AF Solutions Product Education Brief

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Best Practices to Avoid Air Embolic Events with Medtronic 4FC12 FlexCath Advance™ Sheath

Overview and Objectives:

This educational brief is intended to inform physicians and allied health professionals of changes in the U.S. instructions for use of the Medtronic 4FC12 FlexCath Advance™ Sheath. While the rate of air embolism in the U.S. remains stable and consistent with design predictions, Medtronic has received a higher-than-expected number of reports of air embolic events which occurred during the use of the FlexCath Advance Sheath and have led to death or coma in Japan, where an advisory was issued by JHRS in August 2018 (See Appendix A for translated copy of advisory). The rate of FlexCath Advance air embolic events in the U.S. has been low and acceptable, and the changes in labeling are intended to reinforce best practices to avoid the occurrence of air embolism and ensure consistent product labeling across geographies.

Clarifications Regarding Precautions to Reduce Risk of Air Embolism

The following summarizes the clarifications on precautions that should be taken to reduce the risk of air embolism and which are being incorporated into the labeling. These precautions are consistent with published literature:

- 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 particular 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 catheters.

- The use of catheters other than Medtronic diagnostic and ablation catheters that are 10.5 Fr or smaller has not been fully evaluated; therefore, Medtronic does not recommend their use with FlexCath Advance.

- Avoid placing catheter introducers or sleeves into the valve. These devices could create an air pathway into the sheath and / or may damage the valve.

These recommendations are in the process of being incorporated into labeling. Refer to Appendix B for a summary of the changes to the U.S. instructions for use.

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Appendix A: Japan JHRS Advisory – English Translation
Link to Notification: http://new.jhrs.or.jp/blog/2018/08/30/wn20180830/

Emergency alert regarding Atrial Fibrillation Balloon Ablation complication

August 30, 2018

Serious complications are occurring in succession in cases of atrial fibrillation catheter ablation using balloons.

1. **Severe cerebral infarction, myocardial infarction case related to cryoballoon ablation:** It is speculated that air embolism is the cause. It is presumed that one of the reasons was that a small diameter catheter other than a balloon catheter was inserted in the cryoballoon sheath (FlexCath Advance). As a basic rule, do not insert catheters other than balloons into the balloon sheath. Also, even when using balloon catheters, use extreme caution when inserting or changing them.
2. **Left atrial esophageal fistula case related to hot balloon ablation:** It is presumed that repeated cauterization on the same pulmonary vein was one of the causes. During treatment, keep in mind that the risk of esophageal injury remains even though esophageal cooling is performed.

Although the causes of the complications mentioned above have not been determined yet, we are **urgently calling everyone's attention** to them to prevent new complication cases. Anyone involved in such treatments should proceed with sufficient care.

August 30, 2018
Japanese Heart Rhythm Society

Catheter Ablation Committee
Chairman Sadaichi Yamane
Chairman of Complications Division Masahiko Gouya
Chairman of Safety Measures Kengo Kusano
Chief Director Akihiko Nogami

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Appendix B: Labeling Updates to U.S. Instructions for Use

Warnings and Precautions:

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.

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.

- 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.

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.

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. ~~Assemble the dilator and sheath together.~~
- Flush the full volume (12 cc) of the sheath through the sheath's side port and flush the lumen of the dilator ~~with~~ 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 standard.
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.

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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.

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Brief Statement:

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 Medtronic's website at www.medtronic.com.

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

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