

«Hospital_Name»

«Users_Name»

«Department»

«Customer_Address»

«Zip_Code» «City»

«Country_name»

<Reference: 97174890-FA>

12 February 2024

Urgent Field Safety Notice - Urgent Medical Device Recall POLARSHEATH™ Steerable Sheath

Dear «Users_Name»,

Boston Scientific is conducting a removal of specific batches of POLARSHEATH™ Steerable Sheaths manufactured between 21 Nov 2023 and 31 Jan 2024 that have been distributed in Europe and Japan. Our records indicate that affected batches of this sheath have been distributed to your facility. The POLARSHEATH Steerable Sheath is a single-use, steerable percutaneous introducer sheath designed for maneuverability of the Boston Scientific Cryoablation System catheter, which is advanced through the sheath and into cardiac chambers.

Boston Scientific has identified a tooling error in manufacturing which may have caused delamination of the inner lumen of the sheath shaft in a subset of POLARSHEATH devices. This could result in the embolization of a fragment during use (such as flushing of the sheath or introduction of the dilator or ablation catheter).

The most serious foreseeable harm that could occur if a liner fragment became dislodged and embolized during the procedure is a stroke. Other potential harms include myocardial ischemia or another distal vascular occlusion. The potential for these events to occur is limited to the time during the ablation procedure. To date, there have been no complaints or patient harm reported related to this topic.

Our records indicate that your facility received some of the concerned product. **The table below** provides a **complete list of all affected products, including Product Description, Material Number (UPN), GTIN, Lot/Batch numbers** and expiration date. Please note that **only the devices listed below are affected. No other Boston Scientific product is involved in this Field Safety Notice.**

Further distribution or use of any remaining product affected by this action should cease immediately.

Product Description	GTIN	Material Number (UPN)	Batch Number	Expiration Date
CRBS POLARSHEATH STEERABLE SHEATH	8714729992684	M004CRBS3050	32895945, 32895947, 32903274 32903275, 32903276, 32903277 32903278, 32903340, 32999267 33000331, 33000333, 33000334 33000337, 33000338, 33000339 33052646, 33052647, 33052648 33052649, 33061576, 33171976	21 Nov 2024 – 08 Jan 2025

INSTRUCTIONS:

1- **Please immediately discontinue use of the Boston Scientific product reported in the list and remove all of the affected units from your inventory**, regardless of where these units are stored in your facility. Segregate the units in a secure place, pending return to Boston Scientific.

2- **Please complete the attached Verification Form even if you do not have any product to return.**

3- **When completed, please return the Verification Form to your local Boston Scientific office** for the attention of «Customer_Service_Fax_Number», on or before **20 February 2024**.

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

5- Please pass this notice to any healthcare professional from your organization that needs to be aware and to any organization where the potentially affected devices have been transferred (if appropriate). Please provide Boston Scientific with details of any affected devices that have been transferred to other organizations (if appropriate).

Your Competent Authority is being notified of this Field Safety Notice.

We regret any inconvenience that this action may cause, and we appreciate your understanding as we act to ensure patient safety and customer satisfaction.

If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Yours sincerely,



Marie Pierre Barlanga
Quality Department
Boston Scientific International S.A.

Attachment: Verification Form

Please Complete the form even if you do not have any affected product & send it to your Local Office:
«Customer_Service_Fax_Number»

Verification Form – Urgent Medical Device Recall
POLARSHEATH™ Steerable Sheath
97174890-FA

1. We acknowledge receipt of the Boston Scientific Field Safety Notice dated 12 February 2024.
2. **Boston Scientific records indicate you have received the following affected product** (additionally please check inventory against complete list of affected product provided)

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

3. We confirm that all areas where affected product could be located have been checked.
4. **TICK ONE OF THESE STATEMENTS***, **SIGN THIS FORM** and send it to «Customer_Service_Fax_Number»
 - We do not have any affected product.
 - We have found affected product(s): Please confirm the quantity to return above. *If you are returning product not listed above, please **add the UPN, Lot/Batch/Serial number and the quantity 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

CUSTOMER'S NAME* _____ Title _____

Telephone _____ Email _____

Customer' SIGNATURE* _____ DATE* _____

* Required field

dd/mm/yyyy