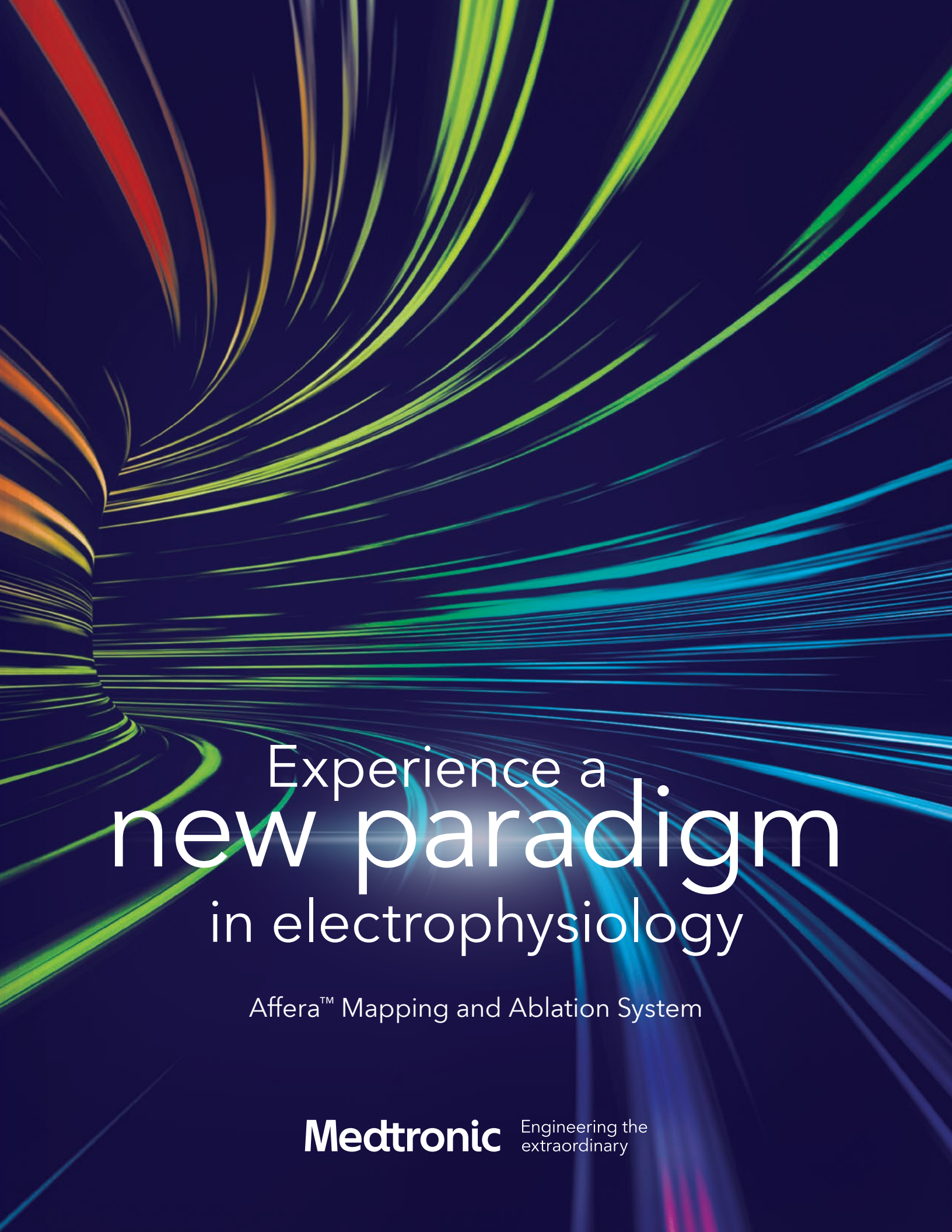
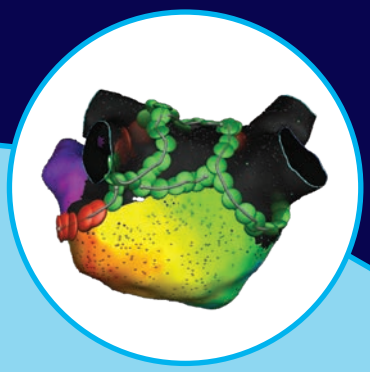

