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FARAPOINT™
Pulsed Field Ablation Catheter

Clinical compendium

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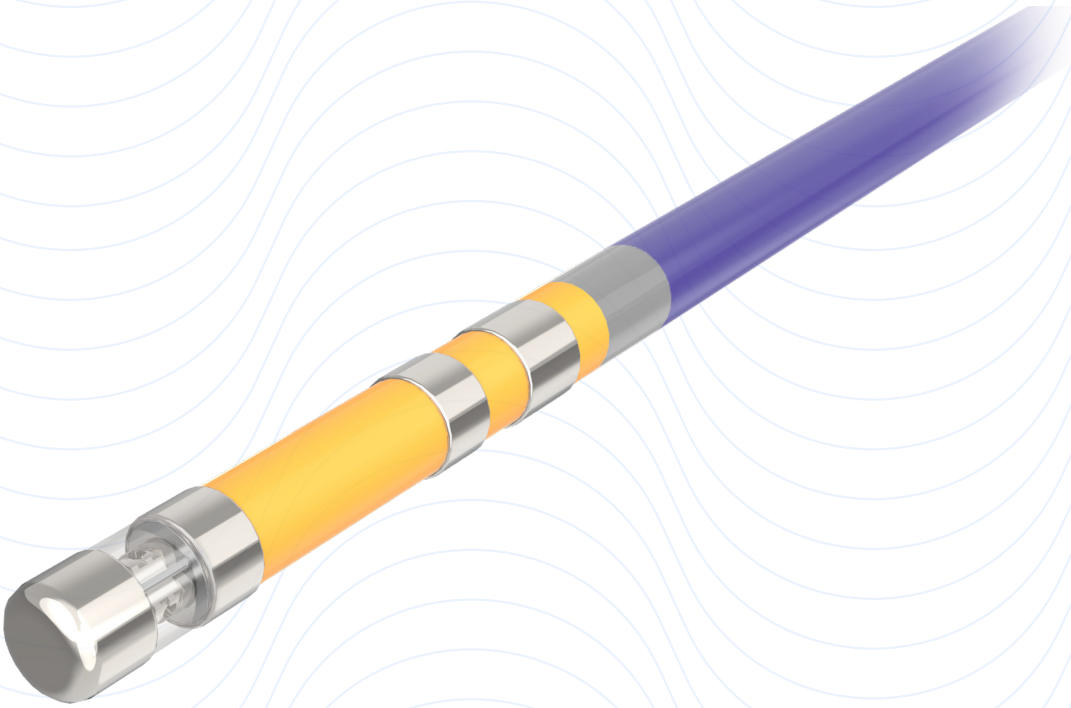

Publication Listing by Topic

Clinical Trial Outcomes Data

- Reddy, et al., Pulsed Field Ablation of Persistent Atrial Fibrillation With Continuous ECG Monitoring Follow-Up: ADVANTAGE AF-Phase 2
- Reddy, et al., Focal Pulsed Field Ablation vs Standard Radiofrequency Ablation for Typical Atrial Flutter: A Sub-study Across Phase 1 and Phase 2 of the Pivotal ADVANTAGE AF Trial
- Malyshev, et al., Does Acute Coronary Spasm From Pulsed Field Ablation Translate Into Chronic Coronary Arterial Lesions?
- Malyshev, et al., Nitroglycerin to Ameliorate Coronary Artery Spasm During Focal Pulsed-Field Ablation for Atrial Fibrillation

Safety

- Reddy, et al., Pulsed Field Ablation of Persistent Atrial Fibrillation With Continuous ECG Monitoring Follow-Up: ADVANTAGE AF-Phase 2
- Reddy, et al., Focal Pulsed Field Ablation vs Standard Radiofrequency Ablation for Typical Atrial Flutter: A Sub-study Across Phase 1 and Phase 2 of the Pivotal ADVANTAGE AF Trial
- Malyshev, et al., Does Acute Coronary Spasm From Pulsed Field Ablation Translate Into Chronic Coronary Arterial Lesions?
- Malyshev, et al., Nitroglycerin to Ameliorate Coronary Artery Spasm During Focal Pulsed-Field Ablation for Atrial Fibrillation

Preclinical:

- Gerstenfeld, et al., Comparison of monopolar or bipolar pulsed field vs. radiofrequency ablation on coronary artery injury in a swine model
- Higuchi, et al., Effect of Epicardial Pulsed Field Ablation Directly on Coronary Arteries

