Setting a new standard in safety.

Engineered for efficiency.

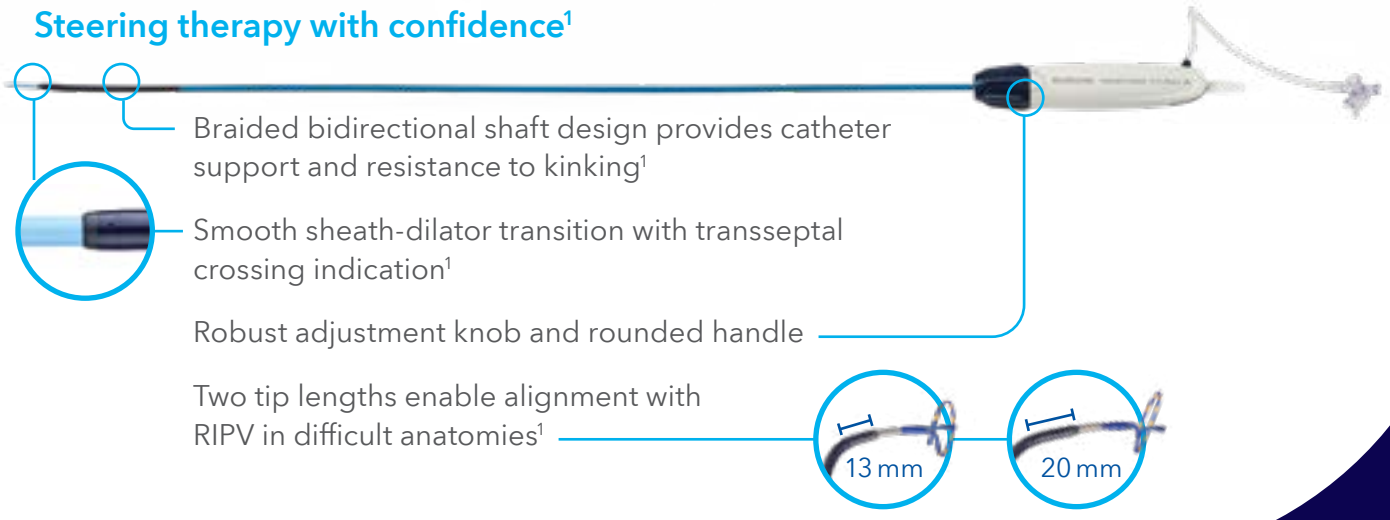
PulseSelect™
Pulsed Field Ablation (PFA) System

Medtronic

FlexCath Contour™

Steerable Sheath – 10 Fr

Steering therapy with confidence[1]



Braided bidirectional shaft design provides catheter support and resistance to kinking[1]

Smooth sheath-dilator transition with transseptal crossing indication[1]

Robust adjustment knob and rounded handle

Two tip lengths enable alignment with RIPV in difficult anatomies[1]

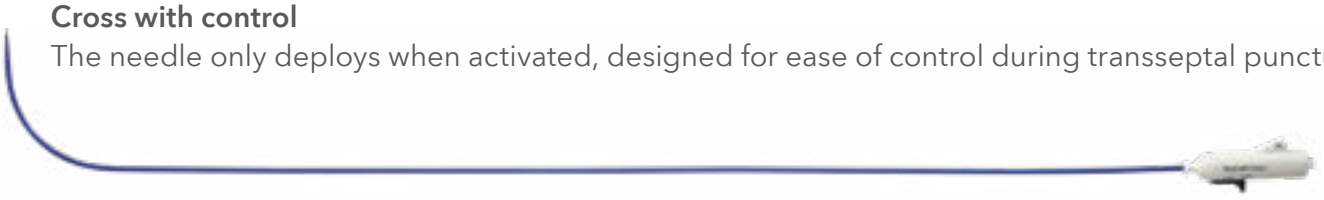
FlexCath Cross™ Transseptal Solution

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



PulseSelect™

Pulsed Field Ablation System

Setting a new standard in safety

Differentiated system safety features

Developed over 15 years of PFA research

Unmatched safety[2,3]

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.[2]

Consistent efficiency

Rapid, effective PVI[2] through consistent and predictable energy delivery and catheter maneuverability.

