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SRN: US-MF-000004702

Urgent Field Safety Notice – Urgent Recall & Correction - POLARx™ and POLARx™ FIT Cryoablation Balloon Catheters, POLARSHEATH™ Steerable Sheaths, and SMARTFREEZE™ Cryoablation System Consoles

Dear Physician or Healthcare Professional,

Boston Scientific is initiating the recall of POLARx™ and POLARx™ Fit Cryoablation Balloon Catheters and POLARSHEATH™ Steerable Sheaths, and the decommissioning of SMARTFREEZE™ Cryoablation System consoles (collectively, the "System").

In 2025, Boston Scientific made the decision to discontinue this cardiac cryoablation product line, and thereafter ceased manufacturing catheters and consoles. Given the availability of new alternative ablation technologies and recent reports of atrio-esophageal (AE) fistula events—despite occurrence rates remaining within expected and documented ranges—Boston Scientific is accelerating discontinuation of the POLARx Cryoablation System.

Patients previously treated with the System should continue to be managed according to standard of care, with any additional management at the discretion of the treating physician.

Background:
In 2024, Boston Scientific notified physicians of potential risk of AE fistula associated with POLARx and POLARx FIT catheters. Although rare, AE fistula is a known and inherent risk for patients undergoing catheter ablation for atrial fibrillation due to the anatomical proximity of the esophagus to the posterior left atrium. The 2024 communication included revised instructions for use (IFU) with additional warnings to emphasize the risk of AE fistula and updated procedural guidance to mitigate this risk.

Current Status:
Boston Scientific has continued to monitor the performance of the System, and in recent months, three (3) additional AE fistula occurrences have been reported, including one (1) associated with a patient death. The observed complaint rate (0.0103%) remains below the range of published societal rates for esophageal injury following AF ablation procedures (up to 0.2%) and the predefined risk threshold for the system's performance. A detailed review of the available data associated with these AE fistula events did not identify any product performance-related issues with components of the System. Overall, the observed AE fistula rate for POLARx and POLARx FIT catheters remains within established risk thresholds and is consistent with published clinical guidelines.

While the occurrence of atrio-esophageal (AE) fistula events remains within anticipated and documented rates[1], new alternative therapies exist that are now widely commercially available. Robust clinical evidence supports that these new alternative technologies do not pose the same risk of thermally mediated injury[2,3]. Given these alternatives, the previously made decision to discontinue this product offering, and recent AE fistula events, Boston Scientific is accelerating the planned discontinuation via recall of POLARx and POLARx FIT catheters and POLARSHEATH sheaths and decommissioning SMARTFREEZE consoles.

Our records indicate that your facility may have received some of the affected POLARx and POLARx FIT Cryoablation Balloon Catheters, POLARSHEATH Steerable Sheaths and SMARTFREEZE Cryoablation System consoles.

- **Table 1** lists the components of the Boston Scientific Cardiac Cryoablation System that are included in this recall.
- **Table 2** lists the consoles that will be decommissioned.

Please note that **only the devices listed in below tables are affected. No other Boston Scientific product is involved in this Field Safety Notice.**

Table 1 Components being Recalled

Product Description	Material Number (UPN)	GTIN Number
CRBS POLARX BALLOON CATHETER ST 28MM OUS	M004CRBS2000	08714729992561
CRBS POLARX FIT BALLOON CATHETER ST OUS	M004CRBS2010	08714729992578
CRBS POLARX FIT BALLOON CATHETER ST US	M004CRBS2060	08714729992622
CRBS POLARX BALLOON CATHETER LT 28MM OUS	M004CRBS2100	08714729992660
CRBS POL333 FIT BALLOON CATHETER LT OUS	M004CRBS2110	00191506016456
CRBS POLARX FIT BALLOON CATHETER LT US	M004CRBS2160	00191506016463
CRBS POLARSHEATH STEERABLE SHEATH	M004CRBS3050	08714729992684
CRBS POLARSHEATH STEERABLE SHEATH US	M004CRBS3150	00191506039776

Table 2 Consoles being Decommissioned

Product Description	Material Number (UPN)	GTIN Number
CRBS SMARTFREEZE CRYO CONSOLE	M004CRBS4000	08714729992691
CRBS SMARTFREEZE CRYO CONSOLE HOSPITAL	M004CRBS400H0	08714729992714
CRBS SMARTFREEZE CRYO CONSOLE REFURB	M004CRBS400R0	08714729992721
CRBS SMARTFREEZE CRYO CONSOLE ZERO COST	M004CRBS400Z0	08714729997481
CRBS SMARTFREEZE CRYO CONSOLE US IDE	M004CRBSUSC4000	08714729992943

