Medtronic

CARDIAC ABLATION SOLUTIONS

PulseSelect™ PFA system

Clinical compendium

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Publications in this compendium reflect on-label usage of the PulseSelect PFA system. If you have questions regarding unapproved usage of Medtronic PFA systems, please contact the Office of Medical Affairs or visit the Cardiac Ablation Solutions SIUU website.

Clinical studies

Clinical trials & sub-analyses

Pulsed Field Ablation for the Treatment of Atrial Fibrillation: PULSED AF Pivotal Trial

Verma A, Haines DE, Boersma LV, et al. *Circulation*. 2023;147(19):1422–1432.

- The PULSED AF pivotal study was a prospective, global, multicenter, single-arm study in which patients with paroxysmal (N=150) or persistent (N=150) symptomatic atrial fibrillation (AF) refractory to class I or III antiarrhythmic drugs were treated with the PulseSelect PFA system.
- Freedom from any atrial arrhythmia recurrence after a 90-day blanking period was 69.5% in the paroxysmal and 62.3% in the persistent AF cohorts.
- The primary safety adverse event rate was 0.7%, with no instances of phrenic nerve injury, atrial esophageal fistula, or pulmonary vein stenosis.

Influence of Monitoring and Atrial Arrhythmia Burden on Quality of Life and Healthcare Utilization in Patients Undergoing Pulsed Field Ablation: A Secondary Analysis of the PULSED AF Trial

Verma A, Haines DE, Boersma LV, et al. *Heart Rhythm*. 2023;20(9):1238–1245.

- This sub-analysis of the PULSED AF trial aimed to determine the influence of monitoring strategies on atrial arrhythmia (AA) detection and AA burden association with quality of life (QoL) and health care utilization (HCU) after treatment with the PulseSelect PFA system.
- Freedom from all AAs varied by up to 20% when different monitoring strategies were used.
- 0% AA burden was observed in 69.4% of paroxysmal AF (PAF) and 62.2% of persistent AF (PsAF) patients. Median burden was <9%.
- AA burden <10% was associated with clinically relevant improvements in QoL and reduced AA-related HCU.

Safety, efficacy, and quality of life outcomes of pulsed field ablation in Japanese patients with atrial fibrillation: results from the PULSED AF trial

Yamane T, Sasano T, Tomita H, et al. *J Interv Card Electrophysiol*. 2025;68(1):149–157.

- In this sub-analysis of the PULSED AF trial examining outcomes of patients treated at 4 Japanese centers, acute PVI was achieved in 100% of PAF and PsAF patients (N=32), with no primary safety events reported through 12 months.
- The 12-month primary efficacy rate was 75.0% for PAF and 56.3% for PsAF, with both groups experiencing significant improvements in AF–related QoL.

Prevalence, Timing, and Impact of Early Recurrence of Atrial Tachyarrhythmias after Pulsed Field Ablation: A Secondary Analysis of the PULSED AF Trial

Boersma LV, Natale A, Haines D, et al. *Heart Rhythm*. 2025;22(4):884–890.

- In a sub-analysis of the PULSED AF trial, early recurrence of atrial tachyarrhythmia (ERAT) within 90 days of index ablation was predictive of late recurrence of atrial tachyarrhythmia (LRAT) between 90 days and 1 year.
- Authors concluded that a blanking period following index ablation with the PulseSelect PFA system was valid given one-third of patients experiencing ERAT did not show LRAT.

First-in-human study

First-in-Human Experience and Acute Procedural Outcomes Using a Novel Pulsed Field Ablation System: The PULSED AF Pilot Trial

Verma A, Boersma L, Haines DE, et al. *Circ Arrhythm Electrophysiol*. 2022;15(1):e010168.

- The first-in-human evaluation of the PulseSelect PFA system showed acute PVI in 100% of patients (38/38) with paroxysmal or persistent AF.
- No serious adverse events attributed to the PFA system occurred during the 30-day follow-up.
- Temperature recorded directly from electrodes within 1 second of ablation showed an average temperature rise of 2.1±2.2°C, and luminal esophageal temperature monitoring performed in 7 patients showed a mean change of 0.06°C during ablation.

Clinical manuscripts

Comparison of HEMOlysis Markers Among Three Pulsed Field Ablation Systems: HEMO-PFA Study

Matsumoto K, Matsumoto K, Tanaka N, et al. *J Cardiovasc Electrophysiol*. 2026.

- The HEMO-PFA study compared hemolysis biomarkers (haptoglobin, lactate dehydrogenase [LDH]) across 3 PFA systems: PulseSelect PFA system, FARAPULSE™* PFA system, and VARIPULSE™* PFA system (N=50 for each system).
- The PulseSelect PFA system was associated with significantly less haptoglobin decrease post procedure compared to the FARAPULSE and VARIPULSE PFA systems.
- Acute kidney injury (AKI) occurred in 2 cases performed with the FARAPULSE PFA system, and 1 cardiac tamponade was reported in the PulseSelect catheter cohort.

Acute Kidney Injury and Haptoglobin Depletion After Pulsed Field Ablation: Impact of Device Type Under Routine Hydration Protocol

Hayashi Y, Miyazaki S, Asano S, et al. *Heart Rhythm*. 2026;23(3):e368-e374.

- Among 211 AF patients treated with either the FARAPULSE PFA system (N=117) or PulseSelect PFA catheter (N=94) who received 1500 mL periprocedural fluid, haptoglobin depletion occurred in 27% (N=43 FARAPULSE PFA patients, N=13 PulseSelect PFA system patients) and AKI in 6% (N=8 FARAPULSE PFA patients, N=5 PulseSelect PFA system patients).
- One patient required rehospitalization and 5 had prolonged hospital stays due to AKI.

- In multivariate analysis, FARAPULSE PFA system use and absence of diabetes mellitus were significantly associated with haptoglobin depletion; however, no significant association was observed between postoperative AKI and haptoglobin depletion, PFA system type, or total PF application number.

Feasibility, procedural efficiency, and early imaging outcomes of concomitant pulsed field ablation and left atrial appendage closure: a prospective single-centre study

Doty B, Mraiyan M, Nair G, Khan M, Gabrah K, Nair DG. *Europace*. 2026;28(2):euag017.

- In 209 patients undergoing concomitant PFA ablation for AF (using multiple PFA systems including the PulseSelect PFA catheter) and left atrial appendage closure (LAAC), 100% acute procedural success was achieved with a total mean procedure time of 57.3±17 min. and fluoroscopy time of 3.4±0.8 min.
- All patients were discharged same day; no pericardial effusion, stroke, phrenic nerve injury, esophageal injury, or AKI was reported at 30 days.

Inflammation and myocardial injury after pulmonary vein isolation with distinct pulsed field ablation modalities: Comparison with thermal ablation

Yano M, Egami Y, Kise M, et al. Int *J Cardiol*. 2026;445:134047.

