Medtronic

Setting a new standard in safety

Engineered for efficiency

PulseSelect™ Pulsed Field Ablation System

PULSED AF[1] 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[1,2]

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

0.7%
safety event rate

- 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

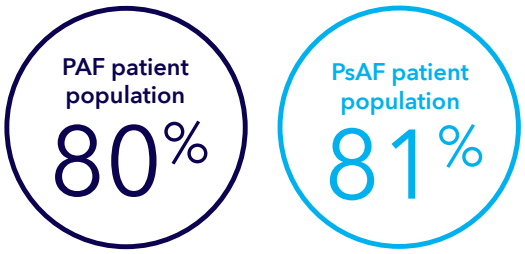
Freedom from AF/AT/AFL

70%
PAF

62%
PsAF

Clinical success

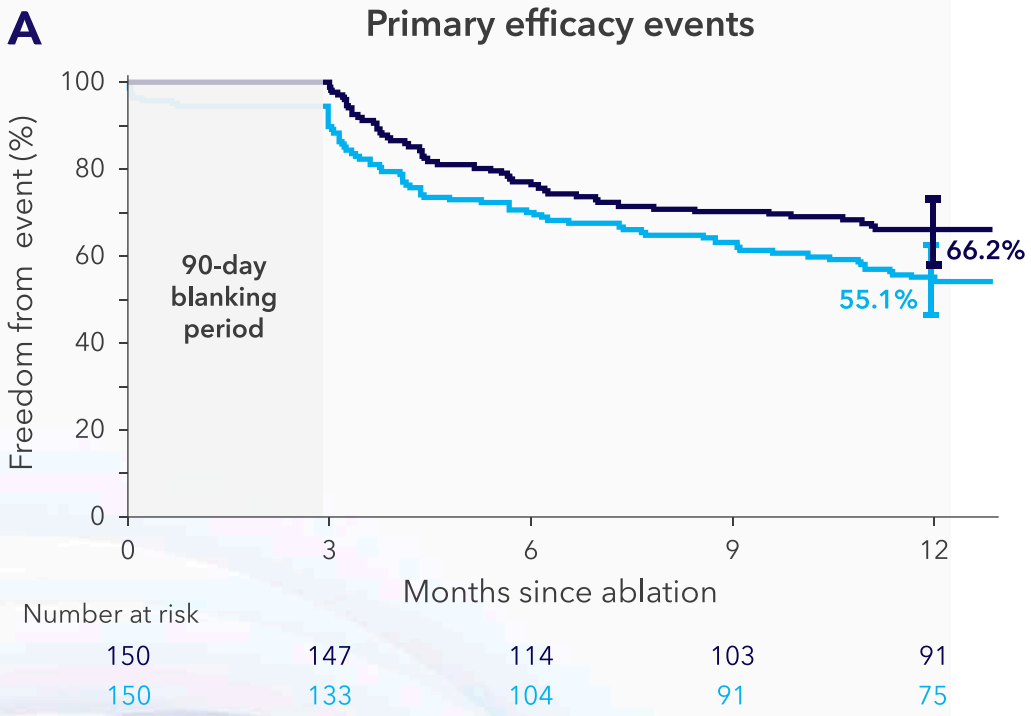
Freedom from recurrence of any symptomatic atrial arrhythmias (post-hoc analysis).



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.

Trial design and study

1 **Rigorous arrhythmia monitoring**

2

3

3-month ECG

4

5

6 **6-month ECG**

24-hour Holter monitoring

7

8

9

10

11

12 **12-month ECG**

24-hour Holter monitoring

Weekly and symptomatic transtelephonic monitoring

Trial design

Paired single-arm, prospective, nonrandomized clinical study.

