



Global real-world safety

70,700+ patients studied

FARAPULSE™ PFA Platform is advancing pulsed field ablation, delivering trusted safety and performance proven in both clinical trials and real-world practice.



OVERALL SAFETY

Low major complication rate in real-world practice

0.8%

Major adverse event rate



CEREBRAL SAFETY

Low cerebrovascular safety event rate

0.11% / 0.09%

Stroke/TIA rates

FARAPULSE Global Real-World Registry Complication Rates

	Total n	% PAF	Major AE Rate n (%)	Stroke n (%)	TIA n (%)	Esophageal Fistula	Persistent Phrenic Nerve Palsy	PV Stenosis	Hemolysis Requiring Hemodialysis n (%)	Coronary Spasm n (%)
MANIFEST-US ¹	41,968	54.2%	261 (0.63%)	40 (0.1%)	36 (0.08%)	0	0	0	7 (0.02%)	40 (0.1%)
MANIFEST-17K ²	17,642	57.8%	173 (0.98%)	22 (0.12%)	21 (0.12%)	0	0	0	5 (0.03%)**	25 (0.14%)
FRANCE-PFA ³	5,223	55.0%	50 (0.1%)	5 (0.09%)	2 (0.04%)	0	0	0	0	4 (0.08%)
MANIFEST-PF ⁴	1,758	57.5%	29 (1.6%)	7 (0.39%)	2 (0.11%)	0	0	0	NR***	1 (0.06%)
DISRUPT-AF ⁵	1,576	55.3%	26 (1.6%)	4 (0.3%)	0	0	0	0	0	1 (0.1%)
FARADISE ⁶	1,158	65.4%	17 (1.5%)	1 (0.1%)	1 (0.1%)	0	0*	0	0	1 (0.1%)
NHS England ⁷	1,034	53.1%	13 (1.3%)	2 (0.2%)	1 (0.01%)	0	0	NR***	NR***	1 (0.01%)
ATHENA ⁸	348	66.9%	0	0	0	0	0	0	0	1 (0.13%)
Total, n (%)	70,707		569 (0.8%)	81 (0.11%)	63 (0.09%)	0	0*	0	12 (0.02%)	74 (0.1%)

Because of patient overlap between MANIFEST-PF and both EU-PORIA and SWISS-AF-PVI, only MANIFEST-PF is included in this analysis.

*There was one reported PNP at 1-month follow-up which was not classified as a per-protocol SAE as the onset date of the event was after the endpoint-specified 7-day window. There was no PNP detected at the end of the index procedure, but pneumonia was reported on the day of the index procedure. Since publication, the patient has recovered.

**Hemolysis requiring hospitalization

***Not reported

Esophageal Fistula, PV Stenosis or Permanent Phrenic Nerve Palsy

ZERO reported events



Additional Safety Endpoints

Hemolysis requiring hemodialysis and coronary spasm were rare

Results from different clinical investigations are not directly comparable. Information provided for educational purposes only.

1. Turagam, Mohit K., et al. "Multicenter Study on the Safety of Pulsed Field Ablation in Over 40,000 Patients: MANIFEST-US." *JACC* (2025)
2. Ekanem, Emmanuel, et al. "Safety of pulsed field ablation in more than 17,000 patients with atrial fibrillation in the MANIFEST-17K study." *Nature medicine* 30.7 (2024): 2020-2029.
3. Chaumont, Corentin, et al. "Countrywide introduction of pulsed field ablation for the treatment of atrial fibrillation: Acute results from the FRANCE-PFA registry." *Heart Rhythm* 02 (2025).
4. Ekanem, Emmanuel, et al. "Multi-national survey on the methods, efficacy, and safety on the post-approval clinical use of pulsed field ablation (MANIFEST-PF)." *Europace* 24.8 (2022): 1256-1266.
5. Wong, Elisabeth, et al. "Early Safety Profile Using Pulsed Field Ablation: Prospective Multicenter DISRUPT-AF Study." Accepted for publication.
6. Boersma, Lucas VA, et al. "Real-world experience with the pentaspline pulsed field ablation system: one-year outcomes of the FARADISE registry." *Europace* 27.9 (2025): euaf182.
7. Mills, Mark T., et al. "Pulsed-field ablation of atrial fibrillation with a pentaspline catheter across National Health Service England centres." *Open Heart* 11.2 (2024).
8. Bisognani, Antonio, et al. "National workflow experience with pulsed field ablation for atrial fibrillation: learning curve, efficiency, and safety." *Journal of Interventional Cardiac Electrophysiology* 67.9 (2024): 2127-2136.