Medtronic

Predictability pays off.

Independent data shows the Sphere-9™ catheter delivers meaningful procedural time savings, enabling increased procedural volume to offset incremental costs.[†,‡,1]

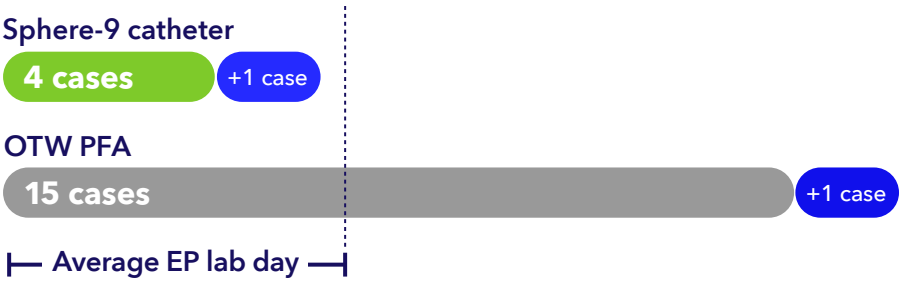
Faster procedures without compromising safety

3x more time saved
with the Sphere-9 catheter
than over-the-wire (OTW) PFA compared to the RF control.[§,◊]

Serious complications occurred in 50/2,986 procedures (1.7%) at similar rates across ablation technologies (p = 0.904).

Time savings means more patients treated

OTW PFA requires **3x more** procedures than the Sphere-9 catheter to save enough time to perform **one additional procedure**.



More complex cases, more savings

$658 savings for PVI+ procedures
Sphere-9 catheter vs. OTW PFA

† Independent analysis from a single U.S. health system (three hospitals).[1]
‡ N = 2,986 patients undergoing AF ablation using RF, the Sphere-9 catheter, or over-the-wire (OTW) PFA. OTW PFA catheter used according to approved labeling only. Additional RF ablation catheter used in 11% (44/402) of OTW PFA cases. Additional HD mapping catheter used in 83% (334/402) of OTW PFA cases and 100% (1347/1347) of RF cases.
§ 28 vs. 9 minutes operator time saved vs. RF ($p < 0.001$ for both).
◊ 31 vs. 9 minutes EP lab time saved vs. RF ($p < 0.001$ for both).

1. Ilkhanoff L, Plasters X, Gaeta S, et al. Offsetting costs of new ablation technologies with increased procedural efficiency and volume. *Heart Rhythm*. Published online April 23, 2026.

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. RF therapy with the Sphere-9 catheter in patients who have a Biotronik ICD/CRT-D device may result in induction of ventricular tachycardia / ventricular fibrillation.

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
Arrhythmia, Atrioesophageal fistula, Cardiac perforation / tamponade, Cardiac or respiratory arrest, Conduction system injury, Coronary artery spasm / occlusion / stenosis, Damage / dislodgement to implantable leads, Damage / dysfunction of cardiac devices, Death, Embolism, Hemoptysis, Infection, Myocardial infarction, Phrenic nerve palsy / paralysis, Pulmonary edema, Pulmonary vein stenosis, Stroke, 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.

710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA

Toll-free: 800.328.2518
Tel: +1.763.514.4000

medtronic.com

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