Experience a
new paradigm
in electrophysiology
Affera™ Mapping and Ablation System
Medtronic
Engineering the
extraordinary

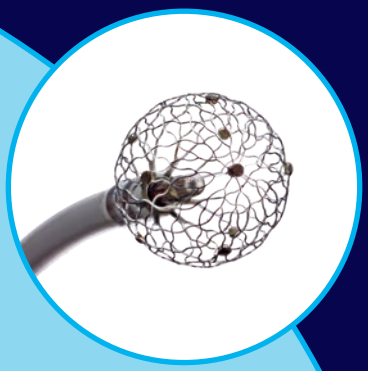
Affera™ Mapping and Ablation System

Experience a new paradigm in EP

The Affera mapping and ablation system is a fully integrated, solution offering more predictable and flexible procedures[1] while empowering physicians to accurately map and safely[2] ablate **using an all-in-one, HD mapping and dual energy (PF and RF)** through a single transseptal access **with a zero exchange workflow.**[1]



Affera™ Prism-1
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

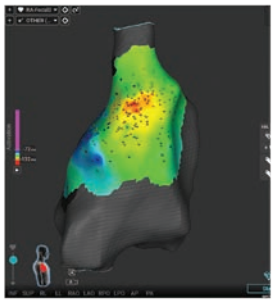
HexaFlow™ irrigation pump
Responsive (controlled by the system automated) irrigation and bubble detection

Affera™ Prism-1 Mapping Software

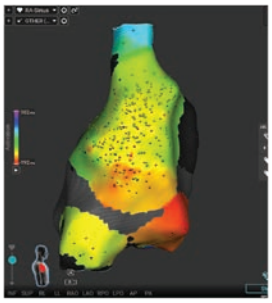
automate | inform | optimize

Automate

Automatic and continuous collection
Collect everything; display the rhythm you want to see.

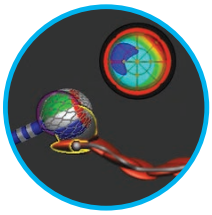


Left: AT at 400 ms

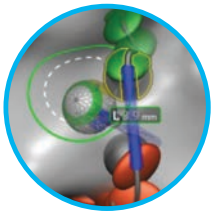


Right: AT at 300 ms

Inform

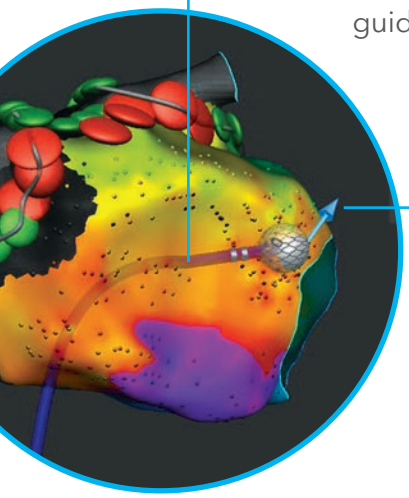


Automatic tags
Instant insights about tip location, orientation, and lesion creation.



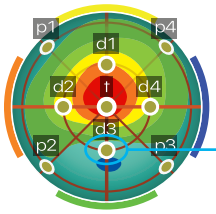
AfferaConnect™ line
Visually confirm ablation groups and lesion set contiguity.

Full shaft visualization
Enhancing catheter guidance and alignment.

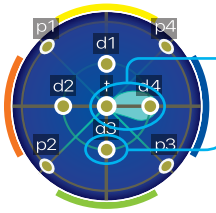


Propagation arrow
Assess wavefront directionality for every beat before, during, and after ablation.