- Post-ablation comparison of myocardial inflammatory responses for the PulseSelect catheter (N=54), FARAPULSE PFA system (N=39), and thermal ablation (RF N=109, cryo N=110); PFA systems showed lower inflammatory response compared to thermal ablation modalities.
- Myocardial injury biomarker elevations were higher following PFA compared to thermal ablation; however, recurrences of AF within 3 months of ablation were similar between groups.

Circular over-the-wire pulsed field ablation for atrial fibrillation: differences in outcomes between conscious sedation or general anesthesia

van der Graaf M, Abeln BGS, Dijk VFV, et al. *J Interv Card Electrophysiol*. 2026;69(2):229–37.

- In 174 AF patients treated using the PulseSelect PFA system under conscious sedation (24.1%) or general anesthesia (GA, 75.9%), 100% acute PVI was achieved in both groups.
- Mean skin-to-skin procedure times were similar for the conscious sedation and GA cohorts: 42.0 vs. 39.0 min, respectively, $p>0.05$.
- No patients in the conscious sedation group required intraprocedural conversion to GA; no intraprocedural complications were reported in either group.

Left Atrial Intracardiac Echocardiography to Assist Zero Fluoroscopy Pulse Field Atrial Fibrillation Ablation - A Beginner's Guide

Ahmed I, Guerrero-Pando C, Denham N, et al. *CJC Open*. 2025;8(2):214–221.

- Step-by-step guide for zero-fluoroscopy PFA using the PulseSelect system guided by left atrial intracardiac echo (ICE) and 3D electroanatomic mapping (EAM).

- In 100 consecutive AF patients undergoing PFA with the PulseSelect system guided by LA ICE and 3D EAM at a single-center, zero fluoroscopy was used in 28% of cases. No major procedural complications were reported.

Differences in Intravascular Hemolysis Between Two Technologies for Pulse Field Ablation of Atrial Fibrillation

Mountantonakis SE, Beccarino N, Goyal A, et al. *Heart Rhythm*. 2026;23(2):e217–e219.

- Prospective study comparing hemolysis rates in patients undergoing AF ablation using the FARAPULSE PFA system (N=70) or PulseSelect PFA system (N=56) showed higher post-ablation free plasma hemoglobin (FPH) for patients treated with the FARAPULSE PFA system compared to patients treated with the PulseSelect PFA catheter ($p<0.001$).
- No cases of clinically significant hemolysis or AKI occurred in either group; subclinical hemolysis was unrelated to patient characteristics but strongly linked to catheter technology and number of applications in the FARAPULSE PFA system group.

Comparison of Hemolysis with Different Pulsed Field Ablation Systems

Kawamura I, Miyazaki S, Kato R, et al. *Heart Rhythm*. 2026;23(2):388–395.

- Prospective single-center study compared hemolysis after PVI using either the PulseSelect PFA system (N=38), FARAPULSE PFA system (N=38), or cryoballoon ablation (N=14).
- FPH increased significantly after ablation in all groups, with greater increases in the FARAPULSE PFA system group; higher levels of hemolysis biomarkers (LDH, total bilirubin, and FPH) and low haptoglobin were more frequent with the FARAPULSE PFA system (86.5%) than PulseSelect PFA system (42.1%, $p<0.001$).
- Hemolysis biomarkers after ablation using the PulseSelect PFA system were comparable to cryoballoon ablation, myocardial injury biomarkers were similar between the two PFA systems, and no cases of AKI occurred in any cohort.

A Comparative Analysis of Long-Term Procedural Outcomes Following Circular Array Pulsed Field and Radiofrequency Ablation

Beccarino N, Sharma N, Nunez-Baez S, et al. *J Cardiovasc Electrophysiol*. 2026;37(3):519–526.

- N=36 AF patients treated with the PulseSelect catheter at a single center were matched for baseline characteristics to a historical cohort of N=36 patients treated with a small-tip, irrigated RF catheter.
- Procedures performed with the PulseSelect catheter were significantly more efficient than those performed with RF, and no major complications were reported in the PFA cohort.
- AF recurrence, new use of antiarrhythmic drugs, or cardioversion at 1 year occurred numerically less frequently in the PFA cohort (22% vs. 36%, $p=0.195$).

Pulse field ablation in patients with paroxysmal and persistent atrial fibrillation using the circular multielectrode array catheter: first outcome data in a real-world prospective study

Tscholl V, Chiba T, Formum P, et al. *J Interv Card Electrophysiol*. 2026.

- In 81 AF patients undergoing PVI using the PulseSelect PFA catheter, 100% achieved acute procedural success.
- After a mean follow-up of 6.7 months, 23.2% of patients experienced arrhythmia recurrence following an 8-week blanking period.
- One stroke was reported within 48 hours of the procedure, with no other intra-procedural major complications reported.

Management of oral anticoagulation after pulsed field ablation for atrial fibrillation: Insights from a multicenter study

Mohanty S, Torlapati PG, Casella M, et al. *Heart Rhythm*. 2026;23(1):16–24.

- Propensity-matched study of 800 AF ablation patients (N=400 PFA, including the PulseSelect PFA system and FARAPULSE PFA system, N=400 RFA) stratified by duration of oral anticoagulation (OAC) continuation post-ablation: 1 month (group 1) or ≥2 months (group 2).
- Stroke/transient ischemic attack (TIA) occurred in 0 patients in PFA group 1 and 2 patients in PFA group 2, compared with 23 events in the RFA cohort (16 in group 1 and 7 in group 2); overall event rates were lower with PFA compared to RFA (0.5% vs. 5.8%; p<0.001).
- Arrhythmia recurrence at 15 months occurred in 73 patients (18.25%) in the PFA cohort and 108 patients (27.0%) in the RFA cohort (p=0.003).

Real-time detection of microembolic signals using carotid echocardiography: A comparative study of 3 pulsed-field systems

Shiomi S, Tokuda M, Takato U, et al. *Heart Rhythm*. 2026;23(1):25–31.

- Prospective study of 33 AF patients undergoing PFA (FARAPULSE PFA system, PulseSelect PFA system, VARIPULSE PFA system, N=11 each) used carotid echocardiography to detect microembolic signals (MES) during ablation and next-day brain MRI to assess silent cerebral events/lesions (SCE/SCL).
- Total MES counts were significantly lower in the FARAPULSE PFA system group compared with the PulseSelect PFA system and VARIPULSE PFA system groups (p<0.001); however, multiple SCEs/SCLs occurred in 4 patients in the VARIPULSE PFA system group and 1 patient in the FARAPULSE PFA system group, while no SCEs/SCLs were observed in the PulseSelect PFA system group.

Intravascular hemolysis after pulsed field ablation for atrial fibrillation: A comparative analysis of 3 systems

Hiyama M, Kimura M, Itoh T, et al. *Heart Rhythm O2*. 2026;7(2):232–240.

