Boston Scientific International S.A.
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«Hospital_Name»
«Users_Name»
«Department»
«Customer_Address»
«Zip_Code» «City»
«Country_name»

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

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

Dear «Users_Name»,

Boston Scientific is initiating a removal of the Imager II Angiographic Catheters - 5F ***curved tip shapes*** which includes all lots/batches of this 5F configuration. This removal is an expansion to a retrieval of 12 specific batches of this catheter which was communicated in February 2020. We have identified an increase in the rate of tip detachment complaints on the 5F curve tip shapes configuration. Investigation has now concluded the need to expand the scope to all lots/batches of the 5F ***curved tip shapes*** of the Imager II Angiographic Catheters. There have been three patient injuries reported since the initial removal of product earlier this year.

Our investigation has concluded the failure is generated by exposure to high humidity and temperature storage conditions and other potential variables that include aging of the units, the amount of stabilizer remaining in the resin used to manufacture the catheter and the manufacturing process to curve the device. No other Imager II catheters are impacted by this removal.

The most common injury related to the tip detaching inside the patient would be the need for intervention to retrieve the fragment or 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.

This removal affects all 5F product with ***curved tip shapes*** listed in Attachment 1. **Further distribution or use of any remaining product affected by this removal should cease immediately**.

PLEASE NOTE: We are aware that hospitals often remove products from the outer carton and store them on 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 in Attachment 1 and consider both the inner and outer packaging UPN codes when searching for affected product, as the UPN numbers on the inner and outer labeling are 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 UPN number whether any product within your inventory is affected. If so, indicate on your Verification Form the quantity of units from each lot/batch that you will be returning. **As the product within these lots/batches are sold as 5-packs, it is important that all reported quantities represent the actual number of single units being returned and not the number of cartons/boxes or multi-packs.**
If you identify any product from the affected lots/batches within your inventory, please segregate the product immediately and return it to BSC in accordance with the enclosed instructions. **If you are a distributor, please note that the depth is to the hospital level and this notification should be forwarded to your customers. If you are a facility that has sent products to another hospital within your network, please ensure that this notification is forwarded to them.**

Please carefully read through the removal instructions included with this notification. Your local sales representative can answer any questions that you may have regarding this notification.

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 **4 September 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. We are committed to continuing to offer products that meet the highest quality standards that you expect from Boston Scientific.

If you have any questions or would like assistance with this Field Safety Notice, please contact your local Sales Representative.

Yours sincerely,

[redacted]

Boston Scientific International S.A.

