Medtronic

FlexCath Cross™ Transseptal Solution +
FlexCath Contour™ Steerable Sheath

Zero

exchange workflow

Tailored

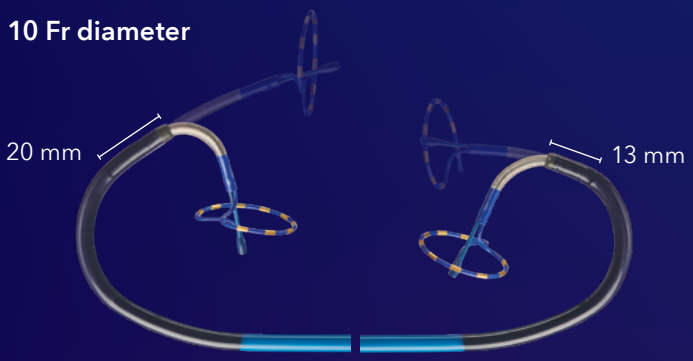
Efficient

Controlled

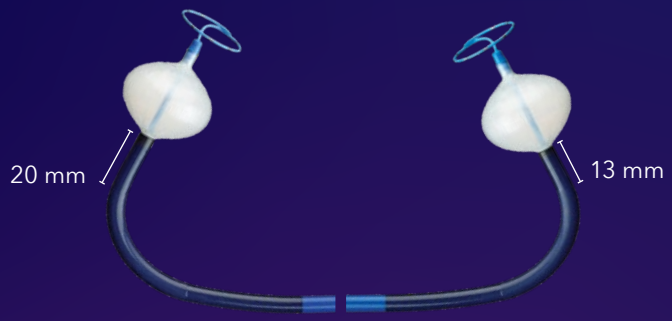
Tailored

Tailored to the single shot procedure of your preference, with multiple French sizes (10 Fr and 12 Fr) and tip lengths (13 mm and 20 mm) to choose from.[1]

10 Fr diameter

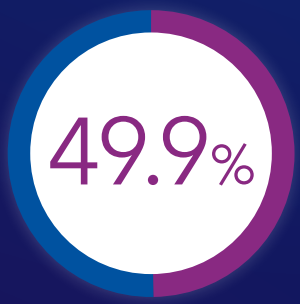


12 Fr diameter

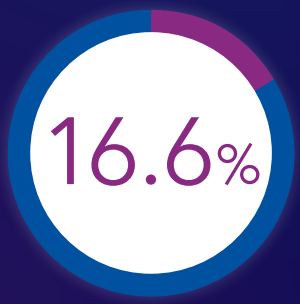


Efficient

Zero in on efficiency with an integrated needle/dilator for zero exchanges between wire and needle.[1]



reduction in **transseptal puncture (TSP) time (minutes)** versus BRK-1™*[2]



reduction in **total procedure time (minutes)** versus NRG™*[3]