FARAPOINT PFA and/or Other Ablation Modalities

- Reddy, et al., Focal Pulsed Field Ablation vs Standard Radiofrequency Ablation for Typical Atrial Flutter: A Sub-study Across Phase 1 and Phase 2 of the Pivotal ADVANTAGE AF Trial

Preclinical:

- Gerstenfeld, et al., Comparison of monopolar or bipolar pulsed field vs. radiofrequency ablation on coronary artery injury in a swine model
- Im, et al., Pulsed field ablation compared to radiofrequency ablation of left ventricular myocardium in swine infarct model
- Younis, et al., Efficacy of Pulsed Field vs Radiofrequency for the Reablation of Chronic Radiofrequency Ablation Substrate: Redo Pulsed Field Ablation

Lesion Characterization and Lesions Beyond CTI

Preclinical:

- Im, et al., Pulsed field ablation compared to radiofrequency ablation of left ventricular myocardium in swine infarct model
- Kawamura, et al., Electrophysiology, Pathology, and Imaging of Pulsed Field Ablation of Scarred and Healthy Ventricles in Swine
- Younis, et al., Efficacy of Pulsed Field vs Radiofrequency for the Reablation of Chronic Radiofrequency Ablation Substrate: Redo Pulsed Field Ablation

Case Studies

- Saleem, et al., Use of a Focal Pulsed Field Ablation Catheter to Target Premature Ventricular Contractions From the Papillary Muscle

  CAUTION: Investigational Device. Limited by Federal (or US) law to investigational use only.

Clinical Publications

2025

Pulsed Field Ablation of Persistent Atrial Fibrillation With Continuous ECG Monitoring Follow-Up: ADVANTAGE AF-Phase 2

Reddy, VY, Gerstenfeld, EP, Schmidt, B, et al.

Circulation (April 2025), available here

- 255 patients with persistent atrial fibrillation (persAF) underwent pulmonary vein isolation (PVI) and posterior wall ablation (PWA) with the FARAWAVE™ Pulsed Field Ablation (PFA) Catheter; 141 (55%) also received CTI ablation with the FARAPOINT™ Pulsed Field Ablation Catheter to treat typical AFL at operator discretion. NTG regimen was recommended for CTI
- Safety event rate was 2.4% at 3 months with no atrio-esophageal fistula, PV stenosis, or phrenic nerve injury at 12 months. Hemolysis occurred in 0.8% of patients
- Primary effectiveness (modeled intermittent monitoring) was 73.4% at 12 months
- There were no reports of clinical coronary spasm, and no ST changes or ventricular fibrillation were observed in the cohort treated with FARAPOINT ablation on the CTI. No hemolysis was reported in the FARAPOINT cohort
- NTG protocol was used successfully in 99.3% (140/141) of patients. 53.9% of the CTI ablation cohort received only 3 mg initial bolus of NTG. 4 ± 2 mg IV NTG was administered on average
- Procedure time averaged 105 ± 36 minutes; fluoroscopy time was 18 ± 12 minutes

Focal Pulsed Field Ablation vs Standard Radiofrequency Ablation for Typical Atrial Flutter: A Sub-study Across Phase 1 and Phase 2 of the Pivotal ADVANTAGE AF Trial

Reddy, VY, Gerstenfeld, EP, Schmidt, B, et al.

Presented at the Heart Rhythm Society 2025 Annual Scientific Sessions (April 2025)

- Compared patients who received CTI ablation using either a standard RF catheter (n=50) in Phase I or the FARAPOINT PFA catheter (n=141) in Phase II of the ADVANTAGE AF trial
- All patients in the study underwent PVI and PWA with FARAWAVE
- Overall procedure time was significantly shorter in the FARAPOINT PFA-CTI group (106 ± 35 min) compared to RFA-CTI (125 ± 45 min, $p = 0.003$), and fluoroscopy time was also less (16.4 ± 12.3 min vs 24.6 ± 15.2 min, $p < 0.001$)
- CTI ablation time was 8.4 ± 13.0 min for FARAPOINT PFA; not collected for RFA. FARAPOINT PFA on the CTI trended toward fewer applications on average (17.5 ± 6.4 vs 22.5 ± 18.0)
- Safety event rates were similar: 2.1% for FARAPOINT PFA-CTI vs 2.0% for RFA-CTI (p = ns). No coronary spasms were observed in the FARAPOINT PFA group, attributed to the use of NTG
- Freedom from recurrence of typical AFL at 1 year was nearly identical: 97.9% for FARAPOINT PFA-CTI vs 98.0% for RFA-CTI

Clinical Publications

2024

Does Acute Coronary Spasm From Pulsed Field Ablation Translate Into Chronic Coronary Arterial Lesions?

