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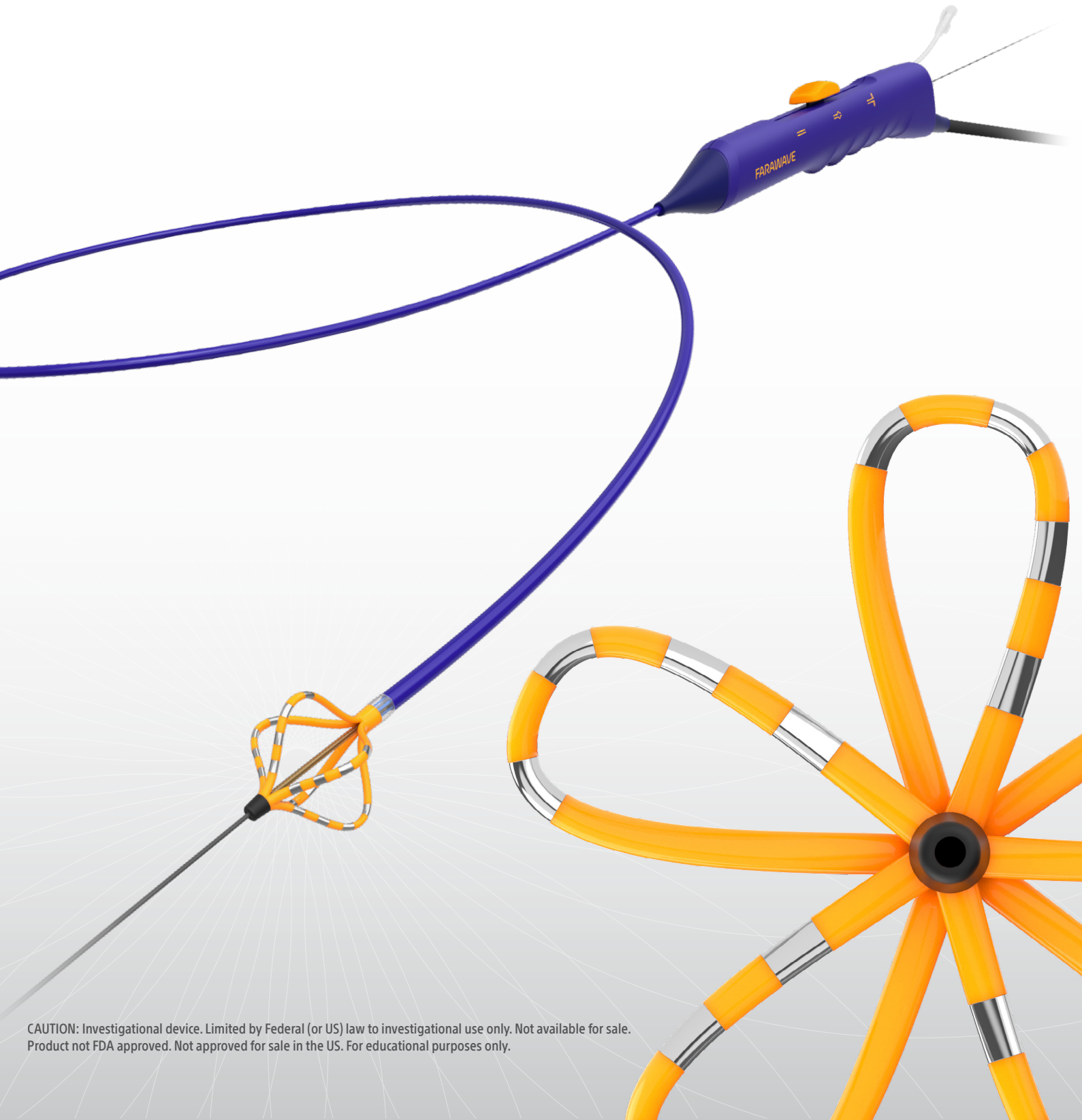
FARAPULSE™
Pulsed Field Ablation System
Clinical Compendium



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*Ablation beyond pulmonary vein isolation is outside the use of labeled indication of the FARAWAVE™ PFA Catheter with the FARAPULSE PFA System

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  *PRECAUTION: Implantable pacemakers and implantable cardioverter/defibrillators may be adversely affected by irreversible electroporation current

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Comparison of Pulsed-Field Ablation versus Very High-Power Short Duration-Ablation for Pulmonary Vein Isolation
Wörmann J, Schipper J, Lüker J, et al.

Journal of Cardiovascular Electrophysiology (October, 2023), available here

- Study that compared the procedural outcome data for PVI between FARAWAVE and very high-power short duration (vHPSD) defined as 70W/7 sec lesions or 70W/5 sec for posterior wall.
- There were 57 patients in each group.
- The FARAWAVE group had significantly shorter procedure duration (65 ± 17 min) versus the vHPSD (95 ± 23 min) with longer fluoroscopy times (15 ± 5 min) vs 12 ± 3 min for vHPSD.
- The freedom from arrhythmia recurrence at a median of 125 days was 80.7% in the FARAWAVE arm versus 77.2% in the vHPSD group.
- Safety event rates were low with 2 tamponades occurring in the FARAWAVE group and 2 groin bleeds in the vHPSD group. One clinically non-significant PV stenosis occurred in the vHPSD group.

Pulsed-Field Ablation Versus Single Catheter High-Power Short-Duration Radiofrequency Ablation for Atrial Fibrillation: Procedural Characteristics, Myocardial Injury and Midterm Outcomes
Badertscher P, Weidlich S, Serban T, et al.

Heart Rhythm (September, 2023), available here

- Compared FARAPULSE to high-power short-duration (HPSD) RF looking at efficiency, safety, myocardial injury and midterm outcomes.
- 115 patients (56% paroxysmal) underwent ablation, 52 patients had FARAPULSE ablation and 63 had HPSD RF ablation.
- PFA procedures were significantly shorter (PFA, 58 [53-71] minutes vs HPSD, 83 [71-99] minutes with significantly longer fluoroscopy times (PFA 13 [10-16] minutes vs HPSD 2.2 [1.3-3.6].
- The postoperative troponin levels were significantly higher in the PFA group (1540 ng/l [1010-1980]) vs HPSD (897 ng/l [725-1240]).
- The AF recurrence free rate at 6 months was 85% for the PFA group and 65% for the HPSD group.
- PFA procedures were shorter, there were higher cardiac troponin levels, and the AF-free survival during mid-term follow-up was similar.

Quantitative Assessment of Transient Autonomic Modulation after Single-Shot Pulmonary Vein Isolation with Pulsed-Field Ablation
Del Monte A, Cespon Fenandez M, Vetta G, et al.