- At a single center, 91 patients underwent PVI using a commercially available PFA system (N=32 PulseSelect catheter, N=29 FARAPULSE PFA system, or N=30 VARIPULSE PFA system); hemolysis biomarkers were evaluated before and after index PVI.

- Haptoglobin reduction pre- to postprocedure was significantly greater for patients treated with the FARAPULSE PFA system compared to the PulseSelect catheter; however, no clinically significant renal injury was reported in any group.

Lesion Durability Using a Circular Pulsed Field Ablation Catheter and Novel Mapping-Navigation System

Verma A, Al-Ahmad A, Račkauskas G, et al. *Circ Arrhythm Electrophysiol*. 2025;18(12):e014102.

- Assessment of chronic PVI durability via invasive remapping regardless of arrhythmia recurrence following index ablations performed by multiple operators using the PulseSelect PFA catheter.
- 95% per vein durability rate was observed 75 days post-ablation in 15 paroxysmal and persistent AF patients (N=55 pulmonary veins); left common pulmonary veins (PVs) were observed in 6/15 patients.
- No serious adverse events were observed.

Pulsed Field Ablation-Related Hemolysis: Comparison Between Technologies

Gianni C, Al-Ahmad A, Elchouemi M, et al. *Circ Arrhythm Electrophysiol*. 2025;18(12):e014021.

- Retrospective analysis of N=552 PFA procedures using the FARAPULSE PFA system (59%), Sphere-9™ catheter (19%), PulseSelect PFA catheter (16%), and VARIPULSE catheter (5.8%).
- Severe hemolysis (reduction in haptoglobin ≤10 mg/dL 1 day postprocedure) occurred in 13% of patients, with lower rates using the Sphere-9 catheter (0%) compared with the FARAPULSE (21%), VARIPULSE (9.7%), and PulseSelect PFA catheter (1.2%) groups.
- Acute kidney injury occurred in 4.4% (23/520) without a significant difference between ablation technologies.

Incidence of cough reflex and vagal response among various pulsed field ablation systems: a multicenter registry study

Kawamura I, Miyazaki S, Nitta J, et al. *Clin Res Cardiol*. 2025:1–11.

- Cough reflex and vagal response incidence compared across 3 PFA systems in a multicenter Japanese registry (N=742 PulseSelect PFA catheter, N=870 FARAPULSE PFA System, N=103 VARIPULSE PFA system); PVI was achieved in 1714/1715 cases and the rate of complications requiring prolonged hospitalization were 1.3%, 2.3%, and 1.0%, respectively.
- Cough reflex occurred in 49.3% of patients, most often during ablation of the left superior PV; compared with the FARAPULSE PFA System, higher odds of coughing were observed with PulseSelect catheter and VARIPULSE PFA System.
- Vagal response occurred in 15.2% of patients, with no significant differences among PFA systems, and no effect of PVI sequence was observed.

Impact of Pulmonary Vein Morphology on the Number of Pulsed Field Ablation Applications Using Circular Multielectrode Catheters

Nagase T, Tashiro H, Himeno M, et al. *J Cardiovasc Electrophysiol*. 2025;37(1):71–80.

- In 45 AF patients (N=180 PVs) treated with the PulseSelect PFA catheter using an application protocol of 4 ostial + 4 antral applications per vein, acute PVI was achieved in 138/180 PVs (77%); additional applications were required in the remaining PVs; final PVI was achieved in 100% patients.
- PVs without antral PVI after the minimal protocol had significantly larger dimensions, including long axis, short axis, and PV areas.
- PV area was the only independent predictor of achieving antral PVI with the minimal protocol; ROC analysis showed AUC 0.825 with a cut-off of 303.1 mm^2.

Does Hemolysis Matter After Pulsed Field Ablation for Atrial Fibrillation? Insights from the Best Ablate Registry

Shamloo AS, Hättasch R, Baldauf CS, et al. *Heart Rhythm O2*. 2025;7(2):197–203.

- Prospective, observational study; N=84 patients undergoing AF ablation with PFA (Sphere-9 catheter 60.7%, PulseSelect PFA catheter 39.3%).
- Postprocedure biomarkers (LDH, haptoglobin, hemoglobin, bilirubin) showed evidence of hemolysis; however, no cases of clinically significant hemolysis were reported (postprocedural haptoglobin concentration of <0.04 g/L or a combination of indirect bilirubin of >1.5 times baseline and LDH more than twice baseline).
- Acute kidney injury occurred in 3.6% (3/84); the number of PFA applications independently predicted hemolysis biomarker changes.

Comparison of Cerebral Micro-Embolization Detected by Transcranial Doppler Examination Between Radiofrequency Ablation and Pulsed Field Ablation for Atrial Fibrillation

Schreiber T, Rennenberg R von, Brämswig TB, et al. *J Cardiovasc Electrophysiol*. 2025;36(12):3288–3295.

- Prospective study of 56 AF patients (N=28 RF, N=14 PulseSelect PFA catheter, N=14 VARIPULSE PFA system), PVI was achieved in all patients.
- Total cerebral MES counts detected by transcranial doppler were higher with PFA compared with RF, with higher counts in the VARIPULSE PFA system group vs. the PulseSelect catheter group ($p<0.001$ for both).
- N=2 patients in the PFA cohort experienced new focal neurological deficits associated with MRI-confirmed cerebral infarctions; however, MES counts for both patients were not higher than the average for all PFA patients.

Incidence of laboratory-defined severe intravascular haemolysis across commercially available pulsed field ablation technologies for atrial fibrillation

Mountantonakis S, Beccarino N, Patel H, et al. *Europace*. 2025;27:euaf185.

- N=245 patients undergoing AF ablation with either the Sphere-9 catheter (N=62), FARAPULSE PFA System (N=108), or PulseSelect PFA catheter (N=75); severe intravascular hemolysis (free plasma Hgb >100 mg/dL) incidence: 0% Sphere-9 catheter, 3.7% FARAPULSE PFA System, 2.7% PulseSelect PFA catheter.
- Total PFA applications were independent predictors of severe hemolysis in the FARAPULSE PFA group only.
- No renal impairment reported in any group.

Haemolysis and myocardial and neural injury after monopolar pulsed field ablation using a novel lattice-tip catheter to treat atrial fibrillation

Gold C, Pratz P, Falagkari A, et al. *Europace*. 2025;27:euaf210.

- N=40 patients assessed for biomarkers of hemolysis, myocardial injury, neurocardiac injury, and renal function with the Sphere-9 catheter; sub-group analysis of 14 first-time PVI-only patients compared to matched FARAPULSE PFA System (N=14) and PulseSelect PFA catheter (N=14) cohorts.
- Hemolysis severity was more pronounced in the FARAPULSE PFA system group vs. the Sphere-9 catheter or PulseSelect PFA catheter groups; myocardial injury biomarkers were numerically more pronounced in the Sphere-9 catheter group; neurological injury biomarkers increased in the FARAPULSE PFA system and PulseSelect PFA catheter cohorts, but not in the Sphere-9 catheter group.
- No hemolysis-related complications, renal impairment, or AKI in any group.

