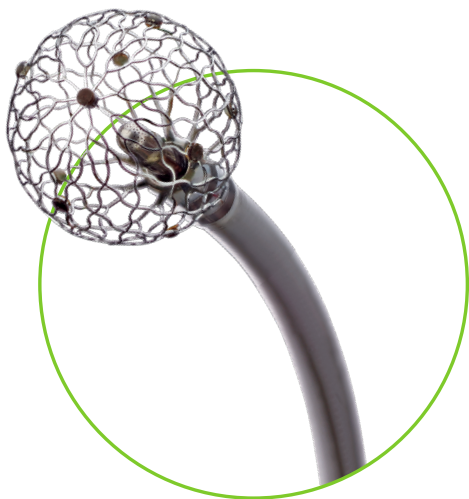


Medtronic

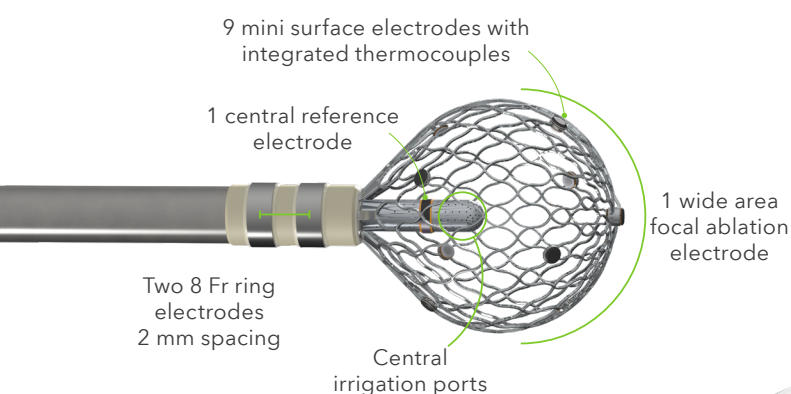
Sphere-9™ catheter

Map. Ablate. Validate.



The Sphere-9 catheter is a sensor-based, bidirectional, irrigated, multi-electrode, high-definition (HD) mapping and ablation catheter with a novel, nitinol lattice tip design. The 9 mini electrodes and single central reference electrode support Close-Unipolar™ HD mapping capabilities for creating anatomical, voltage, and activation maps. The lattice tip delivers lesions using PF and RF energy and the 9 mini surface electrodes, integrated with 9 thermocouples, provide real-time tissue proximity information and tissue temperature feedback.

It is compatible with the Affera™ mapping and ablation system, including all associated mapping software, hardware, and disposable components.



Ordering information

Order number

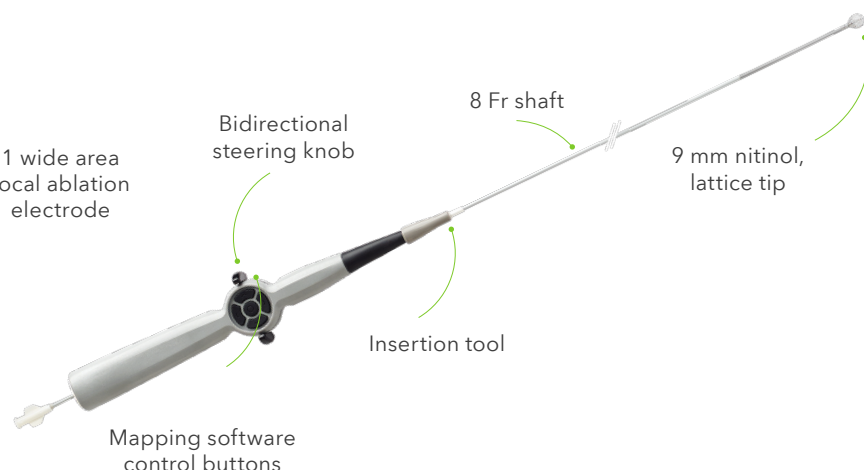
AFR-00001 Sphere-9 catheter

Sphere-9 catheter

Specifications

Form factor	Wide area focal
Energy options	Pulsed field and radiofrequency†
Shaft diameter	8 Fr
Tip diameter	9.3 mm
Shaft length	115 cm (without insertion tool)
Curve diameter	Large "F" (5 cm) Small "D" (3.5 cm)
Irrigation rates	4 mL/min when not ablating 15 mL/min with PF energy delivery 30 mL/min with RF energy delivery
Number of electrodes	1 lattice ablation electrode 9 mini electrodes 2 ring electrodes 1 central electrode
Number of thermocouples	9 mini, outward-facing thermocouples
Sheath compatibility	8.5 Fr nondeflectable and steerable
Sterilization	Single use, sterile device, ethylene oxide (EO) gas
HCPCS c-code (supply code)	C1733

† Four return electrodes with surface area $\geq 124 \text{ cm}^2$ that conform with IEC/EN 60601-2-2 are required for energy delivery.



Compatibility

Affera disposables

Order number	Product name	Details
AFR-00006	Catheter extension cable	Sterile, single-use, 2 m long cable. Compatible with Sphere-9 catheter and Affera system
AFR-00015	Impedance patch kit	Includes 4 kits per order; 6 impedance patches per kit
AFR-00002	Tubing kit	Includes 4 tubing kits per order; compatible with HexaFlow™ irrigation pump

Affera™ capital equipment

Order number	Product	Order number	Product
AFR-00016	Affera™ Prism-2 mapping system	AFR-00008	HexaPulse™ PF generator
AFR-00004	HexaGen™ RF generator	AFR-00013	System cart (optional)
AFR-00005	HexaFlow irrigation pump		

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.

Medtronic products placed on European markets comply with EU and UK legislation (if applicable) on medical devices.

For any further information, contact your local Medtronic representative and/or consult Medtronic's websites.

Medtronic medical devices marketed in Spain are in compliance with the Spanish legislation in force.

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