Journal of Cardiovascular Electrophysiology (September, 2023), available here

- Assessed the effects of FARAPULSE ablation on the ganglionated plexi and autonomic nervous system (ANS) by looking at the degree of acute vagal modulation induced immediately following FARAPULSE ablation.
- De novo PVI patients treated with FARAPULSE (n=40) or cryoballoon (n=36) were assessed with extracardiac vagal simulation (ECVS) to capture the effects of ablation. To capture any transient effects, the subgroup was assessed before PVI, immediately after PVI and 10 minutes after the last ablation application.

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- Baseline values were similar, but the vagal response induced by ECVS almost disappeared in the thermal group but persisted in the FARAPULSE group. Intraprocedural vagal reactions occurred more frequently with FARAPULSE than thermal. The heart rate 24-hour post ablation increased more with thermal than PFA ablation.
- In the subgroup with repeated ANS modulation assessment, PFA had a significant acute suppression of vagal response immediately after ablation which recovered almost completely within a few mins after ablation.
- FARAPULSE was found to be associated with only transitory, short vagal effects on the ANS.

Left Atrial Posterior Wall Isolation with Pulsed Field Ablation in Persistent Atrial Fibrillation
Gunawardene M, Frommeyer G, Ellermann C, et al.

*Ablation beyond pulmonary vein isolation is outside the use of labeled indication of the FARAWAVE PFA Catheter with the FARAPULSE PFA System

Journal of Clinical Medicine (September, 2023), available here

- Persistent AF patients were treated with PVI + (n=16) or PVI ++ posterior wall isolation (n=59) with FARAWAVE with 32 patients being de novo and 43 patients were repeat ablation patients.
- In the redo cohort, 67% of all PVs were isolated.
- PVI + PWI had an average procedure time of 91 ± 30 min and two minor complications occurred.
- The 354 ± 197-day freedom from atrial arrhythmias (allowing AADs) in the PVI + PWI cohort was 79.3%.
- PWI guided by FARAPULSE had favorable outcomes with a low number of complications.

Pulsed-Field vs. Cryoballoon vs. Radiofrequency Ablation: A Propensity Score Matched Comparison of One-Year Outcomes after Pulmonary Vein Isolation in Patients with Paroxysmal Atrial Fibrillation
Maurhofer J, Kueffer T, Madaffari A, et al.

Journal of Interventional Cardiac Electrophysiology (September, 2023), available here

- CBA and RFA AF patients were propensity matched to PFA, (PFA, n=40), (CBA, n=80) and (RFA, n=80).
- Median procedure times were the shortest with CBA (75 min), followed by PFA (94 min) and RFA (182 min), with RFA having the lowest fluoroscopy dose.
- After 1-year of follow-up, freedom from any atrial arrhythmia was 85% for PFA, 66.2% for CBA, and 73.8% for RFA.
- With propensity matched patients, the results were favorable for the initial use of PFA versus CBA and RFA.

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Long-Term Clinical Outcomes of Pulsed Field Ablation in the Treatment of Paroxysmal Atrial Fibrillation
Musikantow D, Neuzil P, Anic A, et al.

JACC: Clinical Electrophysiology (September, 2023), available here

- The first long-term safety and recurrence outcomes for the FARAPULSE PFA system in clinical trial patients.
- 121 PAF patients were treated during these feasibility studies (IMPULSE, PEFCAT, PEFCAT II), of which 49 patients were treated with the optimized waveform ("Biphasic II"). DOI: 10.1016/j.jacep.2021.02.014
- 116 patients were included in long term follow-up with a mean follow-up duration of ~4 years [49 +/- 7 months].
- No new adverse events were reported.
- All Follow-Up Results (Years 1-5) - With the optimized biphasic waveform, there was an 81% (38/47) freedom from AF/AFL recurrence.
- Late Recurrence Follow-Up Analysis (Years 2-5) - 95% freedom from AF/AFL/AT (optimized biphasic waveform).

Early Recurrences Predict Late Therapy Failure after Pulsed Field Ablation of Atrial Fibrillation
Plank K, Bordignon S, Urbanek L, et al.

Journal of Cardiovascular Electrophysiology (September, 2023), available here

- 231 AF patients (55% paroxysmal) were analyzed for a medial follow-up of 367 days.
- 46 (21%) experienced early recurrence of atrial tachyarrhythmia (ERAT) after a median of 23 days post-ablation.
- The KM estimated freedom from AF/AT was 74.2% at 1 year, 81.8% for paroxysmal and 64.8% for persistent AF.
  Multivariate analysis found that ERAT and female sex were independent predictors of late recurrence.

Characterization of Durability and Reconnection Patterns at Time of Repeat Ablation after Single-Shot Pulsed Field Pulmonary Vein Isolation
Ruwald M, Haugdal M, Worck R, et al.

Journal of Interventional Cardiac Electrophysiology (September, 2023), available here

- The pulmonary vein durability rate was 69% in repeat ablation patients (n=26) that had a FARAPULSE procedure an average of 292 ± 119 days after the de novo ablation.
- Patients who underwent posterior wall isolation had a durable PW isolation rate of 80% (4/5).
- Reconnection was observed in the LSPV (27%), LIPV (19%), RSPV (35%), RIPV (42%) with the gaps significantly clustered in the right sided anterior carina compared to other regions.

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Pulsed Field or Conventional Thermal Ablation for Paroxysmal Atrial Fibrillation
Reddy VY, Gerstenfeld EP, Natale A, et al.

New England Journal of Medicine (August, 2023), available here, supplement available here

- The ADVENT Pivotal Trial was the first randomized clinical trial that directly compared FARAPULSE™ PFA to standard-of-care thermal ablation devices (force-sensing radiofrequency (RFA) or cryoballoon ablation (CBA)), for the treatment of paroxysmal atrial fibrillation (PAF).
- It included an experienced group of thermal ablators with limited clinical experience with the novel FARAPULSE technology.
- In this RCT, FARAPULSE demonstrated:
  - Non-inferiority for both the primary safety and effectiveness outcomes compared to thermal ablation technology (posterior probability > .999).
  - Significantly less pulmonary vein cross-sectional narrowing compared to thermal ablation (posterior probability > .999).
  - Significantly shorter procedure times, reduced LA dwell time and total ablation time versus thermal ablation. Lower standard deviations across these characteristics also indicate less variability within the PFA procedures.

Comparison of Pulsed Field Ablation and Cryoballoon Ablation for Pulmonary Vein Isolation
Schipper H, Steven D, Lüker J, et al.

