Medtronic

FlexCath Cross™ transseptal solution

Zero

exchange workflow

Efficiency

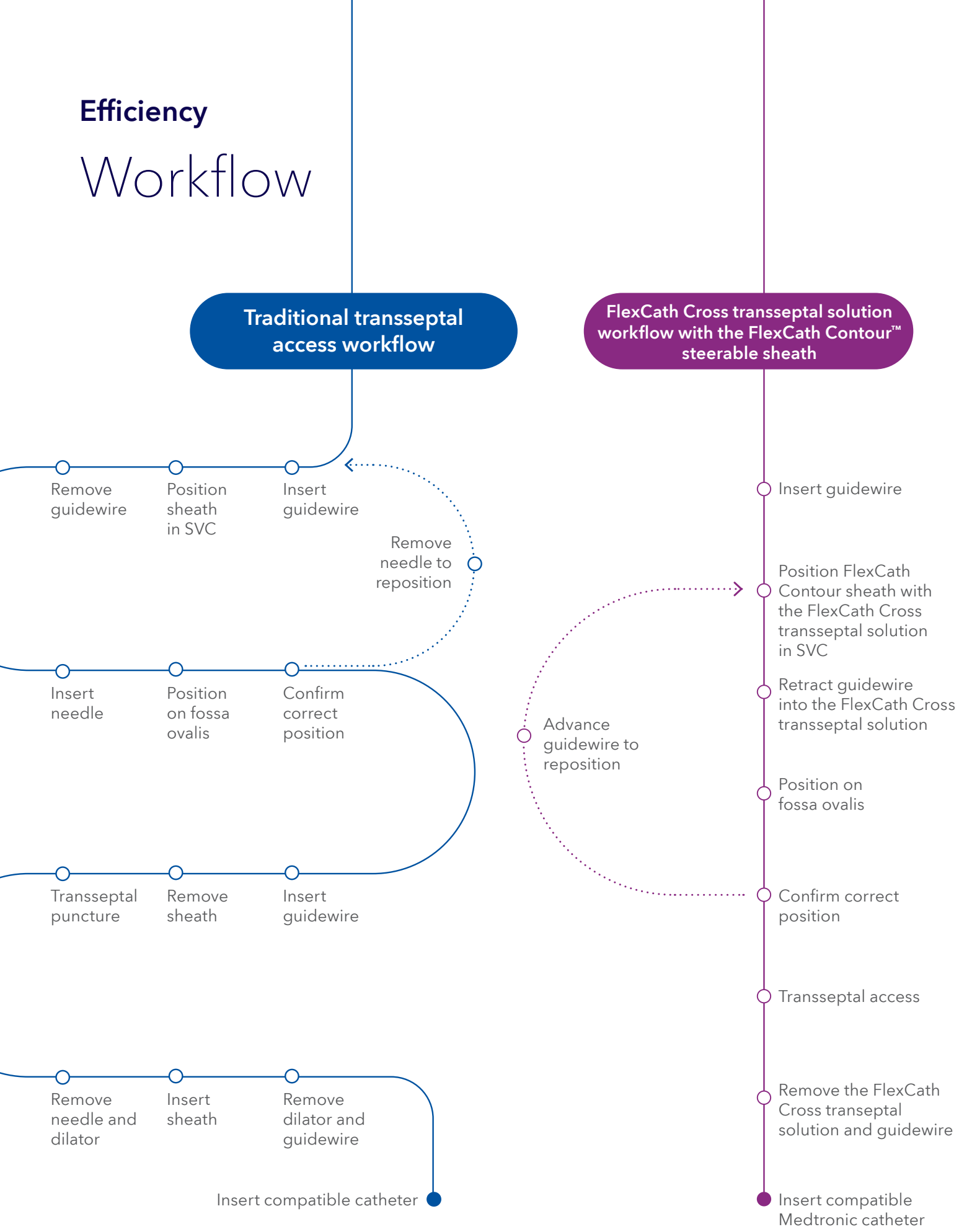
Zero exchange procedure

Zero wire and needle exchanges
Integrated needle/dilator design removes the need for needle and guidewire exchanges.

