

# Medtronic

## FLEXCATH ADVANCE™ 4FC12

Steerable Sheath

Technical Manual





**Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.

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Arctic Front, FlexCath, FlexCath Advance, Medtronic

### Explanation of symbols

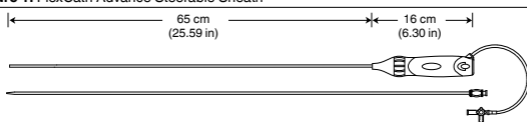
The following list of symbols and abbreviations applies to various products. Refer to the package labels to see which symbols apply to this product.

	Lot number
	Reorder number
	Use-by
	Sterilized using ethylene oxide
	Do not re-use
	Do not re-sterilize
	Do not use if package is damaged
	Consult instructions for use
	Keep dry
	Storage temperature
	Transit temperature
	Humidity limitation
	Product documentation
	Package contents
	Fragile, handle with care
	Inner diameter
	Manufacturer
	Authorized representative in the European Community

## 1 Description

The FlexCath Advance Steerable Sheath (the sheath) is a percutaneous catheter introducer fitted with a hemostasis valve to allow for introduction, withdrawal, and swapping of catheters and wires while minimizing blood loss. A sideport with three-way stopcock is integrated to allow continuous drip infusion, injection through the center lumen, flushing, air or blood aspiration, blood sampling, and pressure monitoring.

Figure 1. FlexCath Advance Steerable Sheath



A dilator is packaged with the sheath. The sheath is available as described in the following table:

Model	Inner diameter	Outer diameter	Usable length
4FC12	4 mm (12 Fr, 0.16 in)	5 mm (15 Fr, 0.20 in)	65 cm (25.59 in)

The sheath can be deflected to provide additional maneuverability to catheters that are advanced through the sheath and into the right or left chamber of the heart.

The sheath can be used with Medtronic diagnostic and ablation catheter sizes up to 10.5 Fr.

### 1.1 Contents of package

The FlexCath Advance Steerable Sheath is supplied sterile. The package contains the following items:

- 1 FlexCath Advance Steerable Sheath
- 1 dilator
- Product documentation

## 2 Indications for use

The FlexCath Advance Steerable Sheath is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart. The sheath deflection facilitates catheter positioning.

## 3 Contraindications

The FlexCath Advance 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.

The sheath should not be used to perform the transeptal puncture.

## 4 Warnings and precautions

**Air aspiration** – Remove the guide wire and dilator from the sheath or insert the catheter into the sheath before slowly aspirating and flushing the sheath. This action minimizes the aspiration of air through the valve of the sheath. Minimize catheter exchanges and always advance and withdraw catheters through the valve slowly. Follow advancement or withdrawal of catheters with appropriate aspiration and flushing according to institutional standards or consensus statements.

**Anticoagulation therapy** – Administer appropriate levels of peri-procedural anticoagulation therapy for patients undergoing left-sided and transeptal cardiac procedures and for selected patients undergoing right-sided procedures. Administer anticoagulation therapy during and post-procedure according to institutional standards to minimize bleeding and thrombotic complications.

**Back-bleeding** – To minimize unintended back-bleeding through the side port, make sure the stopcock is in a closed position after aspiration or flushing. Connecting to a continuous drip provides forward flow, which can minimize back-bleeding.

**Biohazard disposal** – Discard all used sheaths and sterile components in accordance with hospital procedures.

**Device compatibility** – The use of catheters other than Medtronic diagnostic and ablation catheters that are 10.5 Fr or smaller have not been fully evaluated, therefore, Medtronic does not recommend their use with FlexCath Advance.

**Do not resterilize** – Do not resterilize this sheath for purpose of reuse. Resterilization may compromise the structural integrity of the sheath or create a risk of contamination from the sheath that could result in patient injury, illness, or death.

**Embolism risk** – 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. Minimize catheter exchanges and always advance and withdraw catheters through the valve slowly. Follow advancement or withdrawal of catheters with appropriate aspiration and flushing according to institutional standards or consensus statements.

- Monitor the spontaneously-breathing patient for conditions that may induce negative left atrial pressure such as airway collapse, deep breathing, snoring, or apnea (note that these conditions could be more prevalent under sedation). Use caution when administering drugs with respiratory depressive effects in such patients. Negative left atrial pressure may increase the risk of air ingress through the hemostasis valve particularly during insertion and removal of catheter.
- Signs of air ingress may include visible bubbles appearing in the side port tubing or audible sucking sounds coming from the hemostasis valve. Air bubbles may also be visible on fluoroscopy or intracardiac echo (ICE), if used.
- If air embolism is suspected, begin appropriate therapy immediately per treatment guidelines or consensus statements.

**Expiration date** – Check to verify that the sheath is within its expiration date. Do not use if the product date has expired.

**Femoral vein damage** – Take care to minimize damage to the femoral vein and access site upon sheath insertion, manipulation, or withdrawal. Complications associated with femoral vein catheterization include hematoma and thrombosis.

**Fluoroscopy required for sheath placement** – Use of fluoroscopy during sheath manipulation and placement is advised. Manipulating the sheath without fluoroscopy may result in damage to cardiac and vascular structures.

**For single use only** – This sheath is intended only to be used once for a single patient. Do not reuse, reprocess, or resterilize this sheath for purpose of reuse. Reuse, reprocessing, or resterilization may compromise the structural integrity of the sheath or create a risk of contamination of the sheath that could result in patient injury, illness, or death.

