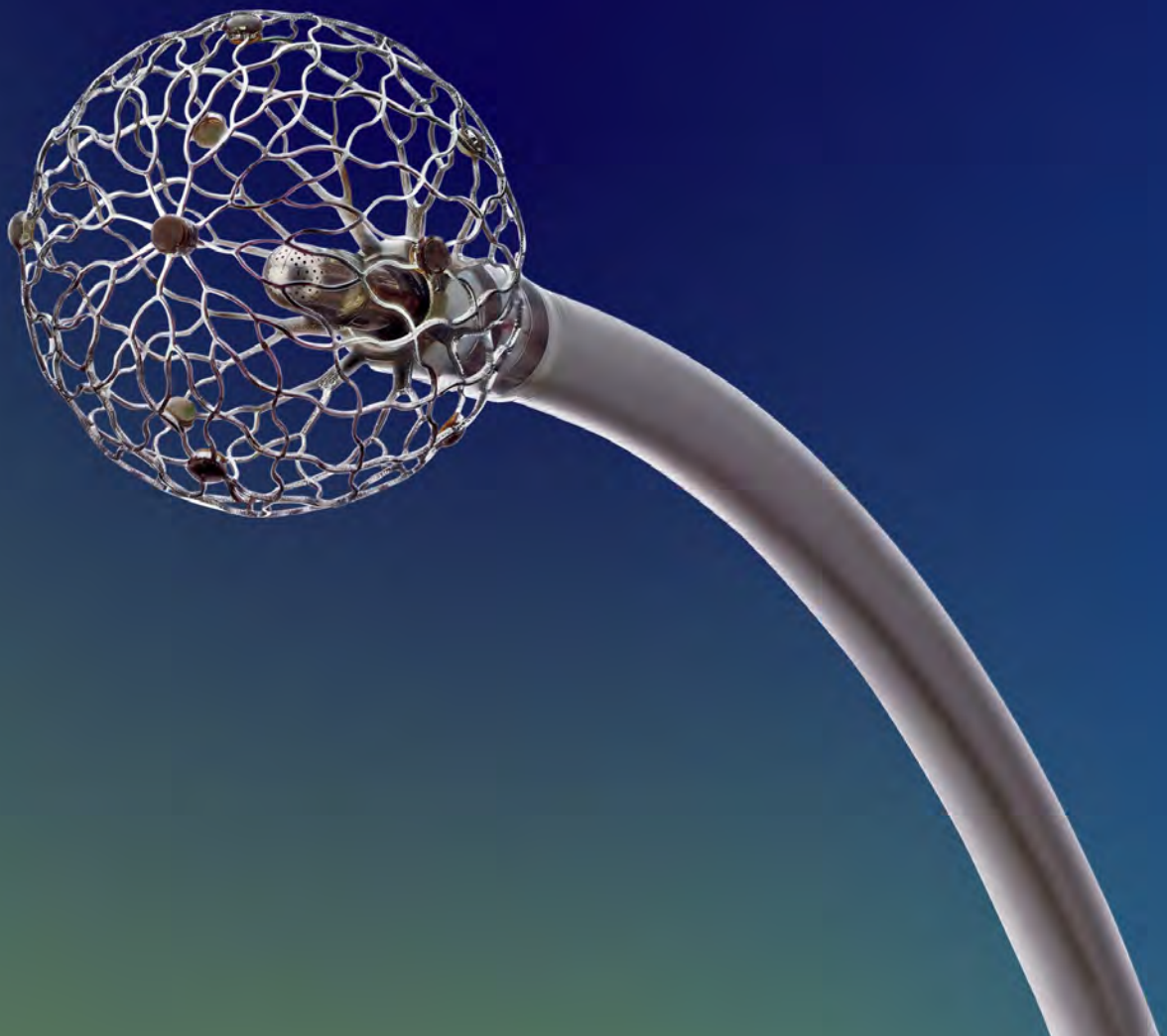
Medtronic

CARDIAC ABLATION SOLUTIONS

Sphere-9™ catheter

Clinical compendium



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For 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

IDE trials and sub-analyses

Dual-energy lattice-tip ablation system for persistent atrial fibrillation: a randomized trial

Anter E, Mansour M, Nair DG, et al. *Nat Med*. 2024;30(8):2303–2310.

- A randomized controlled trial of persistent AF (PsAF) patients undergoing AF ablation (PVI with additional linear ablation) comparing use of the dual-energy Sphere-9 catheter (N=212) or a conventional irrigated, contact force sensing radiofrequency (RF) catheter (N=208).
- Sphere-9 catheter demonstrated numerically higher primary effectiveness relative to the RF control group: 73.8% vs. 65.8%, respectively ($p<0.0001$ for non-inferiority).
- Major procedural or device-related complications occurred in 1.4% Sphere-9 catheter patients and 1.0% RF control patients ($p<0.0001$ for non-inferiority).
- Mean skin-to-skin procedure time was 25 min. shorter in the Sphere-9 catheter cohort compared to the RF control arm (100.9 vs. 126.1 min., $p<0.0001$).