Zero sheath exchanges
Dilators compatible with leading industry sheaths eliminate the need for separate transseptal and therapeutic sheaths.

Efficiency

Workflow



Medtronic FlexCath Contour steerable sheath

Versatile

Versatility for your procedures

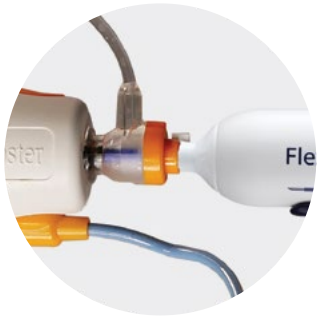
Choose the FlexCath Cross model that fits with your existing compatible sheath preferences for your left-heart procedures.

The FlexCath Cross system is the only transseptal access system on the market **cleared for both mechanical and RF crossing.**

For non-Medtronic products, refer to FDA-approved labeling for additional warnings, precautions, and indications information.

Compatible with industry-leading introducers

Abbott Agilis™* NxT Steerable Introducer



Biosense Webster CARTO VIZIGO®* Bi-directional Guiding Sheath

Boston Scientific Watchman TruSeal™* and FXD™* Access Systems

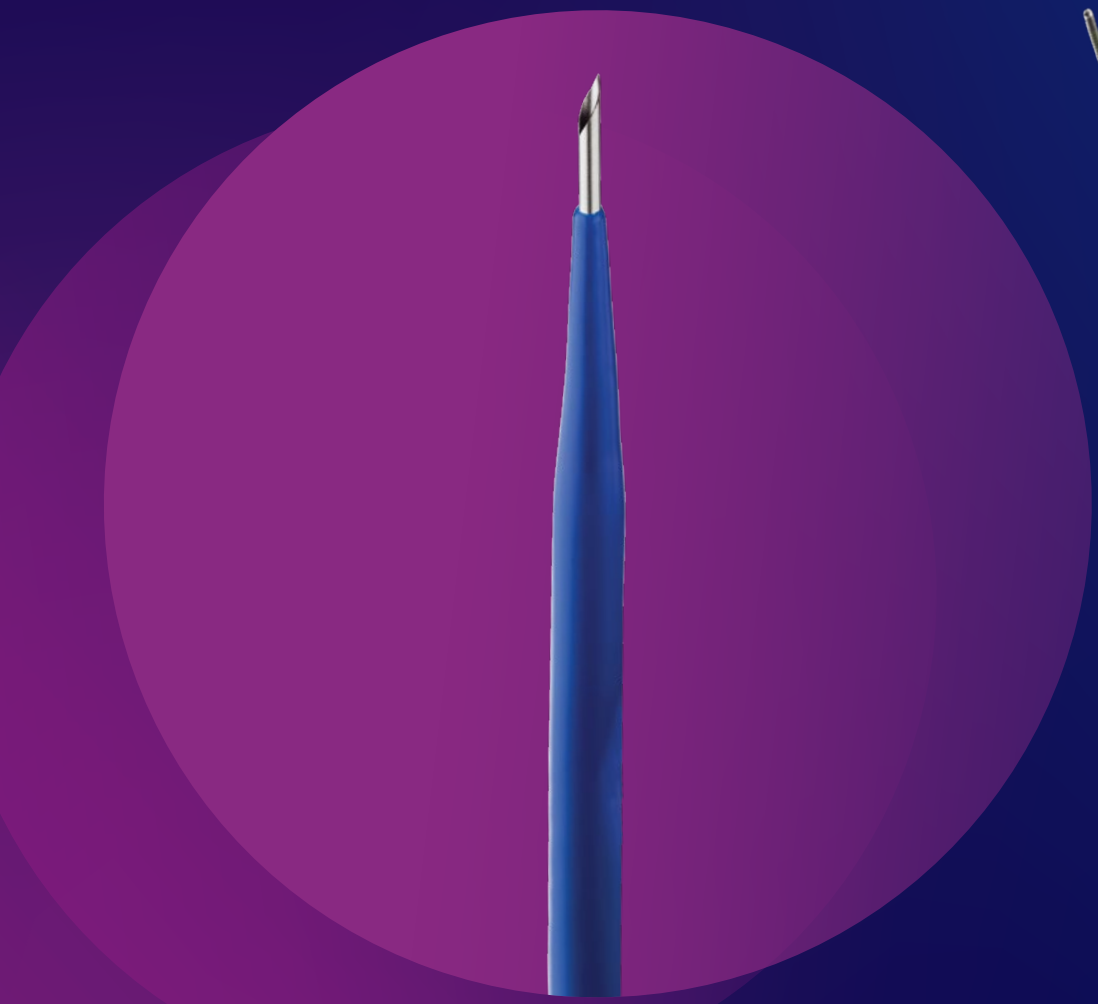
Abbott Swartz™* Braided Transseptal Guiding Introducer, SL1

