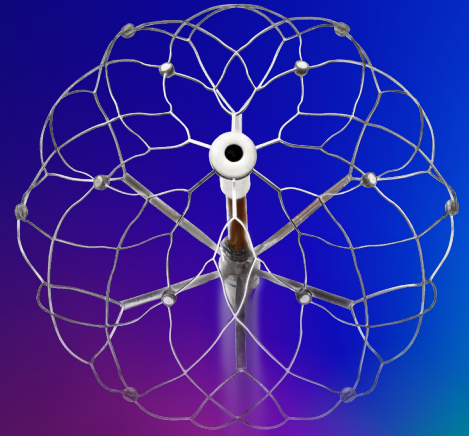


Sphere-360™ catheter evidence

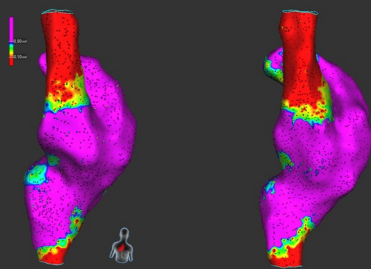
Experience 360° performance

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



Immediately
post-ablation

Four weeks
post-ablation



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

Preclinical evaluations showed:

- No significant lesion regression or expansion²
- 100% transmural lesions³ (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 study¹

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
Applications per PV

22 min
LA dwell time

58 min
procedure time[‡]

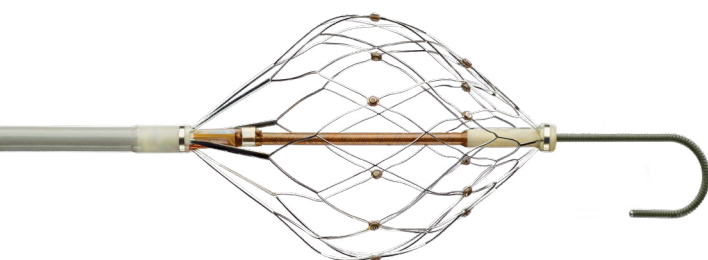
< 7 min
Fluoroscopy time[¶]

< 12 min
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, Dukkupati 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.

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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.

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Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

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02/2026