Malyshev Y, Neuzil P, Petru J, et al.

JACC: Clinical Electrophysiology (May 2024), available here

- 30 patients from 3 earlier studies who were previously reported to have developed vasospasm during PFA (with the FARAWAVE or FARAPOINT) underwent follow-up coronary angiography after a median period of 11 months to assess any observed luminal irregularities
- Result: No patients had new coronary abnormalities or stenosis at the site of previous vasospasm, regardless of PFA catheter type
- The study concluded that PFA-induced vasospasm did not appear to routinely lead to chronic coronary stenosis, though larger and longer-term studies are needed to confirm these findings

Reference for Previously Reported Studies

1. Reddy VY, Petru J, Funasako M, et al. Coronary arterial spasm during pulsed field ablation to treat atrial fibrillation.Circulation. 2022; 146:1808–1819.2
2. Malyshev Y, Neuzil P, Petru J, et al. Nitroglycerin to ameliorate coronary artery spasm during focal pulsed field ablation for atrial fibrillation. J Am CollCardiol EP. 2024. doi: 10.1016/j.jacep.2023.12.015
3. Zhang, C, Neuzil P, Petru J, et al. Coronary artery spasm during pulsed field vs radiofrequency catheter ablation of the mitral isthmus. AMA Cardiol.2024;9:72–77. doi: 10.1001/jamacardio.2023.4405

Nitroglycerin to Ameliorate Coronary Artery Spasm During Focal Pulsed-Field Ablation for Atrial Fibrillation

Malyshev, Y, Neuzil, P, Petru, J, et al.

JACC: Clinical Electrophysiology (May 2024), available here

- Aimed to evaluate the vasospastic potential of FARAPOINT and develop a preventive strategy with NTG. Angiography of the RCA was performed before, during, and after PFA with FARAPOINT
- 39 patients (100%) underwent successful PVI and PWA with FARAWAVE. Ablation of the CTI was performed in 38 consecutive patients using FARAPOINT
- CTI ablation provoked moderate-to-severe RCA vasospasm in 80% of patients without NTG pretreatment (fractional flow reserve (FFR) 0.71 ± 0.08). In this cohort of patients, spasm resolved within 12.3 ± 3.6 minutes without additional treatment
- In other patient cohorts, two NTG prophylaxis protocols were tested:
  - RA-Bolus-NTG: 3 mg bolus into the right atrium followed by 3 x 2 mg every 2 minutes (9 mg maximum). Resulted in 0% severe spasm and 20% total spasm
  - RA-Bolus-i-NTG: 3 mg bolus into the RA followed by 1 mg/min peripheral IV infusion. Resulted in 10% severe spasm and 40% total spasm
- There were no adverse events related to PFA, including no ST-segment elevation, ventricular arrhythmias, or ventricular wall motion abnormalities
- CTI ablation was successful in 100% of patients (38/38) with an average of 10.6 ± 3.0 PFA applications
- Total procedure time (including PVI and PWA) averaged 101 ± 22 minutes; Total fluoroscopy time (including PVI and PWA) was 12.0 ± 4/4 minutes
- Study concluded that focal PFA at the CTI routinely caused subclinical RCA spasm, but appropriate NTG prophylactic protocol effectively prevented severe spasm

Preclinical Publications

2025

Comparison of monopolar or bipolar pulsed field vs. radiofrequency ablation on coronary artery injury in a swine model

Gerstenfeld, EP, Bifulco, S, Lehn, L, et al.

Presented at the Heart Rhythm Society 2025 Annual Scientific Sessions (April 2025), available here

- CTI ablation was performed in 12 swine using FARAPOINT PFA at 2.0kV, investigational monopolar focal PFA at 1.4kV and 2.0kV, or RFA, without nitrate prophylaxis. CA angiography was performed prior to and immediately after CTI ablation and then at regular intervals
- Acute CA spasm occurred with 100% of PFA deliveries regardless of catheter, waveform, or voltage; luminal CA narrowing was greater with PFA than RFA
- At 30 days, there was no angiographic CA stenosis, but mild CA injury characterized by neointimal hyperplasia and tunica media fibrosis was noted in swine treated with PFA and RFA
- Results showed that acute coronary spasm occurred more often with PFA than RFA, but similar chronic, mild coronary artery injury may occur with both modalities
- There was no correlation between distance to the right coronary artery or degree of acute spasm with chronic coronary artery injury

2024

Efficacy of Pulsed Field vs Radiofrequency for the Reablation of Chronic Radiofrequency Ablation Substrate: Redo Pulsed Field Ablation

Younis, A, Buck, E, Santangeli, P, et al.

