Medtronic

Urgent Field Safety Notice

FlexCath Advance™ Steerable Sheath - Model Number 4FC12

Instructions For Use Update

October 2017

Medtronic reference: FA788

Dear Risk Manager,

This notification is to provide you with important information regarding an update to the Medtronic FlexCath Advance Steerable Sheath, Model 4FC12, Instructions for Use (IFU) manual. This IFU revision incorporates current best practices for minimizing the potential for air ingress and the risk of air embolism. This IFU update is not in response to a device design deficiency, device malfunction, or a change in reported field performance data.

Issue Description
Air embolism is a known risk for patients undergoing percutaneous interventions requiring access to the left atrium, such as ablation procedures. According to the 2017 HRS/EHRA/ECAS/APHRS/ SOLAECE Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation, "the most common cause of air embolism is introduction of air via the transseptal sheath."[1]

Medtronic has supplemented the FlexCath Advance Steerable Sheath IFU to highlight the known risk of air embolism more prominently. These updates do not impact current clinical practice as this information is consistent with current training and education materials, and with recommendations from HRS, JHRS, and EHRA. This letter contains a summary of the IFU updates.

Medtronic is not retrieving product from the field. There are no changes to the management of patients who have been or will be ablated with a system using a FlexCath Advance Steerable Sheath.

FlexCath Advance Steerable Sheaths remain available. FlexCath Advance Steerable Sheaths packaged with the updated IFU will be shipped after any local regulatory approvals are obtained for the IFU updates.

Customer Actions
Please complete the following actions:

- Review the **IFU Update Summary** regarding air ingress and air embolism as provided in this letter.
- Please share this information with clinicians in your hospital that use the FlexCath Advance Steerable Sheath. Also share this information with any other organization where these devices may have been transferred.
- Please maintain a copy of this notice in your records.

IFU Update Summary
NOTE: When released in your geography, the updated IFU content may differ from the content of this communication based on the IFU approved by local regulatory agencies, where required.

The FlexCath Advance Steerable Sheath IFU update includes the following additional language emphasizing minimization of catheter exchanges, proper aspiration and flushing techniques, and slow advancement and withdrawal of catheters through the sheath:

- **Warnings and Precautions**: Updated key language includes:
  - **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.

[1] Calkins H, et al. 2017 HRS/EHRA/ECAS/APHRS/SOLAECE Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation. Heart Rhythm. (2017), doi 10.1016/j.hrthm.2017.05.012

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- **Air 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.
- **Frequent flushing** – Continuous drip and/or regular aspiration and flushing of the sheath and dilator lumen are recommended:
  - To minimize blood stagnation, clots, emboli and serious patient injury.
  - After each contrast injection, to prevent contrast solution from sticking inside the lumen.
- **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.
- **Side port aspiration** – Infusion through the side port should only occur after all air is removed from the unit. Aspirate the sheath according to institutional standards or consensus statements.

- **Adverse Events:** Updated key language includes:
  - Air embolism, a known risk, was added to the list of potential Adverse Events. Adding this to the list of Adverse Events in the IFU does not change or impact current clinical practice.

The FlexCath Advance Steerable Sheath IFU update includes current procedural best practice and is provided below for reference:

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

1. Assemble the sheath and dilator together.
   - Flush the sheath side port and dilator lumen with 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 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.
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.

The Competent Authority of your country has been notified of this action.

We are committed to patient safety and welcome any questions you may have regarding this communication. Please contact your Medtronic representative for any questions.

Sincerely,

Country/BU manager