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<Country_Name>

<**Reference: 97605664-FA**> 30 June 2026
SRN: US-MF-000004702

Urgent Field Safety Notice - Urgent Medical Device Recall
Radial Jaw™ 4 Biopsy Forceps

Dear Materials Manager and/or Healthcare Professional,

Boston Scientific is initiating recall of specific lots of Radial Jaw™ 4 Single-Use Biopsy Forceps and Single-Use Hot Biopsy Forceps due to the potential for a breach in the sterile barrier of the device packaging. These devices are used to obtain biopsy samples of mucosal tissue.

A packaging defect involving a channel in the Tyvek patch seal was identified during a vendor evaluation of pouch samples. Testing confirmed that this defect can result in a breach of the sterile barrier of the device packaging. The packaging defect may not be detectable through routine visual inspection, as the channel defect is small and the affected seal area may be partially or fully obscured by the product label.

The most common adverse health consequence reasonably foreseeable to occur is a prolonged procedure of negligible severity to account for device exchange prior to the procedure. It is reasonable to expect that another identical or similar forceps would be readily available for use as they are commonly stocked in facilities where endoscopic procedures are performed. The most serious potential harms are infection and exposure to biohazardous material; however, both outcomes would require an extremely unlikely sequence of events to occur. To date, Boston Scientific has received no complaints associated with this issue and no patient harm has been reported.

Our records indicate that your facility has received some of the concerned 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.**

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, 20-packs and 40-packs, it is important that all reported quantities represent the actual number of single unit 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 above 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- 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- **Please complete the attached Verification Form** even if you do not have any product to return.

4- **When completed, please return the Verification Form to your local Boston Scientific office** for the attention of <Customer_Service_Fax_Number> on or before **24 July 2026**.

5- **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.**

6- 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 Competent Authorities if appropriate.

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,

Conor Dolan
Vice President, Global Quality

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 Box UPN	Inner Box UPN	GTIN	Lot #	Expiration Date Range
RADIAL JAW 4 JUMBO 240CM **BX 5**	M00513363	M00513360	08714729761914	38496094	30 January 2029 to 3 February 2029
RADIAL JAW 4 LC 240CM **BX 20**	M00513321	M00513320	08714729648796	38494988	
RADIAL JAW 4 LC 240CM **BX 40**	M00513322		08714729648802	38497139	
RADIAL JAW 4 LC W/NDL 240CM **BX 20**	M00513331	M00513330	08714729648819	38509777	
RADIAL JAW 4 LC W/NDL 240CM **BX 40**	M00513332		08714729648826	38499451	
RADIAL JAW 4 LC W/NDL 240CM **BX 5**	M00513333		08714729755494	38519443	
RADIAL JAW 4 SC 240CM **BX20**	M00513401	M00513400	08714729777960	38508541	
RADIAL JAW 4 SC 240CM **BX40**	M00513402		08714729778028	38517807	
RADIAL JAW 4 SC 240CM W/NDL **BX20**	M00513411	M00513410	08714729777984	38488064	

<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
Radial Jaw™ 4 Biopsy Forceps
97605664-FA

1- We acknowledge receipt of the Boston Scientific Field Safety Notice dated 30 June 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.

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