Operator learning curve with a novel dual-energy lattice-tip ablation system

Kiehl EL, Mountantonakis SE, Mansour MC, et al. *Heart Rhythm*. 2026;23(1):89–96

- In this sub-analysis of the SPHERE Per-AF trial, long-term effectiveness improved significantly with increasing operator experience for patients treated with the Sphere-9 catheter ($p<0.05$).
- One-year primary composite effectiveness was 65% for the first 5 patients per operator, 75% for patients 6 to 10, and 80% for patients >10.
- Kaplan-Meier effectiveness estimates at 1-year follow-up were significantly higher in the Sphere-9 catheter cohort after 10 procedures were performed compared to the RF control cohort (80% vs. 65%, respectively, $p<0.05$).

Electrophysiology lab efficiency simulation: a comparison between novel dual-energy lattice-tip and conventional contact-force sensing radiofrequency ablation systems

Mountantonakis SE, Anter E, Marschke J, et al. *J Invasive Cardiol*. 2025;37(12).

- In a discrete event simulation using data from the SPHERE Per-AF trial (N=211 Sphere-9 catheter, N=207 RF control), procedure times were shorter and less variable when the Sphere-9 catheter was used compared to the RF control (100.8±31 vs. 125.9±49.2 min.).
- Over a simulation of 1,000 EP lab days with 3 ablation cases per day per therapy, Sphere-9 catheter usage resulted in >10-fold reduction in cumulative overtime (41 vs. 424 hours).
- An additional non-ablation EP case could be added on 73% of days on which the Sphere-9 catheter was used, compared to 40% for the RF control.
- Same-day discharge for the 3rd ablation case in a single day was feasible on 38% of days when the Sphere-9 catheter was used, vs. 17% for the RF control.

Same day discharge can be performed safely after atrial fibrillation catheter ablation using a wide-footprint lattice-tip dual-energy system

Taigen TL, Nair DG, Sharma D, et al. *Heart Rhythm O2*. 2026;7(4):656–663.

- In a sub-analysis of the SPHERE Per-AF trial, same-day discharge (SDD) was safely achieved in 55.9% of patients treated with the Sphere-9 catheter (N=211) and 53.6% of patients treated with the RF control (N=207), with no significant differences in days to discharge or acute safety outcomes.
- In 14 centers with at least 1 SDD, shorter procedures and procedures ending earlier in the day were strong predictors of SDD.
- Neither discharge protocol nor ablation technology predicted 30-day all-cause readmission or serious procedure/device-related adverse events.

Impact of a fully integrated wide-footprint lattice-tip dual-energy mapping and ablation system on fluoroscopy usage

Nair DG, Sharma D, Osorio J, et al. AFS2025-59. *J Cardiovasc Electrophysiol*. 2025;36(5):1171–1172.

- In this sub-analysis of the SPHERE Per-AF trial, patients undergoing ablation with the Sphere-9 catheter (N=249) using zero (<0.5 min., 17.7%), low (≥0.5 - ≤5 min., 45.8%), and conventional (>5 min., 36.5%) fluoroscopy workflows showed no difference in primary effectiveness or major adverse events rates.
- For 34 operators who performed cases using both the Sphere-9 catheter and the control RF ablation system with conventional fluoroscopy usage, average fluoroscopy times were significantly lower in Sphere-9 catheter procedures (8.9 min.) compared to those performed with the control RF system (14.4 min., $p<0.05$).

Impact of linear ablation in persistent atrial fibrillation using a dual energy, wide-footprint catheter - Analysis from the SPHERE Per-AF Randomized Trial

Mansour M, Sharma D, Kiehl EL, et al. *Heart Rhythm*. 2026:S1547-5271(26)00099–8.

- In a sub-analysis of the SPHERE Per-AF trial, a numerical trend toward higher 12-month effectiveness with a PVI plus linear lesion set strategy compared with PVI alone was observed (77% vs. 56%, p=0.07), with a more pronounced effect in the Sphere-9 catheter arm compared to the RF control, although subgroup sizes were small.
- Ablation time for all lesion sets performed with the Sphere-9 catheter was significantly faster compared to the RF control.
- Acute success was achieved in 100% of linear lesion sets performed with the Sphere-9 catheter.

Indirect treatment comparison of two pulsed field ablation systems for the treatment of persistent atrial fibrillation

Matsumoto K, van Bragt KA, Kueffer FJ, Mburu W, Tarakji KG. *J Interv Card Electrophysiol*. 2026;69(3):355–363.

- In a matched-adjusted indirect comparison of the SPHERE Per-AF and ADVANTAGE AF Phase I (N=260) trials, a matched cohort of 205 Per-AF patients treated with the Sphere-9 catheter had a higher probability of long-term treatment success compared to those

undergoing PVI and LA posterior wall isolation with the FARAWAVE™* catheter (77.4% vs. 63.5%, p=0.003).
- While one Sphere-9 catheter was used in more than 97% of SPHERE Per-AF cases (N=212), up to 3 catheters were used per patient in ADVANTAGE AF Phase I.
- Skin-to-skin procedure times were similar between groups; however, 74% shorter average fluoroscopy times were reported in the matched cohort of patients treated with the Sphere-9 catheter (5.1 min. vs. 19.5 min., p<0.01).
- There was no significant difference in primary safety event rates (p=0.72).