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



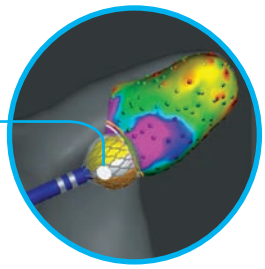
Real-time local impedance
Providing tissue proximity feedback before, and after ablation.



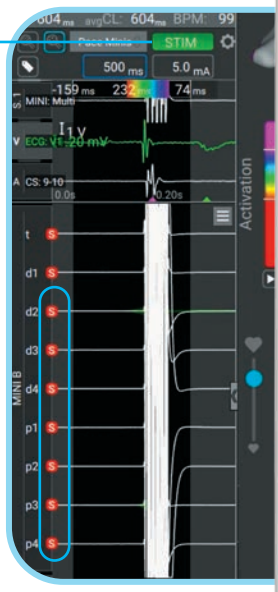
PF Signature™ software
Visual physiologic response of PF energy delivery to the tissue.

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.

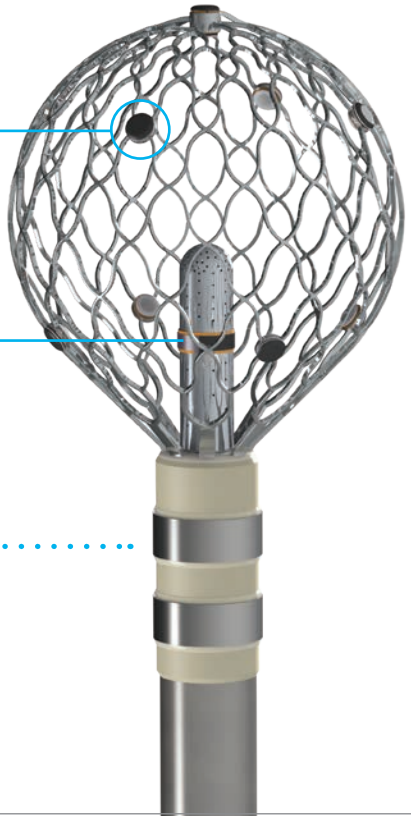


Sphere-9™ Catheter

All in one: map | ablate | validate

Map

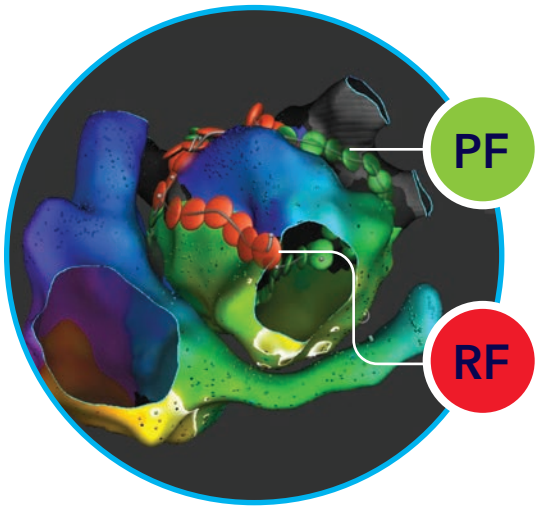
Close-Unipolar™ mapping combines the benefits of bipolar and unipolar electrogram acquisition[4] using nine mini surface electrodes and one central reference electrode.



11 minutes[2]

5,000 points[2]