Differential Subclinical Hemolysis After Pulsed Field Ablation Using the FARAPULSE Pentaspline Catheter Versus the PulseSelect Circular Multielectrode Array Catheter

Kuraoka S, Nozoe M, Mannoji H, et al. *Heart Rhythm O2*. 2025;6(12):1911–1918.

- In a retrospective analysis of 120 AF ablation patients (N=15 RF, N=39 FARAPULSE PFA system, N=66 PulseSelect catheter), PFA was associated with higher post-/pre-ablation ratios of FPH, LDH, and total bilirubin and lower haptoglobin compared with RF.
- In the FARAPULSE PFA system cohort, FPH correlated with the number of applications whereas no correlation was observed in the PulseSelect catheter cohort.
- No cases of AKI were reported.

Near-Zero Fluoroscopy Ablation Workflow With a Circular Multielectrode Pulsed-Field Ablation Catheter

Yamashita K, Kikuchi Y, Yoshiyama K, et al. *Pacing Clin Electrophysiol*. 2025;48(10):1196–1202.

- In 20 AF patients undergoing PulseSelect catheter ablation using 3D EAM and ICE guidance, PVI was achieved in 100% of cases with a median total procedure time of 48.5 min. and fluoroscopy time of 0.0 min., with a maximum fluoro time of 0.2 min. reported across the cohort.
- No procedural complications were reported, and all patients were discharged the next day.

- At 3-month follow-up, arrhythmia recurrence occurred in 2 patients (1 PAF and 1 typical atrial flutter).

Electrical reconnection after pulsed field ablation with a circular over-the-wire catheter in atrial fibrillation

van der Graaf M, Andrade JG, Kibel S, et al. *Europace*. 2025;27(1):euaf216.

- Multicenter observational registry of 27/285 patients undergoing repeat ablation due to recurrent atrial arrhythmias after index PulseSelect catheter ablation; baseline PVI during the index procedure was achieved with a median of 34.0 applications.
- Reported per patient PVI durability was 25.9% (1/19) at Center 1 and 75% (6/8) at Center 2.
- Gaps were most commonly located at the anterior/superior regions of the left PVs and the posterior regions of the right PVs, with no major adverse events reported during repeat procedures.

Comparison of Two Different Pulsed Field Ablation Systems: The Dual Pulse System Study

Subin B, Isenegger C, Spreen D, et al. *J Cardiovasc Electrophysiol*. 2025;36(11):2955–2962.

- In 120 patients undergoing *de novo* PVI (N=90 FARAPULSE PFA system, N=30 PulseSelect PFA system), acute PVI was achieved in 100% of cases.
- Total procedure and LA dwell times were shorter with the FARAPULSE PFA system compared to the PulseSelect PFA system ($p<0.05$ for both).
- The extent of acute antral low-voltage area and postprocedure myocardial injury biomarkers were higher in the PulseSelect PFA system cohort ($p<0.05$ for both).
- Complications occurred in 3 patients (3%) in the FARAPULSE PFA system group and 0 patients in the PulseSelect PFA system group.

Complications associated with pulsed field ablation vs radiofrequency catheter ablation of atrial fibrillation

Cho MS, Lee S-R, Black-Maier E, et al. *Heart Rhythm*. 2025;22(9):2194–2200.

- Analysis of the FDA Manufacturer and User Facility Device Experience (MAUDE) database for reports for approved PFA (including the PulseSelect PFA system) and RF catheters between January and July 2024 (N=1237).
- Esophageal damage and PV stenosis were not reported in PFA cases. The most frequent complications reported with PFA were pericardial effusion, vasovagal response, and hemolysis (reported with the FARAPULSE PFA system only).

Extent of myocardial injury after pulmonary vein isolation using 3 different pulsed field ablation systems

Badertscher P, Brugger J, Isenegger C, et al. *Heart Rhythm*. 2025;22(9):2437–2439.

- In 175 patients undergoing PVI, myocardial injury assessed by high-sensitivity cardiac troponin T release was significantly lower after ablation with the VARIPULSE PFA system

(N=40) compared to the FARAPULSE PFA system (N=95) and PulseSelect PFA system (N=40, p<0.001 for both).
- PVI was acutely successful in 100% of patients.

Comparative Effects of Pulsed Field and Radiofrequency Ablation on Blood Cell Parameters During Pulmonary Vein Isolation

Addeo L, Feo FD, Vaccariello M, et al. *Biomedicines*. 2025;13(8):1828.

- Retrospective analysis of 249 AF patients undergoing pulmonary vein isolation (N=121 PFA, including the PulseSelect PFA system and FARAPULSE PFA system, N=128 RF) found no significant differences between PF and RF groups in post-procedural hemoglobin, hematocrit, red blood cell count, platelet count, or creatinine levels.
- LDH levels increased significantly in the PFA group compared with RF both post-procedure and at discharge (p<0.001).
- Procedural time was shorter with PFA than RF (58.34 vs. 77.23 min., respectively, p<0.001).

Lesion Area, Ablation Time, Fluoroscopic Time, and Short-Term Outcomes among Three Pulsed Field Ablation Systems

Masuda H, Nagashima K, Matsumoto N, et al. *Heart Rhythm*. 2025;S1547–5271(25)02735-3.

- Prospective study of 75 AF patients undergoing PVI with 3 PFA systems (N=25 FARAPULSE PFA system, N=25 VARIPULSE PFA system, and N=25 PulseSelect PFA system).
- Total lesion area was similar across systems. FARAPULSE PFA system cases had the shortest mean PVI time, while cases performed with the VARIPULSE system had the lowest mean fluoroscopy times (p<0.0003 for both).
- One AKI event occurred in the FARAPULSE PFA system cohort, and no other complications were reported. Haptoglobin decline was lowest with the PulseSelect PFA system (p<0.0003).
- During median 118-day follow-up, AF recurrence occurred in 5 patients, with no significant difference across ablation platforms.

Characterisation of Acute Residual Pulmonary Vein Connections Using Electroanatomical Mapping During Pulsed-Field Ablation of Atrial Fibrillation

Mills MT, Sommer P, Day J, et al. *Heart Rhythm*. 2025;22(12):3140–3148.

- Analysis of 535 AF patients across 48 centers undergoing index PFA PVI (N=389 FARAWAVE PFA catheter, N=146 PulseSelect PFA catheter) assessed acute residual PV reconnections using 3D EAM.
- Bilateral first-pass isolation (FPI) was achieved in 75.1% of patients.
- Residual reconnections were more common in superior PVs than inferior PVs (8.9% vs. 3.8%; p<0.001), most frequently in the left superior PV (10.1%).