Economic evaluation of a novel dual-energy, large focal lattice-tip catheter versus conventional contact-force sensing radiofrequency catheter, for persistent atrial fibrillation ablation, from the English National Health Service perspective

Mellor G, Reddy V, Kanagaratnam P, et al. *Open Heart*. 2026;13(1):e003770.

- In a cost-effectiveness analysis using individual patient data from the SPHERE Per-AF trial modeled from the English NHS perspective using a hybrid decision tree and lifetime Markov model (40-year horizon), the Sphere-9 catheter demonstrated lower lifetime cost and improved health outcomes.
- An incremental cost savings of £5,427 per patient and higher quality-adjusted life years (QALYs) were demonstrated for patients treated with the Sphere-9 catheter compared to those treated with the RF control.
- Economic benefits were driven by lower AF recurrence and fewer repeat ablations, including 0.84 fewer repeat ablations per patient and a 12% relative reduction in time spent in AF recurrence states; results remained robust across sensitivity analyses.

First-in-human studies

A Focal Ablation Catheter Toggling Between Radiofrequency and Pulsed Field Energy to Treat Atrial Fibrillation

Reddy VY, Peichl P, Anter E, et al. *JACC Clin Electrophysiol*. 2023;9(8 Pt 3):1786–1801.

- In the first-in-human evaluation of the dual-energy Sphere-9 catheter, 100% acute success for PVI and all linear lesion sets was achieved in 178 patients.
- Invasive remapping approximately 3 months post-ablation of 31 patients treated with the optimized PULSE3 waveform showed 97% PVI durability; 91% of all linear ablation lesions (N=91) were durably blocked.
- One-year Kaplan-Meier estimate for freedom from atrial arrhythmias was 78.1%, with the subset of PsAF patients treated with the optimized PULSE3 waveform showing an 85% success rate (N=54).
- One primary adverse event, inflammatory pericardial effusion not requiring intervention, occurred.

Lattice-Tip Focal Ablation Catheter That Toggles Between Radiofrequency and Pulsed Field Energy to Treat Atrial Fibrillation: A First-in-Human Trial

Reddy VY, Anter E, Rackauskas G, et al. *Circ Arrhythm Electrophysiol*. 2020;13(6):e008718.

- All lesion sets performed in the initial 76-patient cohort treated with the dual-energy Sphere-9 catheter were acutely successful.
- No instances of tamponade, phrenic nerve injury, PV stenosis, stroke, atrioesophageal fistula, or death occurred. One major safety event, a vascular access complication requiring surgical intervention, was reported (1.3%).
- Post-ablation esophagogastroduodenoscopy performed in a subset of 60 patients showed no esophageal injury in the PF-only group and 2 minor mucosal injuries not requiring intervention in the PF/RF group.
- In a subset of 51 patients undergoing postprocedure cerebral imaging, asymptomatic MRI findings were reported in 8 patients, who showed a lower average initial ACT compared to the MRI-negative cohort (266 vs. 335 sec., p=0.00016).

A Lattice-Tip Temperature-Controlled Radiofrequency Ablation Catheter: Durability of Pulmonary Vein Isolation and Linear Lesion Block

Reddy VY, Neužil P, Peichl P, et al. *JACC Clin Electrophysiol*. 2020;6:623–35.

- N=65 patients undergoing AF ablation (PVI + additional linear ablation at operator discretion) with the Sphere-9 catheter using RF energy only.
- Protocol-mandated remapping performed in 27 patients showed 99.1% of pulmonary veins, 91% of MI lines, and 100% of LA roof and CTI lines durably isolated/blocked approximately 3 months post-ablation.
- At 1 year, freedom from atrial arrhythmias was 94.4 ± 3.2%, and no primary adverse events were observed.

A Lattice-Tip Temperature-Controlled Radiofrequency Ablation Catheter for Wide Thermal Lesions: First-in-Human Experience With Atrial Fibrillation

Anter E, Neužil P, Rackauskas G, et al. *JACC Clin Electrophysiol*. 2020;6(5):507–519.

- In 71 patients undergoing AF ablation, acute PVI was achieved in 98.5% of patients using RF energy only delivered by the Sphere-9 catheter.
- Additional linear ablation performed with the Sphere-9 catheter, including MI, LA roof, and CTI, was successful in 95.5%, 95.8%, and 100% of patients, respectively.
- No primary adverse events occurred in the 3-month follow-up period.

Clinical manuscripts

Lattice-tip vs. standard irrigated focal-tip catheter for radiofrequency ablation of the cavotricuspid isthmus - the LINEAR randomized trial

Tzeis S, Asvestas D, Sousonis V, et al. *Europace*. 2026;28(4):euag046.