Mapping controls at your fingertips



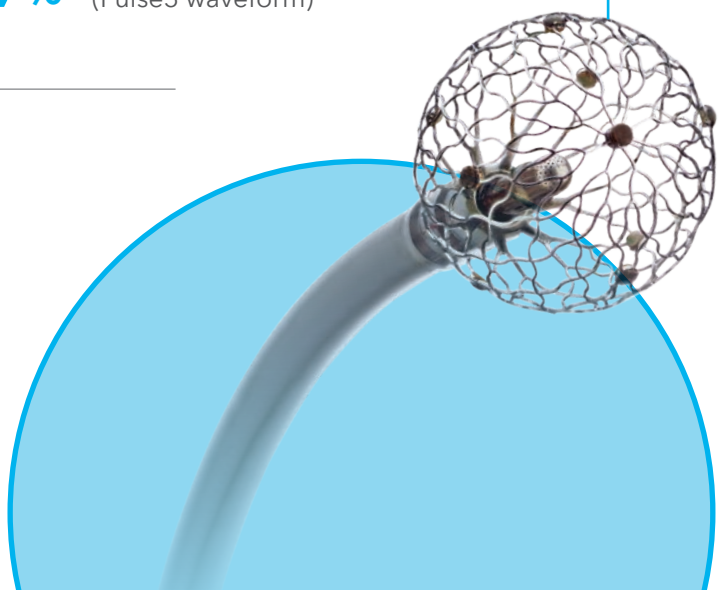
Ablate

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 durable[2] 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.

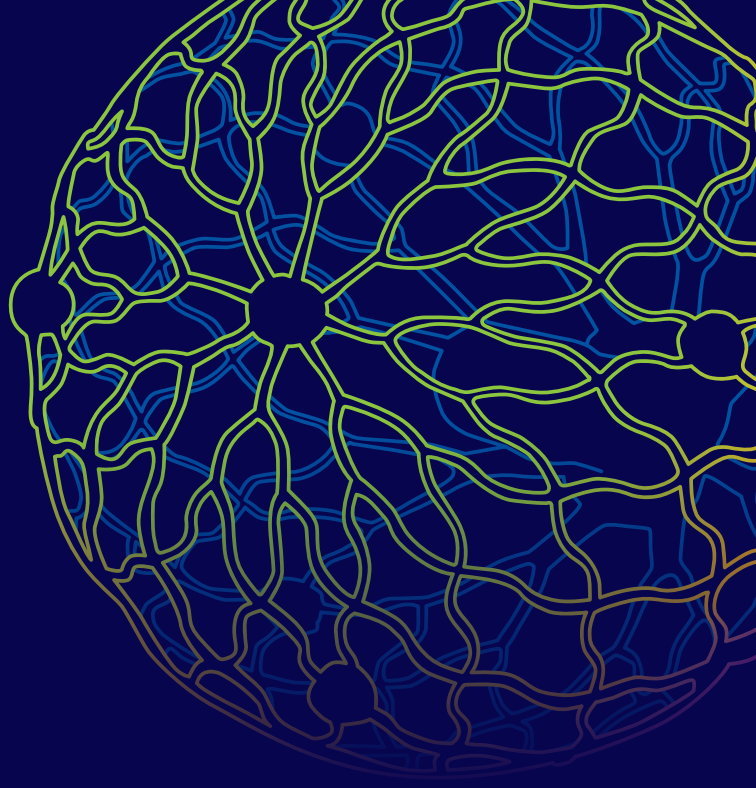
Confirm electrical conduction block with ease using **exclusive pace modes** specifically designed for the Sphere-9 catheter.

SPHERE Per-AF IDE[1]

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 cases[8]

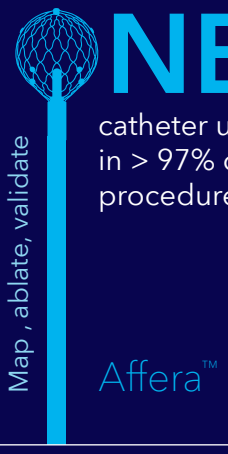
Proven safety‡

1.4%

Primary safety event rate

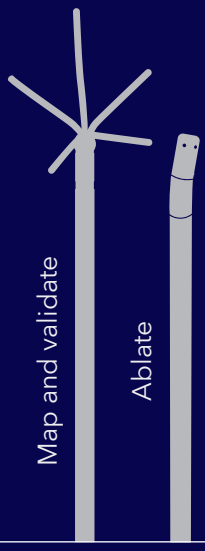
0 PV stenosis
0 Phrenic nerve paralysis
0 Cardiac tamponade
0 Atrio-esophageal fistula

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



ONE
catheter used in > 97% of procedures

Affera™



TWO
catheters used in all procedures

CARTO™*

Superior procedural efficiency over STSF

25+
minutes saved

† 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. 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.

