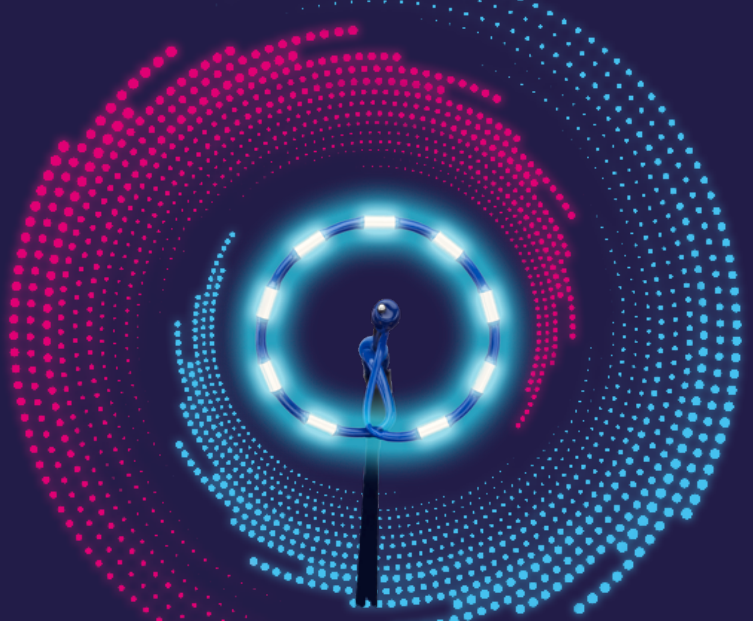
Medtronic

PULSED AF Pivotal Trial Overview



PULSED AF evaluated the safety and effectiveness of the PulseSelect™ Pulsed Field Ablation System for the treatment of patients with paroxysmal or persistent atrial fibrillation. PulseSelect™ Pulsed Field Ablation System is an investigational device that has not been approved for commercial use in EU.

- 0 Esophageal events
- 0 PV stenosis
- 0 Phrenic nerve injury
- 0 Coronary artery spasm

0.7%
Primary safety events

1/300 Stroke	0/300 Pericarditis
1/300 Tamponade	0/300 Vagal nerve injury
0/300 Transient ischemic attack	0/300 Vascular access complications
0/300 Major bleeding	0/300 Cardiovascular Hospitalization
0/300 Myocardial infarction	0/300 Death

Quality of life

Improved significantly and clinically meaningful

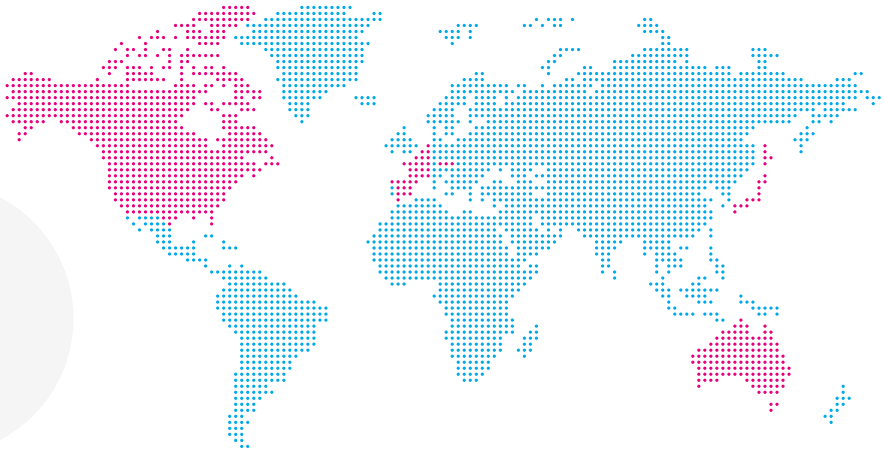
AFEQT score improved by 29.4 and 29.0 (95% CI, 25.5 to 32.5) points in the paroxysmal and persistent populations respectively from baseline to 12 months.

EQ-5D-5L score improved by 0.05 points in paroxysmal **and 0.06** points in persistent atrial fibrillation patients.