- Multicenter, randomized trial (N=102); RF using the Sphere-9 catheter achieved a significantly higher rate of bidirectional CTI block than a standard, irrigated small-tip RF catheter after a 60-min. waiting period with high-density mapping and adenosine testing (94.1% vs. 68.6%, p=0.002).
- The Sphere-9 catheter had a higher rate of first-pass block (90.2% vs. 60.8%, p=0.001), fewer lesions delivered (8.3±2.4 vs. 13.4±4.5), and shorter total ablation time (41±12 s vs. 245±91 sec.) than the small-tip RF catheter; no procedural complications were reported.

Offsetting costs of new ablation technologies with increased procedural efficiency and volume

Ilkhanoff L, Plasters X, Gaeta SA, et al. *Heart Rhythm*. 2026:S1547-5271(26)02162–4.

- Prospective, multicenter analysis of N=2,986 patients showed significantly more EP lab and operator time was saved per case with the Sphere-9 catheter compared to OTW PFA (FARAPULSE™* PFA System and PulseSelect™ PFA system) relative to the RF control group.
- In a lab occupancy model, enough time was saved for 1 extra case/day with the Sphere-9 catheter, partially offsetting higher upfront procedural costs.
- Despite lower procedural costs compared to the Sphere-9 catheter, OTW PFA did not save enough time to feasibly accommodate an additional case, resulting in the inability to offset costs through increased volume.

Variability in Tissue Interface Temperature During Pulse Field Atrial Ablation: Implications for Real-Time Contact Assessment

Power JR, Watanabe K, Shinohara M, et al. *Circ Arrhythmia Electrophysiol*. 2026:e014310.

- N=2,779 PF lesions delivered with the Sphere-9 catheter in 41 patients showed tissue temperature response varied by LA anatomical location, with right pulmonary vein locations demonstrating significantly lower peak and average temperatures.
- In a preclinical model (N=4 swine), higher peak and average temperatures during PFA correlated with increased lesion depth.

Left Atrial Ablation using the Dual-Energy, Lattice-Tip Catheter in the SAFE-Ablation Registry: How to Avoid Procedure-Related Stroke?

Oates CP, Power J, Whang W, et al. *Heart Rhythm*. 2026:S1547-5271(26)02242–3.

- Nonrandomized, single-center registry (N=507); no strokes reported in groups treated using PFA only in the LA or limited RF using "attenuated" energy delivery settings.
- N=4 strokes reported in the cohort treated using a combination of PF and standard RF settings in LA ablation (N=294); however, patients treated with a combination of PF and RF had significantly higher CHA_2DS_2VASc scores and were more likely to have hypertension and history of prior ablation compared to those treated with PF only.

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:euag017.

- N=209 patients undergoing concomitant AF ablation with PFA (including 33% treated with the Sphere-9 catheter) and left atrial appendage closure (LAAC).
- 100% acute procedural success (ablation and LAAC); mean total procedure time 57.3±17 min., fluoroscopy 3.4±0.8 min. (for LAAC only).
- 100% same-day discharge; no tamponade, stroke, phrenic nerve injury, esophageal injury, or acute kidney injury (AKI) in-hospital or at 30 days.

Pulsed-Field vs Thermal Ablation of Atrial Fibrillation in Patients from the Marshall Islands: A Study of Generalized Coronary Spasm

Nair DG, Reddy VY. *JACC Clin Electrophysiol*. 2026:S2405-500X(26)00030–7

- Generalized coronary spasm (Gen-CS) defined as diffuse multivessel coronary constriction with ischemic ECG changes remote from ablation sites.
- Retrospective series, N=12 patients: Gen-CS occurred in Marshallese patients with higher incidence during PFA (5/5, various PFA catheters) vs. thermal ablation (0/7).
- Authors hypothesized population-specific predisposition to Gen-CS during PFA with potential implications for pre-treatment with nitrates and calcium channel blockers.

Dual-energy lattice-tip catheter for posterior mitral line ablation: acute efficacy and 1-year outcomes

Zaher W, Rocca DGD, Mené R, et al. *J Interv Card Electrophysiol*. 2026 Mar 13.

- N=102 consecutive patients at 2 European centers undergoing posterior mitral line ablation with the Sphere-9 catheter: 92.2% acute bidirectional block; 74.5% freedom from atrial arrhythmias at median follow-up 356 days.
- Median ablation duration of 4.0 min.; dual-energy (PF/RF) strategy used in 19.6% of patients, with the remainder treated using PF only.
- Two major complications reported (2.0%).

First Clinical Experience With Reversible Electroporation Mapping in Atrial Flutter

Cespón-Fernández M, Nakasone K, Pannone L, et al. *Circ Arrhythmia Electrophysiol*. 2026:e014359.

PF-REV (PF mapping) settings are not available on the HexaPulse™ PF generator in all geographies, not available for sale in the U.S. This evidence has not been evaluated by the FDA.

Short-Term Procedural Outcomes of Posterior Wall Isolation Using the Affera Pulse Field Ablation System

Thakur U, Junker J, Koh Y, et al. *J Cardiovasc Electrophysiol*. 2026;37(3):554–560.

- Retrospective analysis, N=40 patients; acute posterior wall isolation (PWI) success achieved in 100% of patients using an average of 19.6 PFA applications over a median time of 7.0 min.
- No major complications and 2 minor vascular access complications reported; 95% freedom from atrial arrhythmias at median follow-up of 76 days.

