, ablate, validate

Affera[™]



TWO

catheters used
in all procedures

Map and validate

Ablate

CARTO[™]* 3 SYSTEM

Superior procedural
efficiency over STSF⁹

25⁺

minutes saved⁹

[†] 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. 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. Affera Mapping System Software Manual – M050220C001.
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. Sydney, Australia, September 28, 2024.
9. 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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