

«Hospital_Name»

«Users_Name»

«Department»

«Customer_Address»

«Zip_Code» «City»

«Country_name»

<Reference: 92556729-FA>

«Date_notif_sent»

Cover letter for Distributors – Urgent Medical Device Recall Captivator and Captiflex polypectomy snares

Dear «Users_Name»

Boston Scientific Corporation is conducting a Medical Device Recall of of specific lots/batches of Captivator and Captiflex polypectomy snares. Please find more information in the attached Field Safety Notice.

You are kindly requested to follow the below instructions:

- 1- **Check your Inventory for the products affected by this Field safety Notice.**
- 2- **Please segregate and do not distribute any of the affected products found in your inventory.**
- 3- **Please notify all your customers that have received affected product of the below Field Safety Notice.** To effectively manage this Field Safety Notice, your accounts are to communicate directly with you, not Boston Scientific. If any of your customers are distributors, please notify them that they must communicate this Field Action to the medical facility level.
- 4- **Have all affected product returned to your facility** and held in quarantine for reconciliation.
- 5- **Please complete the attached Verification Form, even if you do not have any product to return.**
- 6- **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 July 2020**.
- 7- **If you have products to return**, please package them in an appropriate shipping box and **contact «Customer_Service_Tel» of your local Boston Scientific office**, to arrange return.

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.

Attachments: - Field Safety Notice
- Distributor Verification Form

«Hospital_Name»

«Users_Name»

«Department»

«Customer_Address»

«Zip_Code» «City»

«Country_name»

Reference: 92556729-FA

«Date_notif_sent»

Urgent Field Safety Notice - Urgent Medical Device Recall Captivator and Captiflex polypectomy snares

Dear «Users_Name»,

Boston Scientific Corporation (BSC) is initiating a removal of specific lots/batches of Captivator and Captiflex polypectomy snares. BSC has noted a potential inability to cut and remove polyps for these lots/batches. No other Captivator or Captiflex snares are impacted by this removal.

The most common potential consequences related to the snares not performing as intended would be a prolonged procedure duration, tissue damage and/or self-limited bleeding. The most severe potential injury would include immediate or delayed haemorrhage and/or perforation requiring intervention up to and including open surgery; the likelihood of these severe injuries occurring is remote and, to date, have not been reported as a complaint. The potential inability to cut may also lead to inadequate removal of target tissue.

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) and 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 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 10 or 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.**

Affected Product Listing

Product Description	Outer Package UPN #	Inner Package UPN #	GTIN	Lot/Batch #	Expiration Date
Captivator™ Snares	M00561291	M00561290	08714729645801	25170944, 25219286, 25368742, 25412118, 25508371	5-Feb-23 through 13-May-23
	M00561311	M00561310	08714729019251	25199777, 25330546, 25374640, 25424470	11-Feb-23 through 31-Mar-23
	M00562321	M00562320	08714729019336	25158564, 25245733, 25245735, 25330549, 25403001, 25439073, 25513671	4-Feb-23 through 14-May-23
	M00562341	M00562340	08714729019350	25077093, 25164173, 25185062, 25187234, 25226123, 25255681, 25336754, 25403003, 25508379, 25524901	20-Jan-23 through 14-May-23
	M00562371	M00562370	08714729019381	25143083, 25508441	2-Feb-23 through 14-May-23
Captiflex™ Snares	M00562401	M00562400	08714729019411	25321152, 25338467, 25426642	6-Mar-23 through 31-Mar-23
	M00562402	M00562400	08714729501640	25111007, 25133479, 25142120, 25299896, 25351474, 25357539, 25402321	28-Jan-23 through 24-Mar-23

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 **27 July 2020**.

4- **If you have products to return**, please package them in an appropriate shipping box and **contact «Customer_Service_Tel» of your local Boston Scientific office**, 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



«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
Captivator and Captiflex polypectomy snares
92556729-FA

1. We acknowledge receipt of the Boston Scientific Field Safety Notice dated «Date_notif_sent».
2. **Boston Scientific records indicate you have received the following affected product** (*additionally please check inventory against complete list of affected product provided*)
!/ REPORT QUANTITY IN SINGLE UNITS AND NOT IN CARTON/BOX/MULTIPACK (IF APPLICABLE)

Material N° (UPN)	Lot / Batch N° / Serial N°	Customer PO	Qty Sent (Box)	Qty to return (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. Contact «Customer_Service_Tel» of your Local Office to arrange return of any affected product
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