A Comparative Analysis of Hemolysis Related to the Bipolar Pentaspline and Monopolar Lattice-Tip Catheters

Shinohara M, Oates C, Power JR, et al. *JACC Clin Electrophysiol.* 2026;12(2):387–389.

- Retrospective analysis of N=75 patients treated with the FARAPULSE PFA system and N=25 with the Sphere-9 catheter; median applications per patient: 60 (FARAPULSE PFA) vs. 88 (Sphere-9 catheter).
- Postprocedure free plasma hemoglobin (FPH) was significantly higher with the FARAPULSE PFA system vs. the Sphere-9 catheter; FARAPULSE PFA use was the only independent predictor of hemolysis (FPH ≥30 mg/dL).
- No renal complications or hemolysis-related symptoms during follow-up.

Use of a large-area focal lattice-tip catheter for cavotricuspid isthmus ablation

Thalmann G, Kueffer T, Storz T, et al. *Heart Rhythm*. 2026;23(2):e281–e283.

- The Sphere-9 catheter achieved acute CTI block in 100% (43/43) of patients with no conduction recovery observed after 10–15-min. waiting period; all procedures were performed under deep sedation.
- Median number of RF lesions delivered was 7 (IQR:6-12) with median ablation duration of 4.2 min.
- No peri-procedural complications were observed.

Atrial electrogram differences between a dual-energy ablation catheter and a conventional mapping catheter

Fazia VML, Zito E, Mohanty S, et al. *Heart Rhythm O2*. 2025;6:2025–6.

- Sphere-9 catheter EGM amplitude and morphology were comparable to a commercially available circular mapping catheter in N=35 patients during mapping of pulmonary veins and LA posterior wall; however, the circular mapping catheter showed sharper EGMs in areas outside PVs and LA posterior wall (mitral isthmus, left atrial appendage, and roof).

Pulsed Field Ablation–Related Hemolysis: Comparison Between Technologies

Gianni C, Al-Ahmad A, Elchouemi M, et al. *Circ Arrhythmia Electrophysiol*. 2025: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.

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.

Pulmonary vein isolation and beyond: feasibility and acute outcomes of the lattice-tip dual-energy catheter for complex ablations

My I, Nies M, Moser F, et al. *Heart Rhythm O2*. 2025;7(2):212–220.

- N=102 consecutive patients undergoing atrial ablation with the Sphere-9 catheter: 41% first-time PVI, 56% redo PVI procedures.
- Median procedure time was 91 min; first-pass pulmonary vein isolation achieved in 100% of patients using PFA only with median ablation time of 25 min.
- Additional LA lines performed in 85% of patients; all lines achieved bidirectional block; procedural complications occurred in 2.9% (3/102).

Single lattice-tip catheter workflow for artificial intelligence-guided spatio-temporal dispersion ablation

Nair DG, Gabrah K, Nair G, Maldonado N, Doty B. *Heart Rhythm*. 2025;23(3):e495–e497.

- N=32 PsAF patients underwent mapping and ablation of spatio-temporal dispersion sites using a single-catheter workflow with the Sphere-9 catheter in addition to PVI.
- All procedures were performed without fluoroscopy; average procedure time 54±11 min.
- AF terminated in 91% of cases.

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.

Hemolysis Induced by Pulsed-Field Ablation of Atrial Arrhythmias: A Comparative Analysis of Current Systems

Bruss J, Kueffer T, Tanner H, et al. *J Cardiovasc Electrophysiol*. 2025;36(10):2498-2506.

- Prospective registry of N=59 patients treated with either the Sphere-9 catheter (N=29) or VARIPULSE PFA system (N=30) plus a matched cohort of patients treated with the FARAPULSE PFA system (N=28) were assessed for biomarkers of hemolysis at baseline and 1-day post-ablation.
- Significantly less haptoglobin decrease with the Sphere-9 catheter post-ablation was observed compared to FARAPULSE PFA system or VARIPULSE PFA catheter ($P<0.001$).
- No hemolysis-related complications were observed in any group.

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=96 treated with the Sphere-9 catheter) or RF (N=98).
- Significantly higher levels of myocardial injury and hemolysis were reported following PFA compared to RF procedures, with 6.7% of PFA patients meeting criteria for acute kidney injury 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).

A Novel Focal Lattice Tip Catheter Toggling Between Pulsed Field Energy and Radiofrequency for Atrial Arrhythmia Ablation: Results from a Real-World, Multicenter Registry

Vetta G, Rocca DGD, Sarkozy A, et al. *Heart Rhythm*. 2025;22(7):e13–e22.

- Real-world, multicenter registry (N=130) patients treated with the Sphere-9 catheter: median LA dwell time was 73 min; 1.5% major complication rate.
- 81.9% of first-time AF ablation (N=72) was performed using PF only, with 100% first-pass isolation of pulmonary veins and LA posterior wall; additional linear ablation performed at operator discretion.
- At median follow-up 288 days, 15 patients (12%) experienced recurrence of atrial arrhythmia.

