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

<**Reference: 92629317-FA**> 1 December 2020

Field Safety Notice - Urgent Medical Device Recall
AXIOS Stent and Electrocautery - Enhanced Delivery System, and Hot AXIOS Stent and Electrocautery - Enhanced Delivery System

Dear «Users_Name»,

Boston Scientific Corporation (BSC) is initiating a voluntary removal of specific lots/batches of the AXIOS Stent and Electrocautery Enhanced Delivery System, and Hot AXIOS Stent and Electrocautery Enhanced Delivery System. During manufacturing BSC identified that the rotating luer fitting at the distal end of the delivery system handle may become detached from the nose of the delivery system handle, which can occur during device preparation, stent delivery, or delivery system removal. This issue only affects the delivery system of the device and there is no effect on implanted stents. There have been no complaints reported to date related to this issue.

The **most common** potential consequences due to delivery system handle separation during AXIOS stent placement for a pseudocyst or walled-off necrosis are a prolongation of procedure in order to exchange out for another device or an additional intervention to treat the patient and/or complete the procedure. In addition, there is a risk of infection as a result of the opening created by the AXIOS delivery system or from additional manipulation of the pseudocyst, walled-off necrosis or biliary tract that is not adherent to the gastric or bowel wall. The **most severe** potential consequences due to delivery system handle separation during AXIOS stent placement are peritonitis and need for surgical intervention. The likelihood of the most severe potential consequence occurring is remote.

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 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.

Product Description	US or Outside US	UPN #	GTIN	Lot/Batch #	Expiration Date Range
Hot AXIOS™ Stent and Electrocautery – Enhanced Delivery System	Outside US	M00553540	08714729904564	26130517	10/5/2022
	Outside US	M00553550	08714729904571	26156059, 26167275, 26167276, 26156742, 26156740	10/9/2022 – 10/12/2022
	Outside US	M00553560	08714729951100	26167277, 26171099, 26152171, 26171383, 26171380, 26152172	10/8/2021 – 10/12/2021
AXIOS™ Stent and Electrocautery - Enhanced Delivery System	US	M00553640	08714729904588	26134666	10/6/2022
	US	M00553650	08714729904595	26152465, 26152466, 26152467	10/8/2022
	US	M00553660	08714729951179	26167271, 26152176, 26167274	10/8/2021 – 10/12/2021

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 **24 December 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,

xxx
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

AXIOS Stent and Electrocautery - Enhanced Delivery System, and Hot AXIOS Stent and Electrocautery - Enhanced Delivery System

92629317-FA

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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)*

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