Simplified adaptability[3]

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

Indicated for use in drug refractory, recurrent, symptomatic paroxysmal (PAF) and persistent (PsAF) patients.

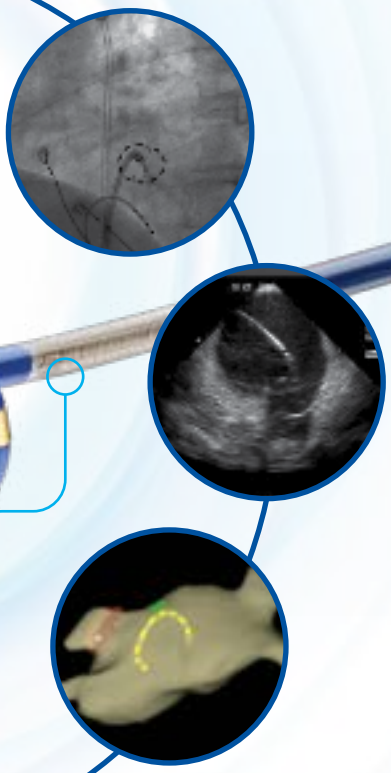
Engineered for efficiency

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

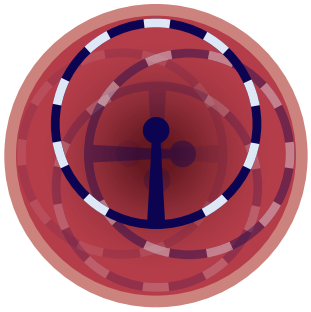
20-degree forward tilt to ensure consistent uniform tissue contact

Full catheter visualization on existing mapping systems and imaging tools[2]

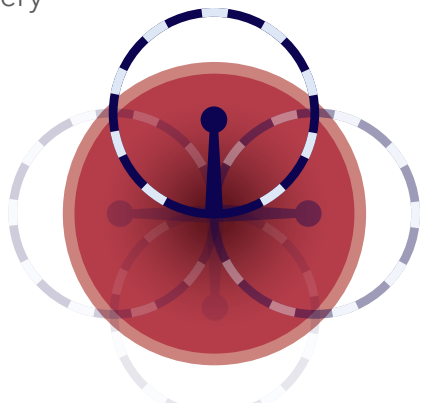
Intuitive stepwise approach to PVI†

All pulmonary veins isolated in less than 30 seconds of total energy delivery[3]

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

†Operators targeted pulmonary vein isolation using a wide antral approach during PULSED AF procedures.

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 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.

0.7%
primary safety event rate
One of the lowest safety event rates of any atrial fibrillation technology to-date.

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.[4]

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.**

[1] Medtronic data on file. 2024.
[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.
[3] Medtronic data on file. November 2023.
[4] Verma A, Boersma L, Haines DE, et al. First-in-Human Experience and Acute Procedural Outcomes Using a Novel Pulsed Field Ablation System: The PULSED AF Pilot Trial. *Circ Arrhythm Electrophysiol*. January 2022;15(1):e010168.

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.