Feasibility of Atrial Linear Ablation Using a Lattice Tip Catheter That Toggles Between Radiofrequency and Pulsed-Field Energy Under Deep Sedation

Hirokami J, Moser F, Schmidt B, et al. *Heart Rhythm*. 2025;22(7):e40–e50.

- N=55 patients undergoing AF ablation with the Sphere-9 catheter at 2 centers, including linear ablation under deep sedation (N=40) or general anesthesia (GA, N=15).
- Acute bidirectional block achieved in 21/21 GA linear lesion sets and 74/76 deep sedation linear lesion sets.
- N=1 pericardial tamponade occurred in the deep sedation group due to a diagnostic catheter in the coronary sinus; no other procedure-related complications observed.

A novel platform allowing for pulsed field and radiofrequency ablation: First commercial atrial fibrillation ablation procedures worldwide with and without general anesthesia

Metzner A, Rottner L, Moser F, et al. *Heart Rhythm*. 2024;21:497–8.

- N=25 patients undergoing AF ablation with the Sphere-9 catheter; 72% under GA and 28% under deep sedation.
- All lesion sets (PVI and additional linear ablation at operator discretion) were acutely successful; average procedure time under deep sedation was 89 min. compared to 99 min. under GA.

Initial real-world data on catheter ablation in patients with persistent atrial fibrillation using the novel lattice-tip focal pulsed-field ablation catheter

Tohoku S, Bordignon S, Schaack D, et al. *Europace*. 2024;26(6):euae129.

- N= 28 patients underwent AF ablation with the Sphere-9 catheter; N=6 under GA, N=22 under deep sedation.
- PVI was successful in 100% of patients. Additional linear ablations were conducted in 21 patients (78%).

- The median procedural and fluoroscopic times were 97 (IQR: 80-114) min. and 8.5 (IQR: 7.2-9.5) min., respectively.
- Early recurrent AF (during 90-day blanking period) was documented in 4/27 patients (15%), including 1 case of recurrent AF during the hospital stay.
- No major nor minor procedural complications occurred.

General anaesthesia and deep sedation for monopolar pulsed field ablation using a lattice-tip catheter combined with a novel three-dimensional mapping system
Rillig A, Hirokami J, Moser F, et al. *Europace*. 2024;26(11):euae270.

- N=63 patients underwent AF ablation with the Sphere-9 catheter; N=23 under GA, N=40 under deep sedation; PVI success 100% in both groups with no map shifts observed.
- Procedure times were similar between cohorts; however, lab occupancy time was significantly reduced for the deep sedation cohort (165 vs. 131 min., $p<0.05$).
- N=1 conversion from deep sedation to GA reported; N=1 complication (pericardial tamponade) occurred in the deep sedation cohort.

Autonomic Changes Are More Durable After Radiofrequency Than Pulsed Electric Field Pulmonary Vein Ablation
Stojadinović P, Wichterle D, Peichl P, et al. *JACC Clin Electrophysiol*. 2022;8:895–904.

- N=31 patients underwent PVI using the Sphere-9 catheter (PFA only, N=18) or conventional, small-tip focal RF (N=13).
- RF ablation resulted in significantly more frequent reduced response of the sinoatrial and AV nodes to high-frequency, high-output pacing compared to PFA, with a greater acceleration of sinus rhythm in the RF group compared to PFA.

Preclinical studies

Maximizing Lesion Depth With the Lattice-Tip Catheter: A Preclinical Comparison of Single, Double, and Mixed Pulsed-Field and Radiofrequency Applications.
Watanabe K, Shinohara M, Yu F, Reddy VY, Koruth JS. *Circ Arrhythm Electrophysiol*. 2026:e014799.

- In a swine model using the Sphere-9 catheter (N=16 swine, N=102 ventricular lesions), researchers compared lesion size from single PF, single RF, repeated PF (PF1–PF2), and mixed PF/RF ablation sequences.
- Stacked PF applications produced lesions with mean depth of 6.8mm and significantly less variability compared with single PF or RF/PF lesions.

Minimal Hemolytic Profile of the Monopolar Lattice-Tip Pulse Field Ablation System: An In Vivo Preclinical Porcine Assessment
Watanabe K, Nies M, Sigg DC, et al. *Circ Arrhythmia Electrophysiol*. 2025:e013787.

- In a preclinical swine study (N=6) evaluating the Sphere-9 catheter, mean plasma-free hemoglobin after up to 120 PF applications remained below the 100 mg/dL threshold for severe hemolysis: 9.1 mg/dL at 60 applications,16.1 mg/dL at 120 applications.
- Hemolysis was not significantly affected by catheter–tissue contact or irrigation during PF applications.

Ultrastructural insights from myocardial ablation lesions from microsecond pulsed field vs radiofrequency energy
Kawamura I, Wang BJ, Nies M, et al. *Heart Rhythm*. 2024;21:389–96.