Global multicenter study

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

150 Paroxysmal
150 Persistent

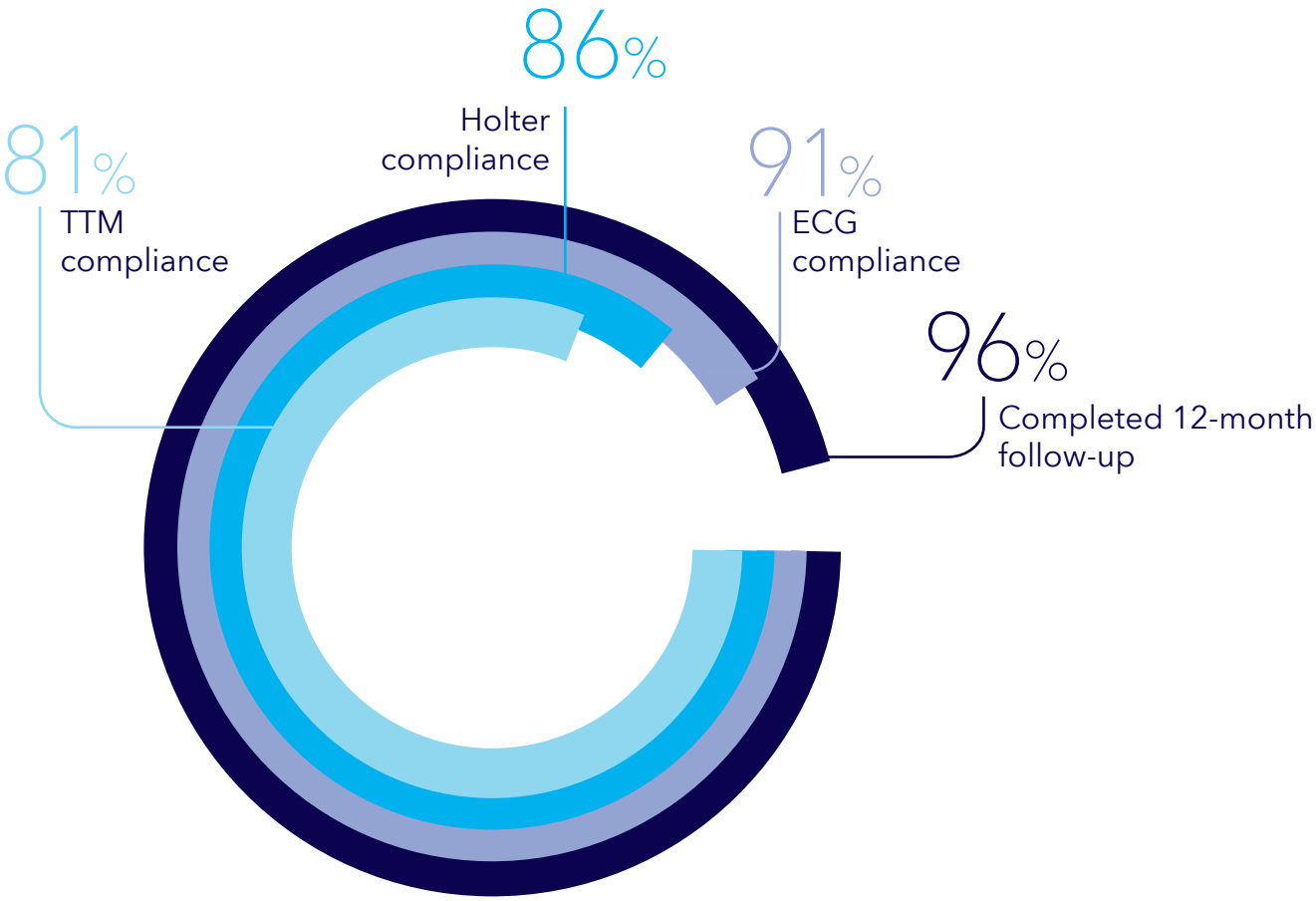
300 patients total

91% first use of the PulseSelect system

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

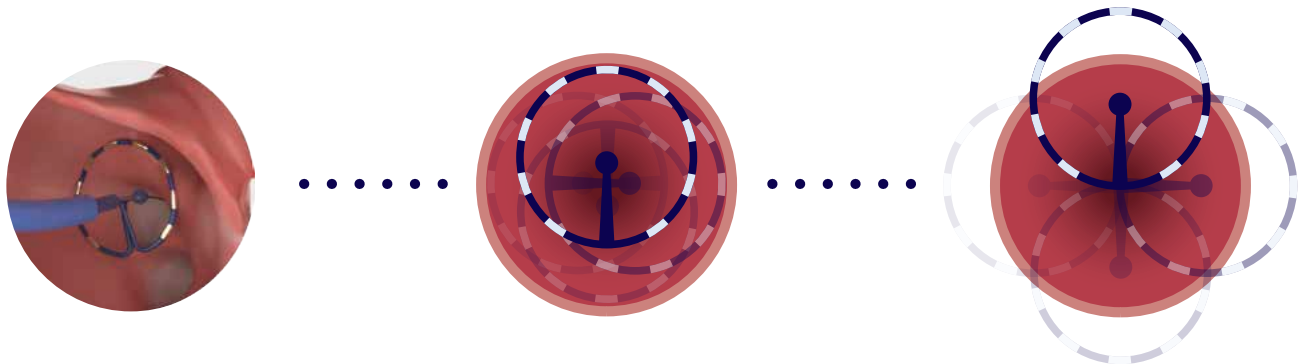
population

High-quality follow up and 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.