Merit Medical HeartSpan™* Sheath Introducer

Controlled

Cross with control

The FlexCath Cross needle is designed to deploy only when activated for ease of control during transseptal puncture.



Ordering info

Product name	Compatible sheath	Order number
FlexCath Cross – AG 61 cm	Agilis NxT – 61 cm	900300
FlexCath Cross – AG 71 cm	Agilis NxT – 71 cm	900301
FlexCath Cross – SL 63 cm	Swartz SL1 – 63 cm	900302
FlexCath Cross – SL 81 cm	Swartz SL1 – 81 cm	900309
FlexCath Cross – VZ 71 cm	CARTO VIZIGO – 71 cm	900303
FlexCath Cross – FCC 65 cm, 10 Fr	FlexCath Contour steerable sheath – 65 cm, 10 Fr	900310
FlexCath Cross – FCC 65 cm, 12 Fr	FlexCath Contour steerable sheath – 65 cm, 12 Fr	900311
FlexCath Cross – MH 63 cm	Merit Medical HeartSpan sheath – 63 cm	900306
FlexCath Cross – MH 81 cm	Merit Medical HeartSpan sheath – 81 cm	900307
FlexCath Cross – WT 75 cm	Watchman TruSeal and FXD access systems – 75 cm	900308

Competitive matrix – transseptal needles

Feature	FlexCath Cross	BRK™*1	SafeSept™*2	NRG™*3	VersaCross™*4
Integrated needle/ dilator design reduces exchanges	✓	✗	✗	✗	✓
Spring-tensioned safety needle	✓	✗	✗	✗	✗
Indicated for both mechanical and RF crossing	✓	✗	✗	✗	✗
Reposition without requiring wire/needle exchange	✓	✗	✗	✗	✓
Engineered to pair with leading sheaths	✓	✗	✗	✗	✗

1. BRK Transseptal Needles. Abbott. https://www.cardiovascular.abbott/us/en/hcp/products/electrophysiology/access-introducers/brk-transseptal-needle.html. Accessed September 11, 2025.
2. SafeSept™* Transseptal Guidewire Transseptal Access System. Pressure Products. https://www.pressure-products.com/wip/safesept.html. Accessed September 11, 2025.
3. NRG™* Transseptal Needle. Boston Scientific. Available at: https://www.bostonscientific.com/us/en/healthcare-professionals/products/transseptal-access-devices/nrg-transseptal-needle/fp00000288.html. Accessed September 16, 2025.
4. VersaCross™* Large Access Solution. Boston Scientific. Available at: https://www.bostonscientific.com/us/en/healthcare-professionals/products/transseptal-access-devices/versacross-access-solution/fp00000300.html. Accessed September 16, 2025.

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.

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.

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