

Medtronic

Setting a new standard in safety

Engineered for efficiency



PulseSelect™
Pulsed Field
Ablation System

PULSED AF¹ clinical summary

PULSED AF demonstrated safety and effectiveness of the PulseSelect™ pulsed field ablation (PFA) system for the treatment of patients with **paroxysmal (PAF)** and **persistent (PsAF)** atrial fibrillation.

Unmatched safety

One of the lowest safety event rates of any IDE trial for AF ablation to date.



0 Esophageal events



0 Phrenic nerve injury



0 PV stenosis



0 Coronary artery spasm

1/300 Cerebrovascular accident
1/300 Tamponade

0/300 Transient ischemic attack
0/300 Major bleeding

0/300 Myocardial infarction
0/300 Pericarditis

0/300 Vagal nerve injury
0/300 Systemic pulmonary embolism

0/300 Pulmonary edema

0/300 Vascular access complications

0/300 Cardiovascular hospitalization

0/300 Death

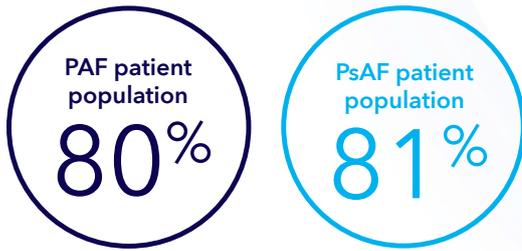
Proven efficacy

Freedom from
AF/AT/AFL



Clinical success

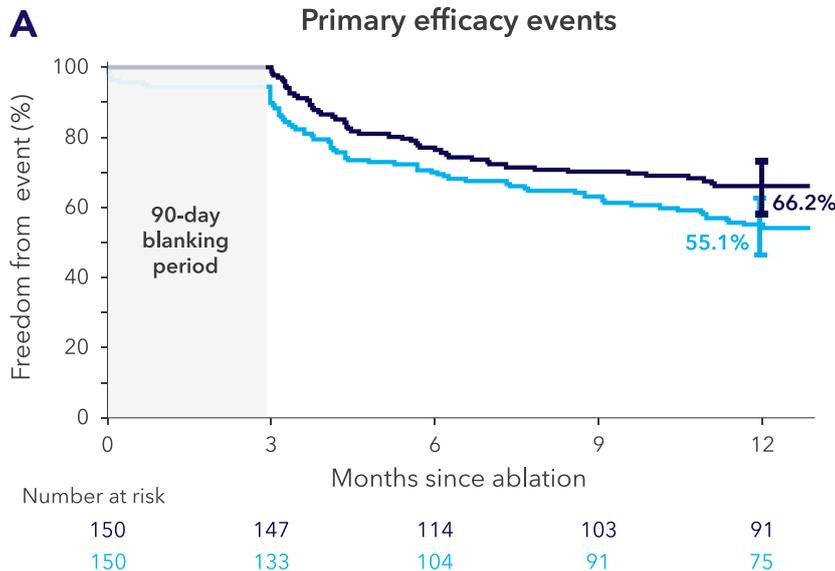
Freedom from recurrence of any symptomatic atrial arrhythmias (post-hoc analysis).



Primary effectiveness

(composite endpoint definition)

Acute procedure failure, AF/AFL/AT recurrence, cardioversion, repeat ablation, new/re-initiated/increased AADs, any subsequent AF surgery.



Quality-of-life scores improved post-ablation compared to baseline



AFEQT score improved by 29.4 (95% CI, 25.8 to 33.1) **and 29.0** (95% CI, 25.5 to 32.5) points in the paroxysmal and persistent populations respectively from baseline to 12 months.



EQ-5D-5L score improved by 0.05 (95% CI, 0.02 to 0.08) points in paroxysmal **and 0.06** (95% CI, 0.04 to 0.09) points in persistent atrial fibrillation patients.

Rigorous arrhythmia monitoring

1

2

3

3-month ECG

4

5

6-month ECG

24-hour Holter monitoring

6

7

8

9

10

11

12-month ECG

24-hour Holter monitoring

Weekly and symptomatic transtelephonic monitoring

12

Trial design and study population

Trial design

Paired single-arm, prospective, nonrandomised clinical study.



Global multicentre study

9 countries: Austria, Belgium, France, Spain, Netherlands, United States, Canada, Australia, Japan.

41 sites

67 operators

150 Paroxysmal

150 Persistent

300 patients total

The study population included recurrent symptomatic paroxysmal and persistent atrial fibrillation patients refractory to class I or III antiarrhythmic drugs.