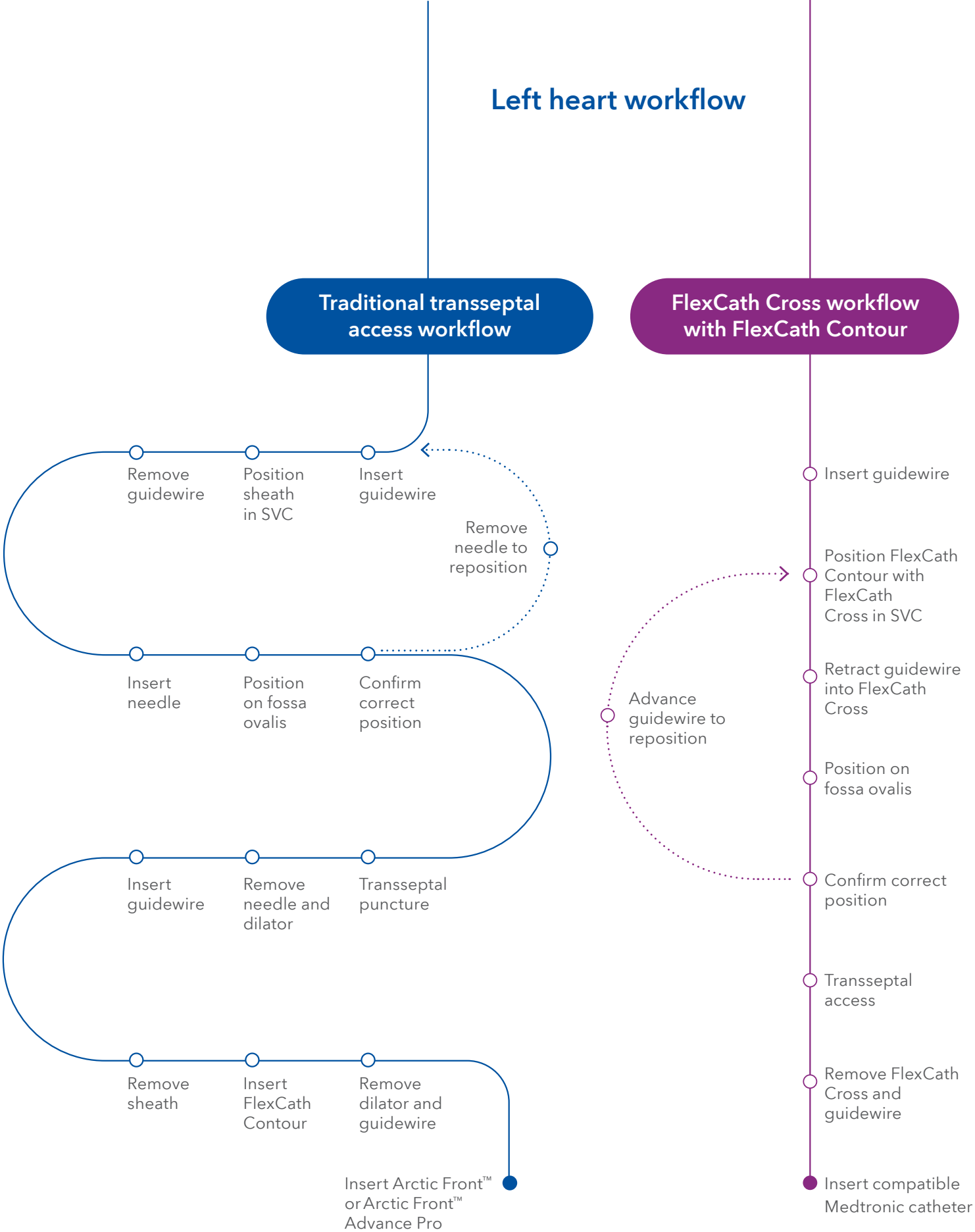
Controlled

The sharp FlexCath Cross needle is designed to deploy only when activated for ease of control.[1]

Smooth transition

with FlexCath Contour redesigned distal tip.[1]

Left heart workflow



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 Brief Statement

Indications
The FlexCath Cross Transseptal Solution is indicated to puncture the interatrial septum to gain access to the left side of the heart whereby various cardiovascular catheters are introduced.

Contraindications
Myocardial infarction within the last two weeks; patients with: an active infection, atrial thrombus, known or suspected atrial myxoma; patients that have experienced: a recent cerebrovascular accident (CVA) or unstable angina; patients who do not tolerate anticoagulation therapy; or patients with an interatrial septal patch

Warnings and Precautions
Read the instructions for use before using this device to mitigate the risks and potential complications associated with use of the device. This is a single-use device only and is not intended for use in children, or in pregnant or nursing patients. Only physicians fully trained in cardiac transseptal catheterization procedures should use this device and patient's hemodynamic/physiologic parameters should be monitored.