Paroxysmal
65 ± 29 minutes

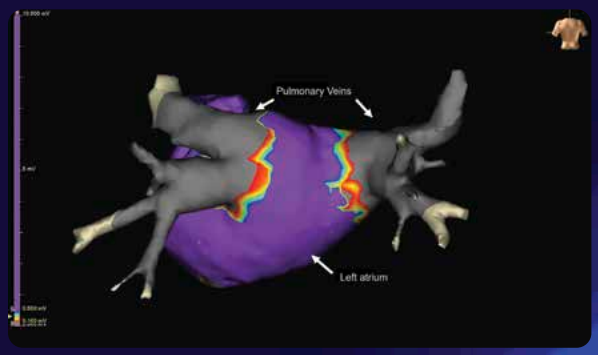
Persistent
70 ± 31 minutes

Total PFA energy delivery under 30 seconds

Seconds PAF

Seconds PsAF

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



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

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

†Operators targeted pulmonary vein isolation using a wide antral approach during PULSED AF procedures.
‡87% of operators performed less than 10 cases during trial.
§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.
[2] Medtronic data on file. November 2023.

PulseSelect™ Pulsed Field Ablation (PFA) System Brief Statement
Indications (or Intended Use): The PulseSelect™ Pulsed Field Ablation (PFA) System is indicated for use in cardiac electrophysiological mapping (stimulation and recording) and for treatment of drug refractory, recurrent, symptomatic paroxysmal atrial fibrillation or persistent atrial fibrillation (episode duration less than 1 year).
Contraindications: The PulseSelect PFA loop catheter is contraindicated for use in patients with the following conditions: • Active systemic infections • A known sensitivity to Heparin • Blood clotting abnormalities • Permanently implanted metallic objects in the left atrium. The catheter is also contraindicated in conditions where the manipulation of the catheter within the heart would be unsafe, such as intracardiac mural thrombus. The catheter is not recommended for use in patients who cannot undergo standard anticoagulation protocol for a left-sided cardiac procedure, or who have had a recent coagulopathy or embolic event.
Warnings and Precautions: To reduce the possibility of hazards associated with use of the PulseSelect PFA loop catheter: • Use the catheter only in the recommended anatomical location. • Maintain the catheter position during the ablation. • If coughing occurs, reposition the catheter more proximally and review sedation management. • Ensure electrodes are not in contact with any metal during ablations (for example the guide wire). • Maintain substantially circular array to ensure uniform field distribution. • If the electrode array is deployed to deliver ablation energy, avoid continuing to move the slide control forward to prevent the guide wire lumen from coming too close to the electrode array. It is recommended that the array be captured while it is submerged to help reduce the possibility of air becoming entrapped around the electrode array during capture and catheter insertion. Catheter integrity – Use care to avoid damage to the catheter. • Do not bend or kink the leading end of the catheter. Doing so could cause damage to the catheter lumen and make it unusable. • Monitor the catheter throughout the procedure. If a flash is observed in the luer, replace the catheter immediately. Electrode-electrode contact – Avoid contact between electrodes. Contact between electrodes may create a short circuit. Embolism risk – Introducing any catheter or sheath into the circulatory system entails the risk of air, gas, or thromboembolism, which can occlude vessels and lead to tissue infarction with serious consequences. • Avoid unnecessary catheter exchanges to minimize sheath-related embolic events. • Always advance and withdraw components slowly to minimize the vacuum created and the risk of air embolism. • Aspirate and flush the sheath frequently to help minimize the potential for embolic events resulting from the introduction of air or clot formation within the sheath. Fluoroscopy use during catheter placement – Only perform catheter ablation after giving adequate attention to the potential radiation exposure associated with the procedure, and taking steps to minimize this exposure. Give careful consideration before using the device in pregnant women. For single use only – The PFA catheter is intended only to be used once for a single patient. Do not reuse, reprocess, or resterilize the PFA catheter. Careful manipulation of the catheter is necessary to avoid cardiac damage, perforation, or tamponade. • Do not use excessive force to advance, withdraw, or rotate the catheter, especially if resistance is encountered. Excessive force may lead to catheter damage and blood loss. • Use imaging guidance during catheter advancement, manipulation, and placement. • Vascular perforation is an inherent risk of catheter placement. • Performing ablation with the PFA catheter array inside the sheath may result in damage to the array or the sheath and should be avoided. • Performing steering manipulation with the PFA catheter array inside the sheath may result in damage to the catheter steering mechanism or the sheath and should be avoided. • The PFA generator is capable of delivering significant energy. Do not touch the ablation electrodes of the PFA catheter while operating the generator. • If