[1] Joglar JA, Chung MK, Armbruster AL, et al. 2023 ACC/AHA/ACCP/HRS guideline for the diagnosis and management of atrial fibrillation: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2024;149(1):e1–e156. doi:10.1161/CIR.0000000000001193
[2] Verma A, Hocini M, Andrade J, Gerstenfeld E, Kapa S, Lakkireddy D, et al. 2026 HRS/EHRA scientific statement on pulsed field ablation for cardiac arrhythmias. Heart Rhythm. 2026. doi:10.1016/j.hrthm.2026.02.006
[3] Turagam M, Aryana A, Day J, et al. Multicenter study on the safety of pulsed field ablation in over 40,000 patients: MANIFEST-US. J Am Coll Cardiol. 2026;87(2):172–193. doi:10.1016/j.jacc.2025.10.051

Actions to be taken:

- **Immediately stop further use or distribution** and segregate all POLARx and POLARx FIT Catheters, POLARSHEATH sheaths, and SMARTFREEZE consoles listed in tables 1 and 2 above.
- **Continue to follow the standard of care** post ablation when monitoring patients treated with POLARx and POLARx FIT Cryoablation products.
- **Return** POLARx and POLARx FIT catheters and POLARSHEATH sheaths to Boston Scientific in accordance with the below instructions.
- **A Boston Scientific representative will contact your facility to schedule a time to decommission your SMARTFREEZE Console.**
- **Share this communication** with any healthcare professionals in your hospital that use the Boston Scientific POLARx Cryoablation System and with any other organization to which these systems may have been transferred.
- **Call your Boston Scientific representative with any questions** about credits and/or recall/destruction of other components.

Instructions for completing the Verification Form:

1- **Please complete the attached Verification Form** even if you do not have any devices to return. In the Product Table on the form, list **only the recalled devices** (POLARx / POLARx FIT catheters and POLARSHEATH sheaths) by entering the UPN, Lot/Batch number, and quantity.

Do not list SMARTFREEZE consoles in the Product Table, as consoles are not part of the device recall (they will be handled separately for de-installation).

2- **When completed, please return the Verification Form to your local Boston Scientific office** for the attention of «Customer_Service_Fax_Number» on or before **27 April 2026.**

3- **If you have devices to return,** please package them in an appropriate shipping box**. After receipt of the Verification Form, Boston Scientific will contact you to arrange return.**

Your national Competent Authority has been informed of this communication. Any adverse events or quality concerns associated with use of these devices should be reported to Boston Scientific and Competent Authorities if appropriate.

Boston Scientific is providing this information to support safe patient management and informed clinical decision-making. Patient safety remains Boston Scientific's highest priority. If you have additional questions regarding this communication, please contact your local Boston Scientific sales representative.

Sincerely,

Alexandra Naughton
Vice President, Quality Assurance

Attachment: Verification Form

«Sold_to» - «Hospital_Name» - «City» - «Country_Name»

Please complete the form even if you do not have any affected device(s) and send it to your Local Office:
«Customer_Service_Fax_Number»

Verification Form – Recall and Correction

POLARx™ and POLARx™ FIT Cryoablation Balloon Catheters, POLARSHEATH™ Steerable Sheaths (recalled devices), and SMARTFREEZE™ Cryoablation System Consoles (decommissioning only)

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1- We acknowledge receipt of the Boston Scientific Letter dated 9 April 2026.

2- Boston Scientific records indicate you have received some of the recalled devices; please check your inventory against the complete list of affected devices provided in Table 1. **This Verification Form must be completed, signed, and returned by all customers, even if no affected devices are present. Do not include SMARTFREEZE consoles on this form, as consoles are handled separately for de-installation.**

3- We confirm that all areas where affected **devices** could be located have been checked.

4- **TICK ONE OF THESE STATEMENTS***, **SIGN THIS FORM** and send it to «Customer_Service_Fax_Number»

q We do not have any affected **device(s)** to return.

❑ We have found affected device(s) (POLARx / POLARx FIT catheters and/or POLARSHEATH steerable sheaths): Please update below table with the UPN, Lot/Batch number and the quantity to return. **Do not list SMARTFREEZE consoles in the table.**

Material N° (UPN)	Lot / Batch N°	Qty to return

TO RETURN PRODUCTS:

1- After receipt of the Verification Form, Boston Scientific will contact you to arrange return.
2- Prepare the package.
3- Follow the instructions given by your Local Office about collection of the package.

NAME* _____ Title _____

Telephone _____ Email _____

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