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<Reference: 92688876-FA> 13 April 2021

Urgent Field Safety Notice
POLARSHEATH™ Steerable Sheath

Subject: Field Safety Notice – Instructions for Use (IFU) Update for POLARSHEATH Steerable Sheath (UPN M004CRBS3050; Boston Scientific Field Action Reference: 92688876-FA).

Dear «Users_Name»,

This Field Safety Notice (FSN) provides important information regarding updates to the IFU for the POLARSHEATH™ Steerable Sheath 12F (UPN M004CRBS3050), as detailed in **Appendix 1**. The affected device information is listed below.

Product Description	Material Number (UPN)	GTIN Number	Lot Number	Expiration Date
POLARSHEATH Steerable Sheath	M004CRBS3050	08714729992684	All	All

Summary

- Since commercialization in 2020, Boston Scientific has received reports of air embolism associated with use of the POLARSHEATH product during atrial fibrillation ablation procedures from a limited number of facilities. There have been no reported deaths associated with these events.

- A comprehensive investigation identified that reinforcement of best clinical practices and the instructions outlined in the IFU with respect to preparation, handling, and operation of the POLARSHEATH reduced complaints associated with air ingress.

- This letter contains recommendations, in the form of updated IFU, (Appendix 1) intended to reinforce existing instructions for use for the POLARSHEATH Steerable Sheath, share best practices, and optimize product use/handling.

- Boston Scientific is not removing any POLARSHEATH devices from the field; devices remain available for clinical use.

- There are no changes to the management of patients who have been or will be ablated with a system using a POLARSHEATH Steerable Sheath.

- The updated IFU will be packaged with POLARSHEATH Steerable Sheaths that are shipped after all applicable regulatory approvals are obtained for the IFU updates.

Description

Since commercial introduction of the POLARSHEATH Steerable Sheath in 2020, reports of air embolism during atrial fibrillation ablations have been received from a limited number of facilities; there have been no reported deaths associated with these events. Boston Scientific conducted a comprehensive investigation of all POLARSHEATH complaints received, including those with reports of air embolism. As part of these investigation efforts, it was identified that training on the reinforcement of the IFU content led to a corresponding reduction in complaints. Therefore, Boston Scientific has revised the POLARSHEATH IFU to further emphasize best practices during use of this device. These updates are aimed at further reducing the potential for air ingress into the sheath and the associated risk of air embolism. Boston Scientific is communicating these updates to all global customers in the interest of minimizing the occurrence of air embolism and promoting consistent use of the IFU in all geographies.

Air embolism is a known risk for patients undergoing percutaneous interventions requiring access to the left atrium, such as atrial fibrillation 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] Boston Scientific has supplemented the POLARSHEATH IFU to further highlight the known risk of air embolism and provide additional guidance for actions to be taken and considered during use of this device to minimize the risk of air ingress. These updates align with current best clinical practices related to left atrial catheterization as well as current literature and societal guidance. This information is also consistent with the use of large bore sheaths, for which these considerations are of particular importance in minimizing the risk of air ingress. Affected worldwide regulatory authorities are being notified of this FSN, as required.

[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

Recommendations
1- Review the content of the IFU Update detailed in **Appendix 1**, relating to air ingress and air embolism.

2- Share this information as appropriate to provide awareness of this information, particularly with clinicians in your hospital that use the POLARSHEATH Steerable Sheath. Also share this information with any other organization to which these devices may have been transferred.

3- Maintain a copy of this notice in your records.

4- Immediately post this information in a visible location near the product to ensure this information is easily accessible to all users of the device.

5- Continue to report all adverse events or quality concerns experienced with use of this device to Boston Scientific (in accordance with all applicable local regulations).

6- Complete the attached mandatory Acknowledgement Form and return it to **to your local Boston Scientific office** for the attention of «Customer_Service_Fax_Number» by **30 April 2021**.

Patient safety remains Boston Scientific's highest priority. As such, we are committed to transparent communication with our physician customers to ensure you have timely, relevant information for managing your patients. If you have additional questions regarding this information, please contact your local Boston Scientific sales representative.

Sincerely,

[redacted]

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Attachment: Acknowledgment Form

APPENDIX 1 – Updates to POLARSHEATH™ Instructions for Use

Table 1 below provides the updates to the various sections of the IFU for the POLARSHEATH Steerable Sheath 12F (UPN M004CRBS3050). These updates include additional warnings, additional product preparation and operations instructions and a clarification on device compatibility and disposal. The updated wording is provided in red bolded text.