JACC: Clinical Electrophysiology (February, 2024), available here

- 6 swine underwent RFA at three sites: RA (intercaval line with gaps), LA (PVI with gaps and superficial posterior wall ablations), and LV (short chronic RFA)
- After ~5 weeks, animals were re-treated: RA with FARAPOINT, LA with FARAWAVE, and LV randomized to FARAPOINT or RFA. Each group received acute or acute-over-chronic lesions
  - RA: PFA re-ablation resulted in complete block. Chronic RFA lesions went from width of 4 to 7 mm (chronic RFA) to 16 to 28 mm (PFA over chronic RFA)
  - LA: PFA re-ablation resulted in complete PVI and transmural ablation of the PW
  - LV: Avg. depth for acute RFA was 7.6 ± 1.3 mm vs 3.9 ± 1.6 mm in the acute over chronic RFA lesions ($P < 0.01$). In contrast, the mean depth for acute PFA was 7.0 ± 1.6 mm, similar to when ablating with PFA over RFA (7.1 ± 1.3 mm; $P = 0.94$)
- PFA resulted in lesions that were deeper than RFA when ablating over chronic superficial RFA lesions

2023

Electrophysiology, Pathology, and Imaging of Pulsed Field Ablation of Scarred and Healthy Ventricles in Swine

Kawamura, I, Reddy, VY, Santos-Gallego, CG, et al.

Circulation: Arrhythmia and Electrophysiology (January, 2023), available here

- Explored ventricular PFA's ability to penetrate scarred tissue and induce ventricular arrhythmias; assessed the influence of QRS gating during pulse delivery

Preclinical Publications

- PFA (using FARAPOINT) successfully penetrated scar without significant difference in lesion depth between lesion at the infarct border (5.9 ± 1.0 mm, n=41) and healthy myocardium (5.7 ± 1.3 mm, n=26; P=0.53)
- While ungated PFA occasionally induced sustained ventricular arrhythmias (2.1%), gated delivery eliminated this risk entirely
- Compared to conventional imaging, dark-blood late gadolinium enhancement (LGE) MRI provided improved endocardial border detection as well as lesion boundaries
- The study concluded that epicardial lesion creation is feasible and immunohistochemical stains can provide additional insights into early detection of lesions
- PFA effectively penetrated not only myocardial infarction-related scar but also RFA-associated scar, reaching depths of up to 8.6 mm

2022

Pulsed field ablation compared to radiofrequency ablation of left ventricular myocardium in swine infarct model

Im, SI, Higuchi, S, Gerstenfeld, EP, et al.

Heart Rhythm (May, 2022), available here

- Aimed to evaluate the lesion characteristics of PFA (using FARAPOINT and an early version of FARAFLEX™ Mapping and Pulsed Field Ablation Catheter) and RFA in healthy and infarcted LV myocardium in 10 swine
- In infarcted left ventricular tissue, PFA produced significantly deeper lesions than RFA (6.1 ± 1.7 mm vs. 3.8 ± 1.7 mm; p = 0.005), while lesion depth in healthy tissue was comparable (PFA 6.0 ± 1.6 mm vs RFA 6.1 ± 1.7 mm)
- There was no significant difference in histologic lesion depth in healthy myocardium or scar between FARAPOINT vs FARAFLEX
- Among 41 PFA lesions (21 healthy, 20 scarred), no vascular injury occurred—however RFA led to adventitial edema and thrombosis
- PFA safely ablated viable myocardium within scarred tissue with greater lesion depth than RFA

Effect of Epicardial Pulsed Field Ablation Directly on Coronary Arteries

Higuchi, S, Im, SI, Stillson, C, et al.

JACC: Clinical Electrophysiology (October, 2022), available here

- 15 lesions were delivered using FARAPOINT PFA (8 left anterior descending arteries, 3 left circumflexes, and 4 controls)
- Angiography showed acute luminal narrowing (47%) after PFA, which resolved over 30 mins. Epicardial PFA lesions extended into the myocardium with a median depth of 4.1 mm (IQR: 3.6-5.6 mm) passing across the CAs and adipose tissue
- Chronic analysis showed 87.5% had minimal to mild stenosis associated with neointimal hyperplasia and tunica media fibrosis
- Epicardial PFA directly on coronary arteries allowed the creation of myocardial lesions but led to a CA response characterized by acute moderate spasm and chronic mild stenosis via neointimal hyperplasia

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EP-2215206-AA

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