91%

first use of the PulseSelect system

High-quality follow up and compliance



Completed 12-month follow-up



Holter compliance



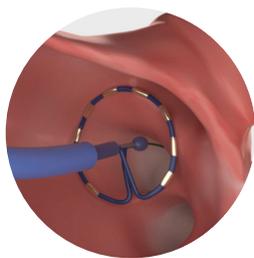
ECG compliance



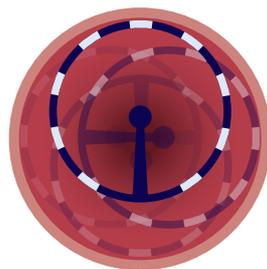
TTM compliance

Intuitive stepwise approach to PVI[‡]

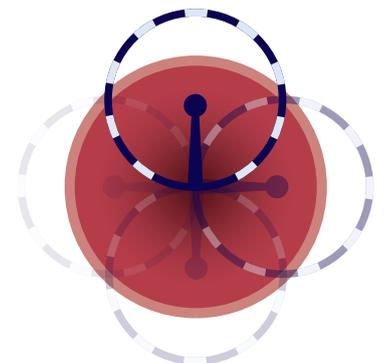
- Recommended minimum of eight applications per vein
- Tailorable based on anatomy size and shape



Over-the-wire catheter positioning



Ostial applications
Stepwise catheter rotation for overlapping lesions

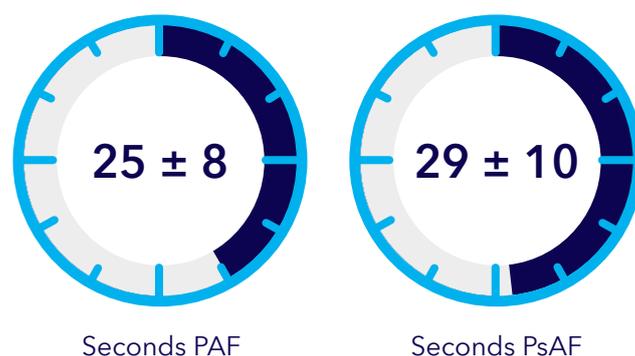
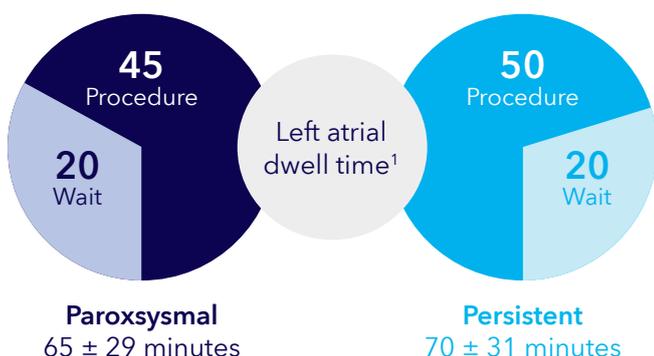


Antral applications
Stepwise catheter rotation for overlapping lesions

Engineered for efficiency

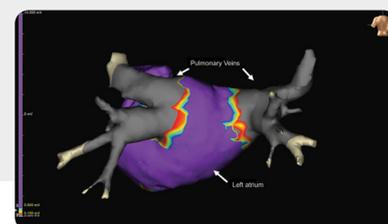
Procedure times 50 minutes or under
when excluding the 20-minute trial-mandated wait period.

Total PFA energy delivery under 30 seconds



Parameter	Paroxysmal (n = 150)	Persistent (n = 150)
Skin-to-skin procedural time (min) [‡]	134 ± 50	145 ± 60
Device left atrial dwell time (min) [‡]	65 ± 29	70 ± 31
Fluoroscopy time during procedure (min)	26 ± 17 [§]	29 ± 21
Number of applications per procedure	48 ± 15	57 ± 20

The PulseSelect™ system was used in conjunction with multiple commercially available mapping systems.



PULSED AF patients were sedated with general anesthesia, deep sedation or conscious sedation, and paralytics were not required.

[‡]87% of operators performed less than 10 cases during trial

[‡]Operators targeted pulmonary vein isolation using a wide antral approach during PULSED AF procedures.

[§]Data were available for 149 patients.

¹ Verma A, Haines DE, Boersma LV, et al. Pulsed Field Ablation for the Treatment of Atrial Fibrillation: PULSED AF Pivotal Trial. *Circulation*. May 9, 2023;147(19):1422-1432.

Product CE Mark according to law.

See the device manual for information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at www.medtronic.eu.

For applicable products, consult instructions for use on manuals. medtronic.com. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat®* Reader with the browser.

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