Journal of Cardiac Electrophysiology (August, 2023), available here

- Retrospective analysis of de novo paroxysmal or persistent AF PVI with FARAWAVE (PFA) (n=54) and the POLARx Cryoballoon (CBA) (n=54).
- The total procedure times excluding the LA mapping were significantly shorter for the PFA group (58.0 ± 12.5 min) vs CBA (73.0 ± 24.8 min). Fluoroscopy time was significantly longer in the PFA arm. Subgroup analysis showed a significant reduction in procedure time with continued use of FARAPULSE.
- At 273 ± 129 days, the arrhythmia recurrence free rate was similar for both devices, 74% for PFA and 72% for CBA.
- HR changes between baseline and 3 month follow up did not differ between both groups (PFA: 4 ± 8 beats/min, CBA: 4 ± 11 beats/min).

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Pulsed Field Ablation-Based Pulmonary Vein Isolation Using a Simplified Single-Access Single-Catheter Approach — The Fast and Furious PFA Study
Tilz R, Vogler J, Kirstei B, et al.

Circulation Journal (August, 2023), available here

- 50 paroxysmal (56%) and persistent AF patients underwent wide area circumferential ablation (WACA) with FARAPULSE.
- The mean procedure time was 27.4 ± 6.6 min with a mean LA dwell time of 14.4 ± 5.5 min.
- The mean time to ambulation was 3.3 ± 3.1 hours with a low rate of periprocedural complications.
- At a mean follow-up of 6.5 ± 2.1 months, 82% (41/50) patients remained in sinus rhythm.

Pulsed-Field Ablation on Mitral Isthmus in Persistent Atrial Fibrillation - Preliminary Data on Efficacy and Safety
Davong B, Adeliño R, Delasnerie H, et al.
*Ablation beyond pulmonary vein isolation is outside the use of labeled indication of the FARAWAVE PFA Catheter with the F ARAPULSE PFA System

JACC: Clinical Electrophysiology (July, 2023), available here

- PVI, posterior wall (PW) and mitrial isthmus (MI) ablation were performed in 45 patients with persistent AF.
- The acute success of PVI, PW isolation, and MI block was 100%.
- There were 2 (4.4%) coronary artery spasms which were reversible after intravenous nitrate infusion.
- During a mean follow-up of 107 ± 59.5 days, there was a 20% rate of arrhythmia recurrence.

Pulmonary Vein Isolation Durability and Lesion Regression in Patients with Recurrent Arrhythmia after Pulsed Field Ablation
Kueffer T, Stefanova A, Madaffari A, et al.

Journal of Interventional Cardiac Electrophysiology (July, 2023), available here

- Redo ablation was performed on 29/341 (8.5%) of patients for arrhythmia recurrence.
- At 6-months post index ablation, mapping identified 69/110 (63%) durable PV isolation. In 6 (21%) all PVs were durability isolated.
- PV reconnections were often found on the right sided veins and on the anterior aspects of the upper veins.
- Importantly, only minor regression was observed between the index and redo procedures (median of 3 mm).

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Acute Lesion Extension Following Pulmonary Vein Isolation with Two Novel Single Shot Devices: Pulsed Field Ablation versus Multielectrode Radiofrequency Balloon
My I, Lemoine M, Butt M, et al.

Journal of Cardiovascular Electrophysiology (July, 2023), available here

- Compared lesion formation and lesion extent (measured with mapping and biomarkers) between FARAPULSE and HELIOSTAR (multi-electrode RF balloon).
- 60 paroxysmal patients (28 PFA, 32, RF balloon) underwent PVI, high density mapping and Troponin I was quantified.
- The posterior wall ablation area was significantly larger in the PFA group.
- In a subset of 38 patients, the serum Troponin was significantly higher in the PFA group, likely due to it creating larger lesions.

Pulsed Field Versus Cryoballoon Pulmonary Vein Isolation for Atrial Fibrillation: Efficacy, Safety, and Long-Term Follow-Up in a 400-Patient Cohort
Urbanek L, Bordignon S, Schaack D, et al.

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

- 400 patients were treated with FARAPULSE (n=200) or cryoballoon ablation (CBA) (n=200).
- The mean procedure times were significantly shorter in the FARAPULSE group (34.5 [29-40] mins) vs CBA (50 [45-60] mins) with similar fluoroscopy times.
- The overall procedural complication rates were 6.5% in the CBA and 3.0% in the FARAPULSE group driven by a higher rate of phrenic nerve palsy in the CBA group.
- The 1-year freedom from arrhythmia recurrence rates in paroxysmal AF were similar with 83.1% in the CBA group and 80.3% in the FARAPULSE group.

European Real-World Outcomes with Pulsed Field Ablation in Patients with Symptomatic Atrial Fibrillation - Lessons from the Multicenter EU-PORIA Registry
Schmidt B, Bordignon S, Neven K, et al.

EURPOACE (July, 2023), available here

- Registry to study the real-world adoption, workflow, acute and long-term outcomes after pulsed field ablation (PFA) in an all-comer atrial fibrillation (AF) patient population in high-volume European centers, inclusive of learning curve.
- This registry demonstrated consistent, short procedure times with a median of 58 minutes despite a large number of operators with varied experience and workflow.
- There was a low rate of safety events (3.6%) and promising one-year efficacy rate (74%) in a large spectrum of AF patients.
- Operator experience and previous primary ablation modality did not have an effect on the one-year AF/AT recurrence rates showing a rapid adoption of the technology by new operators and prior RF and cryo users.
- A small subset of 149 patients (12%) returned for repeat ablation during follow-up. In these patients, EAM revealed a high rate of PVI with 72% of pulmonary veins being durably isolated.

2023 CLINICAL PUBLICATIONS

Electrophysiological Findings during Re-Do Procedures after Single-Shot Pulmonary Vein Isolation for Atrial Fibrillation with Pulsed Field Ablation
Magni F, Scherr D, Manninger M, et al.

Journal of Interventional Cardiac Electrophysiology (May, 2023), available here

- Patients who had a de novo procedure with FARAWAVE that had recurrence and subsequent repeat ablation (14/447) procedures were analyzed. The mean time to recurrence was 4.9 ± 1.9 months.
- PV reconnection was found in zero (35.7%), one (21.4%), two (14.3%) or three (28.6%) of patients.
- Durable PVI was observed in over 1/3 of redo patients. The most common arrhythmia recurrence following PVI only was AF. Concomitant (35.7%) or isolated AFL/AT (14.3%) recurrence was observed in 50% of patients.

Lesion Formation Following Pulsed Field Ablation for Pulmonary Vein and Posterior Wall Isolation
Sohns C, Fink T, Braun M, et al.