Attachment: Verification Form

Attachment 1

Imager II UPNs for 5F *curved tip shapes*: all batches are impacted

Product Description	Outer Package UPN #	Inner Package UPN #	GTIN	Lot/Batch #	Expiration Date
Imager™ II Angiographic Catheter -5F ***curved tip shapes***	M001314041	M001314040	8714729354864	All	All
	M001314051	M001314050	8714729354871	All	All
	M001314061	M001314060	8714729354888	All	All
	M001314071	M001314070	8714729354895	All	All
	M001314081	M001314080	8714729354901	All	All
	M001314091	M001314090	8714729354918	All	All
	M001314101	M001314100	8714729354925	All	All
	M001314111	M001314110	8714729354932	All	All
	M001314121	M001314120	8714729354949	All	All
	M001314131	M001314130	8714729354956	All	All
	M001314141	M001314140	8714729354963	All	All
	M001314151	M001314150	8714729354970	All	All
	M001314161	M001314160	8714729354987	All	All
	M001314171	M001314170	8714729354994	All	All
	M001314181	M001314180	8714729355007	All	All
	M001314191	M001314190	8714729355014	All	All
	M001314211	M001314210	8714729355038	All	All
	M001314221	M001314220	8714729355045	All	All
	M001314231	M001314230	8714729355052	All	All
	M001314241	M001314240	8714729355069	All	All
	M001314251	M001314250	8714729355076	All	All
	M001314261	M001314260	8714729355083	All	All
	M001314271	M001314270	8714729355090	All	All
	M001314301	M001314300	8714729355120	All	All
	M001314311	M001314310	8714729355137	All	All
	M001314321	M001314320	8714729355144	All	All
	M001314331	M001314330	8714729355151	All	All
	M001314341	M001314340	8714729355168	All	All
	M001314351	M001314350	8714729355175	All	All
	M001314361	M001314360	8714729355182	All	All
	M001314371	M001314370	8714729355199	All	All
	M001314391	M001314390	8714729355212	All	All
	M001314401	M001314400	8714729355229	All	All
	M001314411	M001314410	8714729355236	All	All
	M001314421	M001314420	8714729355243	All	All
	M001314431	M001314430	8714729355250	All	All
	M001314441	M001314440	8714729355267	All	All
	M001314451	M001314450	8714729355274	All	All
	M001314461	M001314460	8714729355281	All	All
	M001314471	M001314470	8714729355298	All	All
	M001314481	M001314480	8714729355304	All	All
	M001314501	M001314500	8714729355328	All	All
	M001314521	M001314520	8714729355342	All	All
	M001314531	M001314530	8714729355359	All	All
	M001314541	M001314540	8714729355366	All	All
	M001314551	M001314550	8714729355373	All	All
	M001314561	M001314560	8714729355380	All	All
	M001314571	M001314570	8714729355397	All	All
	M001314581	M001314580	8714729355403	All	All
	M001314591	M001314590	8714729355410	All	All
	M001314621	M001314620	8714729355441	All	All
	M001314631	M001314630	8714729355458	All	All
	M001314641	M001314640	8714729355465	All	All
	M001314651	M001314650	8714729355472	All	All
	M001314661	M001314660	8714729355489	All	All
	M001314671	M001314670	8714729355496	All	All
	M001314681	M001314680	8714729355502	All	All

Product Description	Outer Package UPN #	Inner Package UPN #	GTIN	Lot/Batch #	Expiration Date
Imager™ II Angiographic Catheter - 5F ***curved tip shapes***	M001314691	M001314690	8714729355519	All	All
	M001314701	M001314700	8714729355526	All	All
	M001314711	M001314710	8714729355533	All	All
	M001314751	M001314750	8714729355571	All	All
	M001314761	M001314760	8714729355588	All	All
	M001314771	M001314770	8714729355595	All	All
	M001314781	M001314780	8714729355601	All	All
	M001314791	M001314790	8714729355618	All	All
	M001314801	M001314800	8714729355625	All	All
	M001314811	M001314810	8714729355632	All	All
	M001314821	M001314820	8714729355649	All	All
	M001314831	M001314830	8714729355656	All	All
	M001314841	M001314840	8714729355663	All	All
	M001314851	M001314850	8714729355670	All	All
	M001314861	M001314860	8714729355687	All	All
	M001314871	M001314870	8714729355694	All	All
	M001314881	M001314880	8714729355700	All	All
	M001314891	M001314890	8714729355717	All	All
	M001314901	M001314900	8714729355724	All	All
	M001314911	M001314910	8714729355731	All	All
	M001315031	M001315030	8714729355779	All	All
	M001315051	M001315050	8714729355793	All	All
	M001315061	M001315060	8714729355809	All	All
	M001315071	M001315070	8714729355816	All	All
	M001315081	M001315080	8714729355823	All	All
	M001315131	M001315130	8714729355878	All	All
	M001315141	M001315140	8714729355885	All	All
	M001315151	M001315150	8714729355892	All	All
	M001315191	M001315190	8714729355939	All	All
	M001315211	M001315210	8714729355953	All	All
	M001315231	M001315230	8714729355977	All	All
	M001315281	M001315280	8714729356028	All	All
	M001315291	M001315290	8714729356035	All	All
	M001315301	M001315300	8714729356042	All	All
	M001315311	M001315310	8714729356059	All	All
	M001315321	M001315320	8714729356066	All	All
	M001315331	M001315330	8714729356073	All	All

«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"
92484513C-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)*
/!\ 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

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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
Imager™ 5F II Angiographic Catheter

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. 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 *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 February 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,

[redacted]

Attachment: Verification Form

Boston Scientific International S.A.

«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
Imager™ 5F II Angiographic Catheter
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)*

/!\ **REPORT QUANTITY IN SINGLE UNITS AND NOT IN CARTON/BOX/MULTIPACK** (IF APPLICABLE)

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