- In a swine model (N=1), PFA using the Sphere-9 catheter produced rapid and homogeneous cardiomyocyte disruption within 1 hour, as assessed by transmission electron microscopy, with lesion changes progressing by 4 hours with worsening interstitial edema.
- Compared with RF ablation also delivered with the Sphere-9 catheter, PFA lesions demonstrated preserved microvasculature, minimal erythrocyte extravasation, and sharply demarcated lesion borders, whereas RF lesions showed more hemorrhage, capillary occlusion, and a more gradual transition between injured and normal myocardium.

Reversible Pulsed Electrical Fields as an In Vivo Tool to Study Cardiac Electrophysiology: The Advent of Pulsed Field Mapping
Koruth JS, Neuzil P, Kawamura I, et al. *Circ Arrhythmia Electrophysiol*. 2023;16:E012018.

PF-REV (PF Mapping) settings are not available on the HexaPulse™ PF generator in all geographies, not available for sale in the U.S. This evidence has not been evaluated by the FDA.

Effect of Pulsed-Field and Radiofrequency Ablation on Heterogeneous Ventricular Scar in a Swine Model of Healed Myocardial Infarction
Younis A, Zilberman I, Krywanczyk A, et al. *Circ Arrhythmia Electrophysiol*. 2022;15:683–92.

- In a swine infarct model (N=9), lesions created using Sphere-9 catheter PFA were compared to those created using a small-tip focal RF catheter.
- PFA resulted in deeper, more transmural lesions with well-demarcated borders compared to RF in heterogeneous scar areas.

Pulsed-Field Ablation in Ventricular Myocardium Using a Focal Catheter: The Impact of Application Repetition on Lesion Dimensions
Yavin HD, Higuchi K, Sroubek J, Younis A, Zilberman I, Anter E. *Circ Arrhythmia Electrophysiol*. 2021;14:E010375.

- PFA in a swine ventricular model (N=12) showed acute lesion depth increased significantly from 5.6 to 8.8mm with 1 and 4 applications, respectively.
- The effect of PF repetition was maintained in the chronic phase (mean: 23 days post-ablation) with lesion depths of 3.9mm and 7.3mm for 1 and 4 applications, respectively.

Pulsed Field Ablation Using a Lattice Electrode for Focal Energy Delivery: Biophysical Characterization, Lesion Durability, and Safety Evaluation
Yavin H, Shapira-Daniels A, Barkagan M, et al. *Circ Arrhythmia Electrophysiol.* 2020;13:E008580.

- In N=25 swine, PFA with the Sphere-9 catheter achieved acute conduction block in 100% of linear lesions with a median 2.1 applications/cm; chronic histology at ~35 days demonstrated 100% transmural lesions (0.4–3.4 mm thickness) with median lesion width of 19.4 mm.
- Posterior PFA created transmural lesions without esophageal injury and caused, at most, transient (<5 min.) phrenic nerve stunning without histologic damage.

Focal Pulsed Field Ablation for Pulmonary Vein Isolation and Linear Atrial Lesions: A Preclinical Assessment of Safety and Durability
Koruth JS, Kuroki K, Kawamura I, et al. *Circ: Arrhythmia Electrophysiol*. 2020;13:E008716.

- In N=12 swine, PFA delivered with the Sphere-9 catheter achieved 100% acute thoracic vein isolation and successful linear lesions; durable isolation improved from 61.5% with low-dose PFA to 100% with high-dose PFA.
- Histology showed homogeneous fibrosis with sparing of nerves, vessels, epicardial fat, and the esophagus for PF lesions; direct esophageal PFA caused no injury, while RF produced transmural esophageal ulceration.

Feasibility, safety, and durability of porcine atrial ablation using a lattice-tip temperature-controlled radiofrequency ablation catheter
Koruth JS, Kuroki K, Iwasawa J, et al. *J Cardiovasc Electrophysiol*. 2020;31:1323–31.

- In N=5 swine, RF using the Sphere-9 catheter achieved 100% acute pulmonary vein isolation (7/7) and 100% durable isolation in all veins treated with 5-sec. applications as assessed at remapping 4-weeks post-ablation.
- Histology demonstrated 100% transmural lesions across pulmonary veins and atrial linear ablation sites (including mitral and cavotricuspid isthmus lines, 53/53), with lesion lengths up to 2.5 cm with 3 applications.

Larger and deeper ventricular lesions using a novel expandable spherical monopolar irrigated radiofrequency ablation catheter
Kitamura T, Hocini M, Bourier F, et al. *J Cardiovasc Electrophysiol.* 2019;30:1644–51.

Extended duration RF delivery settings are not available on the HexaGen™ RF generator in all geographies, not available for sale in the U.S. This evidence has not been evaluated by the FDA.

Expandable Lattice Electrode Ablation Catheter: A Novel Radiofrequency Platform Allowing High Current at Low Density for Rapid, Titratable, and Durable Lesions
Barkagan M, Leshem E, Rottmann M, Sroubek J, Shapira-Daniels A, Anter E. *Circ Arrhythmia Electrophysiol.* 2019;12:e007090.

