PLACE 2026
PLATFORM OF LABORATORIES FOR ADVANCES IN CARDIAC EXPERIENCE

CONGRESSO
ROMA, 25 - 27 Giugno 2026

MAPPING, IMAGING E CATETERI IBRIDI

# When signal matters: the critical role of electrode spacing in Pulsed Field Ablation

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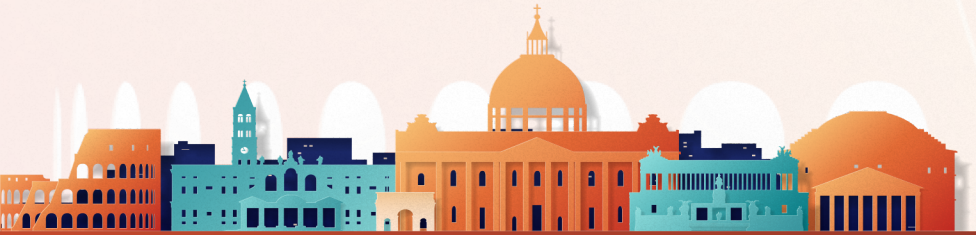


# Conflitti di interesse

- Medtronic: fees for proctorships, speaker activity and advisory board membership

# Current state and unmet needs in EP

The incidence and prevalence of AF are rapidly rising, justifying the term "**global epidemic**"[1]

**1 out of 3 patients** above the age of 35 will experience AF in their lifetime[2]

With 60 million AF patients[3] today, **5 million patients will be added** every year by 2030[4]

## EP continues to demand:

Efficient procedural workflows[5]

More predictable clinical outcomes[5]

Safe and durable lesions[5]


- [1] Kornej J, et al. *Circ Res*. 2020;127:4-20.
- [2] Hindricks G, et al. 2020 ESC Guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS): The Task Force for the diagnosis and management of atrial fibrillation of the European Society of Cardiology (ESC) Developed with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC. *Eur Heart J*. 2021;42:373-498. Erratum in: *Eur Heart J*. 2021;42:507. Erratum in: *Eur Heart J*. 2021;42:546-547. Erratum in: *Eur Heart J*. 2021;42:4194.
- [3] Roth GA, et. al. *J Am Coll Cardiol*. 2020;76:2982-3021.
- [4] Di Carlo A, et al. *Europace*. 2019;21:1468-1475.

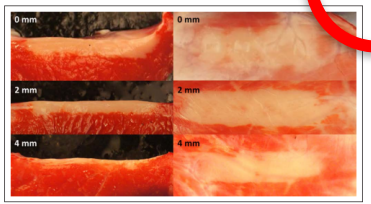
# COMPLEXITY OF PFA PARAMETERS

**Catheter design dependent**

- Bipolar vs Unipolar
- Electrode material
- Electrode design
  - ✓Shape
  - ✓Electrode size
  - ✓Number of electrodes
  - ✓Ectrode spacing (if more than one electrode)

**Ablation preset or generator preset**

- Electric filed Distribution
- Pulse parameters
  - ✓duration (ns to ms)
  - ✓Number
  - ✓Frequency (pulse repetition)
  - ✓Voltage applied
  - ✓Current measured

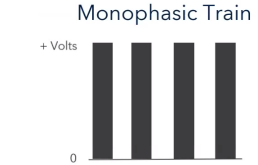


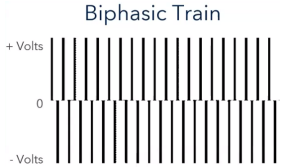

**Operator dependent**

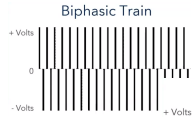
Electrode positioning with respect to target tissue

**Generator dependent**

Application parameters
- Shape
- Duration






Howard et all. Circ Arrhythm Electrophysiol. 2022;15:e011110

Farapulse
First Cases in Italy July 2022

PulseSelect
First Cases in Italy March 2024

Varipulse
First Cases in Italy in April 2024

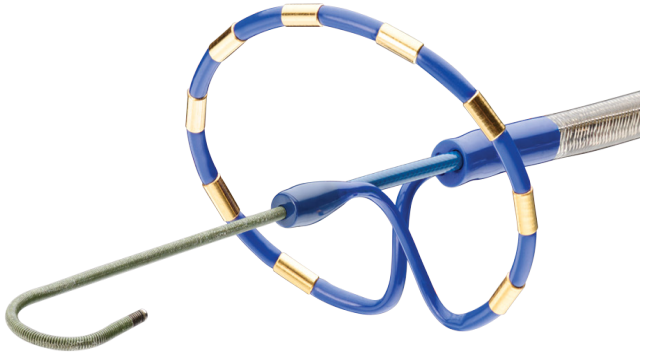
Sphere 9 - Affera
First Cases in Italy December 2024