*Ablation beyond pulmonary vein isolation is outside the use of labeled indication of the FARAWAVE PFA Catheter with the FARAPULSE PFA System

PACE (May, 2023), available here

- Lesion formation was assessed with late gadolinium enhancement CMR (LGE-CMR) 3-months after FARAPULSE ablation.
- In 10 patients, PVI and posterior wall isolation (PWI) was performed with FARAWAVE. The mean procedure duration was 62 ± 7 min with a mean LA dwell time of 13 ± 2 min.
- The mean LA scar burden was 8.1 ± 2.1% with a mean scar width of 12.8 ± 2.1 mm. At 7 months, 9/10 (90%) of patients were recurrence free.
- LGE CMR analysis found homogenous and continuous lesion patterns with no evidence of PV stenosis or collateral damage to adjacent structures.

Safety and Effectiveness of Pulsed Field Ablation to Treat Atrial Fibrillation: One-Year Outcomes From the MANIFEST-PF Registry
Turagam MK, Neuzil P, Schmidt B, et al.

Circulation (May, 2023), available here

- Multi-national retrospective survey of all patients treated with FARAPULSE from 24 EU centers (77 operators), 1,568 patients.
- Low complication rates; 1.9% major complication rate and 4.0% minor complication rate with no reported esophageal damage or PV stenosis.
- There was an 81.6% 1-year freedom from AF/AFL/AT for paroxysmal AF patients with no difference in recurrence free outcomes based on the procedural volume (PFA procedure numbers).

2023 CLINICAL PUBLICATIONS

Bronchial Safety After Pulsed-Field Ablation for Paroxysmal Atrial Fibrillation
Füting A, Reinsch N, Brokkaar L, et al.

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

- Respiratory tract CT scans were performed on 60 patients post FARAPULSE ablation to look for bronchial damage with either straight-tip (n=30) or J-tip (n=30) guidewires.
- In 12/30 patients with the straight-tip, extra-stiff guidewire, small amounts of old blood without active bleeding were detected with no evidence of thermal lesions. There was no clinical relevance at 30 days post-procedure.
- Use of the straight-tip guidewire may lead to asymptomatic bronchial damage which was not detected when the J-tip guidewire was used.

Pulsed Field Ablation to Treat Atrial Fibrillation: Autonomic Nervous System Effects
Musikantow DR, Neuzil P, Petru J, et al.

JACC: Clinical Electrophysiology (April, 2023), available here

- Heart rate was assessed pre and post PVI using FARAPULSE (n=40), Cryoablation (n=40) and radiofrequency (n=40) PVI ablation to understand the impact of pulsed field ablation on the ganglionated plexi (GP).
- Between baseline and 3 months, heart rates increased by 8.9 ± 11.4 (RF), 11.1 ± 9.4 (CB), and -0.1 ± 9.2 (PFA) beats/min.
- Unlike thermal ablation, FARAPULSE PFA had minimal effects on the GPs.

PFA for Treatment of AF in Patients with Congenital Anomalies of Cardiac Veins
Castiglione A, Küffer T, Gräni C, et al.
*Ablation beyond pulmonary vein isolation is outside the use of labeled indication of the FARAWAVE PFA Catheter with the FARAPULSE PFA System

Journal of Cardiovascular Electrophysiology (March, 2023), available here

- Five patients with congenital anomalies were treated with FARAPULSE.
- PVs were isolated with no phrenic nerve palsy or other complications.
- Pre-procedural imaging and 3D mapping was found to be well suited, efficient, and versatile in AF patients with anomalous cardiac veins.

2023 CLINICAL PUBLICATIONS

Effects of Pulsed Field Ablation on Autonomic Nervous System in Paroxysmal Atrial Fibrillation: A Pilot Study
Guo F, Wang J, Deng Q, et al.

Heart Rhythm (March, 2023), available here

- Nerve injury biomarkers and DW-MRI were conducted on 18 patients in a pilot study.
- Serum nerve injury biomarkers did not differ between pre- and post--ablation. Heart rate variability did not differ and there were no acute cerebral microemboli events.
- FARAPULSE PVI did not induce nerve injury in this study.

Visualization of Fibroblast Activation Using 68Ga- FAPI PET/CT after Pulmonary Vein Isolation with Pulsed Field Compared with Cryoballoon Ablation
Kupusovic J, Kessler L, Bruns F, et al.

Journal of Nuclear Cardiology (March, 2023), available here

- Fibroblast activation was used as a surrogate for ablation damage after FARAPULSE(n=15) and CBA (n=11) ablation.
- Fibroblast activation tissue response was less pronounced in the PFA patient cohort vs CBA.

A Randomized Controlled Trial of Pulsed Field Ablation versus Standard-of-Care Ablation for Paroxysmal Atrial Fibrillation: The ADVENT Trial Rationale and Design
Reddy VY, Lehmann JW, Gerstenfeld EP, et al.

Heart Rhythm O2 (March, 2023), available here

- The ADVENT (Randomized Controlled Trial for Pulsed Field Ablation versus Standard of Care Ablation for Paroxysmal Atrial Fibrillation) trial was a multicenter, prospective, single-blind, randomized controlled trial comparing PVI using PFA vs conventional thermal (cryoballoon and contact force radiofrequency) ablation for the treatment of drug-resistant paroxysmal AF.

Pulsed Field Ablation in Real-World Atrial Fibrillation Patients: Clinical Recurrence, Operator Learning Curve and Re-Do Procedural Findings
Ruwald MH, Johannessen A, Lock Hansen M, et al.

Journal of Interventional Cardiac Electrophysiology (February, 2023), available here

- 121 patients underwent PVI with FARAPULSE. The mean procedure time was significantly reduced from the initial cases from 85 ± 34 min to 72 ± 18 min.
- There was one phrenic nerve palsy with partial remission at follow-up. The KM event-free estimate at 365 days was 80% (88% paroxysmal, 69% persistent).
- In 5/8 re-do procedures, the gaps were primarily located in the right pulmonary veins.

2022 CLINICAL PUBLICATIONS

Pulsed-Field Ablation for the Treatment of Left Atrial Reentry Tachycardia

Kueffer T, Seiler J, Madaffari A, et al.

*Ablation beyond pulmonary vein isolation is outside the use of labeled indication of the FARAWAVE PFA Catheter with the FARAPULSE PFA System

Journal of Interventional Cardiac Electrophysiology (December, 2022), available here

- Left atrial reentry tachycardia were treated with FARAPULSE (n=22).
- Lesion used to treat the ATs included, 20 roof lines, 13 anterior lines, and 6 mitral isthmus lines with no reported complications.