Potential Adverse Events or Potential Complications
Potential adverse include, but are not limited to: Access site complications (hematoma, infection, thrombosis, ecchymosis, AV fistula, pseudoaneurysm, bleeding from puncture site, hemorrhage); Air embolism; Arrhythmias; Artery or venous dissection; Artery spasm and/or damage; Cardiac tamponade; Cerebral infarct; Chest pain / discomfort; Dissection; Femoral vein injury; Heart block; Hemothorax; Infection/sepsis; Myocardial infarction; Obstruction or perforation or damage to vascular system; Pacemaker/defibrillator lead displacement; Pericardial effusion or tamponade; Pulmonary edema; Tear in the vascular intima; Thromboembolism; Transient ischemic attack (TIA); Vascular bleeding; Vasovagal reaction; Radiation exposure events.

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Arctic Front™ Family of Cardiac Cryoablation Catheters Brief Statement

Indications (or Intended Use)
The Arctic Front Advance and Arctic Front Advance Pro Cardiac Cryoablation Catheters are indicated for the treatment of drug refractory recurrent symptomatic paroxysmal and persistent atrial fibrillation (episode duration less than 6 months).

The Arctic Front Advance and Arctic Front Advance Pro Cardiac Cryoablation Catheters are also indicated for the treatment of recurrent symptomatic paroxysmal atrial fibrillation as an alternative to antiarrhythmic drug therapy as an initial rhythm control strategy.

Contraindications
Use of the cryoballoon is contraindicated: 1) In the ventricle because of the danger of catheter entrapment in the chordae tendineae, 2) In patients with one or more pulmonary vein stents, 3) In patients with cryoglobulinemia, 4) In patients with active systemic infections, and 5) In conditions where the manipulation of the catheter within the heart would be unsafe (e.g., intracardiacmural thrombus).

Warnings and Precautions
Do not reprocess or resterilize this device for the purpose of reuse. Administer appropriate levels of peri-procedural anticoagulation therapy for patients undergoing left-sided and transseptal cardiac procedures. The Arctic Front family of Cryoballoons have not been studied for the safety of changes in anticoagulation therapy in patients with paroxysmal atrial fibrillation. Atrial Fibrillation patients with significant left ventricular dysfunction, advanced heart failure, severe left atrial enlargement or significant structural heart disease were excluded from the clinical trials that supported the approved indications. Do not inflate the balloon inside the sheath or while the catheter is positioned inside a pulmonary vein. Always inflate the balloon in the atrium and then position it at the pulmonary vein ostium. If the balloon cannot be inflated or deflated using the CryoConsole, have a Manual Retraction Kit on hand during the procedure. (Refer to the CryoConsole Operator's Manual for more detailed instructions on the Manual Retraction Kit). Disconnect the catheter's electrical connection before cardioversion or defibrillation.

Catheter handling: • Use extreme care when manipulating the catheter. • Do not use excessive force to advance, withdraw, or rotate the catheter, especially if resistance is encountered. • Do not use the catheter if it is kinked, damaged, or cannot be straightened. • If the catheter becomes kinked or damaged while in the patient, remove it and use a new catheter. • Straighten the shaft before inserting or withdrawing the catheter. • Do not at any time preshape or bend the catheter shaft or balloon segment. • Catheter advancement should be performed using fluoroscopy or other appropriate techniques. • Do not position the cryoballoon catheter within the tubular portion of the pulmonary vein.

Do not advance the balloon beyond the guide wire or circular mapping catheter to reduce the risk of tissue damage. Ensure that the guide wire or circular mapping catheter is inserted into the catheter and through the balloon portion for adequate support during vascular access insertion. Do not pass the catheter through a prosthetic heart valve (mechanical or tissue). Do not pull on the balloon catheter, circular mapping catheter, sheath, umbilical cables, or CryoConsole while the balloon catheter or circular mapping catheter are frozen to tissue. Before moving these components, use appropriate techniques to ensure that the balloon catheter and circular mapping catheter are not adhered to tissue.

