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

<**Reference: 92484513-FA**> «Date_notif_sent»

Field Safety Notice - Urgent Medical Device Recall
"Name of the Product"

Dear «Users_Name»,

Boston Scientific Corporation (BSC) is initiating a removal of specific lots/batches of Imager II 5F Angiographic Catheters. BSC has noted an increase in the rate of tip detachment complaints involving units within these lots/batches. The preliminary investigation indicates that these batches meet design and manufacturing requirements, however external factors may have contributed to the tips of devices in these batches becoming brittle, leading to the tip detaching. No other Imager II Catheters are impacted by this removal.

The most common injury would be related to the tip detaching inside the patient resulting in either the need for intervention to retrieve the fragment or in the fragment remaining in the patient's vessel potentially requiring additional intervention and/or prolonged hospitalization. There is a possibility that a potentially life-threatening embolism of the device fragment could result.

Our records indicate that your facility received some of the concerned product. Th**e 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 *5-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.**

Product Description	Outer Package UPN #	Inner Package UPN #	GTIN	Lot/Batch #	Expiration Date
Imager™ II Angiographic Catheter	M001314051	M001314050	08714729354871	134092	23-Aug-2020
	M001314051	M001314050	08714729354871	134600	12-Sep-2020
	M001314061	M001314060	08714729354888	134011	20-Aug-2020
	M001314141	M001314140	08714729354963	133737	10-Aug-2020
	M001314341	M001314340	08714729355168	139512	12-Mar-2021
	M001314581	M001314580	08714729355403	134631	13-Sep-2020
	M001314591	M001314590	08714729355410	132447	13-Jun-2020
	M001314661	M001314660	08714729355489	132355	8-Jun-2020
	M001315151	M001315150	08714729355892	132823	26-Jun-2020
	M001315151	M001315150	08714729355892	133447	13-Jul-2020
	M001315151	M001315150	08714729355892	133448	16-Jul-2020
	M001315151	M001315150	08714729355892	134946	25-Sep-2020

Please ensure Imager II 5F Angiographic Catheters are stored per the DFU recommendations: Imager II 5F Angiographic Catheters must be stored in a cool, dry, dark place.

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 **XX January 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 Barlangua
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
"Name of the Product"

92484513-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** (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