Findings from Repeat Ablation using High-Density Mapping after Pulmonary Vein Isolation with Pulsed Field Ablation

Tohoku S, Chun J, Bordignon S, et al.

EUROPACE (November, 2022), available at here

- In redo patients initially treated with FARAPULSE using the 5S strategy, the incidence of pulmonary vein (PV) reconnection was assessed (inclusive of learning curve).
- Among the 360 patients, 25 patients (19 paroxysmal) underwent a redo procedure in 6.1 ± 4 months.
- The PV durable isolation rate was 90.9% as assessed by high-density mapping.
- The mechanism of all but one atrial tachyarrhythmia was macro-reentry.
- The mean % of isolated posterior wall surface area was 72.7 ± 19.0%.
- There was a low rate of PV reconnection (9.1%) in redo patients and the unique features of the FARAWAVE catheter design and optimized workflow enabled wide antral lesion creation without regression over time.

Pulsed Field Ablation-Based Pulmonary Vein Isolation in Atrial Fibrillation Patients with Cardiac Implantable Electronic Devices: Practical Approach and Device Interrogation (PFA in CIEDs)

Chen S, Chun J, Bordignon S, et al.

*PRECAUTION: Implantable pacemakers and implantable cardioverter/defibrillators may be adversely affected by irreversible electroporation current

Journal of Interventional Cardiac Electrophysiology (November, 2022), available here

- A pilot patient cohort (n=20) underwent PFA ablation for AF (PVI) with different CIEDs.
- CIEDs included pacemaker, implantable cardioverter-defibrillators (ICD), or cardiac resynchronization therapy plus defibrillator (CRT-D).
- CIED pre- and post-PFA interrogation of the devices showed no significant alterations to the parameters or function of the CIEDs and no lead dislodgement.

2022 CLINICAL PUBLICATIONS

Initial Experience with Pulsed Field Ablation for Atrial Fibrillation
Magni F, Mulder B, Groenveld H, et al.

Frontiers in Cardiovascular Medicine (November, 2022), available here

- 100 subjects (80% paroxysmal AF) underwent AF ablation with FARAWAVE.
- The learning curves of 2 operators (junior/senior) who performed >20 procedures showed no difference in procedure time, senior (46.9 ± 9.7 min) and junior (45.9 ± 9.9 min).
- The 2 complications that occurred were bleeding at the access site.

Pulsed Field Ablation in Patients with Complex Consecutive Atrial Tachycardia in Conjunction with Ultra-High-Density Mapping: Proof of Concept
Gunawardene M, Schaeffer B, Jularic M, et al.
*Ablation beyond pulmonary vein isolation is outside the use of labeled indication of the FARAWAVE PFA Catheter with the FARA-PULSE PFA System

Journal of Cardiovascular Electrophysiology (Sept, 2022), available here

- Fifteen patients with atrial tachycardia (AT) underwent high density mapping to ID critical sites for AT maintenance.
- FARAWAVE ablation was performed with 100% success, 63% terminated with the first application and 2 ATs in the right atrial requiring RF ablation.
- No procedure-related complications occurred.

Pulsed-Field Ablation-Based Pulmonary Vein Isolation: Acute Safety, Efficacy and Short-Term Follow-up in a Multi-Center Real World Scenario
Lemoine MD, Fink T, Mencke C, et al.

Clinical Research in Cardiology (Sept, 2022), available here

- 138 patients (62% persistent AF) from 2 centers were treated with FARAWAVE.
- Mean procedure time was 78 ± 22 min including pre- and post-procedure HD voltage mapping. FARAWAVE LA dwell time was 23 ± 9 min with a fluoroscopy time of 16 ± 7 min.
- There were 3 groin complications (2.2%), 1 pericardial tamponade (0.7%) and 1 transient ST-elevation (0.7%).
- The one-year freedom from recurrence rate was 90% in paroxysmal patients (n = 47) and 60% in persistent AF patients (n = 82).

2022 CLINICAL PUBLICATIONS

Cerebral Safety After Pulsed Field Ablation for Paroxysmal Atrial Fibrillation
Reinsch N, Füting A, Höwel D, et al.

Heart Rhythm (Sept, 2022), available here

- In 30 patients treated with FARAWAVE, Nation Institute of Heath Stroke Scale (NIHSS) scores were assessed 2- and 30-days post PVI. One day after PVI, DW-MRI and FLAIR imaging was done to document the occurrence of silent cerebral events (SCE)/silent cerebral lesions (SCL).
- NIHSS scores were 0 for all patients. Cerebral MRI scans were normal in 29/30 (97%) of patients. In one patient (3%), a single cerebral lesion was observed. 40-days post-procedure, a follow-up MRI cerebral scan showed complete lesion regression.

Catheter Ablation Induced Phrenic Nerve Palsy by Pulsed Field Ablation—Completely Impossible? A Case Series
Pansera F, Bordignon S, Bologna F, et al.

European Journal Case Report (Sept, 2022), available here

- Case series on three patients that had FARAWAVE PFA-induced phrenic nerve (PN) injury during PVI. Cases 1 and 3 had PAF without evidence of structural heart disease and case 2 had Pers AF and ischemic cardiomyopathy with preserved ejection fraction.
- Transient right hemidiaphragm palsy was seen during PFA delivery in the RSPV (Cases 1 and 2) and the RIPV (Case 3).
- The palsy lasted < 1 min and was followed by spontaneous full recovery in all cases (Case 1, 40 sec, Cases 2 and 3 lasted a few seconds).
- Transient PN palsy fully recovered rapidly suggesting PN hyperpolarization of neuronal cells or depletion of acetylcholine in the motoric endplate. Further studies are needed to understand the mechanism.

Multi-National Survey on the Methods, Efficacy, and Safety on the Post-Approval Clinical Use of Pulsed Field Ablation (MANIFEST-PF)
Ekanem E, Reddy VY, Schmidt B, et al.

Europace (August, 2022), available here

- The MANIFEST-PF registry was a retrospective survey of 24 centers with 90 operators, 1758 patients that assessed the real-world performance (use case, acute effectiveness, safety) of FARAPULSE.
- Procedure time was 65 min, fluoroscopy time was 13.7 min. There was a 99.9% mean acute PVI success rate.
- There were no esophageal complications reported, no phrenic nerve injury persisting beyond hospital discharge and no reported PV stenosis. There was a 1.6% rate of major complications, a 3.87% rate of minor complications and 0.46% rate of energy specific adverse events.
- Root cause analysis showed that most of the pericardial tamponades and stroke were attributable to catheter workflow and manipulation, independent of energy modality. Complications were plotted on a timeline, and it indicated an improvement in complication rate over time.

