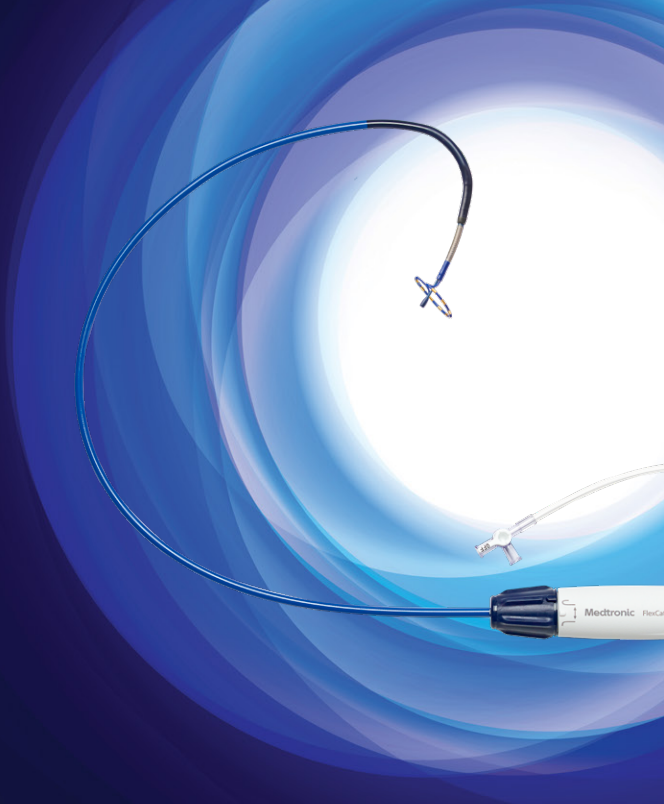
Medtronic

FlexCath Contour™ Steerable Sheath – 10 Fr

Steering therapy with confidence[1]



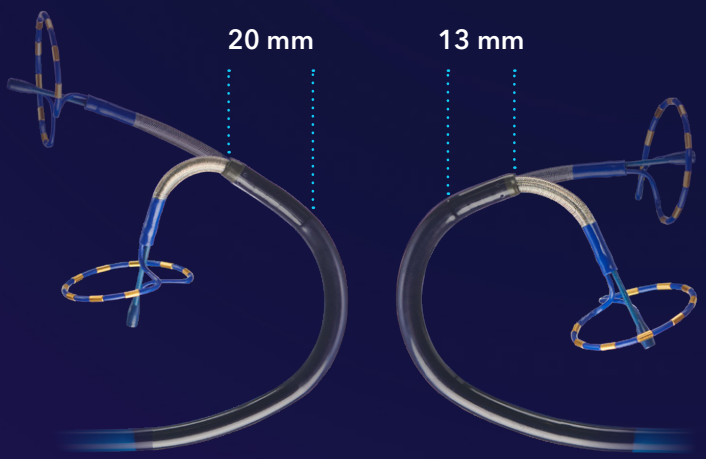
For use with the PulseSelect™ Pulsed Field Ablation Catheter, FlexCath Contour 10 Fr is a bidirectional sheath designed to enable maximum reach, enhanced anatomical access, and overall maneuverability.[1]

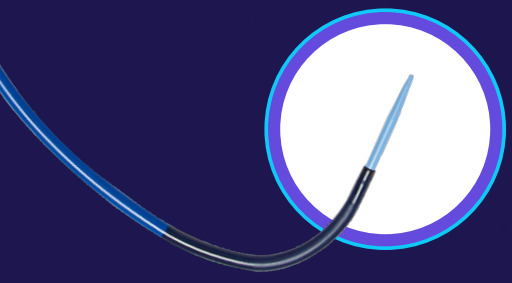
Enhanced maneuverability

Designed to maintain shape and performance throughout the procedure with increased bidirectional deflection and a new tip length configuration.[1]

Two tip lengths

enable options for greater access to the RIPV[1]





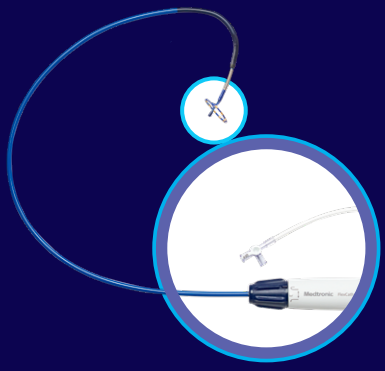
Refined transitions

The distal tip of the sheath has been designed with a gradual approach angle and flexible material to enable a smooth sheath-dilator transition into patient vasculature and across the septum.[1]

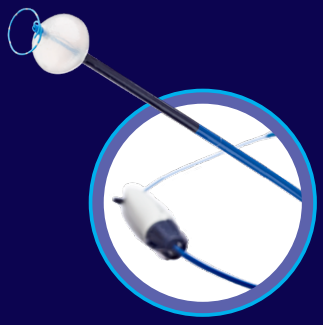
Zero exchange workflow[1]

The FlexCath Contour sheath is designed for transseptal needle introduction and is compatible with the FlexCath Cross™ transseptal solution, eliminating the need to exchange between sheaths, guidewires, or needles.

The FlexCath Contour steerable sheath family



FlexCath Contour 10 Fr with the PulseSelect pulsed field ablation catheter



FlexCath Contour 12 Fr with the Arctic Front Advance Pro™ cryoablation catheter

Ordering information

Order number	
10FCC13	FlexCath Contour 10 Fr – 13 mm configuration
10FCC20	FlexCath Contour 10 Fr – 20 mm configuration

Reference

[1] Cowart R. UC202406738. Medtronic data on file. 2023.

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.

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