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<**Reference: 97654746-FA**> 24 August 2026
SRN: US-MF-000004702

Urgent Field Safety Notice - Urgent Medical Device Recall Imager™ II Angiographic Catheters

Dear Materials Manager and/or Healthcare Professional,

Boston Scientific is initiating a recall of Imager™ II Angiographic Catheters ("Catheters") due to a manufacturing issue affecting the catheter tip. This recall affects the devices identified in Attachment 1.

Boston Scientific has determined that these Catheters were manufactured with reduced levels of stabilizing agents in the tips. This may increase the risk of tip degradation and detachment.

Although no increase in tip detachment complaints has been identified for the affected lots, the devices were manufactured outside the approved design specification and are being removed from the market. In addition, as previously communicated, Boston Scientific has made the decision to discontinue selling this product.

The most common adverse health consequence of tip detachment in the intravascular space with a likelihood of occurrence of every time used is a delay in procedure to exchange for a new device. Although considered remote, the most serious potential adverse health consequence within the intravascular space is life threatening embolism resulting from a device fragment obstructing blood flow resulting in end organ failure.

Our records indicate that your facility has received some of the affected product. **The table below (Attachment 1) provides a complete list of all affected products**, including Product Description, Material Number (UPN), GTIN, Lot/Batch numbers and expiry 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.

PLEASE NOTE: We are aware that hospitals often remove products from the outer carton and store on the shelves in the inner-pouch only. If this is a practice at your facility**, it is very important that you carefully use the product table and consider both the inner and outer packaging UPN codes when searching for affected product, as the UPN numbers on the inner and outer labelling may be different. The product information listed on your specific Verification Form (enclosed with this letter) provides outer package product coding only** and should be utilized when reporting product to return.

Verify by product batch/lot number in the product table to determine if the batch within your inventory is affected. If so, indicate on your Verification Form the quantity of units from each batch that you will be returning. **As the product within these batches are sold as 5-packs, it is important that all reported quantities represent the actual number of single units being returned and not the number of cartons/boxes or multi-packs.**

INSTRUCTIONS:

1- **Please immediately discontinue use of the Boston Scientific product reported in the list** (Attachment 1) **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- Immediately post this information in a visible location near the affected products to ensure this information is readily accessible to all handlers and users of the device.

3- **Continue to follow the standard of care** when monitoring patients treated with the product

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

5- **When completed, please return the Verification Form to your local Boston Scientific office** for the attention of <Customer_Service_Fax_Number> on or before **18 September 2026**.

6- **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.**

7- Please pass this notice to any health 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 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 where required, to the applicable Competent Authority.

Patient safety is Boston Scientific's highest priority. As such, we are committed to transparent communication with physicians and healthcare professionals to ensure you have timely, relevant information for managing your patients. If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Yours sincerely,

Richard Kirkendall

Attachment: Verification Form

FOR BOSTON SCIENTIFIC INTERNAL USE ONLY
Account Email: <Contact Email>
Language: <Language(s)>
LFAC Team: <LFAC_Distribution_Email_Address>
Country Code-Sold to: <Country_Code>-<Sold_to_b>

Attachment 1 - Affected Product

Description	Outer Package UPN	GTIN	Inner Package UPN	GTIN	Lot #	Expiration Date Range
Imager™ II Angiographic Catheters	M001314001	08714729354826	M001314000	08714729736028	**All**	8 October 8, 2026 to June 9, 2028
	M001314011	08714729354833	M001314010	08714729736035		
	M001314021	08714729354840	M001314020	08714729736042		
	M001314031	08714729354857	M001314030	08714729736059		
	M001314041	08714729354864	M001314040	08714729736066		
	M001314051	08714729354871	M001314050	08714729736073		
	M001314061	08714729354888	M001314060	08714729736080		
	M001314081	08714729354901	M001314080	08714729736103		
	M001314101	08714729354925	M001314100	08714729736127		
	M001314141	08714729354963	M001314140	08714729736165		
	M001314151	08714729354970	M001314150	08714729736172		
	M001314301	08714729355120	M001314300	08714729736325		
	M001314321	08714729355144	M001314320	08714729736349		
	M001314341	08714729355168	M001314340	08714729736363		
	M001314351	08714729355175	M001314350	08714729736370		
	M001314361	08714729355182	M001314360	08714729736387		
	M001314521	08714729355342	M001314520	08714729736547		
	M001314581	08714729355403	M001314580	08714729736608		
	M001314621	08714729355441	M001314620	08714729736646		
	M001314661	08714729355489	M001314660	08714729736684		
	M001314671	08714729355496	M001314670	08714729736691		
	M001314761	08714729355588	M001314760	08714729736783		
	M001314771	08714729355595	M001314770	08714729736790		
	M001314821	08714729355649	M001314820	08714729736844		
	M001314861	08714729355687	M001314860	08714729736882		
	M001314881	08714729355700	M001314880	08714729736905		

<Sold_to> - <Hospital_Name> - <City> - <Country_Name>

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
Imager™ II Angiographic Catheters
97654746-FA

1- We acknowledge receipt of the Boston Scientific Field Safety Notice dated 24 Aug 2026.

2- **Boston Scientific records indicate you have received the following affected products** *(additionally please check inventory against complete list of affected products provided)*

/!\ REPORT QUANTITY IN SINGLE UNITS AND NOT IN CARTON/BOX/MULTIPACK (IF APPLICABLE)

Material N° (UPN)	**Lot / Batch N°**	**Customer PO**	**Qty Sent** (Box)	**Qty to return** (Single Units)

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.

NAME* _____Title _____

Telephone _____ Email _____

Customer' **SIGNATURE*** _____ **DATE*** _____

* Required field

dd/mm/yyyy