Affera™ Mapping and Ablation System Brief Statement
Indications
The Sphere-9 catheter is indicated for use in cardiac electrophysiological mapping (stimulation and electrogram recording) and for treatment of drug refractory, recurrent, symptomatic persistent atrial fibrillation (episode duration less than 1 year) and radiofrequency ablation of cavotricuspid isthmus dependent atrial flutter when used with the Affera mapping system.

The Affera Mapping System is intended to be used for catheter-based cardiac electrophysiological mapping. The mapping system allows pacing and real-time visualization of compatible catheters as well as display of cardiac maps in multiple formats. The acquired patient signals, including intracardiac electrograms, may also be recorded and displayed on the system's display screen.

Contraindications
Do not use this device under the following circumstances:
- In patients with an active systemic infection.
- In patients who have had cardiac surgery in the preceding eight weeks, as the risk of perforation may increase.
- In patients with intracardiac thrombus or myxoma, as the catheter may precipitate an embolus.
- In coronary vessels with diameter smaller than the expandable ablation electrode, as the catheter may damage the coronary vessels.
- In patients with prosthetic valves, as the catheter may damage the prosthesis.
- Using the transaortic retrograde approach in patients who have had aortic valve replacement.
- Using the transseptal approach in patients with an interatrial baffle or patch, as the opening could persist and result in an iatrogenic atrial shunt.

Warnings and Precautions
Do not reuse, reprocess, or resterilize devices labeled single-use only. Only use with compatible devices listed in the IFU. The Affera Mapping System requires use of a disposable Location Reference Patch Kit to detect patient displacement and respiratory motion.

Treatment location should be confirmed using alternative techniques (e.g. fluoroscopy, intracardiac electrograms, intracardiac echocardiography) before treatment.

A connection to a compatible cardiac stimulator is allowed provided the stimulator is electrically isolated or physically disconnected when RF or PF energy is applied to the patient, outputs of the generator and stimulator must be isolated to prevent patient injury or damage to equipment.

The pacing functionality in the Affera Mapping System is not a life support device and is for diagnostic purposes only. Pacing may induce intentional or unintentional life-threatening cardiac arrhythmias.

Intravenous heparin must be used to reduce the likelihood of thromboemboli developing during the procedure. Patient injury may result from excessive delivery of fluids. Anticoagulation treatment should adhere to consensus guidelines,

Avoid steering the Sphere-9 catheter near other catheters to reduce the possibility of the catheters becoming entangled. Cardiac devices may be damaged by energy delivery. Catheter interactions with implantable leads may result in lead dislodgement or possible thrombus.

Cardiac ablation may induce intentional or unintentional life-threatening cardiac arrhythmias.

Care should be taken when ablating near sensitive structures (i.e., conduction system, coronary arteries) as unintended patient harm may occur. Catheter entrapment within the heart is a possible complication of cardiac ablation procedures that could necessitate surgical intervention.

The Affera Mapping and Ablation System has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. System operation may be temporarily interrupted if exposed to excessive external electromagnetic disturbance or ESD.

Potential Adverse Events or Potential Complications
Atrioesophageal fistula, Cardiac perforation / tamponade, Cardiac or respiratory arrest, Stroke Conduction system injury, Coronary artery spasm / occlusion / stenosis, Damage / dislodgement to ICD or implantable pacemaker, Death, Embolism, Hemoptysis, Infection, Myocardial infarction, Phrenic nerve palsy / paralysis, Pulmonary edema, Pulmonary vein stenosis, Valve damage, Vessel dissection

Refer to the device technical manual for detailed information regarding the procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at www.medtronic.com.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

Medtronic

710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA

Toll-free in USA:
800.633.8766
Worldwide: +1.763.514.4000
medtronic.com

UC202501929 EN 10/2024