Volt
First Cases in Italy May 2025

Farapoint
First Cases in Italy March 2026

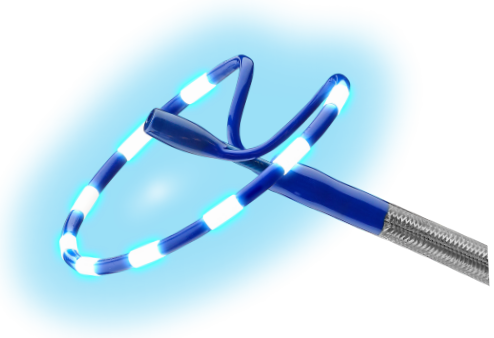
# System Safety features

- Automatic overcurrent detection for safe energy delivery
- R-wave gating for synchronization of energy delivery
- Test pulse for detection for phrenic nerve proximity



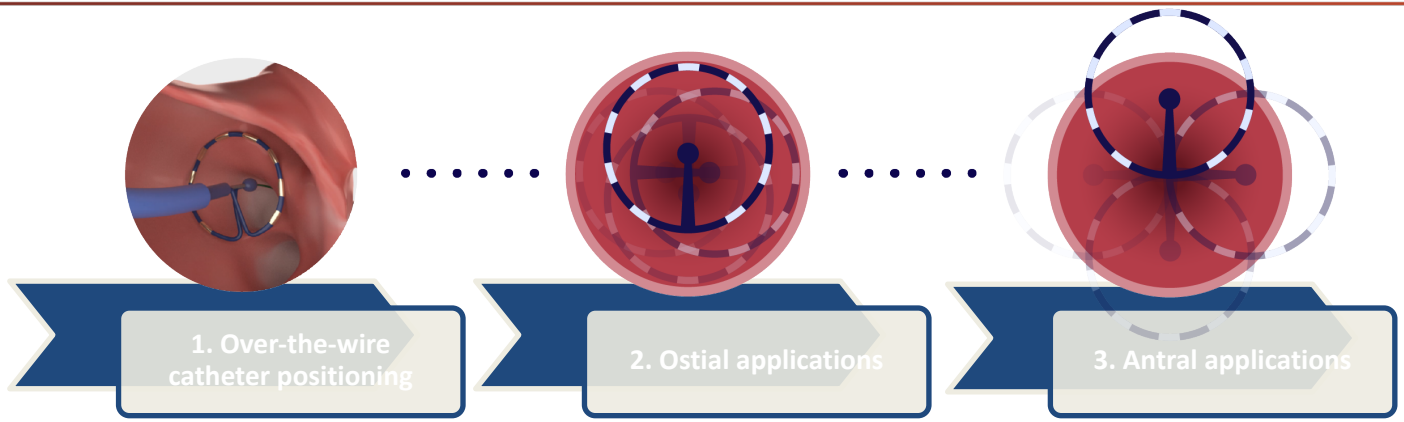
## **Fixed electrode distance** means:

- **Predictable** electric field in tissue;
- No undershoot with **certain** lesion formation;
- No overshoot with **no safety issues.**

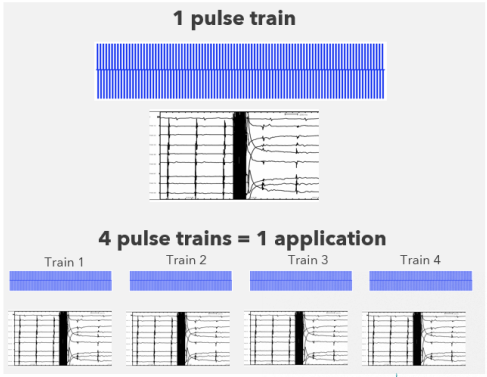


- 9 electrodes built to **sense, ablate and pace**
- **25 mm** diameter loop
- **20°** forward tilted array
- **9 Fr** shaft with bidirectional steering
- **0.032”** over-the-wire design