2022 CLINICAL PUBLICATIONS

Pulsed Field Ablation for Pulmonary Vein Isolation: Real-World Experience and Characterization of the Antral Lesion Size Compared with Cryoballoon Ablation
Blockhaus C, Guelker J, Feyen L, et al.

Journal of Interventional Cardiac Electrophysiology (August, 2022), available here

- Single-center study looking at procedural characteristics and the size of acute PVI antral lesions with high-density mapping in 43 patients treated with PFA compared to 20 patients treated with cryoballoon ablation.
- All patients had 100% acute vein isolation with no early reconnections. The acute antral lesion size of PFA lesions (67.03 ± 12.69%) were significantly larger compared to cryoballoon (57.39 ± 10.91%).
- In the PFA group there was no acute phrenic nerve injury, and 1 (4.34%) patient stroke.

Validation of a Multipolar Pulsed-Field Ablation Catheter for Endpoint Assessment in Pulmonary Vein Isolation Procedures
Kueffer T, Baldinger S, Servatius H, et al.

EUROPACE (June, 2022), available here

- In 56 patients undergoing PVI with FARAWAVE, the accuracy of FARAWAVE to detect residual PV connections was assessed with high-density mapping.
- Acute PVI was achieved in 100% of PVs.
- The accuracy of the PV assessment with FARAWAVE was 91%. In 14/213 (6.6% of veins), FARAWAVE incorrectly indicated residual PV conduction due to high-output pace-capture.
- Lowering the output to 5 V/1 ms reduced this observation to 0.9% (2/213) and increased the accuracy to 97%.
- FARAWAVE offered reliable endpoint assessment for PVI and lowering the pacing output increased the accuracy from 91% to 97%.
- At a median of 3.2 months, 3/56 (5.4%) underwent a redo procedure. The durable PV isolation rate was 10/12 (83%).

5S Study: Safe and Simple Single Shot Pulmonary Vein Isolation with Pulsed Field Ablation Using Sedation
Schmidt B, Bordignon S, Tohoku S, et al.

Circulation: Arrhythmia and Electrophysiology (June, 2022), available here

- Single-center study looking at the adoption and the process of streamlining the procedure in the first 191 patients treated with FARAPULSE PFA. Electrogram validation was performed with a circular mapping catheter (CMC) in the first 25 patients, cerebral MRI was performed in 53 patients and esophageal endoscopy was performed in 52 patients.
- Electrogram information was 100% congruent between the CMC and FARAWAVE. PVI rate was 100%. No esophageal temperate rise or esophageal thermal injuries were observed. Two minor strokes occurred in the first 25 patients, likely due to air embolism during catheter exchanges.
- After the first 25 patients, the procedure times were significantly reduced from an average of 46 ± 14 min to 38 ± 13 min. During short term follow-up, 9% (17/191) of patients had atrial arrhythmia recurrence.

2022 CLINICAL PUBLICATIONS

Characterization of Circumferential Antral Pulmonary Vein Isolation Areas Resulting from Pulsed-Field Catheter Ablation
Bohnen M, Weber R, Minners J, et al.

Europace (June, 2022), available here

- In 40 patients, pre- and post-procedure 20-pole circular mapping catheter voltage mapping was done to evaluate PV isolation and area of isolation.
- Isolation gaps were located most frequently in the anterior antral PV segments of the left PVs.
- Additional areas of isolation beyond the antral PV segments were found on the posterior wall and roof regions.

First Experience with Pulsed Field Ablation as Routine Treatment for Paroxysmal Atrial Fibrillation
Füting A, Reinsch N, Höwel D, et al.

Europace (May, 2022), available here

- Single-center 30 patient study looking at phrenic nerve injury and high-density mapping pre-and post-ablation.
- Acute PVI rate was 100%, the median procedure time was 116 min and the FARAWAVE catheter dwell time was 29 min. There was no esophageal or phrenic nerve injury.
- 97% of patients were in sinus rhythm after 90 days.

Troponin Release After Pulmonary Vein Isolation Using Pulsed Field Ablation Compared to Radiofrequency and Cryoballoon Ablation
Krisai P, Knecht S, Badertscher P, et al.

Heart Rhythm (May, 2022), available here

- Troponin T is a measure of myocardial cell death. Troponin T was measured in 60 patients one day before and the morning after PVI ablation with FARAWAVE, radiofrequency or cryoballoon ablation. No additional lesion sets were performed.
- Post-procedure Troponin T levels with PFA were 1.6x and 1.9x higher vs. RF and Cryo, respectively with no significant difference between the RF and cryo groups.

Pulsed Field Ablation Combined with Ultra-High-Density Mapping in Patients Undergoing Catheter Ablation for Atrial Fibrillation: Practical and Electrophysiological Considerations
Gunawardene M, Schaeffer B, Jularic M, et al.

Journal of Cardiovascular Electrophysiology (March, 2022), available here

- 20 consecutive patients underwent PVI with FARAWAVE. Additional ablations were performed off-label in a sub-set of patients. PFA lesion size and decrease in voltage were assessed with high-density voltage mapping.
- High density mapping showed PV reconnection in 5 cases (6.25%). Gaps were located at the anterior-superior PV ostia and were successfully closed with additional PFA. Voltage was significantly decreased following PFA with almost no complex electrogram fractionation at the lesion border zones.
- High-density mapping for FARAWAVE PFA lesion showed wide, antral, circumferential lesion with significantly decreased atrial tissue voltage and little evidence of fraction in the lesion border zones.

2021 CLINICAL PUBLICATIONS

Does Pulsed Field Ablation Regress Over Time? A Quantitative Temporal Analysis of Pulmonary Vein Isolation
Kawamura I, Neuzil P, Shivamurthy P, et al.

Heart Rhythm (June, 2021), available here

- Patients with PAF underwent PVI with FARAWAVE. A comparison of voltage maps immediately after PFA and at a median of 84 days (interquartile range 69–90 days) later revealed that there was no significant difference in either the left and right-sided PV antral isolation areas or nonablated posterior wall area.
- The distances between low-voltage edges on the posterior wall were also not significantly different between the 2 time points.
- The level of PV antral isolation after PFA with FARAWAVE persisted without regression.

Pulsed Field Ablation Prevents Chronic Atrial Fibrotic Changes and Restrictive Mechanics After Catheter Ablation for Atrial Fibrillation
Nakatani Y, Sridi-Cheniti S, Cheniti G, et al.

