

Medtronic

Sphere-360™

pulsed field ablation catheter



The Sphere-360™ pulsed field ablation (PFA) catheter is a non-irrigated, electrophysiology mapping and ablation catheter with a novel nitinol lattice design. Its six-panel electrode array delivers pulsed field energy and contains six bipolar mini electrode pairs for local electrograms. The conformable lattice creates circumferential ablation lesion around a pulmonary vein and is fully integrated with the Affera™ mapping and ablation system.

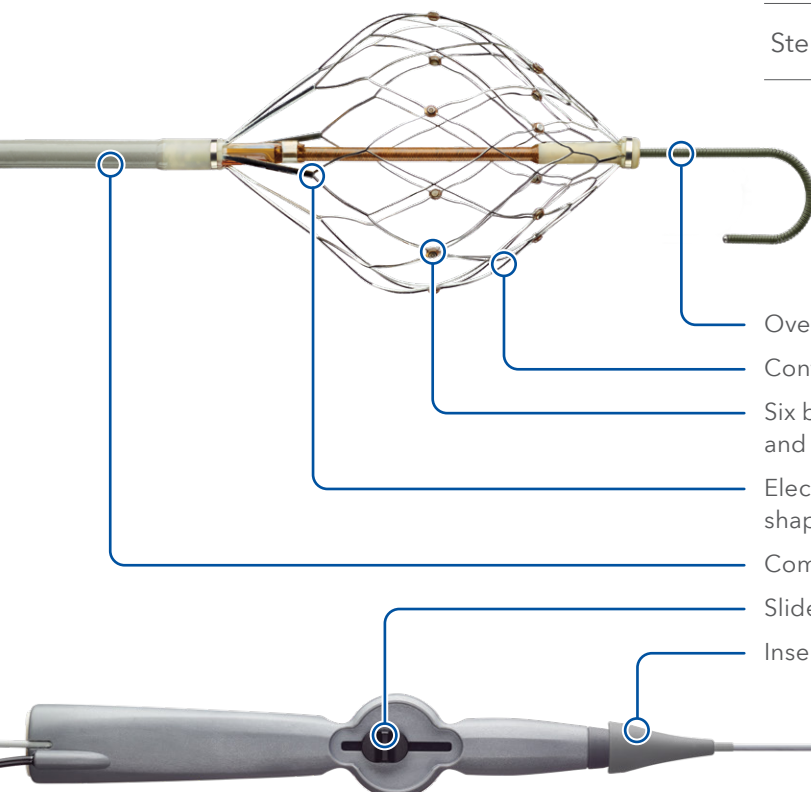
Ordering information

Order number

AFR-00012	Sphere-360™ catheter
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Specifications

Form factor	Large lattice single shot
Energy	Pulsed field
Shaft diameter	2.7 mm (8 Fr)
Tip diameter	Expands to 34 mm
Insertable shaft length	101 cm
Number of electrodes	6 mini electrode pairs
Sheath compatibility	FlexCath Contour™ steerable sheath (10 Fr) or similar, minimum 3.3 mm (10 Fr) deflectable sheath
Guidewire compatibility	PV tracker or similar 0.032 in (0.82 mm) J-tip guidewire
Transseptal solution	FlexCath Cross™ transseptal solution
Sterilization	Single use, sterile device, ethylene oxide (EO) gas



- Over-the-wire for enhanced stability
- Conformable lattice expandable to 34 mm
- Six bipolar electrode pairs enable mapping and stimulation
- Electromagnetic sensors for tracking and shape visualization
- Compatible with a 10 Fr deflectable sheath
- Slider to control lattice shape
- Insertion tool

Affera disposables

Order number	Product name	Details
AFR-00006	Catheter extension cable	Sterile, single-use, 2 m long cable. Compatible with Sphere-360 catheter and Affera system
AFR-00022-C	Sphere-360™ ablation cable	Cable connecting catheter to the PF generator module of the Affera ablation system for energy delivery
AFR-00015	Impedance patch kit	Includes 4 kits per order; 6 impedance localization patches per kit

Affera capital equipment

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

Access components

Order number	Product name	Order number	Product name
10FCCC13	FlexCath Contour™ steerable sheath	990045	PV tracker J-tip guidewire
900310	FlexCath Cross™ transseptal solution		

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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