NEMESIS-PFA: Investigating Collateral Tissue Injury Associated with Pulsed Field Ablation

Lakkireddy D, Katapadi A, Garg J, et al. *JACC Clin Electrophysiol*. 2025;11(8):1747–1756.

- Multicenter, observational registry of patients undergoing AF ablation with PFA (N=773, including N=111 treated with the PulseSelect PFA catheter) or RF (N=98).
- Significantly higher levels of myocardial injury and hemolysis biomarkers were reported following PFA compared to RF procedures, with 6.7% of PFA patients meeting criteria for AKI and N=2 requiring dialysis.
- Patients treated with the FARAPULSE PFA system showed numerically higher postprocedure plasma-free hemoglobin compared to the Sphere-9 catheter (p=0.096).

Feasibility of deep sedation for catheter ablation of atrial fibrillation using pulsed field ablation

Patel R, Sam R, Singh L, et al. *J Interv Card Electrophysiol*. 2025;68(6):1283–1286.

- Retrospective analysis of 100 AF patients undergoing PFA under deep sedation using either the PusleSelect PFA system or FARAPULSE PFA system showed no airway complications, no conversions to GA, and no map shifts requiring remapping.
- Acute PVI was achieved in 100% of procedures, with mean total electrophysiology laboratory time of 149.7 min., including mean procedure time of 98.3 min. and non-procedure time of 51.4 min.

Direct Comparison of Two Commercially Available Pulsed Field Ablation Systems for Atrial Fibrillation; Procedure Characteristics and Acute Outcomes

Abeln BGS, van der Graaf M, Musat DL, et al. *J Cardiovasc Electrophysiol*. 2025;36(8):1957–1965.

- International multicenter registry including 402 patients undergoing AF ablation with either the FARAPULSE PFA system (N=227) or PulseSelect PFA system (N=175); acute procedural success was achieved in 100% of patients.
- Median procedure time was shorter with the FARAPULSE PFA system compared with the PulseSelect PFA system (36.0 min. vs. 49.0 min., respectively, p<0.001).
- Major adverse events occurred at similar rates between groups (N=1 in each group); however, minor vascular access complications were more frequent with the FARAPULSE PFA system (11.9% vs. 1.1%, p<0.001).

Incidence and Characteristics of Superior Vena Cava Impact After Pulsed-Field Ablation of the Right Pulmonary Veins

Matsuura H, Kamakura T, Oshima T, et al. *J Cardiovasc Electrophysiol*. 2025;36(8):1948–1956.

- In 68 patients undergoing PVI with PFA using the VARIPULSE PFA system (N=17), PulseSelect PFA system (N=26), or FARAPULSE PFA system (N=25), the impact on superior vena cava (SVC) voltage post-ablation was evaluated with RA 3D EAM.
- New SVC low-voltage areas (≥0.5 cm^2, <0.5 mV) occurred in 56 patients (82.4%), including circumferential SVC impact in 10 patients (14.7%).

- Whole circumferential SVC impact was more common in patients with SVC deformity compared with those without, and the anatomical distance between the right superior PV and SVC correlated with the occurrence of SVC impact.

Different Incidence and Size of Silent Strokes After Pulsed Field Ablation With Circular Shaped Ablation Catheters

Miyazaki S, Kawamura I, Iwasa Y, et al. *Circ: Arrhythmia Electrophysiol*. 2025;18(5):e013719.

- Single-center study of 16 AF patients undergoing AF ablation with PFA (N=7 VARIPULSE PFA system, N=9 PulseSelect PFA system)
- SCE/SCLs on MRI occurred in 8 patients (50%), with significantly higher incidence in the VARIPULSE PFA system group than the PulseSelect PFA system group (85.7% vs. 22.2%; p=0.04).
- Patients treated with the VARIPULSE PFA system had more lesions (median 13 [3–19]) and higher rates medium/large lesions (85.7% vs. 11.1%, p<0.01), whereas only 1 medium lesion was observed in the PulseSelect PFA system group.

Pulsed field ablation using a circular electrode array catheter in patients with atrial fibrillation: A workflow optimization study evaluating the role of mapping

Gunawardene MA, Hartmann J, Dickow J, et al. *Int J Cardiol Heart* Vasc. 2025;58:101674.

- Single-center workflow study evaluated 35 patients undergoing PVI with the PulseSelect PFA system in 3 procedural phases: learning phase with 3D EAM (phase I, N=10), fluoroscopy-only phase (blinded to 3D EAM, phase II, N=15), optimized workflow phase (3D EAM + predefined lesion strategy, phase III, N=10).
- First-pass PVI rates differed by workflow strategy (phase I 86%, phase II 81%, phase III 100%; p=0.0079). In the fluoroscopy-only phase II, insufficient isolation occurred in 19% of PVs, with conduction gaps most commonly at the anterior aspect of PVs and carina region.
- All 142 PVs were isolated after additional PFA applications with no procedural complications reported.

Acute outcomes and learning curve from the initial patients treated with the PulseSelect system: a real-world multicenter experience of pulsed field ablation

Molon G, Nardi S, Mitacchione G, et al. *J Interv Card Electrophysiol*. 2025;68(7):1475–1485.

- Multicenter prospective registry evaluated 131 AF patients treated with the PulseSelect PFA system across 6 European centers.
- Median procedure and fluoroscopy times were 55.0 min. and 16.0 min., respectively; acute PVI success was achieved in 100% of patients with a median of 8 PFA applications per PV.
- GA was used in 75.5% of cases and moderate-to-deep sedation in 24.5%.
- No major complications were reported, and procedural time decreased significantly after the first 2–3 cases at each center.

Early insights on adverse events associated with PulseSelect™ and FARAPULSE™: analysis of the MAUDE database

Futela P, Kowlgi GN, DeSimone CV, et al. *J Interv Card Electrophysiol*. 2025;68(6):1359–1361.

- An analysis of the FDA MAUDE database for adverse event reports post-FDA approval through June 13, 2024 for the PulseSelect PFA system and FARAPULSE PFA system.
- Among the 61 patient-related events with the FARAPULSE PFA system, there were 13 PFA energy-related complications, including 7 hemolysis/AKI (4 requiring dialysis), 3 conduction abnormalities, 2 coronary vasospasm, and 1 phrenic nerve irritation.
- The 6 patient-related events for the PulseSelect PFA system included: 2 air embolisms, 1 case of hemoptysis and hypoxia, 1 pericardial effusion, 1 hemothorax, and 1 event of temporary sinus asystole.

Comparative evaluation of 2 pulsed field ablation systems for atrial fibrillation: insights from real-world clinical implementation and short-term outcomes

Zylla MM, Mages C, Rahm A-K, et al. *Heart Rhythm*. 2025;22(9):2201–2208.