Europace (May, 2021), available here

- Cardiac magnetic resonance was performed pre-ablation, acutely (< 3 h), and 3 months post-ablation in 41 patients with PAF undergoing PVI with PFA (n = 18) or thermal ablation (n = 23, 16 radiofrequency ablations, 7 cryoballoon ablations).
- Tissue changes were more homogeneous after PFA than after thermal ablation, with no sign of microvascular damage or intramural hemorrhage. In the chronic stage, the majority of acute LGE had disappeared after PFA, whereas most LGE persisted after thermal ablation.
- The maximum strain on PV antra, the LA expansion index, and LA active emptying fraction declined acutely after both PFA and thermal ablation but recovered at the chronic stage only with PFA.
- In this study, PFA induced large acute LGE lesions which mostly disappeared in the chronic stage, suggesting a reparative process involving less chronic fibrosis.

Pulsed Field Ablation of Paroxysmal Atrial Fibrillation: 1-Year Outcomes of IMPULSE, PEFCAT, and PEFCAT II
Reddy VY, Dukkipati SR, Neuzil P, et al.

JACC-EP (May, 2021), available here

- In 3 multicenter studies (IMPULSE, PEFCAT and PEFCAT II), PAF patients underwent PVI using a basket and flower PFA catheter.
- Invasive remapping was performed at 2 to 3 months, and reconnected PVs were reisolated with PFA or radiofrequency ablation. After a 90-day blanking period, arrhythmia recurrence was assessed over 1-year follow-up.
- In 121 patients, acute PVI was achieved in 100% of PVs with PFA alone.
- PV remapping, performed in 110 patients at 93.0 ± 30.1 days, demonstrated durable PVI in 84.8% of PVs (64.5% of patients), and 96.0% of PVs (84.1% of patients) treated with the optimized biphasic energy PFA waveform.
- The 1-year Kaplan-Meier estimates for freedom from any atrial arrhythmia for the entire cohort and for the optimized biphasic energy PFA waveform cohort were 78.5 ± 3.8% and 84.5 ± 5.4%, respectively.

2021 CLINICAL PUBLICATIONS

How Does the Level of Pulmonary Venous Isolation Compare between Pulsed Field Ablation and Thermal Energy Ablation (Radiofrequency, Cryo, or Laser)?
Kawamura I, Neuzil P, Shivamurthy P, et al.

Europace (May, 2021), available here

- In a clinical trial (NCT03714178), PAF patients under-went PVI with FARAWAVE using a biphasic waveform, and after 75 days, detailed voltage maps were created.
- Comparative voltage mapping data were retrospectively collected from consecutive PAF patients who (i) underwent PVI using thermal energy, (ii) underwent re-ablation for recurrence, and (iii) had durably isolated PVs. The left and right PV antral isolation areas and non-ablated posterior wall were quantified.
- There was no significant difference between the PFA and thermal ablation cohorts in either the left- and right-sided PV isolation areas, or the non-ablated posterior wall area.

Pulsed Field Ablation Selectively Spares the Oesophagus During Pulmonary Vein Isolation for Atrial Fibrillation
Cochet H, Nakatani Y, Sridi-Cheniti S, et al.

Europace (February, 2021), available here

- Cardiac magnetic resonance (CMR) imaging was performed before, acutely (< 3 h) and 3 months post-ablation in 41 PAF patients undergoing PVI with PFA (N = 18, FARAPULSE) or thermal methods (N = 23, 16 radiofrequency, 7 cryoballoon).
- Esophageal and aortic injuries were assessed by using late gadolinium-enhanced (LGE) imaging. Phrenic nerve injuries were assessed from diaphragmatic motion on intra-procedural fluoroscopy.
- Acutely, thermal methods induced high rates of esophageal lesions (43%), all observed in patients showing direct contact between the esophagus and the ablation sites.
- Esophageal lesions were observed in no patient ablated with PFA (0%, P < 0.001 vs. thermal methods), despite similar rates of direct contact between the esophagus and the ablation sites (P = 0.41).
- Acute lesions were detected on CMR on the descending aorta in 10/23 (43%) after thermal ablation, and in 6/18 (33%) after PFA (P = 0.52). CMR at 3 months showed a complete resolution of esophageal and aortic LGE in all patients.

Pulsed Field Ablation: A Promise That Came True
Ante A, Breskovic T, Sikiric I.

Current Opinion in Cardiology (Jan, 2021), available here

- Pulsed field ablation is a nonthermal ablative modality that uses short living, strong electrical field created around catheter to create microscopic pores in cell membranes (electroporation). When adequately dosed/ configured it shows a preference for myocardial tissue necrosis.
- First in human series using pulsed field ablation for atrial fibrillation ablation have been completed and data published for several platforms. Acute safety outcomes are similar across the platforms with a low complication rate for complications typically reported for thermal ablation methods (esophageal injury, pulmonary vein stenosis, phrenic nerve palsy).
- Promising acute data on pulmonary vein isolation had been corroborated with satisfactory 1-year clinical follow-up for a single platform (i.e., FARAPULSE), whereas reports are pending for the rest. Research efforts are being expanded to a development of focal catheters, and therefore, pulsed field ablation application for ventricular arrhythmias.

2020 CLINICAL PUBLICATIONS

Pulsed Field Ablation in Patients with Persistent Atrial Fibrillation
Reddy VY, Anic A, Koruth J, et al.

JACC (Sept, 2020), available here

- PersAFOne was a single-arm study evaluating biphasic, bipolar PFA with FARAWAVE for PVI and LAPW ablation to assess the safety and lesion durability of pulsed field ablation (PFA) for both PVI and LAPW ablation in persistent AF.
- In 25 patients, acute PVI (96 of 96 pulmonary veins) were 100% acutely successful with the FARAWAVE catheter. Using the focal PFA catheter, acute cavotricuspid isthmus block was achieved in 13 of 13 patients.
- Post-procedure EGD and repeat cardiac computed tomography revealed no mucosal lesions or PV narrowing, respectively.
- Invasive remapping at 2 to 3 months demonstrated durable isolation (defined by entrance block) in 82 of 85 PVs (96%) and 21 of 21 LAPWs (100%) treated with the pentaspline catheter.

Ostial Dimensional Changes After Pulmonary Vein Isolation: Pulsed Field Ablation vs. Radiofrequency Ablation
Kuroki K, Whang W, Eggert C, et al.

