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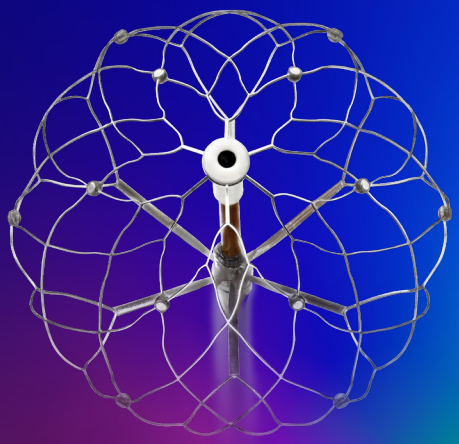
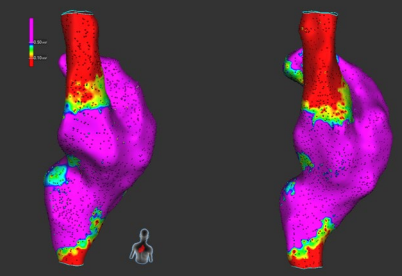
Sphere-360™ catheter evidence

Experience 360° performance

Exclusively integrated with the Affera™ mapping and ablation system, the Sphere-360 catheter delivers circumferential, homogeneous lesions from the entire lattice for safe, durable PVI.[1]





Yavin HD, et al. *J Interv Card Electrophysiol.* 2023;66:1741-1748.

Preclinical evaluations showed:

- No significant lesion regression or expansion[2]
- 100% transmural lesions[3] (N = 149 venous histology samples from 13 swine, 4.0 ± 2.0 mm lesion depth)
- No PV stenosis, phrenic nerve injury, or esophageal injury[2,3]
- Minimal microbubbles on intracardiac echocardiography (ICE)[2,3]

Sphere-360 CE Mark study[1]

Prospective, single-arm, multicenter trial designed to evaluate safety, effectiveness, and lesion durability of the Sphere-360™ catheter when used for the treatment of symptomatic drug refractory paroxysmal atrial fibrillation (PAF, n=100)

Read the manuscript

12-month freedom from AF/AFL/AT†

88%

PULSE3
n = 50

PV durability†

PFA lesion durability demonstrated by invasive remapping 75 days post-ablation

Per PV n = 154	98%
Per patient n = 40	93%

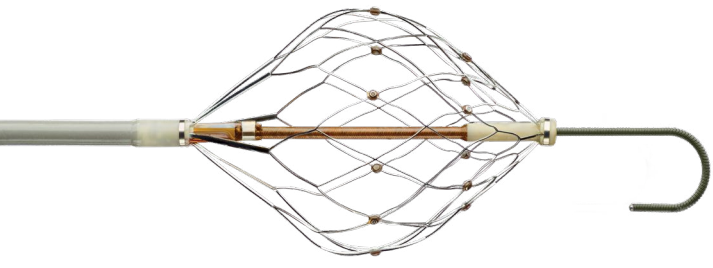
Safety outcomes§

0%

Primary safety event rate
n=100

Procedural characteristics§

4.0 ± 1.3	22 min	58 min	< 7 min	< 12 min
Applications per PV	LA dwell time	procedure time◊	Fluoroscopy time¶	PV transpired time



Sphere-360 IDE study is ongoing

Horizon 360 is a prospective, single-arm, unblinded premarket clinical study to evaluate the safety and effectiveness of the Sphere-360 catheter and Affera mapping and ablation system for the treatment of recurrent, symptomatic PAF (NCT07308847).

More information

Full circle ablation | 360 integration | Consistent outcomes

† Fifty patients treated with the PULSE3 optimized and most recent waveform configuration, 40 of which completed the optional remapping procedure.

‡ See manuscript for all adverse event incidence.

§ Total cohort (n = 100).

◊ Includes 20-minute wait time.

¶ Four patients treated using no fluoroscopy, 26 patients treated with less than or equal to three minutes of fluoroscopy.

1. Reddy VY, Peichl P, Kautzner J, et al. One-year outcomes of a conformable single-shot pulsed-field ablation catheter for the treatment of paroxysmal atrial fibrillation. *Heart Rhythm*. October 2025;22(10):2551–2561.

2. Yavin HD, Higuchi K, Younis A, Anter E. Lattice-tip catheter for single-shot pulmonary vein isolation with pulsed field ablation. *J Interv Card Electrophysiol*. October 2023;66(7):1741–1748.

3. Koruth J, Kawamura I, Dukkipati SR, Neuzil P, Reddy VY. Preclinical assessment of the feasibility, safety and lesion durability of a novel 'single-shot' pulsed field ablation catheter for pulmonary vein isolation. *Europace*. April 2023;25(4):1369–1378.

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

medtronic.eu

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