- Performance comparison of the first 40 AF patients treated with either the PulseSelect PFA system or FARAPULSE PFA systems at a single center.
- There were no significant differences in median procedure duration, LA dwell time, fluoroscopy duration, or rate of procedural complications between groups.
- With the PulseSelect PFA system, there was a statistically significant reduction in fluoroscopy duration and LA-dwell time when the first 10 and last 10 procedures were compared ($p<0.05$ for both).

Methods and techniques to optimize energy delivery using the circular array pulsed field ablation catheter

Mountantonakis S, Beccarino N, Abrams M, et al. *Heart Rhythm*. 2025;22(7):e74–e84.

- Describes techniques for lesion delivery with the PulseSelect PFA system during PVI, emphasizing integration of fluoroscopy, 3D EAM, and ICE to optimize energy delivery, confirm lesion placement, and improve procedural reproducibility.

First Invasive Remapping to Assess Long Term Durability of Pulmonary Vein Isolation Using a Circular Pulsed Field Ablation Catheter

Nair G, Doty B, Maldonado N, Gabrah K, Reddy VY, Nair DG. *J Arrhythm*. 2025;1880-276:43–44.

- An evaluation of chronic PVI durability via invasive remapping regardless of arrhythmia recurrence during initial real-world use of the PulseSelect PFA system.
- 98% per vein and 96% per patient durability rates were observed for 25 AF patients (N=104 PVs) approximately 2 months post-ablation.
- Mean skin-to-skin index procedure time was 36 min., and no fluoroscopy was used.
- No periprocedural complications were observed.

Comparative Analysis of Real-World Clinical Outcomes of a Novel Pulsed Field Ablation System for Pulmonary Vein Isolation: The Prospective CIRCLE-PVI Study
Katov L, Teumer Y, Bothner C, Rottbauer W, Weinmann-Emhardt K. *J Clin Med*. 2024;13(23):7040.

- A prospective, single-center study enrolled 125 consecutive AF patients undergoing first-time PVI with PFA (N=25 PulseSelect PFA system, N=100 FARAPULSE PFA system).
- Acute PVI was achieved in 100% of patients.
- Median procedure, LA dwell, and fluoroscopy times were similar between groups.
- No procedure-related complications were observed in either group.

Pulsed-field ablation for paroxysmal atrial fibrillation: An indirect comparison of effectiveness among three proprietary devices conducted in the absence of randomized trials
Messori A, Mamone D, Rivano M, Romeo MR, Vaiani M, Trippoli S. *Int J Cardiol*. 2024;406:132025.

- Indirect comparative analysis examined arrhythmia recurrence rates for the FARAWAVE PFA system, PulseSelect PFA system, and VARIPULSE PFA system using reconstructed patient data from Kaplan–Meier curves across 9 studies including 1916 patients.
- Results from pivotal trials showed no statistically significant difference between systems and a similar time course of arrhythmia-free survival among the 3 PFA systems.

Brief Comparative Review of 2 Novel Pulsed Field Ablation Systems Designed for Pulmonary Vein Isolation
Kandah D, Meyers J. *JACC Clin Electrophysiol*. 2024;10(5):1010–1013.

- Comparative review summarizes design and clinical trial data for two PFA systems: FARAPULSE PFA system and PulseSelect PFA system.
- An IDE trial comparison of the PULSED AF and ADVENT studies suggested shorter procedure and LA dwell times with the FARAPULSE PFA system, whereas safety outcomes trended favorably with the PulseSelect PFA system, with no reported atrioesophageal fistula or phrenic nerve injury in either system.

Preclinical studies

An Ex Vivo Evaluation of Air Intrusion Into Pulsed Field Ablation Sheaths During Ablation and Mapping Catheter Insertion
Gier C, Simon E, Ahmed A, et al. *J Cardiovasc Electrophysiol*. 2025;36(12):3231–3237.

- In an *ex vivo* model simulating negative left atrial (LA) pressure, 55 trials evaluating multiple PFA sheaths and catheters showed a mean air intrusion volume of 9.6 ± 5.2 mL during catheter insertion and removal.

- FARAWAVE™* catheter insertion/removal through the 13F FARADRIVE™* sheath showed significantly more air intrusion than FARAWAVE catheter insertion/removal through the 13F Agilis™* NxT sheath and PulseSelect catheter insertion/removal through the 12F FlexCath Contour™ steerable sheath ($p<0.05$ for both).

Managing Catheter Knotting in Pulse-Select Pulsed Field Ablation: Mechanisms and a Practical Strategy for Resolution

Takigawa M, Kato R, Honda M, et al. *J Arrhythm*. 2025;41(6):e70250.

- Two reproducible catheter knotting mechanisms associated with catheter manipulation and guidewire positioning (intra-loop and extra-loop deformation) were observed in a bench study of N=25 PulseSelect PFA catheters.
- Retraction to the sheath tip, guidewire withdrawal, and gradual catheter advancement with or without rotation successfully resolved catheter knotting in 24/25 cases (96%), with 21 cases (84%) resolved on the first attempt.

Arrhythmogenicity of monophasic and biphasic PFA waveforms in a porcine model

Kumru HT, Mattison L, Tarakji KG, Verma A, Sigg DC. *J Cardiovasc Electrophysiol*. 2024;35(12):2487–2490.

- Preclinical study evaluated arrhythmogenic risk of PFA waveforms using the PulseSelect PFA catheter at right ventricular sites (N=2 swine, N=5 delivery locations), comparing monophasic and biphasic pulse waveforms delivered across the T-wave.
- Monophasic pulse waveforms induced ventricular fibrillation in 7/7 deliveries when applied during the T-wave, whereas biphasic pulse waveforms did not induce ventricular arrhythmias despite identical voltage (1500 V), pulse width, and number of pulses.

Hemolysis After Pulsed Field Ablation: The Role of Dose and Contact in an Acute Porcine Model

Mattison L, Verma A, Tarakji KG, Sigg DC. *Circ Arrhythm Electrophysiol*. 2024;17(12):e013317.

- Preclinical study (N=6 swine) evaluated hemolysis after PulseSelect PFA system ablation, comparing biomarker levels with tissue contact (N=2) and non-contact (N=4) following up to 128 PF applications.
- FPH increased linearly with PFA applications, rising by 0.0003 g/dL per application with tissue contact and 0.00056 g/dL per application without contact.
- FPH levels remained below the threshold for severe hemolysis (0.04 ± 0.01 g/dL with contact; 0.08 ± 0.01 g/dL without contact) after 128 applications, with LDH, creatinine, and bilirubin remaining within normal limits and no hematuria or proteinuria observed.

Determination of lethal electric field threshold for pulsed field ablation in ex vivo perfused porcine and human hearts

Kos B, Mattison L, Ramirez D, et al. *Front Cardiovasc Med*. 2023;10:1160231.