Heart Rhythm (May, 2020), available here

- Data were analyzed from 4 PAF ablation trials using either PFA or RFA.
- Baseline and 3-month cardiac computed tomography scans were reconstructed into 3-dimensional images, and the long and short axes of the PV ostia were quantitatively and qualitatively assessed in a randomized blinded manner.
- PV ostial diameters decreased significantly less with PFA than with RFA (% change; long axis: 0.9% ± 8.5% vs. −11.9% ± 16.3%; $P < .001$ and short axis: 3.4% ± 12.7% vs. −12.9% ± 18.5%; $P < .001$).
- PV narrowing/stenosis was present in 0% and 0% vs. 12.0% and 32.5% of PVs and patients who underwent PFA and RFA, respectively.
- In this study, unlike after RFA, the incidence and severity of PV narrowing/stenosis after PV isolation was virtually eliminated with PFA.

2019 CLINICAL PUBLICATIONS

Pulsed Field Ablation for Pulmonary Vein Isolation in Atrial Fibrillation
Reddy VY, Neuzil P, Koruth JS, et al.

JACC (July, 2019), available here

- Two trials were conducted to determine whether PFA allows durable pulmonary vein (PV) isolation without damage to collateral structures, in patients with PAF.
- Ablation was performed using proprietary bipolar PFA waveforms: either monophasic with general anesthesia and paralytics to minimize muscle contraction, or biphasic with sedation because there was minimal muscular stimulation. No esophageal protection strategy was used. Invasive electrophysiological mapping was repeated after 3 months to assess the durability of PV isolation.
- 81 patients, all PVs were acutely isolated by monophasic (n = 15) or biphasic (n = 66) PFA. With successive waveform refinement, durability at 3 months improved from 18% to 100% of patients with all PVs isolated. Beyond 1 procedure-related pericardial tamponade no additional primary adverse events over the 120-day median follow-up, including: stroke, phrenic nerve injury, PV stenosis, and esophageal injury.

2018 CLINICAL PUBLICATIONS

Ablation of Atrial Fibrillation with Pulsed Electric Fields
Reddy VY, Koruth J, et al.

JACC-EP (April, 2018), available here

- The first acute clinical experience of AF ablation with PFA, both epicardial box lesions during cardiac surgery, and catheter-based PVI.
- PFA was performed using a custom over-the-wire endocardial catheter for percutaneous transseptal PV isolation, and a linear catheter for encircling the PVs and posterior left atrium during concomitant cardiac surgery.
- Catheter PV ablation was successful in 15 patients (100%) 57 PVs Using 3.26 lesions/PV and surgical box lesions were successful in 6 of 7 patients (86%) 2 lesions/patient. No complications.

2023 PRECLINICAL PUBLICATIONS

Electrophysiology, Pathology, and Imaging of Pulsed Field Ablation of Scarred and Healthy Ventricles in Swine
Kawamura I, Reddy V, Santos-Gallego C, et al.

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

- 6 swine were infarcted to assess penetration of scar, risk of arrhythmias and lesion imaging evaluation.
- FARAPULSE PFA successfully penetrated scar without significant differences in the lesion depth of infarcted tissue (5.9 ± 1.0 mm) vs healthy (5.7 ± 1.3 mm) myocardium.
- In ungated QRS PFA applications, sustained ventricular arrhythmias requiring defibrillation occurred in 4/187 (2.1%) applications with zero occurring during gated applications.
- Dark-blood late-gadolinium-enhanced sequences allowed for improved endocardial border detection.

2022 PRECLINICAL PUBLICATIONS

Effect of Epicardial Pulsed Field Ablation Directly on Coronary Arteries
Higuchi S, Im S, Stillson C, et al.

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

- 4 swine, FARAWAVE lesions were delivered directly to the left anterior descending artery, left circumflex artery or normal myocardium.
- Angiography was performed to quantify the degree of coronary artery narrowing and histology was performed at 4 and 8 weeks.
- Acute luminal narrowing immediately after PFA was 47% which gradually resolved over 30 minutes.
- Epicardial lesions had a median depth of 4.1 mm and 87.5% of the arteries had minimal to mild stenosis via neointimal hyperplasia.

Pulsed Field Ablation of Left Ventricular Myocardium in a Swine Infarct Model
Im S, Higuchi S, Lee A, et al.

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

- 10 swine were infarcted to evaluate how PFA and RF perform in areas of myocardial scar.
- In myocardial scar, lesion depth was not different between the FAWAVAVE or the FOCAL PFA catheter.
- In myocardial scar, lesion depth was significantly greater for PFA vs. RF.
- In a pre-clinical animal model, unlike RF, FARAPULSE PFA was able to effectively ablate surviving islands of myocardium in infarct-related ventricular substrate.

2020 PRECLINICAL PUBLICATIONS

Pulsed Field Ablation vs Radiofrequency Ablation: Esophageal Effects in a Novel Preclinical Model
Koruth JS, Kuroki K, Kawamura I, et al.

Circulation: Arrhythmia and Electrophysiology (January, 2020), available here

- A novel preclinical model was created to nonsurgical assess the response to esophageal injury. This was accomplished by delivering the energy source from within the inferior vena cava, against the esophagus (which was purposefully mechanically deviated towards the IVC).
- Biphasic pulsed field ablation induced no chronic histopathologic esophageal changes, whereas radiofrequency catheter ablation demonstrated a spectrum of esophageal lesions including esophageal ulcers, abscess, and fistula.

2019 PRECLINICAL PUBLICATIONS

Preclinical Evaluation of Pulsed Field Ablation: Electrophysiological and Histological Assessment of Thoracic Vein Isolation
Koruth JS, Kuroki K, Iwasawa J, et al.

Circulation: Arrhythmia and Electrophysiology (December, 2019), available here

- In this study, the safety, efficacy, and durability of achieving catheter-based electrical isolation of PVI using optimized monophasic and biphasic PFA waveforms and describe procedural and histological characteristics of PFA in swine atrial tissue.
- Both waveforms created confluent myocardial lesions that demonstrated a myocardial-specific ablative effect.
- Biphasic PFA was more durable than monophasic PFA and radiofrequency ablation lesions.

Endocardial Ventricular Pulsed Field Ablation: A Proof-of-Concept Preclinical Evaluation
Koruth JS, Kuroki K, Iwasawa J, et al.

EP Europace (December, 2019), available here

- Assessment of safety and feasibility of FARAPULSE PFA in swine ventricles with a prototype steerable endocardial catheter.
- Gross measurements, available for 28 of 30 ablation sites, revealed average lesion dimensions to be 6.5 ± 1.7 mm deep and 22.6 ± 4.1 mm, with a maximum depth and width of 9.4 mm and 28.6 mm respectively. In PFA lesions, fibrous tissue homogeneously replaced myocytes. When present in the lesion zone, nerve fascicles and vasculature were preserved.

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