the system is to be tested outside of the body, the electrode array must be immersed in saline solution in a plastic container. Never test PFA delivery in direct contact with skin. Use of imaging during catheter manipulation and placement is strongly advised. Manipulating the catheter without imaging may result in damage to cardiac and vascular structures. Other devices, wires, or catheters – Avoid catheter entanglement with other devices, wires, or catheters, for example, intracardiac echo catheters. Failure to do so may increase the risk of entrapment of the array or damage to the array, which may affect retrieval of the device into the transseptal sheath. Phrenic nerve injury – To reduce the potential for phrenic nerve injury, assess for proximity of the ablation catheter to the nerve using an appropriate technique such as pacing for local phrenic nerve capture or using the test pulse feature before ablation. Stop ablation immediately if phrenic nerve impairment is observed and assess for injury. Sheath and guide wire required – Do not attempt to advance or withdraw the catheter through the vasculature without the use of a sheath and guide wire, as it may result in damage to cardiac and vascular structures. Implanted devices, such as pacemakers and implantable cardioverter-defibrillators (ICDs), may be adversely affected by PFA energy. • Keep external sources of pacing and defibrillation available during ablation. • Program pacemaker sensing parameters to asynchronous pacing to ensure that PFA energy is not sensed as an intrinsic event. • Deactivate ICD detection during the delivery of PFA energy. • Perform complete implantable device testing before and after ablation. • Monitor surface and intracardiac electrograms or vital signs during PFA energy delivery to assess for device interaction. Take appropriate action if any interaction is detected. • Refer to the appropriate implantable device technical manual for additional information. Electrical safety requirements – The PFA generator meets the requirements of IEC 60601-1. It is the user's responsibility after installation to verify and ensure that the generator meets the applicable local electrical safety requirements. Electric shock – To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth. Electromagnetic interference (EMI) radiated – The generator emits energy during ablation at a frequency level that may cause EMI with unshielded electronic equipment. To minimize EMI, the generator should be moved away from any other electronic device. If EMI is apparent during the application of energy, EMI may be reduced by repositioning the generator or other equipment. Electromagnetic interference (EMI) susceptibility – The generator has been designed to minimize electromagnetic interference (EMI). If interference should occur, move the generator away from the device generating the interference or place the generator at a different angle. Leakage current from connected devices – Use only isolated equipment (IEC 60601-1 Type CF equipment, or equivalent) with the PFA system and catheters or patient injury or death may occur.
Potential Adverse Events or Potential Complications: Potential adverse events associated with cardiac catheter ablation procedures include, but are not limited to, the following conditions: • Access site complications (such as, bruising, ecchymosis, arteriovenous fistula, hematoma, pseudoaneurysm) • Anemia • Arrhythmias, proarrhythmia (such as, atrial flutter, bradycardia, heart block, tachycardia) • Bleeding, possibly requiring transfusion • Bruising • Cardiopulmonary arrest • Perforation of the heart or other organs during transseptal puncture or other procedures • Cardiac tamponade • Catheter entrapment in cardiac structures requiring intervention • Cerebrovascular accident [such as stroke, transient ischemic attack (TIA)] • Chest discomfort, pain, or pressure • Collateral damage to the conduction system or coronary vasculature • Cough • Death • Embolism • Esophageal damage (including atrial esophageal fistula) • Hemoptysis • Hypotension • Hypertension • Infections (such as, sepsis) • Myocardial infarction or ischemia • Nerve injury or nerve damage (for example phrenic nerve injury) • Pericarditis or endocarditis • Pericardial effusion • Pneumothorax • Pulmonary edema • Pulmonary vein dissection • Pulmonary vein stenosis • Radiation injury or damage and late malignancy • Skin laceration or puncture • Sore throat • Unintended complete or incomplete atrioventricular node (AV-Node) or sinus node block or damage • Valvular insufficiency or damage.
Refer to the device technical manual for detailed information regarding the procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at www.medtronic.com.
Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

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