Setting a new standard in safety.

Engineered for efficiency.

PulseSelect™
Pulsed Field Ablation (PFA) System

Medtronic

PulseSelect™

Pulsed Field Ablation System

Setting a new standard in safety

Differentiated system safety features

Developed over 15 years of PFA research

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

Unmatched safety

Engineered with differentiated safety features from 15 years of PFA research, and backed by the results of one of the safest IDE AF ablation trials to date.

Consistent efficiency

Rapid, effective PVI through consistent and predictable energy delivery and catheter maneuverability.

Simplified adaptability

Seamless transition to PFA with freedom to adapt to your preferred workflow.

Indicated for use for paroxysmal (PAF) and persistent (PsAF) patients.

PULSED AF[2]

Trial design

Paired single arm. Prospective, non-randomized, Global IDE clinical study.

9 countries
41 sites
67 operators
300 PFA subjects

0.7%

primary safety event rate

One of the lowest safety event rates of any atrial fibrillation technology to-date.

0 Esophageal events

0 PV stenosis

0 Phrenic nerve injury

0 Coronary spasm noted

Total of 13 adverse events measured, resulted in 1 cerebrovascular accident and 1 tamponade.

Engineered for efficiency

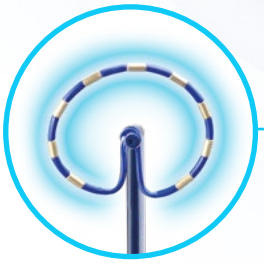
PulseSelect™
PFA Catheter

9 electrodes built to **sense, ablate, and pace**

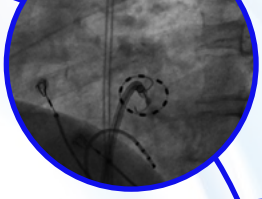
25 mm diameter loop

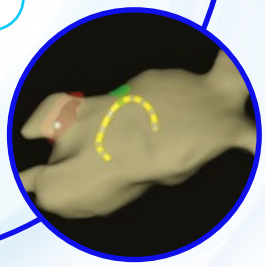
9 Fr shaft with bidirectional steering

Fixed electrode spacing
to produce predictable, consistent, and contiguous energy delivery



20-degree forward tilt
to ensure consistent uniform tissue contact

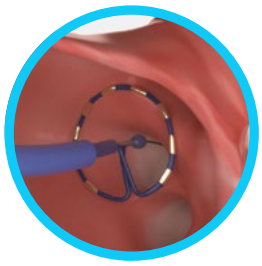




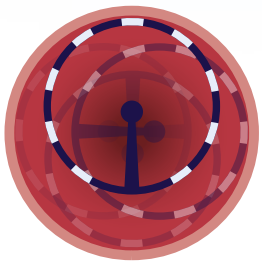
Full catheter visualisation on existing mapping systems and imaging tools[1]

Intuitive stepwise approach to PVI†

All pulmonary veins isolated in less than 30 seconds of total energy delivery[1]



Over-the-wire
for enhanced stability and self-centering control



Ostial applications
Stepwise catheter rotation for overlapping lesions

Antral applications
Stepwise catheter rotation for overlapping lesions

Proven efficacy
Freedom from AF/AFL/AT

70% PAF

62% PsAF

Consistent efficiency
Left atrial dwell time **50 minutes or under** when excluding the 20-minute trial-mandated wait period.

65 **(± 29) minutes** PAF

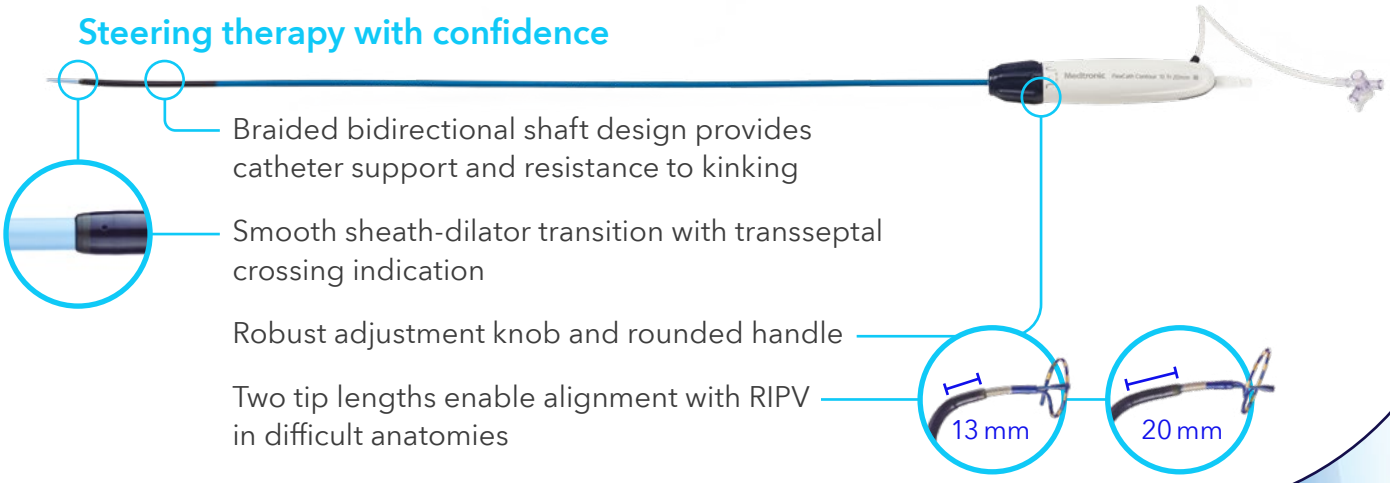
70 **(± 29) minutes** PsAF

1st
PFA IDE trial completed

Only
PFA IDE trial to demonstrate efficacy for **both PAF and PsAF patients.**

FlexCath Contour™ Steerable Sheath – 10 Fr

Steering therapy with confidence



Braided bidirectional shaft design provides catheter support and resistance to kinking

Smooth sheath-dilator transition with transseptal crossing indication

Robust adjustment knob and rounded handle

Two tip lengths enable alignment with RIPV in difficult anatomies

FlexCath Cross™ Transseptal Solution

Experience the full potential of a zero exchange workflow

Zero sheath exchanges
The integrated needle and dilator design removes the need for needle, guidewire, transseptal, and therapeutic sheath exchanges.

Versatility for your procedures
Compatible with the industry-leading introducers and with both mechanical and RF crossing.

Cross with control
The needle only deploys when activated, designed for ease of control during transseptal puncture.

†Operators targeted pulmonary vein isolation using a wide antral approach during PULSED AF procedures.
[1] Medtronic data on file. November 2023.
[2] 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.

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Brief Statement
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.