# PVI Ablation Strategy

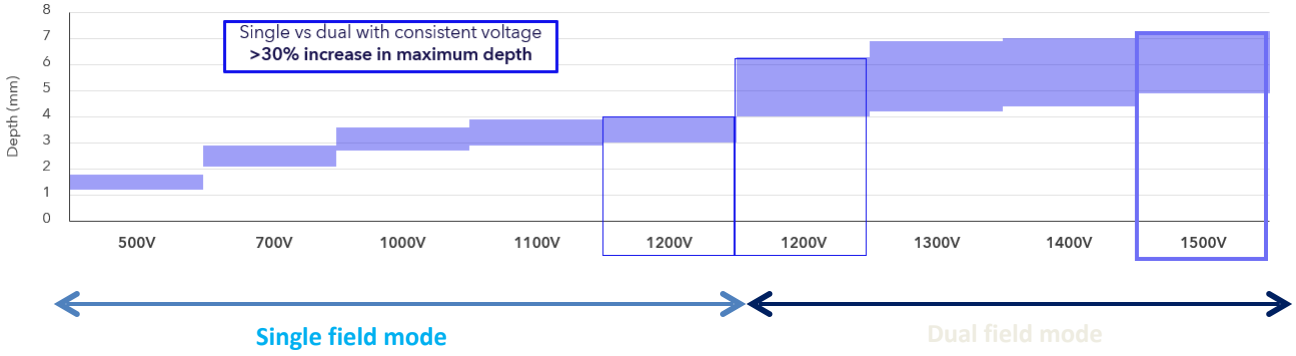


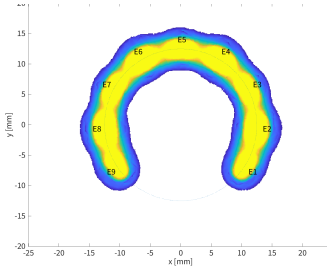

- **4 pulse trains** delivered per application
- **1 application per catheter positions**
- Standard approach: **4 ostial** and **4 antral** applications
- Number of applications may vary based on **anatomy or signal**

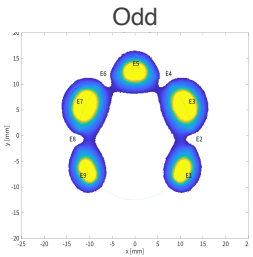


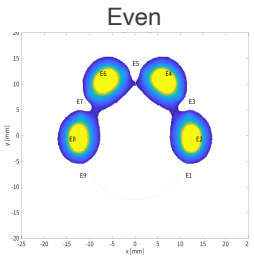
# Advanced bipolar vectoring and field shaping

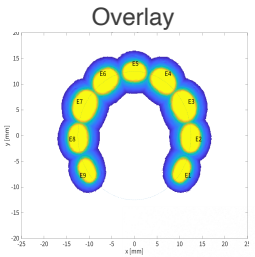
- **Vectoring used to maximize field depth while limiting voltage required**





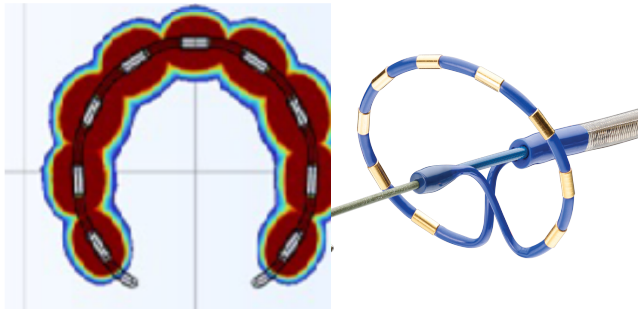



# Catheter shape and energy vectoring – electrode spacing

## Fixed electrode spacing and effects on electric field distribution

Electrode distance may affect lesion formation and safey

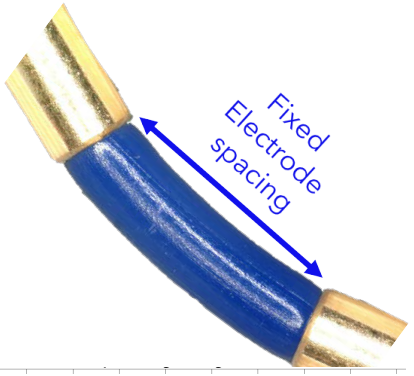


**Fixed electrode distance** means:

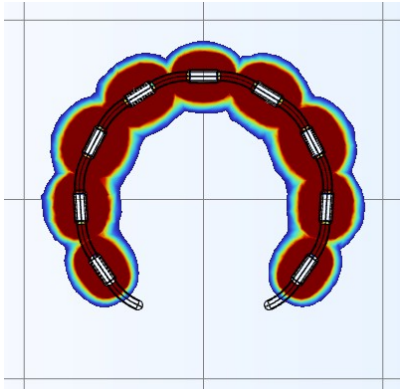
- **Predictable** electric field in tissue
- No undershoot with **certain** lesion formation
- No overshoot with **no safety issues**

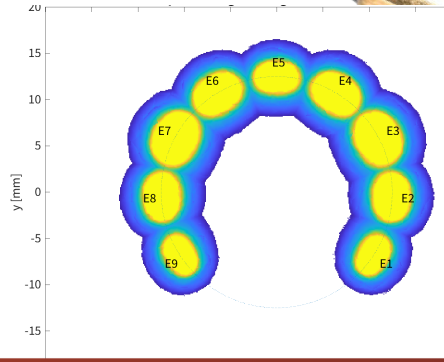
## Fixed Electrode Spacing

Consistent field regardless of catheter position[1]




Fixed Equal spaced






1 Howard, Brian, et al. "Effects of Electrode-Tissue Proximity on Cardiac Lesion Formation Using Pulsed Field Ablation." Circulation: Arrhytmia and Electrophysiology. (2022).