- In N=3 swine, the Sphere-9 catheter delivered higher RF energy at lower current density, resulting in significantly wider lesions compared to a small-tip, irrigated RF catheter in N=6 thigh muscles.
- Atrial lines created in N=8 swine with the Sphere-9 RF catheter were wider and required 85% shorter ablation time compared to a small-tip, irrigated RF catheter.
- At 30 days, 100% of ablation lines created with the Sphere-9 catheter remained contiguous compared with only 14.3% lines created with a standard irrigated RF catheter, without steam pops, thrombus, or collateral tissue damage reported in the Sphere-9 catheter cohort.

Novel Irrigated Temperature-Controlled Lattice Ablation Catheter for Ventricular Ablation: A Preclinical Multimodality Biophysical Characterization
Shapira-Daniels A, Barkagan M, Yavin H, et al. *Circ Arrhythm and Electrophysiol*. 2019;12:e007661.

Extended duration RF delivery settings are not available on the HexaGen™ RF generator in all geographies, not available for sale in the U.S. This evidence has not been evaluated by the FDA.

Case reports

- Kantheti HS, Natarajan R, Mughal A. Termination of Longstanding Persistent Atrial Fibrillation Using a Novel Large Focal Lattice-Tip Pulsed Field Ablation Catheter: A Case Report. *Cureus*. 2026;18:e104019. https://doi.org/10.7759/cureus.104019
- Hanna DB, Sharma D, Axline D, et al. Three-Dimensional Printing in Guiding Management of Left Atrial Appendage Occlusion Device Migration. *JACC Case Rep*. 2026;31:106518. https://doi.org/10.1016/j.jaccas.2025.106518
- Malyar CV, Mahmoodi BK, Yap S-C. Ventricular Fibrillation Triggered by Cavotricuspid Isthmus Radiofrequency Ablation with a Dual-Energy Lattice-Tip Catheter in a Patient with an Implantable Cardioverter-Defibrillator. *HeartRhythm Case Rep*. 2025. https://doi.org/10.1016/j.hrcr.2025.11.004
- Mannion J, Gorry C, Foley B, Tuohy S. Remote diffuse multi-coronary artery spasm following pulmonary vein and posterior wall isolation, using a focal monopolar pulsed-field ablation catheter. *HeartRhythm Case Rep*. 2025. https://doi.org/10.1016/j.hrcr.2025.08.003
- Curti E, Brasca FM, Girardengo G, et al. Reversible pulsed field ablation for facilitating safe and effective mitral isthmus block. *J Interv Card Electrophysiol*. 2025:1–3. https://doi.org/10.1007/s10840-025-02100-0

PF-REV (PF Mapping) settings are not available on the HexaPulse™ PF generator in all geographies, not available for sale in the U.S. This evidence has not been evaluated by the FDA.

- Zaher W, Combes N, Boveda S, et al. Unexpected Ventricular Fibrillation Triggered by Pulsed Field Ablation for Atrial Fibrillation. *HeartRhythm Case Rep*. 2025. https://doi.org/10.1016/j.hrcr.2025.05.023
- Mannion J, Rathore F, David J, Lyne J. Using a Novel Pulsed Field Ablation Technique to Identify the Critical Isthmus Within a Tachycardia Circuit. *J Innov Card Rhythm Manag*. 2025;16:6195–8. https://doi.org/10.19102/icrm.2025.16023

PF-REV (PF Mapping) settings are not available on the HexaPulse™ PF generator in all geographies, not available for sale in the U.S. This evidence has not been evaluated by the FDA.

- Kneizeh K, Vlachos K, Monaco C, Jaïs P, Pambrun T, Derval N. Acute Nonsustained Mitral Isthmus Block Obtained With Sphere-9 Lattice-Tip Catheter Completed With Vein of Marshall Ethanol Infusion. *J Cardiovasc Electrophysiol*. 2025. https://doi.org/10.1111/jce.16541

Affera™ Integrated Mapping and Ablation System 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.

The Affera Integrated Mapping System is intended to be used for catheter-based cardiac electrophysiological mapping. The mapping system allows pacing and real-time visualization of compatible catheters as well as display of cardiac maps in multiple formats. The acquired patient signals, including body surface electrocardiograms and intracardiac electrograms, may also be recorded and displayed on the system's display screen.

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. Only use with compatible devices listed in the instructions for use. The Integrated Affera Mapping System requires use of a set of proprietary localization patches to detect patient displacement and respiratory motion and deliver low energy patient auxiliary signals.

Treatment location should be confirmed using alternative techniques (e.g. fluoroscopy, intracardiac electrograms, intracardiac echocardiography) before treatment.

A connection to a compatible cardiac stimulator is allowed provided the stimulator is electrically isolated or physically disconnected when RF or PF energy is applied to the patient, outputs of the

generator and stimulator must be isolated to prevent patient injury or damage to equipment.
The pacing functionality in the Affera Integrated Mapping System is not a life support device and is for diagnostic purposes only. Pacing may induce intentional or unintentional life-threatening cardiac arrhythmias.
Intravenous heparin must be used to reduce the likelihood of thromboemboli developing during the procedure. Patient injury may result from excessive delivery of fluids. 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 Affera Integrated Mapping and Ablation System has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. System operation may be temporarily interrupted if exposed to excessive external electromagnetic disturbance or electrostatic discharge.

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.

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/sphere9

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