Trial design & study population

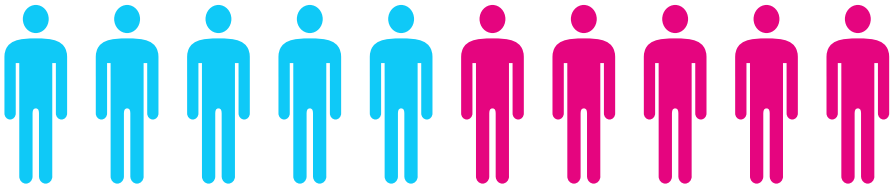
Trial design

Prospective controlled paired single arm clinical study

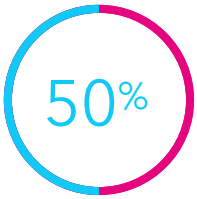


Global multicenter study

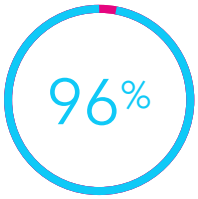
9 countries: Australia, Austria, Belgium, Canada, France, Japan, Netherlands, Spain, United States.
41 sites
67 operators



150 Paroxysmal
150 Persistent

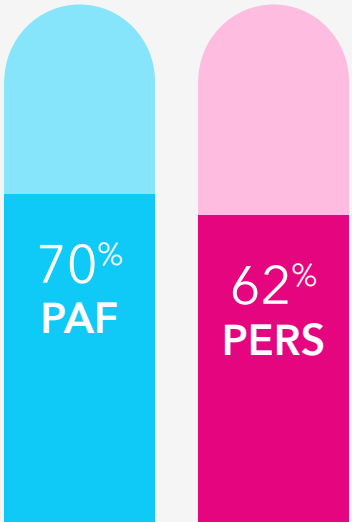


The study population included 50% (150) recurrent symptomatic paroxysmal, and 50% (150) persistent atrial fibrillation patients refractory to class I or III anti-arrhythmic drugs.



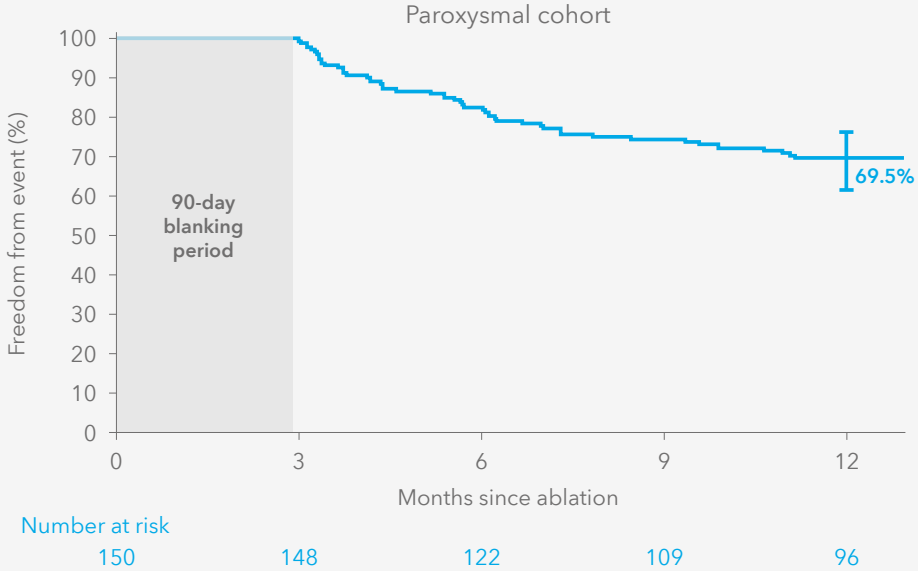
96% (287) of patients completed 12-month follow up.

