



Experience a
new paradigm
in electrophysiology

Affera™ Mapping and Ablation System

Medtronic Engineering the
extraordinary

All-in-one – map | ablate | validate

Sphere-9™ Catheter

Unparalleled versatility

- HD mapping leveraging close-unipolar EGMs¹
- One, single catheter with dual-energy² capabilities, RF and PF

Absolute control

- Tissue contact and stability through innovative 9 mm, conformable lattice tip
- 9 mini electrodes providing accurate, real-time tissue temperature monitoring¹

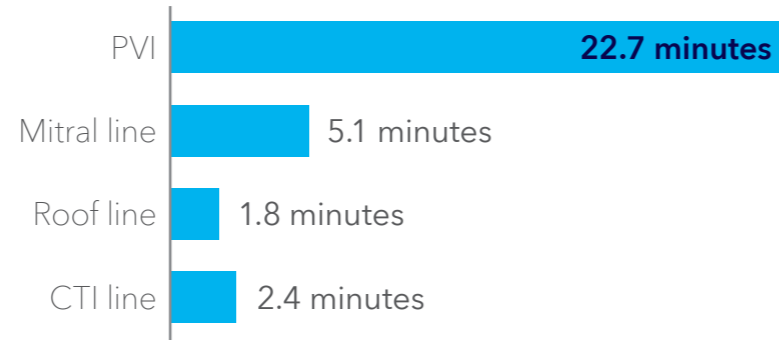
Optimized workflow

- Safe^{1,2} and effective^{1,2} procedures in less time² using fewer wide-area focal lesions^{1,3}
- Single transeptal access and zero exchanges for optimized workflow

11
mapping minutes
Average time to complete pre-ablation map²

97%
durable lesions
Per-vein durability at 3 months³

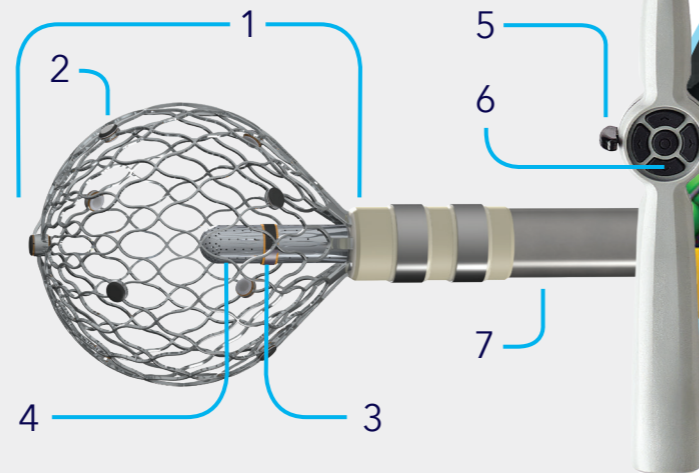
0.6%
device-related primary adverse events
Using RF or PF energy⁴



Transpired ablation time (n = 76, PF/RF)²

Sphere-9 Catheter at a glance

1. Nitinol lattice ablation electrode
2. Nine platinum-iridium mini electrodes
3. Central reference electrode
4. Central irrigation
5. 8Fr Bi-directional steerability (D-F)
6. Handle controller for mapping management
7. Magnetic location sensors for curve visualization



Elevating the norm

Affera™ Prism-1 Mapping Software

Built with user experience in mind, the Affera Prism-1 mapping software addresses the most common needs of today's electrophysiologists with elegant features and an innovative suite of software functionalities to enhance clinical workflows, now and in the future.

Intuitive interface

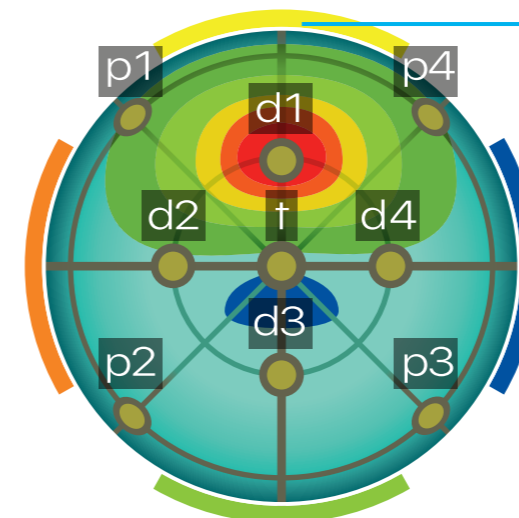
A modern, sleek interface designed to enhance and streamline the interpretation of complex information

Integrated platform

Purposefully built for an optimized Sphere-9 user experience and forthcoming developments and catheter technologies