Circulation: Arrhythmia and Electrophysiology

ORIGINAL ARTICLE

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

Atul Verma, MD; Lucas Boersma, MD; David E. Haines, MD; Andrea Natale, MD; Francis E. Marchlinski, MD; Prashanthan Sanders, MBBS; Hugh Calkins, MD; Douglas L. Packer, MD; John Hummel, MD; Birce Onal, PhD; Sofi Rosen, PhD; Karl-Heinz Kuck, MD; Gerhard Hindricks, MD; Bradley Wilsmore, MBBS

**Table 5. Electrical Isolation of PVs**

| | n | Electrical isolation achieved, % |
|---|---|---|
| All patients | 38 | 100% |
| All PVs | 152 | 100% |
| Left superior PV | 37 | 100% |
| Left common PV | 1 | 100% |
| Left inferior PV | 37 | 100% |
| Right superior PV | 38 | 100% |
| Right middle PV | 1 | 100% |
| Right inferior PV | 38 | 100% |

PV indicates pulmonary vein.

**Table 6. Adverse Event Incidence in PULSED AF**

| | Adverse event | No. of adverse events (n=38) |
|---|---|---|
| SAEs included in the primary safety end point | Pulmonary vein stenosis (>70% diameter reduction) | 0/38 |
| | Phrenic nerve injury/diaphragmatic paralysis ongoing at 30 d post-ablation | 0/38 |
| | Atrioesophageal fistula | 0/38 |
| | Cardiac tamponade/perforation | 0/38 |
| | Cerebrovascular accident | 0/38 |
| | Major bleeding requiring transfusion | 0/38 |
| | Myocardial infarction | 0/38 |
| | Pericarditis requiring intervention | 0/38 |
| | Transient ischemic attack | 0/38 |
| | Vagal nerve injury resulting in esophageal dysmotility or gastroparesis | 0/38 |
| | Vascular access complications requiring intervention | 0/38 |
| | Death | 0/38 |
| | Any PFA system-related or PFA procedure-related cardiovascular and pulmonary adverse event that prolongs or requires hospitalization for >48 h (excluding recurrent AF/AFL/AT) | 0/38 |
| Serious procedure-related events | Vascular access site hemorrhage | 1/38 |

AF indicates atrial fibrillation; AFL, atrial flutter; AT, atrial tachycardia; PFA, pulsed field ablation; PULSED AF, Pulsed Field Ablation to Irreversibly Electroporate Tissue and Treat AF; and SAE, serious adverse event.

- ✓ 100% pulmonary vein isolation was achieved using only PFA
- ✓ No PFA system–related serious adverse events

*Verma et al. Circ Arrhythm Electrophysiol.* 2022;15:e010168. DOI: 10.1161/CIRCEP.121.010168

Circulation

ORIGINAL RESEARCH ARTICLE

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

Atul Verma, MD; David E. Haines, MD; Lucas V. Boersma, MD; Nitesh Sood, MD; Andrea Natale, MD; Francis E. Marchlinski, MD; Hugh Calkins, MD; Prashanthan Sanders, MBBS; Douglas L. Packer, MD; Karl-Heinz Kuck, MD; Gerhard Hindricks, MD; Birce Onal, PhD; Jeffrey Cerkvenik, MS; Hiroshi Tada, MD; David B. DeLurgio, MD; on behalf of the PULSED AF Investigators