**Frequent flushing** – Continuous drip and/or regular aspiration and flushing of the sheath and dilator lumen are recommended:

- To minimize blood stagnation, clots, air emboli, and serious patient injury
- After each contrast injection, to prevent contrast solution from sticking inside the lumen
- Ensure the full volume of the sheath is flushed. The measured volume of the sheath is 12cc.

**Handling and care** – Use extreme care when manipulating the sheath. Lack of careful attention can result in injury such as perforation, tamponade, induction of arrhythmia, or heart block.

- Do not use excessive force to advance or withdraw the sheath, especially if resistance is encountered.
- Avoid positioning the sheath around the chordae tendineae, as this increases the likelihood of entrapment within the heart, which may necessitate surgical intervention or repair of injured tissues.
- Do not use the sheath if it is kinked or damaged.

**Prosthetic heart valves** – 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.

**Qualified users** – This sheath should be used only by, or under the supervision of, physicians trained in cardiac catheterization procedures.

**Required use environment** – Cardiac catheterization procedures should be performed only in a fully equipped facility.

**Side port obstruction** – Prevent any obstruction of the side port to ensure effective saline flush.

**Side port aspiration** – Infusion through the side port should only occur after all air is removed from the unit. Aspirate the sheath slowly according to institutional standards or consensus statements.

**Significant blood leakage** – Ensure that there is not significant blood leakage through the hemostatic valve during the procedure.

**Sterile package inspection** – Inspect the sterile packaging and sheath before use. If the sterile packaging or the sheath exhibits damage, do not use the sheath. Contact your local Medtronic representative.

**Transseptal puncture** – The sheath and dilator have not been tested for compatibility with transseptal needles.

**X-ray and fluoroscopic exposure** – The use of fluoroscopy during catheter ablation procedures presents the potential for significant x-ray exposure to both patients and laboratory staff. Extensive exposure can result in acute radiation injury and increased risk for somatic and genetic effects. 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 sheath in pregnant women.

## 5 Adverse events

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 (atrial fibrillation, atrial flutter, tachycardia)
- Cardiac arrest
- Chest discomfort, pain, or pressure
- Coronary artery spasm, dissection, thrombosis
- Death
- Endocarditis
- Heart block, requiring permanent pacemaker
- Hemothorax
- Myocardial infarction
- Perforation of venous cardiac or surrounding tissue
- Pericardial effusion, tamponade
- Pericarditis
- Pleural effusion
- Pneumothorax
- Pseudoaneurysm
- Pulmonary edema
- Pulmonary embolism
- Stroke
- Thrombus
- Transient ischemic attack (TIA)
- Vasovagal reaction

## 6 Instructions for use

**Note:** Before introducing the sheath into the patient, test the deflection mechanism to ensure that it is operational.

1. Use caution when preparing and assembling the sheath and dilator.
  - Flush the full volume (12cc) of the sheath through the sheath's side port and flush the lumen of the dilator using sterile saline solution.
  - Ensure that the sheath is in the neutral (non-deflected) position and wet the dilator shaft with sterile saline solution.
  - Insert the distal tip of the dilator straight through the center of the valve and fully into the sheath until the dilator hub snaps into the sheath hub.
  - Wet the shaft of the catheter with sterile saline solution.
2. Using an aseptic technique, create a vascular access with an appropriate introducer.
3. After access, administer anticoagulation therapy during and post-procedure according to institutional standards.
4. Insert a compatible guide wire (see Chapter 7, "Specifications", page 5) through the vasculature and position the guide wire using standard vascular access techniques.
5. Insert the dilator and sheath over the guide wire and advance into the desired position.
6. Slowly remove the guide wire and dilator from the sheath. Slowly aspirate blood through the side port and then flush the sheath, taking care to prevent air bubbles.
7. Once the sheath is positioned, manage flushing and/or continuous drip according to institutional standards or consensus statements.
8. Insert and position the catheter. Slowly aspirate and flush the sheath.

**Note:** Do not push the protective sleeve of the Arctic Front family cryoablation catheters into the hemostasis valve. This could create an air pathway into the sheath and/or may damage the valve.

9. Prior to sheath withdrawal, ensure that the sheath is in the neutral (non-deflected) position.
10. Slowly withdraw the sheath from the body and obtain appropriate hemostasis according to institutional standards or consensus statements.

## 7 Specifications

Overall length	81 cm (31.89 in)
Usable length	65 cm (25.59 in)
Inner diameter	4 mm (12 Fr, 0.16 in)
Outer diameter	5 mm (15 Fr, 0.20 in)
Dilator length	87 cm (34.25 in)
Radiopaque marker	5 mm (0.20 in) proximal to sheath tip
Guide wire compatibility	0.81 mm (0.032 in) and 0.89 mm (0.035 in)
Environmental parameters	
Recommended transit temperature	–35°C to 58°C (–31°F to 136°F); 85% relative humidity (non-condensing)
Recommended storage temperature	Average of 22°C (71°F) with a standard deviation of 2.7°C (4.86°F) and actionable control limits of 15°C to 30°C (59°F to 86°F)
Operation	15°C to 30°C (59°F to 86°F) at altitudes less than 2400 m (8000 feet) above sea level

## 8 Medtronic disclaimer of warranty

For complete warranty information, see the accompanying disclaimer of warranty document.

## **9 Service**

Medtronic employs highly trained representatives and engineers located throughout the world to serve you and, upon request, to provide training to qualified hospital personnel in the use of Medtronic products. Medtronic also maintains a professional staff to provide technical consultation to product users. For more information, contact your local Medtronic representative, or call or write Medtronic at the appropriate telephone number or address listed on the back cover.



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## Technical manuals

[www.medtronic.com/manuals](http://www.medtronic.com/manuals)

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