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«Hospital_Name»
«Users_Name»
«Department»
«Customer_Address»
«Zip_Code» «City»
«Country_name»

<Reference: 92646283-FA> 21 January 2021

Urgent Field Safety Notice - Urgent Medical Device Recall Single-Use Polypectomy Snares: Captivator™, Captivator™ II, Captiflex™, and Sensation™

Dear «Users_Name»,

Boston Scientific Corporation is conducting a removal of specific lots of the Captivator™ Single-Use Polypectomy Snares, Captivator™ II Single-Use Polypectomy Snares, Captiflex™ Single-Use Polypectomy Snares, and Sensation™ Single-Use Polypectomy Snares as detailed in Attachment 1.

Boston Scientific has received complaints that the inner pouch for the specified lots of polypectomy snare devices impacted by this removal may have an incomplete seal which could result in a sterile barrier breach rendering the device non-sterile. The most common health risk is a negligible prolongation in procedure in order to exchange for another device. Use of a polypectomy snare from a package with a sterile barrier breach may present a remote potential for a risk of infection, representing the most severe health consequence. Boston Scientific is not aware of any patient consequences resulting from this issue.

Our records indicate that your facility 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 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 sold as 5, 10, 20 or 40-multi 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 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 **25 February 2021**.

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 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 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 Barlangua
Quality Department
Boston Scientific International S.A.

Attachment: Verification Form

Attachment 1 – Product Listing

Product Description	Outer Box UPN #	Inner Pouch UPN #	Outer Box GTIN	Inner Pouch GTIN	Lot/Batch #	Expiration Date Range
Sensation™ Single-Use Polypectomy Snares	M00560311	M00560310	08714729283904	08714729747598	24818278 24906823 25042455	11/21/2022 - 1/13/2023
	M00560321	M00560320	08714729283928	08714729747611	24685766 24817145 24899710 24739786 25006735 24861901	10/30/2022 - 1/7/2023
	M00562651	M00562650	08714729158110	08714729748069	24685764 24890051 24824132	10/30/2022 - 12/8/2022
	M00562652	M00562650	08714729268802	08714729748069	25023345	1/10/2023
	M00562671	M00562670	08714729158141	08714729748083	24699718 24939626 24861739	11/3/2022 - 12/15/2022
	M00562672	M00562670	08714729268819	08714729748083	24824134 25006729 24709534	11/3/2022 - 1/7/2023
	M00562673	M00562670	08714729501664	08714729748083	25023203 24697822 24739587 24942292 24909214 24824136	10/31/2022 - 1/12/2023
	M00562691	M00562690	08714729158158	08714729748106	24856636 24927642 24699218	10/31/2022 - 12/12/2022
	M00562692	M00562690	08714729268826	08714729748106	24835709 24818605 25023343	11/22/2022 - 1/9/2023
	M00562693	M00562690	08714729501671	08714729748106	24909216 24758832 24872119 24994171 25048397 24751265 24929431 24995438	11/10/2022 - 1/14/2023

Attachment 1 – Product Listing Continued

Product Description	Outer Box UPN #	Inner Pouch UPN #	Outer Box GTIN	Inner Pouch GTIN	Lot/Batch#	Expiration Date Range
Captivator™ II Single-Use Polypectomy Snare	M00561191	M00561190	08714729855934	08714729861263	25053639	1/15/2023
	M00561221	M00561220	08714729855903	08714729861294	24948407	10/27/2022 - 12/17/2022
					24670592	
					24679619	
					24676929	
					24939628	
	M00561222	M00561220	08714729861300	08714729861294	24770325	10/25/2022 - 12/18/2022
					24952552	
					24665104	
	M00561223	M00561220	08714729861317	08714729861294	24679614	10/28/2022 - 1/15/2023
					25054403	
	M00561233	M00561230	08714729861348	08714729861324	24772995	11/14/2022
Captivator™ Single-Use Polypectomy Snare	M00561311	M00561310	08714729019251	08714729747680	24725319	11/5/2022 - 11/20/2022
					24782695	
	M00562301	M00562300	08714729019312	08714729747833	24842597	11/20/2022 - 11/26/2022
					24812577	
	M00562321	M00562320	08714729019336	08714729747857	24889757	11/4/2022 - 12/6/2022
					24719202	
					24709536	
					24773287	
	M00562341	M00562340	08714729019350	08714729747871	24782693	11/6/2022 - 12/5/2022
					24732964	
					24889755	
					24780939	
	M00562451	M00562450	08714729071068	08714729747970	24882357	11/6/2022 - 12/4/2022
					24782689	
					24782687	
					24729758	
Captiflex™ Single-Use Polypectomy Snare	M00562401	M00562400	08714729019411	08714729747932	24961643	12/18/2022
	M00562402	M00562400	08714729501640	08714729747932	24961645	11/27/2022 - 1/4/2023
					24989260	
					24844193	
	M00562422	M00562420	08714729501657	08714729747956	25010054	1/8/2023
	M00562471	M00562470	08714729019459	08714729747994	25016793	1/9/2023

«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

Single-Use Polypectomy Snares: Captivator™, Captivator™ II, Captiflex™, and Sensation™

92646283-FA

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1. We acknowledge receipt of the Boston Scientific Field Safety Notice dated 21 January 2021.

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