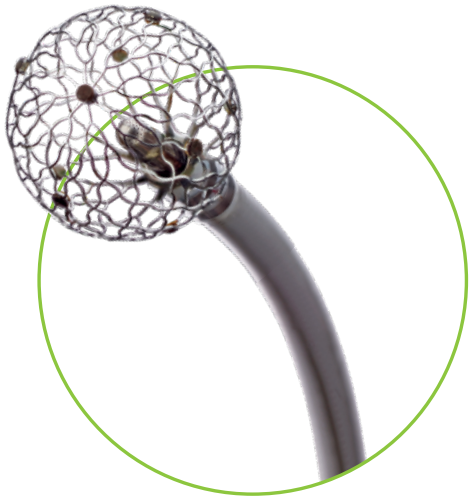
Medtronic

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

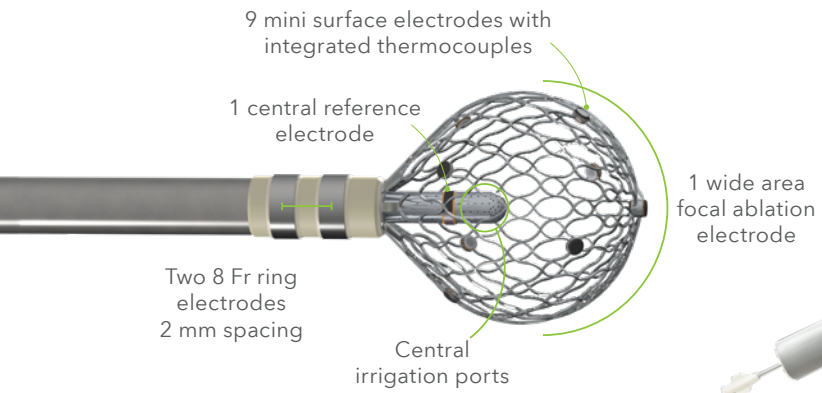
AFR-00001	Sphere-9 catheter

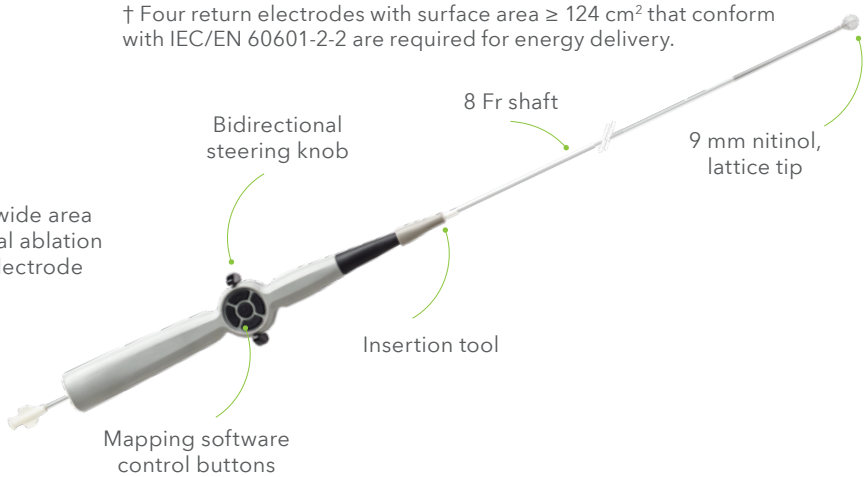
Sphere-9 catheter

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 ≥ 124 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		

Sphere-9™ Catheter 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.

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. The Sphere-9 catheter is designed for use only with compatible devices.

Intravenous heparin must be used to reduce the likelihood of thromboemboli developing during the procedure. 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 Sphere-9 catheter has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment.

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.

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