non-randomized clinical study

**Global multicenter study**

- **9 countries**
- **41 sites**
- **67 operators**

## Safety outcomes

0 Esophageal events 0

PV stenosis

0 Phrenic nerve injury

**Safety**

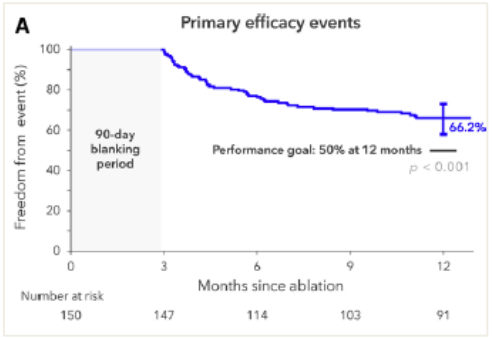
**0.7%**

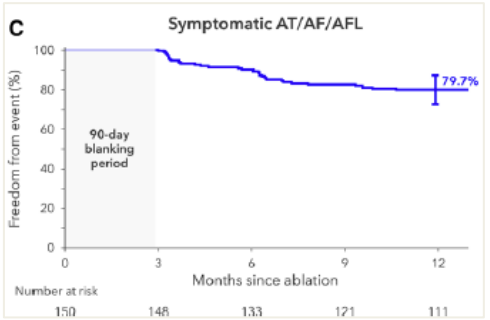
Primary adverse events

1/300 Stroke / TIA/ Tamponade
0/300 Transient ischemic attack
0/300 Major bleeding
0/300 Myocardial infarction 0/300 Pericarditis

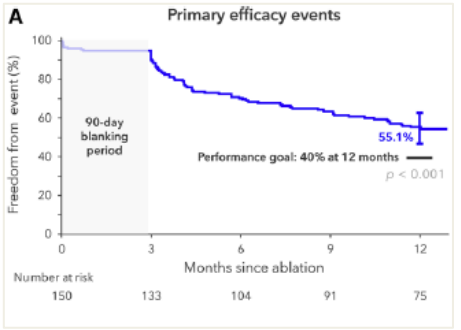
0/300 Vagal nerve injury
0/300 Vascular access complications
0/300 Cardiovascular Hospitalization
0/300 Death
0/300 pulmonary edema
0/300 systemic pulmonary embolism

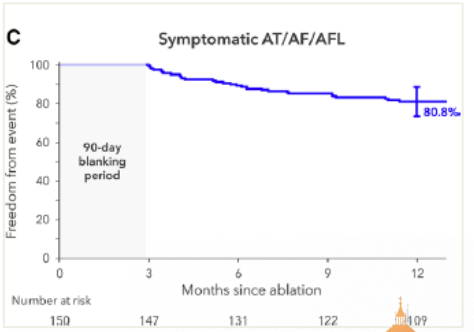
## 150 Paroxysmal AF Patients




## 150 Persistent AF Patients



# Pivotal Study- Dati Procedurali

Circulation

ORIGINAL RESEARCH ARTICLE

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

Atul Verma, MD; David E. Haines, MD; Lucas V. Boersma, MD; Nitesh Sood, MD; Andrea Natale, MD; Francis E. Marchlinski, MD; Hugh Calkins, MD; Prashanthan Sanders, MBBS; Douglas L. Packer, MD; Karl-Heinz Kuck, MD; Gerhard Hindricks, MD; Birce Onal, PhD; Jeffrey Cerkvenik, MS; Hiroshi Tada, MD; David B. DeLurgio, MD; on behalf of the PULSED AF Investigators

- 89 % delle procedure in **anestesia generale**
- 95% delle procedure con usi di **mappaggio /sistema di navigazione**
- **Tempo procedura**: 135/145 min con 20 min di attesa da protocollo
- **N° applicazioni/procedura** 48/57

Including 20 minutes waiting time

| Measure | Paroxysmal (n=150) | Persistent (n=150) |
|---|---|---|
| Skin-to-skin procedural time, min* | 134±50; 125 (102–157) | 145±60; 133.5 (107–173) |
| Device left atrial dwell time, min† | 65±29; 58.5 (46–76) | 70±31; 62.5 (51–84) |
| Time between first and last application, min† | 58±28; 53 (40–68) | 64±28; 60 (45–77) |
| Fluoroscopy time during procedure, min | 26±17‡; 21 (15–31) | 29±21; 23 (14–38) |
| Total pulsed field ablation energy delivered, s | 25±8; 23 (19–28) | 29±10; 27 (23–34) |
| Number of applications per procedure | 48±15; 43.5 (37–54) | 57±20; 52.5 (44–67) |
| Type of anesthesia used | | |
| General | 134 (89) | 126 (84) |
| Deep sedation | 8 (5) | 10 (7) |
| Conscious sedation | 8 (5) | 14 (9) |
| Neuromuscular blockade use | 7 (5) | 11 (7) |
| Isoproterenol or adenosine used to assess PVI | 26 (17) | 33 (22) |
| Intraprocedural cardioversions | 25 (17) | 98 (65) |
| Esophageal temperature change from baseline, °C | 0.4±0.5§; 0.3 (0.1–0.5) | 0.3±0.4‖; 0.2 (0.0–0.5) |
| Mapping/navigation system used | | |
| CARTO | 39 (26) | 35 (23) |
| EnSite | 86 (57) | 88 (59) |
| Rhythmia | 17 (11) | 15 (10) |
| None of the above | 8 (5) | 12 (8) |

