URGENT Field Safety Notice

Medtronic CryoCath FlexCath 12 Steerable Sheaths: Potential Leak in Hemostatic Valve

Medtronic ref.: FA523

July 2011

Dear Doctor:

Medtronic CryoCath would like to inform you of an observation related to a potential leak in the hemostatic valve of the FlexCath 12 Steerable Sheath, Model 3FC12, and make sure you are aware of the best approach to recognize and manage the observation.

Historically, at a rate of 0.35%, physicians using FlexCath with Arctic Front Cryoablation Catheters have reported cases of blood and saline solution leaking out of, and air ingress into, the FlexCath 12 hemostatic valve. This includes reported instances of the introduction of air bubbles through the valve during aspiration of the side port of the sheath. In May 2011 Medtronic CryoCath observed that the rate of occurrence of hemostatic valve leaking related issues rose from 0.35% to 2.47%.

To date, there have been no reports of compromised patient safety associated with the leaking valve. Potential clinical implications of a leaking valve include blood loss, the risk of air or gas embolism, and the lack of adequate anticoagulation if heparinized saline leaks out through the valve. We have received one report of a transient ST segment elevation which resolved during the procedure.

Medtronic CryoCath is working urgently on a number of fronts to mitigate this observation and will continue to communicate with you as appropriate.

We recommend that physicians continue to use the FlexCath 12 Steerable Sheath and as with any catheter usage, remain vigilant when flushing and aspirating the FlexCath sheath and watch closely for any blood loss, saline leakage or air ingress as stated within the existing FlexCath 12 Steerable Sheath and Arctic Front CryoAblation Catheter Instructions For Use. Signs of air ingress include visible bubbles appearing in the tubing or internal side of the silicone disk in the sheath and audible sucking sounds coming from the hemostatic valve.

As described on page 5 of the FlexCath Instructions for Use, the following important procedural recommendations should be followed:

- **Embolism risk –** Introducing any catheter or sheath into the circulatory system entails the risk of air or gas embolism, which can occlude vessels and lead to tissue infarction with serious consequences. Always advance and withdraw components slowly to minimize the vacuum created and therefore minimize the risk of air embolism.

- **Frequent flushing–** Regular flushing of the sheath and dilator lumen is recommended:
    - To prevent blood stagnation, clots, emboli and serious patient injury
    - After each contrast injection, to prevent contrast solution from sticking inside the lumen

  Air aspiration– Remove the guide wire and dilator from the sheath or insert the catheter into the sheath prior to aspirating and flushing the sheath, minimizing the aspiration of air through the valve of the sheath.

The national Competent Authority of your country has been notified of this action. We request that you inform others within your organization of this notice as appropriate.

If you experience this or any other product issue in your facility, please contact your local AFS Medtronic representative for assistance. Gulf Medical LTD. Mr. Omar Chalbout Tel: +966503963422

Sincerely,

Sincerely,

Mohammed Barhoumi
Business Director
Cardiac Rythm Disease Management
Middle East