Table 1: Updates to POLARSHEATH Instructions for Use

Section	Labeling Updates
Warnings	Introducing catheters and sheaths into the circulatory system entails the risk of air emboli**. Air embolism can occlude blood vessels resulting in serious consequences such as tissue infarction and/or end organ failure.** Always advance/withdraw the POLARSHEATH slowly. Always advance/withdraw catheters slowly through the POLARSHEATH valve and minimize catheter exchanges.
	To minimize potential for air ingress, avoid actions that may induce strong negative pressure (vacuum) or create a leak pathway. • **Do not aspirate via the side port if the sheath lumen is occupied (i.e., by the dilator or components of the cryoablation catheter) as the aspiration may draw air across the sheath valve into the POLARSHEATH.** • **Do not aspirate via the side port while the Cryoablation Balloon Catheter is being introduced into the POLARSHEATH as this risks air ingress. Using high pressure flushing with heparinized saline, ensure that egress of heparinized saline from the hemostatic valve is observed during the introduction of the catheter.** • **Avoid compromising the seal of the valve on the body of the Cryoablation Balloon Catheter or holding open any portion of the valve membrane, such as by placing an introducer across the valve, as this may damage the valve and create a pathway for air to enter the POLARSHEATH. Do not push the introducer sleeve of the POLARx through the hemostasis valve.**
	The POLARSHEATH has undergone evaluation with Boston Scientific Cryoablation Balloon Catheters to ensure compatibility. The use of other diagnostic and ablation catheters has not been evaluated and Boston Scientific does NOT recommend their use. The potential for blood leakage and air emboli may be increased if catheters with diameter less than 11F are used within the POLARSHEATH.
	Monitor the spontaneously-breathing patient for risk factors which may lead to negative left atrial pressures. Negative left atrial pressure may increase the risk of air ingress through the hemostasis valve particularly during insertion and removal of the catheter. Such risk factors may include, among others, pre-existing low left atrial pressure (e.g., noted at time of transseptal puncture), hypovolemia, airway collapse, deep breathing, snoring, or apnea, and may be more prevalent under sedation. Use additional caution when using drugs with respiratory depressive effects in such patients.
	Air ingress may be recognized by the visual presence of air bubbles in the side port tubing or by an audible sucking sound emanating from the hemostasis valve. Imaging modalities employed during the procedure, such as fluoroscopy or intracardiac echocardiography, may also demonstrate the presence of air. If air embolism is suspected, begin appropriate management immediately as indicated by treatment guidelines or consensus statements.
	Ensure there is no significant blood leakage through the hemostatic valve during the procedure. **Connecting POLARSHEATH to a continuous drip provides forward flow, which can minimize back-bleeding.**

	To minimize unintended back-bleeding through the side port, make sure the stopcock is in a closed position to the POLARSHEATH at all times unless aspirating or flushing.
Product Preparation	8.1.5. Attach a three-way stopcock to the side port. **Ensure familiarity with its operation, specifically taking note of the attachment mechanism and the positions that indicate open and closed paths to the POLARSHEATH side port. Ensure the stopcock is compatible with the side port tubing and will maintain a secure connection throughout use. Ensure the stopcock and side port tubing are clear of air at all times and that the stopcock does not allow a pathway for air ingress. If any port of the stopcock remains unattached to tubing, it is best practice to cap that port or attach a syringe to it to prevent inadvertently opening a path to air.**
	8.1.6. Flush the POLARSHEATH side port with sterile saline solution. **The full volume of the sheath is approximately 13 mL. Flush and aspirate as necessary to remove all air from the sheath prior to inserting the dilator.**
	8.1.7. Flush the dilator with sterile saline and wet the dilator shaft with sterile saline solution before insertion through the hemostatic valve.
	8.1.8. Insert the dilator into the valve and fully into the POLARSHEATH. **Ensure that the distal tip of the dilator is inserted in a straight orientation through the center of the POLARSHEATH valve and that the dilator is advanced into the sheath until the dilator hub snaps into the sheath hub.**
Product Operation	8.2.5. Slowly aspirate and then flush the POLARSHEATH, taking care to avoid introducing air bubbles. Avoid rapid aspiration and flushing as this may entrain air into the sheath. **Ensure the sheath, side port tubing and stopcock are all free of air before continuing.**
	8.2.6. Connect a continuous heparinized saline drip or maintain anticoagulation therapy per institutional protocol. **Ensure irrigation tubing, stopcock and side port tubing are completely free of air before beginning infusion.** **NOTE: In order to minimize the potential for air ingress:** ○ **Use high pressure flushing with heparinized saline, to ensure that egress of heparinized saline from the hemostasis valve is observed during the introduction of the catheter.** ○ **Continuous irrigation is recommended while the catheter is inserted to replenish fluid displaced out of the sheath by catheter movement.**
Device Compatibility	The POLARSHEATH is compatible for use with the Boston Scientific Cryoablation Catheter System. **The compatibility of POLARSHEATH with catheters other than Boston Scientific Cryoablation Balloon Catheters has not been confirmed, and Boston Scientific does not recommend the use of other diagnostic or ablation catheters with the POLARSHEATH.**
Disposal	**In the event that an incident occurs in relation to the device, including all patient deaths for procedures where the BSC product was used, the event should be reported to Boston Scientific and the relevant regulatory authority, where applicable for your geography. Return any device related to a complaint, patient harm, injury, or death to Boston Scientific using a Boston Scientific Returned Product Kit.**

Please complete the form & Send it to:
«Customer_Service_Fax_Number»

«Sold_to» - «Hospital_Name» - «City» - «Country»

Acknowledgement Form – Field Safety Notice

POLARSHEATH™ Steerable Sheath

92688876-FA

By signing this form, I confirm that

I have read and understood
the Boston Scientific Field Safety Notice

dated 13 April 2021 for the

POLARSHEATH™ Steerable Sheath devices.

NAME* _____Title _____

Telephone _____ Department _____

SIGNATURE* _____ **DATE*** _____
* Required field dd/mm/yyyy