Freedom from AF/AT/AFL



AT/AF/AFL

Paroxysmal cohort



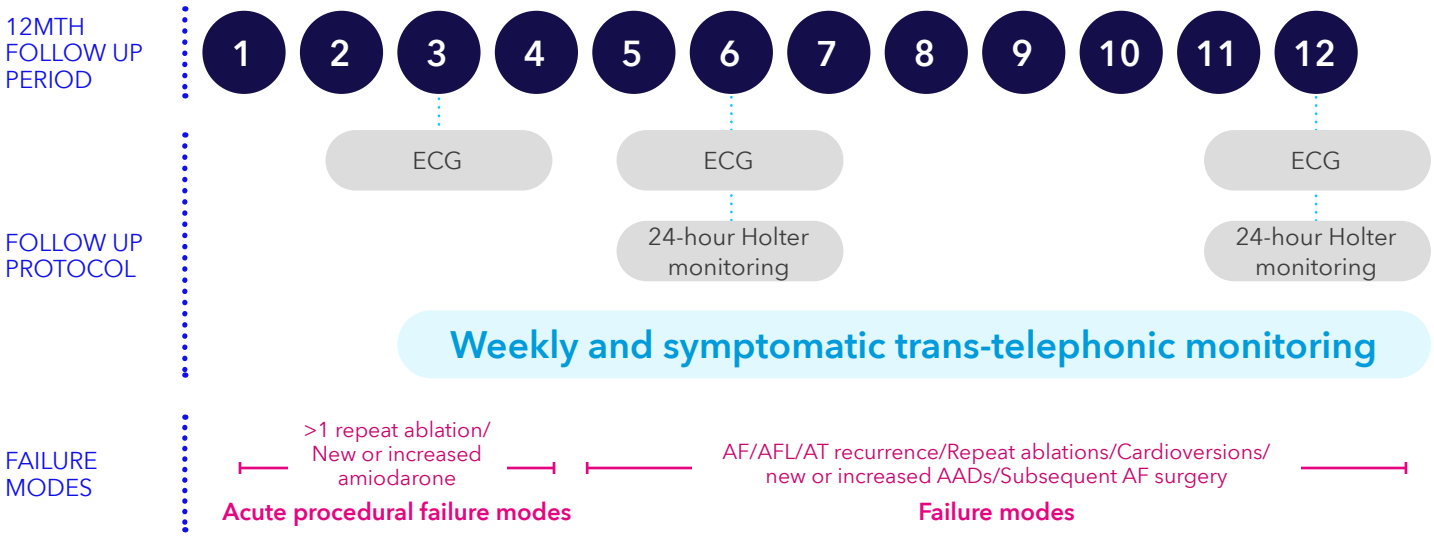
Outcomes

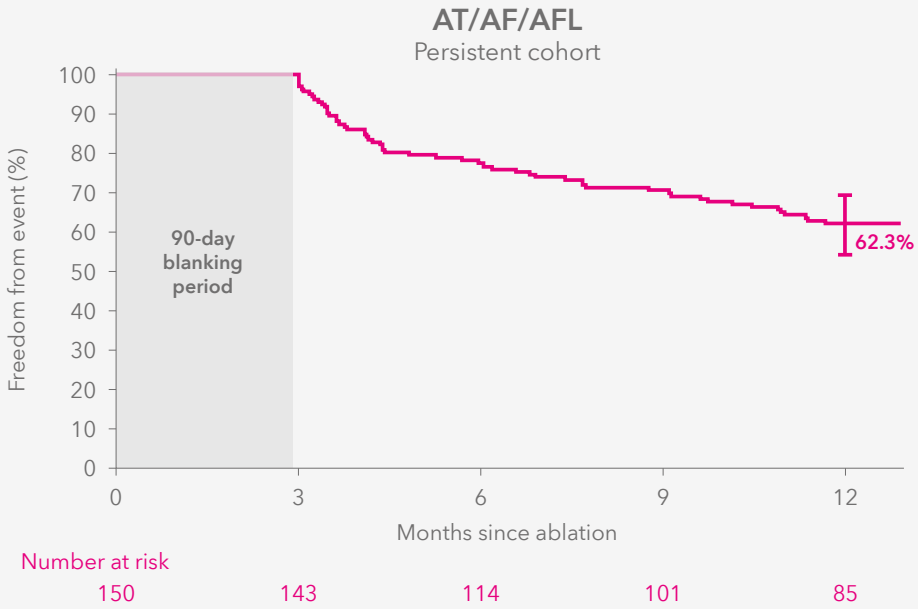
80% PAF

Freedom from recurrence of any symptomatic atrial arrhythmias

81% PERS

Rigorous arrhythmia monitoring





Primary effectiveness

66% PAF

55% PERS

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

Efficiency

Time between first and last application

Paroxysmal AF
58± 28 minutes

Persistent AF
64 ± 28 minutes

Procedure times under 50 minutes

when excluding the 20 minute trial-mandated wait period.

Total PFA energy delivery under 30 seconds

67 operators

91% first use of the PulseSelect system

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Caution: The products are limited to investigational use only and are not approved for commercial use in any geography. CE Mark pending.

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