- *Ex vivo* electroporation study evaluated lethal electric field thresholds (LET) for PFA using a pair of parallel needle electrodes and proprietary Medtronic PFA generator in porcine

hearts (N=6, 51 lesions) and human donor hearts (N=3, 21 lesions) using a biphasic waveform and monophasic 100 µs pulses.
- Median LET values for the biphasic waveform were 535 V/cm in porcine myocardium and 416 V/cm in human myocardium, while monophasic 100 µs pulses in porcine hearts produced a lower median LET of 368 V/cm.
- Results demonstrated anisotropic lesion behavior influenced by myocardial fiber orientation and suggested that cardiac tissue exhibits relatively low electroporation thresholds compared with most other tissues.

Effects of Electrode-Tissue Proximity on Cardiac Lesion Formation Using Pulsed Field Ablation

Howard B, Verma A, Tzou WS, et al. *Circ Arrhythm Electrophysiol*. 2022;15(10):e011110.

- *Ex vivo* porcine heart study (N=8 hearts, 32 ablations) evaluated the effect of electrode–tissue distance on lesion formation during biphasic, bipolar PFA using a 4-electrode prototype PFA catheter and proprietary waveform.
- Lesion depth decreased with increasing electrode–tissue distance: 4.3 ± 0.4 mm at 0 mm, 2.7 ± 0.4 mm at 2 mm, and 1.3 ± 0.4 mm at 4 mm offset; lesion width also decreased: 9.4 ± 1.1 mm, 7.5 ± 0.8 mm, and 5.8 ± 1.4 mm, respectively.
- Results demonstrated that PFA can create cardiac lesions even without direct electrode-tissue contact, but maximal lesion depth and transmurality occur when electrodes are in direct contact with tissue.

Characterization of Phrenic Nerve Response to Pulsed Field Ablation

Howard B, Haines DE, Verma A, et al. *Circ Arrhythm Electrophysiol*. 2022;15(6):e010127.

- *In vivo* porcine study evaluated phrenic nerve response to PFA with the PulseSelect catheter using a three-phase experimental design in a swine model, including dose-response testing (N=12), repetitive delivery testing (N=4), and chronic histopathology assessment (N=6).
- Acute experiments demonstrated a dose-dependent phrenic nerve response, ranging from no effect to temporary stunning; the magnitude and duration of stunning increased with higher PFA dose and closer catheter proximity to the nerve.
- In the chronic phase, SVC isolation was achieved while preserving phrenic nerve function, and gross and histopathologic evaluation at 4 weeks showed no structural nerve injury or diaphragmatic damage.

Safety and chronic lesion characterization of pulsed field ablation in a Porcine model

Stewart MT, Haines DE, Miklavčič D, et al. *J Cardiovasc Electrophysiol*. 2021;32(4):958–969.

- Preclinical study (N=6 swine) evaluated overlapping PFA deliveries using a the PulseSelect catheter in the SVC, right atrial appendage (RAA), and right superior PV with low-dose (±700 V) and high-dose (±1500 V) applications.

- All targeted structures achieved acute isolation and developed circumferential, contiguous, transmural lesions that matured into replacement fibrosis at 4 weeks without evidence of stenosis, aneurysm, thrombus, or extracardiac injury.
- Minimal electrode temperature increases were observed (~0.7 °C for 700 V and ~5 °C for 1500 V), and no ventricular arrhythmias or phrenic nerve injury occurred.

Reduction in Pulmonary Vein Stenosis and Collateral Damage with Pulsed Field Ablation Compared to Radiofrequency Ablation in a Canine Model

Howard B, Haines DE, Verma A, et al. *Circ Arrhythm Electrophysiol*. 2020;13(9):e008337.

- Randomized preclinical study (N=8 canines) compared the PulseSelect PFA system with irrigated radiofrequency (IRF) for PV ablation at proximal and distal sites, with serial CT imaging through 12 weeks.
- Maximum reduction in PV cross-sectional area at 4 weeks was −46.1 ± 45.1% after IRF vs. −5.5 ± 20.5% after PFA ($p \leq 0.001$); severe stenosis (>70% diameter reduction) occurred in 6/32 IRF sites (18.8%) and 0/32 PFA sites (0%).
- Histopathology showed vagus nerve, lung, and esophageal injury with IRF but none with PFA.

Intracardiac pulsed field ablation: Proof of feasibility in a chronic porcine model

Stewart MT, Haines DE, Verma A, et al. *Heart Rhythm*. 2019;16(5):754–764.

- Preclinical study (N=6 swine) evaluated feasibility and safety of intracardiac PFA delivered using the PulseSelect catheter at the right superior PV, LAA, and RAA compared to RF.
- Acutely, greater electrogram amplitude reduction was observed with PFA vs. RFA (72.2 ± 23.1% vs. 56.4 ± 27.5%; $p=0.005$) and loss of pace capture in 100% of PFA vs. 92% of RF lesions ($p=0.005$).
- At 2-week follow-up, PFA produced homogeneous transmural replacement fibrosis with fewer necrotic myocyte "sequesters" and less epicardial fat inflammation than RF; no collateral injury to lungs, esophagus, or phrenic nerves was observed.

Cardiac ablation via electroporation

Hong J, Stewart MT, Cheek DS, Francischelli DE, Kirchhof N. *Annu Int Conf IEEE Eng Med Biol Soc*. 2009;2009:3381–3384.

- Early feasibility study (N=4 sheep) evaluated electroporation-based cardiac ablation using prototype clamp and linear probe devices designed to deliver pulsed electric fields to cardiac tissue.
- Electroporation created lesions with high transmurality rates, including 100% transmural lesions in the superior and inferior vena cava.
- Histopathology demonstrated well-demarcated lesions with myocyte swelling and contraction band necrosis without significant thermal injury, and esophageal testing showed muscle layer injury with preserved epithelial layers.

Case reports

- Mizuno Y, Munehisa Y, Kumazawa D, Onodera K, Satomi K, Yamashita K. Zero-fluoroscopy pulsed field ablation of atrial fibrillation in a patient with cor triatriatum sinister: a case report. *HeartRhythm Case Rep*. 2026;12:426–431. https://doi.org/10.1016/j.hrcr.2026.01.002.
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- Oda Y, Nogami A, Igarashi D, Usui R, Uno K. A Case Report of Persistent Phrenic Nerve Injury by Pulsed Field Ablation: Lessons from Anatomical Reconstruction and Electrode

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PulseSelect™ Pulsed Field Ablation (PFA) System Brief Statement

Indications (or Intended Use) The PulseSelect™ Pulsed Field Ablation (PFA) System is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and for treatment of drug refractory, recurrent, symptomatic paroxysmal atrial fibrillation or persistent atrial fibrillation (episode duration less than 1 year).