# Pulsed field ablation (PFA) durability research[1,2]

Reproducible durability[1,2] in paroxysmal (PAF) and persistent (PsAF) patients using the PulseSelect™ PFA system

**Nair, et al.[1]**

**25**
PAF and PsAF patients

Remapped at **~60 days**

Durable PVI confirmed

**98%** per vein
102/104 pulmonary veins durably isolated

**96%** per patient
24/25 patients all PVs durably isolated

**Verma, et al.[2]**

**15**
PAF and PsAF patients

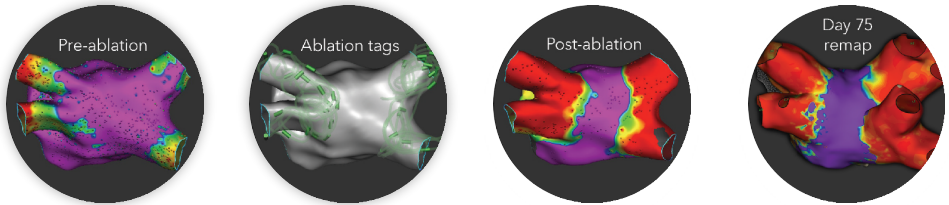
Remapped at **~75 days**

Durable PVI confirmed

**95%** per vein
52/55 pulmonary veins durably isolated

**93%** per patient
14/15 patients all PVs durably isolated

**Reproducible durability[1,2]**
**with the PulseSelect PFA system**




**Verma, et al.[2] Voltage maps created using the Affera™ mapping system**

•1. Nair, et al. First Invasive remapping to assess long term durability of pulmonary vein isolation using a circular pulsed field ablation catheter. Presented at APHRS 2024.
•2. Verma A, et al. Chronic Durability of Pulmonary Vein Isolation using the PulseSelect Pulsed Field Ablation Catheter Integrated with a Novel Mapping and Navigation System. AF Symposium; January 16–18, 2025; Boston, MA.

# Unlocking New Clinical Opportunities

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

Giulio Molon[1] · Stefano Nardi[2] · Gianfranco Mitacchione[3] · Antonio Dello Russo[4] · Danilo Ricciardi[5] · Roberto Mantovan[6] · Luca Bontempi[7] · Alessandro Costa[1] · Luigi Argenziano[2] · Edoardo Casali[8] · Vincenzo Turco[8] · Giuseppe Boriani[8]

### Study details and design

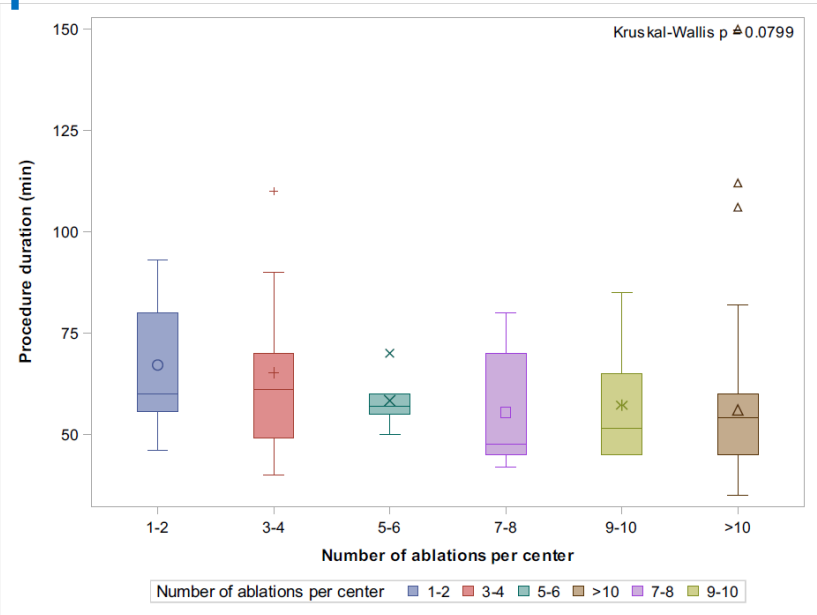
- **Multicenter** observational study
- Included the **first consecutive patients** who underwent PVI using the PulseSelect system at six European centers
- Focused on patients with **atrial fibrillation (AF)**