Always advance and withdraw components slowly to minimize the vacuum created and therefore minimize the risk of air embolism. Do not expose the catheter handle or coaxial and electrical connectors to fluids or solvents. The use of fluoroscopy during catheter ablation procedures presents the potential for significant x-ray exposure to both patients and laboratory staff. Give careful consideration before using the device in pregnant women. Flush the guide wire lumen before initial insertion and then frequently throughout the procedure to prevent coagulation of blood in the lumen. Flush the guide wire lumen with saline after each contrast injection. Use only 0.081 cm (0.032 in) or 0.089 cm (0.035 in) guide wires with the catheter. Do not connect the cryoablation catheter to a radiofrequency (RF) generator or use it to deliver RF energy. Use only isolated equipment (IEC 60601-1 Type CF equipment, or equivalent) with the CryoConsole and catheters. Avoid catheter entanglement with other catheters, devices, or wires.

Before powering up an RF generator or applying RF energy, disconnect the cryoablation catheter from the CryoConsole. Always deflate the balloon and withdraw the balloon into the transseptal sheath before removing the balloon from the left atrium. If the sterile packaging or catheter is damaged, do not use the catheter. Use only Medtronic cryoablation catheters, 12 FR inner diameter sheaths, circular mapping catheters, refrigerant tanks, and components with the CryoConsole. Closely monitor patients undergoing cardiac ablation procedures during the postablation period for clinical adverse events. This cryoablation system should be performed only in a fully equipped facility under the supervision of physicians trained in cryoablation procedures.

Potential Adverse Events or Potential Complications
Potential complications/adverse events from cardiac catheterization and ablation include, but are not limited to, the following: Access site complications (e.g., bruising, ecchymosis); Anemia; Anxiety; Arrhythmia (e.g., atrial flutter, bradycardia, heart block, tachycardia); Back pain; Bleeding from puncture sites; Bronchial constriction; Bronchial fistula; Bronchitis; Bruising; Cardiac ischemia; Cardiac tamponade; Cardiopulmonary arrest; Cerebral vascular accident; Chest discomfort/pain/pressure; Cold feeling; Coronary artery spasm; Cough; Death; Diarrhea; Dizziness; Embolism; Entrapment; Esophageal damage (including atrioesophageal fistula); Fatigue; Fever; Headache; Hemoptysis; Hypotension/Hypertension; Infection (e.g., sepsis, urinary); Lightheadedness; Nausea/vomiting; Perforation; Pericardial effusion; Pericarditis; Phrenic nerve injury; Pleural effusion; Pneumonia; Pneumothorax; Pseudoaneurysm; Pulmonary edema; Pulmonary hemorrhage; Pulmonary vein dissection; Pulmonary vein stenosis; Renal insufficiency or renal failure; Shivering; Shortness of breath; Sore throat; Tissue infarction (e.g., myocardial infarction or renal infarction);Transient ischemic attack; Vagal nerve injury (e.g., gastroparesis); Vasovagal reaction; Visual Changes (e.g., blurred vision).

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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

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. • Do not deliver energy near permanently implanted metallic objects • 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.

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Order information

PulseSelect™ pulsed field ablation procedures

Order number	Product name/detail
10FCC13	FlexCath Contour 10 Fr; 13 mm configuration
10FCC20	FlexCath Contour 10 Fr; 20 mm configuration
900310	FlexCath Cross-Contour 10 Fr configuration

Arctic Front family of cryoballoon procedures

Order number	Product name/detail
12FCC13	FlexCath Contour 12 Fr; 13 mm configuration
12FCC20	FlexCath Contour 12 Fr; 20 mm configuration
900311	FlexCath Cross-Contour 12 Fr configuration

1. Cowart R. UC202406738. 2023. Medtronic data on file.
2. Rizzi S, Pannone L, Monaco C, et al. First experience with a transseptal puncture using a novel transseptal crossing device with integrated dilator and needle. *J Interv Card Electrophysiol.* December 2022;65(3):731–737.
3. Yong JS, et al. Use of the Novel AcQCross Transseptal System Improves Procedural Efficiency Compared to Conventional Transseptal Puncture Technique. Presented at: AF Symposium 2022; January 13–19, 2022; New York, NY.

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