FlexCath Contour™ Steerable Sheath Brief Statement
Intended Use: The FlexCath Contour steerable sheath facilitates introducing various cardiovascular catheters into the heart.
Indications for Use: The FlexCath Contour steerable sheath is indicated for percutaneous catheter, or transseptal needle introduction into the vasculature and into the chambers of the heart, including the left side of the heart through the interatrial septum. The sheath deflection facilitates device positioning.
Contraindications: The FlexCath Contour steerable sheath is contraindicated for placement in the left atrium or ventricle if: • The patient has an intra-atrial septal patch or has had other surgical intervention in or adjacent to the intra-atrial septum. • The patient has had a previous embolic event from the left side of the heart within two months of the procedure. • The patient has known or suspected atrial myxoma.
Compatible Catheter Sizes: FlexCath Contour Steerable Device (10 Fr): The sheath can be used with Medtronic diagnostic and ablation catheter sizes from 7 Fr (2.3 mm) up to 9.5 Fr (3.2 mm). FlexCath Contour Steerable Device (12 Fr): The sheath can be used with Medtronic diagnostic and ablation catheter sizes from 7 Fr (2.3 mm) up to 10.5 Fr (3.5 mm).
Warnings and Precautions: This is a single use sheath to be used in a single patient. Do not resterilize this sheath for purpose of reuse. The dilator is compatible with transseptal needles that are at least 89 cm in length and less than 21 Gauge outer diameter. Do not use the sheath if it is kinked or damaged. Only physicians trained in left-sided catheterization should use this sheath during transseptal puncture. Administer appropriate levels of peri-procedural anticoagulation therapy for patients undergoing left-sided, right-sided, and transseptal cardiac procedures. Administer anticoagulation therapy during and post-procedure according to patient conditions and institutional standards. Introducing any catheter or sheath into the circulatory system entails the risk of air embolism, which can occlude vessels and lead to tissue infarction with serious consequences. To minimize the risk of air embolism, observe and remove any air prior to introducing the sheath and during the procedure. Do not advance the dilator or sheath through the interatrial septum without first confirming left atrial access to prevent advancing these components into an undesired location. Remove the guide wire and dilator from the sheath or insert the catheter into the sheath before slowly aspirating and flushing the sheath. Minimize catheter exchanges and always advance and withdraw catheters slowly. Follow advancement or withdrawal of catheters with appropriate aspiration and flushing according to institutional standards or consensus statements. Connect to a continuous drip to minimize back-bleeding. Do not pass the sheath through a prosthetic heart valve (mechanical or tissue). The sheath may become trapped in the valve, damaging the valve and causing valvular insufficiency or premature failure of the prosthetic valve. Cardiac catheterization procedures should be performed only in a fully equipped facility. This sheath should be used only by, or under the supervision of, physicians trained in cardiac catheterization procedures. Use extreme care when manipulating the sheath. Do not use excessive force to advance or withdraw the sheath, especially if resistance is encountered. Only physicians trained in left-sided catheterization should use this sheath during transseptal puncture.
Potential Adverse Events or Potential Complications: Potential adverse events associated with cannulation of the peripheral vasculature and intracardiac placement of the sheath and dilator may include the following conditions: Access site complications (hematoma, infection, thrombosis, ecchymosis, AV fistula, bleeding from puncture site, hemorrhage); Air embolism; Arrhythmia (such as atrial fibrillation, atrial flutter, heart block requiring permanent pacemaker, ventricular tachycardia); Cardiac arrest; Chest discomfort, pain, or pressure; Coronary artery spasm; Damage to heart tissue or vasculature; Death; Endocarditis; Entrapment of the sheath within the patient; Hemothorax; Iatrogenic atrial septal defect (iASD); Infection (such as pericarditis, sepsis, urinary); Myocardial infarction; Perforation of venous, cardiac or surrounding tissue; Pericardial effusion, tamponade; Pericarditis; Pleural effusion; Pneumothorax; Pseudoaneurysm; Pulmonary edema; Pulmonary embolism; PV stenosis; Stroke; Thrombus; Transient ischemic attack (TIA); Valve damage; Vasovagal reaction
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.

FlexCath Cross™ Transseptal Solution Indications (or Intended Use)
Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use. FlexCath Cross devices are FDA cleared. Not all FlexCath Cross devices are CE marked.

Medtronic

710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA

Toll-free in USA:
800.633.8766
Worldwide: +1.763.514.4000
medtronic.com

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