### Patient population and Operator Experience

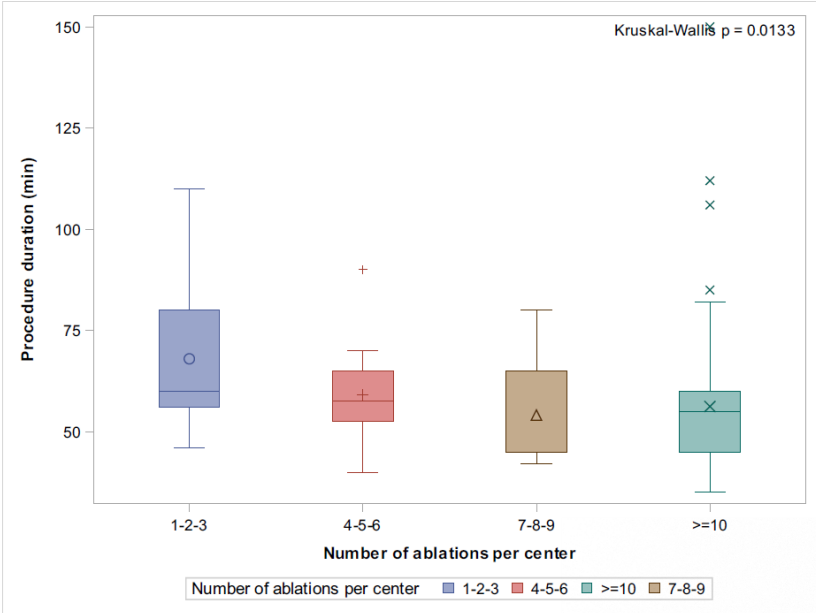
- Patients with **symptomatic AF**
- Both **paroxysmal** and **persistent** AF cases were represented
- Procedures were performed by **operators with varying levels of experience** with the new technology

Molon, G., Nardi, S., Mitacchione, G., Dello Russo, A., Ricciardi, D., Mantovan, R., Bontempi, L., Costa, A., Argenziano, L., Casali, E., Turco, V., & Boriani, G. (2025). *Acute outcomes and learning curve from the initial patients treated with the PulseSelect system: A real-world multicenter experience of pulsed field ablation*. *Journal of Interventional Cardiac Electrophysiology, 68*(7), 1475–1485. https://doi.org/10.1007/s10840-025-02036-5

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




Reduction in procedural times when procedures are grouped in pairs.




More pronounced decrease in procedural durations when procedures are grouped in sets of three.

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

Patients (**mean age 61.7** — 9.7 years; **31.3% female**) had predominantly **paroxysmal AF (80.9%)**. Median procedural and fluoroscopy times were 55.0 and 16.0 min, respectively. General anesthesia was used in 75.5% of cases, while in the remaining 24.5% moderate sedation protocols allowed procedures (even in 15.1% without an anesthesiologist). Acute PVI success was 100%, and no major complications were observed. A short learning curve was noted, with significant reductions in procedural times after the initial 2–3 cases at each center.

- The PulseSelect system showed short procedural times, with a rapid learning curve, thus leading with high procedural efficiency.
- In 1 out of 4 cases general anesthesia was not applied, and no major complications were observed.
- Notably, no esophageal, complications, symptomatic pulmonary vein stenosis, or persistent phrenic nerve injuries were observed

# The REAL PULSE global registry: real-world acute efficacy and safety outcomes for the use of a circular multielectrode array pulsed field ablation system for atrial fibrillation treatment

Atul Verma, MD, Giulio Molon, MD ..... and Lucas Boersma, on behalf of the REAL PULSE Registry Investigators

**REAL PULSE global registry** (NCT06393920) is an ongoing, prospective, post-market study that **evaluates procedural efficacy and safety outcomes** associated with a **circular multielectrode array PFA system** (PulseSelect, Medtronic, USA). **Acute procedure characteristics, efficacy, and safety outcomes are presented here**.

Patients with **paroxysmal atrial fibrillation (PAF) and persistent (PsAF)** were enrolled at **26 sites globally across 9 countries in Europe (Netherlands, Italy, France, Spain, Germany), North America (US, Canada), and Asia (China, South Korea)** from July 2024 to December 2025, and monitored by local standards-of-care. These data include enrolled patients that received ***de novo*** **AF ablation.**

**Table 3. Primary Safety Event reported within 7 days of Index Procedure All (N=760)**

| | |
|---|---|
| Pulmonary vein stenosis requiring intervention | 0 |
| Phrenic nerve injury/diaphragmatic paralysis | 0 |
| Atrioesophageal fistula | 0 |
| Cardiac tamponade/perforation | 0 |
| Cerebrovascular accident / TIAs | 0 |
| Vascular complications with intervention | 0 |
| Death | 0 |

# Clinical data – hemolysis

## PFA-related hemolysis: Comparison between technologies

C Gianni, A Al-Ahmad, M Elchouemi, V Micro La Fazia, S Mohanty, JD Allison, MA Bassiouny, WD Bode, JD Burkhardt, PC Coffeen, GJ Gallinghouse, RP Horton, D Kessler, JE Sanchez, A Natale. Circulation: Arrhythmia and Electrophysiology. 2025. DOI. 10.1161/CIRCEP.125.014021.