Insightful algorithms

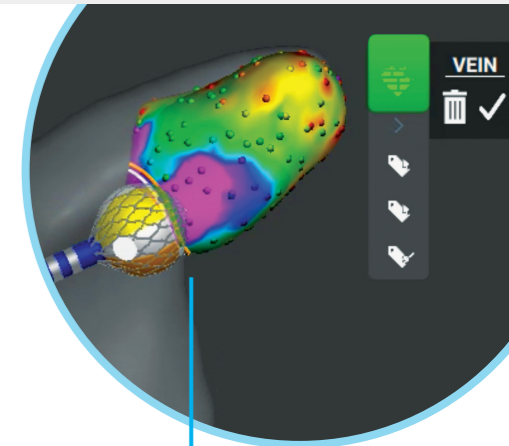
Innovative clinical tools to enhance performance and remove complexity



Sensor globe aggregates real time clinical information

- Tissue temperature
- Local impedance for contact verification

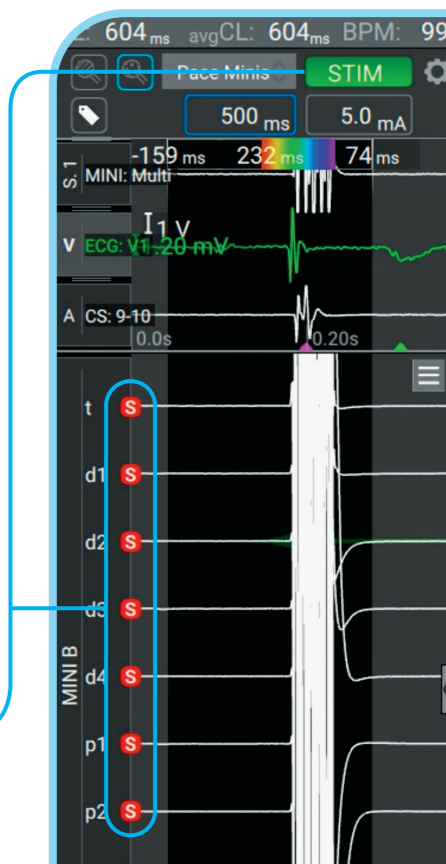
Precise delineation of complex anatomical regions and ridges with **vein mode**



AutoTags and **TagConnect™** features highlight visual contiguity and orientation of ablation tags

Propagation arrow provides real time spatiotemporal activation information regarding the area of interest

Leverage custom pacing modes and configure pacing period and amplitude using **integrated stimulator**



Affera Mapping and Ablation System ordering details

Capital Components

Product Description	Details
Affera Prism-1 Mapping System	Includes Software, CIU, Window Field Generator, Workstation (PC mouse, keyboard), Bard and Cardiolab interface accessories, cables/accessories
HexaGen™ RF Generator	Includes RFG, remote control, foot pedal, cables/accessories
HexaFlow™ Irrigation Pump	Includes pump, cables/accessories
HexaPulse™ PF Generator	Includes PFG, cables/accessories

Note: Capital systems are customized to support the individual needs and country requirements of each customer. Please work directly with your local sales representative to identify the correct order code.

Disposable Components

Ordering Number	Product Description	Details
AFR-00001	Sphere-9 Catheter	Single use, HD mapping and ablation catheter
AFR-00007	Location Reference Patch Kit	Includes 4 procedure kits
AFR-00006	Catheter Extension Cable	Single use cable for use with Sphere-9 catheter
AFR-00002	Tubing Kit	Includes 4 procedure kits, compatible with HexaFlow irrigation pump

References:

- Anter E, Neuzil 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.
- 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.
- Reddy VY, Peichl P, Anter E, et al. B-PO01-055 ATRIAL FIBRILLATION ABLATION USING A FOCAL LATTICE-TIP CATHETER THAT TOGGLES BETWEEN PULSED FIELD AND RADIOFREQUENCY ENERGY: EFFECT ON THE ESOPHAGUS. *Heart Rhythm.* August 2021;18(8):S73.
- CR-00014 Rev C. Medtronic data on file.

Note:

Formal product names in IFUs and user manuals may differ:
 Sphere-9™ Catheter = Sphere-9™ Mapping and Ablation Catheter
 Tubing Kit = HexaFlow™ Tubing Set

Brief statement

See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative or consult the Medtronic website at www.medtronic.com.

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Medtronic

Europe

Medtronic International
 Trading Sàrl.
 Route du Molliau 31
 Case postale
 CH-1131 Tolochenaz
medtronic.eu
 Tel: +41 0 21 802 70 00
 Fax: +41 0 21 802 79 00

United Kingdom/Ireland

Medtronic Limited
 Building 9
 Croxley Green Business Park
 Hatters Lane
 Watford
 Herts WD18 8WW
medtronic.co.uk
 Tel: +44 0 1923 212213
 Fax: +44 0 1923 241004

Technical Support

Toll-free: 00800-22556338
 Toll (paid): +31 (45) 5664621
rs.casemeatechservice@medtronic.com

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