Contraindications

The PulseSelect PFA loop catheter is contraindicated for use in patients with the following conditions: Active systemic infections, A known sensitivity to Heparin, Blood clotting abnormalities

The catheter is also contraindicated in conditions where the manipulation of the catheter within the heart would be unsafe, such as intracardiac mural thrombus.

The catheter is not recommended for use in patients who cannot undergo standard anticoagulation protocol for a left-sided cardiac procedure, or who have had a recent coagulopathy or embolic event.

Warnings and Precautions

To reduce the possibility of hazards associated with use of the PulseSelect PFA loop catheter:

• Use the catheter only in the recommended anatomical location. • Maintain the catheter position during the ablation. •Do not deliver energy near permanently implanted metallic objects • If coughing occurs, reposition the catheter more proximally and review sedation management. • Ensure electrodes are not in contact with any metal during ablations (for example the guide wire). • Maintain substantially circular array to ensure uniform field distribution. • If the electrode array is deployed to deliver ablation energy, avoid continuing to move the slide control forward to prevent the guide wire lumen from coming too close to the electrode array. It is recommended that the array be captured while it is submerged to help reduce the possibility of air becoming entrapped around the electrode array during capture and catheter insertion. Catheter integrity – Use care to avoid damage to the catheter. • Do not bend or kink the leading end of the catheter. Doing so could cause damage to the catheter lumen and make it unusable. • Monitor the catheter throughout the procedure. If a flash is observed in the luer, replace the catheter immediately. Electrode-electrode contact – Avoid contact between electrodes. Contact between electrodes may create a short circuit. Embolism risk – Introducing any catheter or sheath into the circulatory system entails the risk of air, gas, or thromboembolism, which can occlude vessels and lead to tissue infarction with serious consequences. • Avoid unnecessary catheter exchanges to minimize sheath-related embolic events. • Always advance and withdraw components slowly to minimize the vacuum created and the risk of air embolism. • Aspirate and flush the sheath frequently to help minimize the potential for embolic events resulting from the introduction of air or clot formation within the sheath. Fluoroscopy use during catheter placement – Only perform catheter ablation after giving adequate attention to the potential radiation exposure associated with the procedure, and taking steps to minimize this exposure. Give careful consideration before using the device in

pregnant women. For single use only – The PFA catheter is intended only to be used once for a single patient. Do not reuse, reprocess, or resterilize the PFA catheter. Careful manipulation of the catheter is necessary to avoid cardiac damage, perforation, or tamponade. • Do not use excessive force to advance, withdraw, or rotate the catheter, especially if resistance is encountered. Excessive force may lead to catheter damage and blood loss. • Use imaging guidance during catheter advancement, manipulation, and placement. • Vascular perforation is an inherent risk of catheter placement. • Performing ablation with the PFA catheter array inside the sheath may result in damage to the array or the sheath and should be avoided. • Performing steering manipulation with the PFA catheter array inside the sheath may result in damage to the catheter steering mechanism or the sheath and should be avoided. • The PFA generator is capable of delivering significant energy. Do not touch the ablation electrodes of the PFA catheter while operating the generator. • If the system is to be tested outside of the body, the electrode array must be immersed in saline solution in a plastic container. Never test PFA delivery in direct contact with skin. Use of imaging during catheter manipulation and placement is strongly advised. Manipulating the catheter without imaging may result in damage to cardiac and vascular structures. Other devices, wires, or catheters – Avoid catheter entanglement with other devices, wires, or catheters, for example, intracardiac echo catheters. Failure to do so may increase the risk of entrapment of the array or damage to the array, which may affect retrieval of the device into the transseptal sheath. Phrenic nerve injury – To reduce the potential for phrenic nerve injury, assess for proximity of the ablation catheter to the nerve using an appropriate technique such as pacing for local phrenic nerve capture or using the test pulse feature before ablation. Stop ablation immediately if phrenic nerve impairment is observed and assess for injury. Sheath and guide wire required – Do not attempt to advance or withdraw the catheter through the vasculature without the use of a sheath and guide wire, as it may result in damage to cardiac and vascular structures.

Implanted devices, such as pacemakers and implantable cardioverter-defibrillators (ICDs), may be adversely affected by PFA energy. • Keep external sources of pacing and defibrillation available during ablation. • Program pacemaker sensing parameters to asynchronous pacing to ensure that PFA energy is not sensed as an intrinsic event. • Deactivate ICD detection during the delivery of PFA energy. • Perform complete implantable device testing before and after ablation. • Monitor surface and intracardiac electrograms or vital signs during PFA energy delivery to assess for device interaction. Take appropriate action if any interaction is detected. • Refer to the appropriate implantable device technical manual for additional information.

Electrical safety requirements – The PFA generator meets the requirements of IEC 60601-1. It is the user's responsibility after installation to verify and ensure that the generator meets the applicable local electrical safety requirements.

Electric shock – To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth. Electromagnetic interference (EMI) radiated – The generator emits energy during ablation at a frequency level that may cause EMI with unshielded electronic equipment. To minimize EMI, the generator should be moved away from any other electronic

device. If EMI is apparent during the application of energy, EMI may be reduced by repositioning the generator or other equipment.

Electromagnetic interference (EMI) susceptibility – The generator has been designed to minimize electromagnetic interference (EMI). If interference should occur, move the generator away from the device generating the interference or place the generator at a different angle.

Leakage current from connected devices – Use only isolated equipment (IEC 60601-1 Type CF equipment, or equivalent) with the PFA system and catheters or patient injury or death may occur.

Potential Adverse Events or Potential Complications

Potential adverse events associated with cardiac catheter ablation procedures include, but are not limited to, the following conditions: • Access site complications (such as, bruising, ecchymosis, arteriovenous fistula, hematoma, pseudoaneurysm) • Anemia • Arrhythmias, proarrhythmia (such as, atrial flutter, bradycardia, heart block, tachycardia) • Bleeding, possibly requiring transfusion • Bruising • Cardiopulmonary arrest • Perforation of the heart or other organs during transseptal puncture or other procedures • Cardiac tamponade • Catheter entrapment in cardiac structures requiring intervention • Cerebrovascular accident [such as stroke, transient ischemic attack (TIA)] • Chest discomfort, pain, or pressure • Collateral damage to the conduction system or coronary vasculature • Cough • Death • Embolism • Esophageal damage (including atrial esophageal fistula) • Hemoptysis • Hypotension • Hypertension • Infections (such as, sepsis) • Myocardial infarction or ischemia • Nerve injury or nerve damage (for example phrenic nerve injury) • Pericarditis or endocarditis • Pericardial effusion • Pneumothorax • Pulmonary edema • Pulmonary vein dissection • Pulmonary vein stenosis • Radiation injury or damage and late malignancy • Skin laceration or puncture • Sore throat • Unintended complete or incomplete atrioventricular node (AV-Node) or sinus node block or damage • Valvular insufficiency or damage.

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.

Learn more at medtronic.com/pulseselect

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