**Reason to Read:** Incidence and severity of hemolysis varies with different PFA devices.

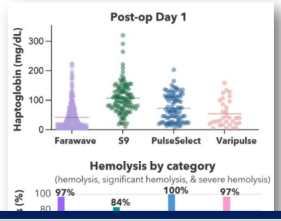
*Patients and Design:*

- 554 AF patients with PFA and haptoglobin (Hp) measured at baseline and day 1 post-operative.
  - PFAs: 59% Farawave, 19% Affera S9, 16% PulseSelect, & 6% Varipulse.
- 3 categories of Hp reduction: hemolysis (Hp reduction >10 mg/dL), significant hemolysis (Hp post-op day 1 ≤25 mg/mL), and severe hemolysis (Hp post-op day 1 ≤10 mg/mL).

*Results:*

- Hp decreased by mean of 76±4 mg/dL from baseline for total cohort.
  - Greatest reduction in Farawave (94±4 mg/dL) and Varipulse (85±3 mg/dL) compared with Pulseselect (62±3 mg/dL) o
- Hemolysis observed in majority of cases (95%),
  - Significant and severe hemolysis occurred
    Farawave with 46% & 21%, Varipuls
    23% & 1%, and Sphere-9 with 5% &
- Linear relationship between Hp reduction and nu
  - Hp decreased per application, including: 0.
- 23 of 520 (4.4%) patients with hemolysis develo

Authors conclude that PFA-induced hemolysis was




## Hemolysis, myocardial and neural injury after monopolar PFA using a novel lattice-tip catheter to treat AF

C Gold, P Pratz, A Falagkari, V Johnson, F Post, E Roth, J Kupusovic, J Erath-Honold, D Linz, D Leistner, R Wakil, L Rottner. Europace. 2025. DOI: 10.1093/europace/euaf210

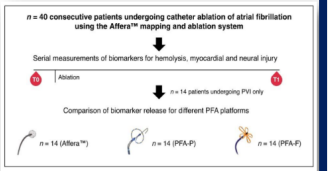
**Reason to Read:** Insights into safety and tissue-specific effects of different PFA technologies for AF, highlighting waveform and catheter design influences.

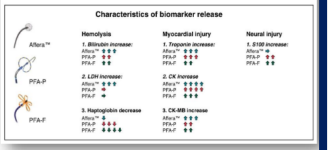
*Patients and Design:*

- Biomarkers for hemolysis, myocardial injury, neurocardiac injury and renal function assessed pre- (T0=Baseline) and within 24h post-ablation (T1).
- Analysis of first-time PVI-only procedures comparing biomarker changes:
  - N=14 Sphere-9 (MDT): Affera; Monopolar, monophasic
  - N=14 PulseSelect (MDT): PFA-P, bipolar, biphasic
  - N=14 Farapulse (Boston Sci): PFA-F, bipolar, biphasic

*Main results (see Figure for the summary of all results):*

- Hemolysis occurred across all PFA platforms:
  - Most pronounced A Haptoglobin decrease in PFA-F (Farapulse; P<0.001)




FA-F,

Affera.

is common and occurs across all PFA platforms.

s with no indication of neural damage.

## THE PULSESELECT ADVANTAGE:

**New Study Further Confirms Superior Safety Profile to Farapulse**

A newly accepted Heart Rhythm publication from McGill University (Canada) adds another important data point to the growing body of evidence supporting a more favorable hemolysis profile for PulseSelect compared to Farapulse.

**Study context**

- 224 patients (PAF+PERS) were evaluated by 4 experienced operators
- 209 patients treated with PulseSelect™ (circular array a Farapulse (pentaspline system)
- PVI alone was performed in 73 patients, with additional non-PV lesion sets (e.g. posterior wall) in the remainder

The authors clearly acknowledge that this is not an even split between technologies, and that the Farapulse cohort is small. Importantly, they took steps to address this limitation analytically, and their results are consistent with other publications, both pre-clinical work and the growing body of real-world evidence.

**What the analysis showed:**

- Predictors of significant hemolysis, two factors emerged: Higher lesion count and use of a Farapulse catheter
- With PulseSelect, increases in hemolysis biomarkers were mild, including when posterior wall isolation was performed they still remained within the mild range.
- In contrast, in the Farapulse arm, hemolysis biomarkers were double, despite a similar number of applications.

Publication

# Take Home Message

- Effective in achieving PVI
- Safety confirmed
- Shorter procedure time
- Short learning curve